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Proposed Registration Decision

PRD2018-06

Pydiflumetofen, A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide, and A21461 Fungicide

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Overview

Proposed Registration Decision for Pydiflumetofen

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Pydiflumetofen Technical, A19649 Fungicide and A19649TO Fungicide, containing the technical grade active ingredient Pydiflumetofen to manage certain important diseases on both major and minor crops in Canada. Also being registered are A20259 Fungicide containing pydiflumetofen and difenoconazole, A20560 Fungicide containing pydiflumetofen and fludioxonil, and A21461 Fungicide containing pydiflumetofen, azoxystrobin and propiconazole to manage certain diseases on several crops. A19649TO Fungicide is also proposed for use on turf and golf courses in Canada.

A number of these pydiflumetofen end-use products are formulated with the active ingredients fludioxonil, difenoconazole, azoxystrobin and propiconazole. These active ingredients are currently registered for the proposed uses in Canada and there are no major new uses for any of these active ingredients.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Pydiflumetofen Technical, A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide and A21461 Fungicide.

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 human health 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.

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

² "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

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

Before making a final registration decision on Pydiflumetofen, the PMRA will consider any comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on Pydiflumetofen, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

What Is Pydiflumetofen?

Pydiflumetofen is a conventional fungicide active ingredient that works by inhibiting respiration in susceptible fungi. It controls or suppresses economically important diseases of field crops, fruit crops, vegetable crops, ornamentals, turf and golf courses.

Health Considerations

Can Approved Uses of Pydiflumetofen Affect Human Health?

Products containing pydiflumetofen are unlikely to affect your health when used according to label directions.

Potential exposure to pydiflumetofen may occur through the diet (food and water), when handling and applying the end-use products, or when entering an area that has been treated with these products. 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

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*.

to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient pydiflumetofen was of low acute toxicity via the oral, dermal and inhalation routes. It was minimally irritating to the eyes and non-irritating to the skin. It did not cause an allergic skin reaction. Based on these findings, hazard statements for acute toxicity are not required on the label.

The three end-use products, A19649TO Fungicide, A20259 Fungicide, and A20560 Fungicide, were all of low acute toxicity via the oral, dermal and inhalation routes. They were non-irritating to the skin and eyes and did not cause allergic skin reactions. The end-use product A19649 Fungicide had a similar acute toxicity profile, except that it was minimally irritating to the eyes. Based on these findings, hazard statements for acute toxicity are not required on the product labels.

The end-use product A21461 Fungicide was of moderate acute toxicity via the oral route and of low acute toxicity via the dermal and inhalation routes. It was moderately irritating to the eyes, minimally irritating to the skin, and did not cause an allergic skin reaction. Based on these findings, the signal word and hazard statements “POISON” and “WARNING – EYE IRRITANT” are required on the product label.

Short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of pydiflumetofen to cause neurotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive endpoints used for risk assessment were effects on body weight, liver, activity level, and behaviour. There was no evidence that pydiflumetofen damaged genetic material; however, it did cause liver tumours in mice. There was some evidence that the young animal was more sensitive to pydiflumetofen than the adult animal. The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

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

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation that would ingest the most pydiflumetofen relative to body weight, are expected to be exposed to less than 30% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pydiflumetofen is not of health concern for all population subgroups.

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

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 9% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was children 3-5 years old.

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

Residue trials conducted throughout Canada and the United States using pydiflumetofen on various crops are acceptable. The proposed MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when pydiflumetofen is used according to the proposed label directions and restricted-entry intervals are observed.

Adults, youth and children golfing can come into direct contact with A19649TO Fungicide residues from treated turf. Therefore, the label requires that individuals do not re-enter treated golf courses until sprays have dried. Taking into consideration the label statements, number of applications and the duration of exposure, risks to individuals golfing are not a concern.

Occupational Risks From Handling Pydiflumetofen

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

Farmers and custom applicators who mix, load or apply A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide and A21461 Fungicide as well as field workers re-entering freshly treated fields, nurseries and greenhouses can come in direct contact with pydiflumetofen residues on the skin. Therefore, the labels specify that a long-sleeved shirt, long pants, chemical resistant gloves, shoes and socks must be worn. Additionally, goggles are required for mixing and loading of A21461 Fungicide. The labels also require that workers do not enter treated fields for 12 hours after application, except for golf courses where re-entry is permitted once sprays have dried. For girdling or turning of grapes, the restricted-entry interval (REI) is 1 day. Taking into consideration these label statements, the number of applications and the duration of exposure for handlers and workers, risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Pydiflumetofen Is Introduced into the Environment?

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

Pydiflumetofen can enter land and water habitats through spray drift and runoff when used as a foliar spray for control of a number of fungal diseases on a variety of crops, turf and golf courses. Pydiflumetofen does not dissolve readily in water and has low potential to enter the atmosphere from soil and water surfaces and be transported long distances. In soil, it does not break down easily in the presence of moisture, light and soil microorganisms and, thus, can remain there for a long time. In the aquatic environment, pydiflumetofen resides primarily in the sediment and breaks down in the presence of microorganisms to form the transformation product SYN545547. Because pydiflumetofen remains in soil for a long time it can be carried down through the soil profile and has a potential to reach groundwater. Pydiflumetofen also has a potential to run off fields and enter adjacent water ditches, ponds and other water bodies. Pydiflumetofen is not expected to accumulate in fish tissues.

When used according to the label directions, pydiflumetofen does not present a risk to earthworms, pollinators and other beneficial arthropods, birds, wild mammals, fresh water algae, aquatic vascular plants, freshwater invertebrates, marine fish, marine algae and crustaceans. However, exposure to pydiflumetofen may affect non-target terrestrial plants, freshwater fish and amphibians. To protect non-target plants, freshwater fish and amphibians from spray drift, spray buffer zones up to 15 meters are required. To protect freshwater amphibians from the potential exposure from runoff, label statements informing users how to reduce runoff will be required. Additional precautionary label statements will be required to inform users of carryover and leaching potential, as well as the toxicity of pydiflumetofen to aquatic organisms.

Value Considerations

What Is the Value of A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide and A21461 Fungicide?

Products containing pydiflumetofen provide a new mode of action fungicide to manage certain diseases on several crops as well as turf and golf courses. As it is a new mode of action, it will help reduce the development of resistance in susceptible fungal pathogens.

The registration of these products addresses grower identified disease priorities on minor crops. Co-formulated products provide multiple modes of action which help delay the development of resistance in target fungi and simultaneously manage diseases that co-occur. These products provide disease reduction at a commercially expected level and help maintain the quality of marketed grains and produce, ornamental crops, and golf courses and sod turf.

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 A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide and A21461 Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with pydiflumetofen on the skin or through inhalation of spray mists, anyone mixing, loading and applying pydiflumetofen and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and goggles. Additionally, airblast applicators applying A19649TO must wear chemical-resistant headgear, while mixers/loaders of A21461 Fungicide must wear goggles or a face shield. Furthermore, standard label statements to protect against drift during application are present on the label.

Environment

To mitigate potential exposure of aquatic organisms to pydiflumetofen through spray drift, spray buffer zones of 1–15 metres are to be specified on the product labels.

To mitigate the potential effects of pydiflumetofen on non-target terrestrial plants, spray buffer zones of 1–15 metres are to be specified on the product labels.

Standard label statements are required to inform users of the toxicity of pydiflumetofen to aquatic organisms and non-target terrestrial plants.

To minimize the potential of pydiflumetofen to be carried-over to the following growing season, a label statement is required to inform users that pydiflumetofen-containing products should not be applied in consecutive years.

Standard statements are required to inform users of conditions that may favour runoff.

Precautionary label statements are required to inform users of conditions where pydiflumetofen may be prone to leaching.

Next Steps

Before making a final registration decision on Pydiflumetofen, A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide, and A21461 Fungicide, the PMRA will consider any comments received from the public in response to this consultation document. The

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

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on Pydiflumetofen A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide, and A21461 Fungicide, (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

Pydiflumetofen

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance Pydiflumetofen

Function Fungicide

Chemical name

1. International Union of Pure and Applied Chemistry (IUPAC) 3-(difluoromethyl)-*N*-methoxy-1-methyl-*N*-[(*RS*)-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide

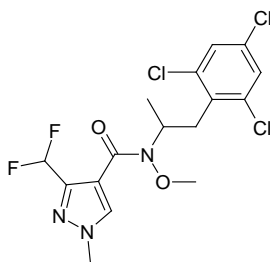
2. Chemical Abstracts Service (CAS) 3-(difluoromethyl)-*N*-methoxy-1-methyl-*N*-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1*H*-pyrazole-4-carboxamide

CAS number 1228284-64-7

Molecular formula C₁₆H₁₆Cl₃F₂N₃O₂

Molecular weight 426.7

Structural formula



Purity of the active ingredient 98.7%

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

Technical Product—Pydiflumetofen Technical

Property	Result
Colour and physical state	Off-white solid
Odour	Odourless
Melting range	112.7°C
Boiling point or range	Decomposes on heating from approximately 283°C

Property	Result		
Density at 20°C	1.55 g/cm ³		
Vapour pressure	1.84 × 10 ⁻⁷ Pa (20°C); 5.30 × 10 ⁻⁷ Pa (25°C)		
Ultraviolet (UV)-visible spectrum	pH	λ_{max} (nm)	ϵ (M ⁻¹ cm ⁻¹)
	Acidic	230	18 323
		295	59.5
	Basic	230	18 633
		295	53.2
	Neutral	230	18 777
		295	1290
Solubility in water at 25°C	1.5 mg/L		
Solubility in organic solvents at 25°C	Solvent		Solubility (g/L)
	Dichloromethane		> 500
	Acetone		220
	Ethyl acetate		130
	Toluene		67
	Methanol		26
	Octanol		7.2
	Hexane		0.270
<i>n</i> -Octanol-water partition coefficient (<i>K</i> _{ow})	<i>K</i> _{ow} = 7000		
	Log <i>K</i> _{ow} = 3.8		
Dissociation constant (p <i>K</i> _a)	Not applicable; no dissociation in the pH range of 2.0-12.0		
Stability (temperature, metal)	Stable for 2 weeks at 54°C; stable for 2 weeks in the presence of metals (aluminum flakes, iron granules) and metal ions (aluminum acetate and iron acetate) at 20°C and 40°C.		

End-Use Product—A19649 Fungicide and A19649TO Fungicide

Property	Result
Colour	Off-white
Odour	Odourless
Physical state	Liquid
Formulation type	Suspension
Guarantee	200 g/L pydiflumetofen
Container material and description	Plastic (HDPE), 0.5–1000 L
Density at 20°C	1.093 g/cm ³
pH of 1% dispersion in water	7.5
Oxidizing or reducing action	No oxidizing or reducing action
Storage stability	Stable for 2 weeks when stored at 54°C in HDPE and PET packaging
Corrosion characteristics	Non-corrosive to the packaging material
Explosibility	Not explosive

End-Use Product—A20259 Fungicide

Property	Result
Colour	White
Odour	Odourless/weak odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	75 g/L pydiflumetofen 125 g/L difenoconazole
Container material and description	Plastic (HDPE), 0.5-1000 L
Density at 20°C	1.088 g/cm ³
pH of 1% dispersion in water	7.3
Oxidizing or reducing action	No oxidizing or reducing action
Storage stability	Stable for 2 weeks when stored at 54°C in HDPE, PET and paper/PETP/Al/PE packaging
Corrosion characteristics	Non-corrosive to the packaging material
Explosibility	Not explosive

End-Use Product—A20560 Fungicide

Property	Result
Colour	Off-white
Odour	Odourless
Physical state	Liquid
Formulation type	Suspension
Guarantee	150 g/L pydiflumetofen 250 g/L fludioxonil
Container material and description	Plastic (HDPE), 0.5–1000 L
Density at 20°C	1.169 g/mL
pH of 1% dispersion in water	7.0
Oxidizing or reducing action	Reducing action; no oxidizing action
Storage stability	Stable for 2 weeks when stored at 54°C in HDPE and PET packaging
Corrosion characteristics	Non-corrosive to the packaging material
Explosibility	Not explosive

End-Use Product—A21461 Fungicide

Property	Result
Colour	Beige (light brown)
Odour	Aromatic odour
Physical state	Liquid
Formulation type	Suspension

Property	Result
Guarantee	75 g/L pydiflumetofen 100 g/L azoxystrobin 125 g/L propiconazole
Container material and description	Plastic (fluorinated and non-fluorinated HDPE), 0.5-1000 L
Density at 20°C	1.074 g/cm ³
pH of 1% dispersion in water	7.2
Oxidizing or reducing action	No oxidizing or reducing action
Storage stability	Stable for 2 weeks when stored at 54°C in fluorinated and non-fluorinated HDPE packaging
Corrosion characteristics	Non-corrosive to the packaging material
Explosibility	Not explosive

1.3 Directions for Use

Products containing pydiflumetofen are applied as preventative foliar treatments at rates ranging between 10–200 g active ingredient per hectare. Spray intervals of 7–14 days are recommended for most crops; although 21–28 days are recommended for turf and peanuts, and 21 days for crops in the Small Fruit Vine Climbing Crop Group. Applications can be made by ground or aerial application equipment.

1.4 Mode of Action

Pydiflumetofen is a member of the succinate-dehydrogenase class of fungicides, which target complex II in fungal respiration. It is classified by the Fungicide Resistance Action Committee as a Group 7 Fungicide.

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 for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredients in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

High performance liquid chromatography methods with tandem mass spectrometric detection (HPLC-MS/MS; QuEChERS method in plant and animal matrices) were developed and proposed for data generation and enforcement purposes. This method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices. The proposed

enforcement method was successfully validated in plant and animal matrices by an independent laboratory. Extraction solvents used in the method were similar to those used in the metabolism studies; thus, further demonstration of extraction efficiency with radiolabelled crops and animal matrices was not required for the enforcement method. Methods for residue analysis are summarized in Table 1, Appendix I.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Pydiflumetofen belongs to the pyrazole-carboxamide succinate dehydrogenase inhibitor class of fungicides. A detailed review of the toxicological database for pydiflumetofen was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes, as well as a number of mechanistic studies to support a proposed mode of action (MOA) for liver tumour formation in mice. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practice. The scientific quality of the data is high and the database is considered adequate to characterize the potential health hazards associated with this active ingredient.

Toxicokinetic data consisted of studies in which rats and mice were administered single gavage doses or repeated low gavage doses of ^{14}C -pydiflumetofen radiolabeled in either the phenyl or pyrazole rings. Toxicokinetic data were also available for pregnant rabbits following repeated gavage administration of non-radiolabeled pydiflumetofen during gestation days 6–27. Additionally, blood samples were taken in a number of the toxicity studies to assess systemic exposure.

Absorption was high following administration of a low dose of ^{14}C -pydiflumetofen in rats, but became limited as the dose increased. A similar pattern of dose-limited absorption was observed following repeated dosing. Peak concentrations in rat blood and plasma were observed within two hours of administration of the low dose and at eight hours following administration of the high dose.

In mice, dose-limited absorption was also evident. Following administration of a low dose, unchanged pydiflumetofen detected in feces represented a small percentage of the administered dose; however, at the highest doses, unchanged pydiflumetofen accounted for up to half of the administered dose.

The tissue distribution of radioactivity was similar, irrespective of dose, label or sex, following administration of single oral doses in rats. Radioactivity was widely distributed, with the highest concentrations observed in the liver and kidney from 0.5 to 120 hours post-dosing. The depletion profile of radioactivity from all tissues mirrored depletion in blood/plasma. At 96 hours post-dose, total tissue and carcass residues accounted for less than 3% of the administered dose.

Following oral or intravenous (IV) administration of ^{14}C -pydiflumetofen in rats, most radioactivity was eliminated by 48 hours post-dose and excretion was essentially complete by 168 hours, irrespective of radiolabel position, dose or sex. The predominant route of excretion

was the feces, with the majority of the absorbed dose eliminated via bile. Radioactivity in bile, as a percent of administered dose, decreased as dose levels increased. There was evidence of enterohepatic recirculation. Urine was a secondary route of excretion and expired air was a negligible route.

In mice, excretion was essentially complete after seven days, irrespective of dose, sex, or radiolabel position, following a single gavage administration of ^{14}C - pydiflumetofen, with the majority excreted in the first 24 hours. The routes of elimination were similar regardless of radiolabel position, sex, or dose, with the majority of the administered dose excreted in the feces. Urinary excretion was a secondary route of elimination.

In pregnant rabbits, systemic exposure did not increase in a proportional manner with dose. Reduced systemic concentrations with repeated exposure suggested metabolic induction.

In both rats and mice, the major metabolites were qualitatively and quantitatively similar irrespective of dose or sex. Pydiflumetofen was extensively metabolised in rats and mice via demethylation, hydroxylation, and dechlorination, followed by glucuronide and sulphate conjugation with the potential for the formation of multiple isomers. Pydiflumetofen also cleaved at the benzylic carbon to yield 2,4,6-trichlorophenol (TCP) and 2-[[3-(difluoromethyl)-1-methyl-1H-pyrazol-4-yl]carbonyl](methoxy)amino]propanoic acid (SYN548263), which were further metabolised. In rats, only TCP sulphate and SYN548263 individually accounted for >10% of the administered dose in excreta.

Pydiflumetofen was of low acute toxicity via the oral, dermal and inhalation routes of exposure in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits and it was not a skin sensitizer when tested in a local lymph node assay (LLNA) in mice.

The end-use products A19649TO Fungicide, A20259 Fungicide, and A20560 Fungicide were of low acute toxicity in rats via the oral, dermal and inhalation routes. They were non-irritating to the skin and eyes of rabbits and were not skin sensitizers when tested in LLNAs in mice. The end-use product A19649 Fungicide had a similar acute toxicity profile, except that it was minimally irritating to the eyes of rabbits.

The end-use product A21461 Fungicide was of moderate acute toxicity in rats via the oral route and of low acute toxicity in rats via the dermal and inhalation routes. In rabbits, it was moderately irritating to the eyes and minimally irritating to the skin. It was not a skin sensitizer when tested in an LLNA in mice.

Repeat-dose dietary toxicity studies with pydiflumetofen in mice, rats, and dogs revealed the liver as the target organ. Decreases in body weight and food consumption were frequently observed. Study duration had an impact on toxicity such that toxic effects were generally observed at lower dose levels in the long-term studies. At lower dose levels, liver findings such as increased liver weight were considered non-adverse, but there was a progression of toxic effects with increasing dosage. Typically, increased liver weights were accompanied by hepatocellular hypertrophy and clinical chemistry alterations such as increased cholesterol, increased alkaline phosphatase and increased triglycerides.

No significant toxicity or signs of dermal irritation were noted in rats following short-term exposure to pydiflumetofen via the dermal route up to the limit dose of testing. A repeated-exposure inhalation toxicity study was not conducted.

Results of a standard genotoxicity study battery, consisting of bacterial gene mutation, chromosome aberration, mammalian gene mutation, and unscheduled DNA synthesis assays, indicated that pydiflumetofen was not genotoxic. There was a positive result at cytotoxic dose levels in the absence of metabolic activation.

Following long-term dietary exposure in rats, body weight, body weight gain, food consumption and food efficiency were decreased in both sexes. There was no evidence of oncogenicity in this study. Hepatocellular hypertrophy associated with cytoplasmic eosinophilic inclusions and, at higher dose levels, increased gamma-glutamyl transferase levels, were also observed.

In the dietary mouse carcinogenicity study, increases in the incidences of hepatocellular hypertrophy, liver masses, and altered hepatic foci were noted. At the higher dose levels, body weight and body weight gain were decreased in both sexes and food consumption and food efficiency were decreased in males. Liver weights were also increased in males at this level. There was an increased incidence of combined liver adenomas and carcinomas in male mice at the high dose level. The number of mice with liver adenomas and carcinomas at low and mid-dose levels were within the historical control range, however, there was a statistically significant increase in the number of mice with multiple liver adenomas at the mid- and high dose levels. Mice with multiple liver carcinomas were observed at the high dose level. The mid-dose level was considered the tumourigenic dose based on the increased number of males with multiple liver adenomas.

A series of mechanistic studies were performed to support a proposed MOA for liver tumour formation based on CAR/PXR induction. This MOA involves a progression from metabolic enzyme activation leading to a transient increase in hepatocellular proliferation, progressing to altered hepatic foci and ultimately tumour formation. In a 28-day dietary mechanistic study performed in mice, there was evidence of hepatocellular proliferation at 10 mg/kg bw/day, a dose corresponding to the low dose in the carcinogenicity study. Liver weight, hepatocellular hypertrophy, as well as metabolic enzyme levels and activity were only significantly increased at 324 mg/kg bw/day, which corresponds to the high dose level in the carcinogenicity study. In an in vitro CAR3 transactivation assay, mouse, rat, and human CAR3 reporter constructs were activated by pydiflumetofen. In two in vitro hepatocyte proliferation indexing assays, mouse and human hepatocyte cultures were compared. In the mouse cell cultures, metabolic enzyme activity was increased along with hepatocellular proliferation; increased metabolic enzyme activity was not accompanied by cell proliferation in human cell cultures.

Temporal concordance of key events was demonstrated in the supporting data, with the occurrence of CAR activation, hepatocellular replicative DNA synthesis, increased mitosis, and elevated enzyme levels within 2 days, increased liver weight within 3 days, hepatocellular hypertrophy by day 7, and altered hepatocellular foci and tumours by day 560.

Several other potential modes of action were investigated. A liver sample enzyme analysis following a 28-day dietary exposure of mice to pydiflumetofen showed that pydiflumetofen was not a peroxisome proliferator. Results of a battery of in vitro and in vivo genotoxicity tests did not suggest genotoxic potential. There was no evidence in the database to suggest hepatocellular damage or sustained regenerative proliferation, hallmarks of the cytotoxic MOA. One component of the CAR/PXR MOA that was not examined was the reversibility of effects following cessation of dosing. Additionally, the oncogenic dose level was not represented in some of the mechanistic studies. Despite these limitations, the weight of evidence supports the proposed CAR/PXR MOA; therefore, a threshold-based risk assessment for liver tumour formation was considered appropriate.

In a dietary two-generation reproductive toxicity study in rats, there was no evidence of toxicity to the reproductive system, to parental animals, or the developing fetus. Offspring of the first generation had decreased body weights; this effect was not observed in the second generation. The body weight effect in the first generation in the absence of maternal toxicity suggests potential sensitivity of the young.

No evidence of sensitivity was noted in gavage developmental toxicity studies in rats or rabbits. No effects were noted in dams or fetuses at doses that were considered adequate based on toxicokinetic data, precluding the need for testing at higher dose levels.

Two gavage acute neurotoxicity studies were performed in rats. There was no evidence of neurotoxicity in the males in the first study, but the females showed low incidences of multiple effects such as ruffled fur, hunched posture and reduced activity, although with a poor dose-response relationship. The second study, conducted only in females, had a narrower dose range and also resulted in multiple low-incidence clinical signs with poor dose-response. When the studies were considered together, it was determined that a NOAEL (no observed adverse effect level) for females could be established at the lowest dose tested.

Results of the toxicology studies conducted on laboratory animals with pydiflumetofen and its associated end-use products are summarized in Tables 2 and 3, Appendix I. The toxicology reference values for use in the human health risk assessment are summarized in Table 4, Appendix I.

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, the standard complement of studies was available for pydiflumetofen, including gavage developmental toxicity studies in the rabbit and rat, and a dietary reproductive toxicity study in the rat.

With respect to potential prenatal and postnatal toxicity, there was some indication of increased sensitivity of offspring compared to parental animals in the reproductive toxicity study. In the absence of maternal toxicity, there was a slight decrease in pup body weight, which was not considered a serious effect. There were no treatment-related adverse effects identified in the rat and rabbit developmental toxicity studies.

Overall, endpoints in the young were well-characterized and the endpoints selected for risk assessment provided adequate margins to the effects noted above. On the basis of this information, the *Pest Control Products Act* factor (PCPA factor) was reduced to 1-fold.

3.2 Determination of Acute Reference Dose (ARfD) – All Populations

To estimate acute dietary risk (1 day), the two-rat acute neurotoxicity studies with a combined NOAEL of 100 mg/kg bw were selected for risk assessment. At the lowest observed adverse effect level (LOAEL) of 300 mg/kg bw, clinical signs, decreased activity and decreased mean body temperature were observed in females. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to 1-fold. The composite assessment factor (CAF) is thus 100.

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{100 \text{ mg/kg bw}}{100} = 1 \text{ mg/kg bw of pydiflumetofen}$$

3.3 Determination of Acceptable Daily Intake (ADI)

To estimate risk from repeated dietary exposure, the mouse carcinogenicity study with a NOAEL of 9 mg/kg bw/day was selected for risk assessment. At the LOAEL of 45 mg/kg bw/day, increased incidences of hepatocellular hypertrophy and eosinophilic altered hepatocellular foci were observed. At this dose level, a statistically significant increase in the number of male mice with multiple liver adenomas was also noted. The selected NOAEL is supported by the NOAEL of 10 mg/kg bw/day in the long-term rat study based on decreased body weight, body weight gain, and food consumption with increased liver weight and liver pathology at the LOAEL of 51/31 mg/kg bw/day in males/females. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to 1-fold. The CAF is thus 100.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{9 \text{ mg/kg bw/day}}{100} = 0.09 \text{ mg/kg bw/day of pydiflumetofen}$$

This ADI provides a margin of 400 to the NOAEL for pup weight effects in the two-generation reproductive toxicity study in rats.

Cancer Assessment

There was a treatment-related increase in the incidence of liver adenomas and carcinomas in male mice in the carcinogenicity study at 288 mg/kg bw/day. There was also a treatment-related increase in the number of male mice with multiple liver adenomas at 45 mg/kg bw/day. The proposed CAR/PXR MOA was supported by the submitted studies. For risk assessment purposes, a threshold approach was considered appropriate for these tumours. The endpoints selected for non-cancer reference values provide a margin of 500 between the ADI and the dose at which multiple adenomas were observed.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Reference Values

Short- and Intermediate-term Dermal and Inhalation

For short- and intermediate-term exposures via the dermal and inhalation routes, the NOAEL of 36 mg/kg bw/day for offspring toxicity from the dietary rat reproductive toxicity study was selected for risk assessment. At a dose level of 116 mg/kg bw/day, decreased pup body weight was observed. The 28-day dermal toxicity study in rats was not designed to assess this endpoint; therefore, this study was not selected for the dermal risk assessment. A repeat-dose inhalation toxicity study was not available. Although the 90-day dog dietary toxicity study had a lower NOAEL (30 mg/kg bw/day) than that selected for risk assessment, this NOAEL was influenced by dose selection. The combined results of the 90-day and 1-year dog studies suggest an overall NOAEL of 100 mg/kg bw/day in dogs.

The target Margin of Exposure (MOE) is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and unborn children. For residential scenarios, the PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act Hazard Characterization* section.

Long-term Dermal and Inhalation

For long-term exposures via the dermal and inhalation routes, the NOAEL of 9 mg/kg bw/day from the dietary mouse carcinogenicity study was selected for risk assessment. At the LOAEL of 45 mg/kg bw/day, increased incidences of hepatocellular hypertrophy and eosinophilic altered hepatocellular foci were observed. The selected NOAEL is supported by the NOAEL of 10 mg/kg bw/day in the long-term rat study based on decreased body weight, body weight gain, and food consumption with increased liver weight and liver pathology at the LOAEL of 51/31 mg/kg bw/day in males/females. Long-term dermal and inhalation toxicity studies were not available.

The target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and unborn children. For

residential scenarios, the PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Characterization section.

3.4.1.1 Aggregate

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal, and inhalation).

3.4.1.2 Toxicology Endpoint Selection for Aggregate Risk Assessment

For oral, dermal, and inhalation aggregate risk assessment of the general population (including pregnant women, infants, and children), the selected endpoint for short-term exposure scenarios was decreased pup weight, observed at a dose level of 116 mg/kg bw/day. The NOAEL in this study was 36 mg/kg bw/day. In the absence of dermal and inhalation studies to assess this endpoint, this oral study is used for all routes of exposure.

The target MOE for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and unborn children. The PCPA factor was reduced to 1-fold as discussed in the *Pest Control Products Act* Hazard Characterization section.

3.4.1.3 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current evaluation, the PMRA did not identify information indicating that pydiflumetofen shares a common mechanism of toxicity with other pest control products. Therefore there is no requirement for a cumulative risk assessment at this time.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to pydiflumetofen during mixing, loading and application. Dermal and inhalation exposure estimates for workers mixing, loading and applying were generated from the Agricultural Handlers Exposure Task Force (AHETF), Outdoor Residential Task Force (ORETF) and Pesticide Handlers Database (PHED, v1.1).

Exposure to workers mixing, loading and applying pydiflumetofen is expected to be of short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying pydiflumetofen to dried shelled peas and beans, soybeans, cereal grains, canola, peanuts, corn, turf (sod farms and golf courses), outdoor ornamentals, greenhouse ornamentals, greenhouse cucumber, potatoes, tuberous & corm vegetables, fruiting vegetables, cucurbit vegetables, leafy greens, leafy petiole

vegetables and small fruit vine climbing. The exposure estimates are based on mixers/loaders/applicators wearing a single layer plus chemical-resistant gloves.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

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.

Exposure estimates were compared to the toxicological end points (no observed adverse effects levels) to obtain the margin of exposure (MOE); the target MOE is 100 (Table 7, Appendix I). Additional PPE, chemical resistant headgear, was required to meet the target MOE of 100 for airblast application to outdoor ornamentals.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with A19649 Fungicide, A19649TO Fungicide, A20259 Fungicide, A20560 Fungicide and A21461 Fungicide to complete tasks such as setting irrigation lines, scouting, hand harvesting, transplanting, detasseling, girdling and turning. Given the nature of activities performed, dermal contact with treated foliage and turf should be primarily via the dermal route of exposure. Inhalation exposure is not expected to be of concern as pydiflumetofen is considered non-volatile with a vapour pressure of 1.84×10^{-10} kPa (20°C); 5.30×10^{-10} kPa (25°C) which is less than the NAFTA criteria for a non-volatile product for outdoor uses [1×10^{-4} kPa (7.5×10^{-4} mm Hg) at 20-30°C]. The duration of exposure is considered to be short- to intermediate-term, with the exception of greenhouse uses which are considered long-term.

Chemical-specific data for assessing human exposures during postapplication activities, specific to grapes, were submitted. However, given the limitations of the study, the study could not be used quantitatively.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values or turf transferable residue values with activity-specific transfer coefficients (TCs). Transfer coefficients are based on data from the Agricultural Re-entry Task Force (ARTF). As such, a default dislodgeable foliar residue value of 25% and a default turf transferable residue value of 1% of the application rate coupled with a 10% daily dissipation of residues were used for the risk assessment, except for greenhouse crops which used a 2.3% daily dissipation rate of residues.

Exposure estimates were compared to the toxicological end point to obtain the margin of exposure (MOE); the target MOE is 100. Only exposures and risks to the activities with the highest TCs are presented as MOEs for these activities exceed the target MOE of 100 (Table 8, Appendix I). A 1-day REI for grape girdling and turning is required to meet the target MOE of 100.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Postapplication Exposure and Risk

There is potential for exposure to golfers (adults, youth and children) re-entering turf treated with A19649TO. Dermal contact with treated surfaces should primarily occur via the dermal route of exposure. The duration of exposure is expected to be of short- to intermediate-term duration.

Dermal exposure to golfers is estimated by coupling the default turf transferable residue value with the activity specific transfer coefficient based on data from the USEPA Residential SOP. Chemical specific turf transferable data were not submitted. As such, a turf transferable residue of 1% of the application rate coupled with a daily dissipation of 10% was used for the exposure assessment. Exposure estimates were compared to the toxicological end point to obtain the MOE; the target MOE is 100 (Table 9, Appendix I).

3.4.3.2 Postapplication Exposure and Risk

There is potential for individuals to be exposed to pydiflumetofen via different routes of exposure concurrently. As such, dermal exposure to golfers was aggregated with dietary exposure. Exposure estimates were compared to the toxicological end point to obtain the MOE; the target MOE is 100 (Table 10, Appendix I).

3.4.3.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift beyond the areas to be treated is expected to be minimal, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.5 Food and Water Residues Exposure Assessment

3.5.1 Exposure from Drinking Water

3.5.1.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of pydiflumetofen in potential drinking water sources (groundwater and surface water) were generated using the Pesticide in Water Calculator (PWC) model. EECs of pydiflumetofen in groundwater were calculated to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PWC are average concentrations in the top 1 m of the water table.

EECs of pydiflumetofen in surface water were calculated to simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a small reservoir, representing a vulnerable drinking water source.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC

estimates are expected to allow for future use expansion into other crops at this application rate. Combined residues of pydiflumetofen and the transformation product SYN545547 were modelled.

Five standard regional scenarios were modelled to represent different regions of Canada. The models were run for various application dates and for 50 years. The highest EECs of all runs are reported in Table 3.5.1-1 below.

Table 3.5.1-1 Level 1 EECs of pydiflumetofen combined residue in potential drinking water sources

Crop/use pattern	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)	
	Daily ¹	Yearly ²	Daily ³	Yearly ⁴
Soybeans/2 × 200 g a.i./ha @ 7-d	152	152	10	3.7

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 concentrations

3.5.2 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products is pydiflumetofen. The residue definition for enforcement in animal commodities is pydiflumetofen. The residue definition for risk assessment in poultry commodities is pydiflumetofen and the metabolite 2,4,6-trichlorophenol (free and conjugated), expressed as parent equivalents. The residue definition for risk assessment in ruminant commodities is pydiflumetofen, the metabolites 2,4,6-trichlorophenol (free and conjugated), SYN547897 (liver and kidney), and SYN548263 (kidney), expressed as parent equivalents. The data gathering/enforcement analytical methods are valid for the quantitation of pydiflumetofen, 2,4,6-trichlorophenol (free and conjugated), SYN547897 and SYN548263 residues in crop and/or livestock matrices. The residues of pydiflumetofen are stable in representative matrices from five crop categories (high water, high oil, high protein, high starch and high acid content) for up to 23 months when stored at ~ -20°C. Therefore, pydiflumetofen residues are considered stable in all frozen crop matrices and processed crop fractions for up to 23 months. Pydiflumetofen residues are stable in all frozen livestock matrices for up to 12 months. Pydiflumetofen residues concentrated in the following processed commodities: dried tomato (10.0-fold), refined peanut oil (2.3-fold), wheat bran (2.3-fold), wheat germ (1.5-fold), and corn flour (1.5-fold). Adequate feeding studies were carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Crop field trials conducted throughout Canada and the United States using end-use products containing pydiflumetofen at approved (or exaggerated) rates in or on grapes, potatoes, tomatoes, bell pepper, non-bell pepper, cantaloupe, summer squash, cucumber, leaf lettuce, head lettuce, spinach, celery, dry bean, dry pea, rapeseed, peanut, soybeans, barley, oats, wheat, field corn, sweet corn and popcorn are sufficient to support the proposed maximum residue limits.

3.5.3 Dietary Risk Assessment

Acute and chronic (non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™).

3.5.3.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic non-cancer analysis for pydiflumetofen: 100% crop treated, default processing factors (where available), the proposed MRLs for the plant commodities, and anticipated residues for all animal commodities. The basic chronic dietary exposure from all supported pydiflumetofen food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 25% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to pydiflumetofen from food and drinking water is 21% (0.018983 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for Children 1-2 years old at 30% (0.026694 mg/kg bw/day) of the ADI.

3.5.3.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the basic acute analysis for pydiflumetofen: 100% crop treated, default processing factors (where available), the proposed MRLs for plant commodities and the anticipated residues in animal commodities. The basic acute dietary exposure (food alone) for all supported pydiflumetofen registered and imported commodities is estimated to be 7% (0.066315 mg/kg bw/day) of the ARfD for the general population (95th percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable: 7.0% of the ARfD for the general population. The highest exposure and risk estimate is for children 3-5 years old at less than 9% (0.084607 mg/kg bw/day) of the ARfD (95th percentile, deterministic).

3.5.4 Aggregate Exposure and Risk

There is potential for individuals to be exposed to pydiflumetofen via different routes of exposure at the same time. As such an aggregate risk assessment was conducted aggregating exposure to individuals golfing and ingesting foods treated with pydiflumetofen. The aggregated risk assessment is considered acceptable.

3.5.5 Maximum Residue Limits

Table 3.5.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Crop Subgroup 4-13A, Leafy Greens	40
Crop Subgroup 22B, Leaf Petioles Vegetables	15
Barley	4
Quinoa	4
Dried tomatoes	3

Commodity	Recommended MRL (ppm)
Oats	3
Raisins	2
Crop Subgroup 13-07F, Small fruits vine climbing , except fuzzy kiwifruit	1.5
Crop Subgroup 20A, Rapeseeds (Revised)	0.9
Wheat bran	0.6
Crop Group 8-09, Fruiting Vegetables	0.6
Crop Group 9, Cucurbit Vegetables	0.5
Dry soybeans	0.4
Wheat germ	0.4
Crop Subgroup 6C, Dried shelled pea and bean (except soybean)	0.4
Rye	0.3
Triticale	0.3
Wheat	0.3
Peanut oil (refined)	0.05
Fat of cattle, goat, horse and sheep	0.03
Meat byproducts of cattle, goat, horse and sheep	0.03
Milk	0.03
Peanuts	0.02
Field corn flour	0.02
Crop Subgroup 1C, Tuberous and Corm Vegetables	0.015
Field corn	0.015
Popcorn grain	0.015
Eggs	0.01
Fat, meat, meat byproducts of hogs	0.01
Fat, meat, meat byproducts of poultry	0.01
Meat of cattle, goat, horse and sheep	0.01
Sweet corn kernels plus cob with husks removed	0.01

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

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

The nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and acute and chronic dietary risk estimates are summarized in Tables 1, 5 and 6, Appendix I.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Pydiflumetofen has low solubility in water, low vapour pressure and low Henry's law constant (Table 11, Appendix I). The intrinsic physico-chemical properties suggest that pydiflumetofen is not likely to volatilize from moist soil or water surfaces under field conditions.

In the terrestrial environment, pydiflumetofen is persistent. Laboratory studies show that transformation processes including hydrolysis, phototransformation, and aerobic/anaerobic biotransformation are very slow and will not contribute significantly to the overall dissipation (Table 11, Appendix I). In the laboratory soil studies, no major transformation product was observed, one minor transformation product (SYN545547) was detected at <3% applied radioactivity (AR). The transformation half-lives ranged between 474 and 5405 days in aerobic soils and >960 days in anaerobic soils. Observations from terrestrial field dissipation studies are consistent with the laboratory results. All but one study on bare soil, including those conducted in southern ecoregions of the United States, show that pydiflumetofen is persistent under field conditions, with DT₅₀ values ranging from 260 to 666 days. The only exception was observed for an Iowa field test which resulted in a DT₅₀ of 57 days. Results suggest that pydiflumetofen is persistent according to the classification scheme of Goring *et al.* (1975) and has a potential to be carried over to the following growing season under field conditions in Canada.

Laboratory experiments show that pydiflumetofen has low mobility to slight mobility in soil according to the classification scheme of McCall *et al.* (1981), depending on soil organic carbon content. The average adsorption coefficient normalized to organic carbon content (K_{oc}) was 2065 (1383 - 2247 L/g). Both the Cohen *et al.* criteria (1984) and GUS index method (Gustafson, 1989) suggest that pydiflumetofen is a borderline leacher, primarily due to its persistence in soil and adsorption to organic matter. Field dissipation studies show that pydiflumetofen is generally confined to the top 30 cm layer. However, in areas that are vulnerable to leaching, it is reasonable to expect some leaching as evidenced in the study conducted in PEI where pydiflumetofen was detected at depth of 60-75 cm. Compared to the parent compound, the transformation product SYN545547 has a higher mobility, with a mean linear adsorption coefficient (K_{oc}) of 703±203 (mean: 360-860) L/g.

In the aquatic environment, hydrolysis is not expected to be a route of dissipation. Pydiflumetofen can be transformed slowly under irradiation. Photolysis half-lives were 99 days in a pH 7 buffer solution and 118 days in a natural water under conditions equivalent to summer light at 30-50 °N. In aerobic water/sediment systems, pydiflumetofen partitioned relatively quickly to the sediment with DT₅₀ of 4.8-13.7 days. Once in the sediment, it was persistent with total system half-lives of 238-278 days. SYN545547, a major transformation product in aerobic water/sediment systems, was continuously formed and reached the maximum amount of 13% AR at the end of the experiment (100 days). In comparison, in anaerobic water/sediment systems, pydiflumetofen partitioned to the sediment less readily (DT₅₀: 33-39 days), but once in the sediment, it was moderately persistent (half-lives: 162-174 days in total systems). SYN545547 was again observed as a major transformation product in anaerobic aquatic systems. Its concentrations increased over time and reached maximum of 32% AR at the end of the 100-day incubation period. Because concentrations of SYN545547 continuously increased over the study periods, its fate in the water/sediment systems is unknown, half-lives of combined residues of pydiflumetofen and SYN545547 were used in modelling of aquatic ecoscenarios.

Although the logK_{ow} of 3.8 for pydiflumetofen suggests a potential for bioaccumulation, bioaccumulation was not observed under laboratory conditions. The results of a bioconcentration study conducted with rainbow trout resulted in lipid-normalized kinetic bioconcentration factors

(BCF_{k,L}) of 189 L/kg lipid for whole fish, respectively. Therefore, pydiflumetofen is not expected to bioaccumulate in organisms.

A summary of environmental fate data is presented in Table 12, Appendix I.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse ecological effects. This integration is achieved by comparing exposure concentrations (i.e., the expected environmental concentration (EEC)) with concentrations at which adverse effects occur (i.e., toxicity endpoints such as LC₅₀, LD₅₀, NOEC or NOEL). For characterizing acute risk, acute toxicity values (e.g., LC₅₀, LD₅₀, and EC₅₀) are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (e.g., community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (e.g., 10 for fish, 2 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e., feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

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 (e.g., direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate (EECs) by an appropriate toxicity value ($RQ = \text{exposure/toxicity}$), and the RQ is then compared to the level of concern (LOC = 1 for most species, 0.4 for pollinators and 2 for beneficial arthropods (acute screening tests for predatory mite and parasitoid wasp)). If the screening level RQ is below the LOC, 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 the available data do not support further refinements, and thus, no further refinements are possible.

The risk of pydiflumetofen and its related end-use products to organisms was assessed based upon the maximum annual application rate of 400 g a.i./ha, applied as two spray applications of 200 g a.i./ha with a 7-day interval. For outdoor ornamentals, pydiflumetofen can be applied at 225 g a.i./ha followed by 175 g a.i./ha. Therefore, the risk to honeybees was assessed based on the maximum single application rate of 225 g a.i./ha. The most sensitive endpoints were selected for the screening level risk assessment and the appropriate uncertainty factors were applied. A

summary of all available sensitivity endpoints for terrestrial and aquatic organisms are presented in Table 13 and Table 14, Appendix I, respectively.

4.2.1 Risks to Terrestrial Organisms

A risk assessment of pydiflumetofen and its end-use products A19649B and A19649TO was undertaken for terrestrial organisms based on available toxicity data for earthworms, honeybees and other beneficial arthropods, birds and small wild mammals and terrestrial plants (Table 13, Appendix I). At the screening level, the maximum annual application rate of 400 g a.i./ha was considered for direct overspray to bare soil surfaces in the field since at a soil half-life of 3118 days (Table 12, Appendix I), there would be no appreciable degradation occurring within the 7-day application interval. For direct overspray to plant surfaces in the field, the maximum annual accumulative application rate of 323 g a.i./ha was considered. This was calculated based on application rates of 2×200 g a.i./ha with a 7-day interval and a default foliar half-life of 10 days.

To convert soil EECs from g a.i./ha to mg a.i./kg soil, it was assumed that pydiflumetofen was homogeneously mixed in the top 15-cm soil layer that has a bulk density of 1.5 g/cm^3 . At the maximum annual application rate of 400 g a.i./ha, the screening level EEC in the soil resulting from direct over-spray was 0.18 mg a.i./kg soil.

For non-target terrestrial organisms, exposure can also result from spray drift. The amount of spray drift depends on the type of equipment used, the size of spray droplets, as well as the type of crops. To calculate off-field EECs, spray drift factors are applied to the in-field EECs. Spray drift factor is defined as the maximum percentage of spray drift deposition at one metre downwind from the point of application. For pydiflumetofen end-use products, application methods include ground spray (fine-sized droplets), early season airblast, late season airblast, and aerial application with medium-sized droplets. Correspondingly, spray drift factors of 11%, 74%, 59% and 23%, respectively, are applied and resulting EECs are summarized in Table 15, Appendix I.

For pollinator risk assessment, the maximum single application rate of 225 g a.i./ha was used to calculate the exposure EECs.

Earthworms

The acute and chronic toxic effects of pydiflumetofen and its end-use product A19649B to earthworms (*Eisenia fetida*) were determined in laboratory studies and the results were compared to the screening level soil EEC of 0.18 g a.i./kg. The resulting risk quotients (RQ) did not exceed the level of concern (LOC) (Table 16, Appendix I). Therefore, risks to earthworms from the use of pydiflumetofen are acceptable.

Beneficial arthropods

To assess the risk to beneficial arthropods, laboratory studies were conducted with the indicator species, *Aphidius rhopalosiphi* and *Typhlodromus pyri*, whereby insects were exposed to pydiflumetofen (applied as A19649B) on glass surface as well as plant materials. The screening

level risk assessment considers the toxicity endpoints obtained from glass plate tests. On an acute basis, the RQ values for both species were below the LOC, indicating negligible risks are expected (Table 17, Appendix I). However, on a chronic basis, the RQ values exceeded the LOC for both species (Table 17, Appendix I). When considering the exposure resulting from spray drift, the RQ values for *T. pyri* exceeded the LOC for all off-field scenarios with the exception of the ground application exposure scenario; whereas for *A. rhopalosiphi*, the only RQ that exceeded the LOC was for the early airblast exposure scenario (Table 17, Appendix I).

Subsequently, a Tier I refinement for chronic risk was performed by considering the toxicity endpoints obtained from the extended tests examining the exposure of *A. rhopalosiphi* and *T. pyri* from pydiflumetofen on plant materials. The results presented in Table 17, Appendix I, showed that one of the RQ values exceeded the LOC; therefore, risks to beneficial arthropods from the use of pydiflumetofen are acceptable.

Honeybees

To assess the risk to honeybees (*Apis mellifera*), both laboratory studies and semi-field studies were conducted and the results are summarized in Table 13, Appendix I. The endpoints derived from the laboratory tests were used for the screening level (Tier I) risk assessment and the results obtained from the semi-field studies were used for Tier II refined risk assessment. The maximum exposure (EECs) was calculated based on the maximum single application rate of 225 g a.i./ha for outdoor ornamentals.

Tier I risk assessment

Potential risk to adult bees following acute contact exposure: During spray application, adult forager bees may be exposed to pydiflumetofen from spray droplets. At the Tier I level, contact exposure is estimated by multiplying a factor of 2.4 µg a.i./bee per kg/ha to the maximum single application rate of 0.225 kg a.i./ha, resulting in a EEC of 0.54 µg a.i./bee. This conversion was based on the maximum residue value reported by Koch and Weiser (1997), and thus serves as an upper-bound estimate. Compared to the acute contact endpoint for pydiflumetofen technical, the RQ was calculated to be less than 0.005; the LOC was not exceeded.

Potential risk to adult bees following acute oral exposure: Pydiflumetofen may be found on treated plant materials including pollen and nectar from deposited spray droplets during the crop blooming period, resulting in the potential for oral exposure to adult forager bees. Moreover, forager bees may bring contaminated pollen and nectar back to the hive, thus exposing bees in the hive. At the Tier I level, oral exposure was estimated by multiplying the single application rate of 0.225 kg a.i./ha by 28.6 µg a.i./bee per kg/ha, resulting in a EEC of 6.44 µg a.i./bee. This conversion was based on consumption rates primarily derived from Rortais *et al.* (2005) and Crailsheim *et al.* (1992 and 1993). Compared to the acute oral endpoint for pydiflumetofen technical, RQ was calculated to be less than 0.06; the LOC was not exceeded.

Potential risk to adult bees following chronic oral exposure: The oral exposure estimate for adult bees is 6.44 µg a.i./bee, calculated as described above. When this estimate was compared to the chronic oral endpoint, the RQ was 0.05, therefore, the LOC was not exceeded.

Potential risk to bee larvae following acute and chronic exposure: The oral exposure estimate for bee larvae was calculated by multiplying the direct single rate by 12.15 µg a.i./larva per kg/ha, resulting in an EEC of 2.73 µg a.i./larva. This conversion was based on consumption rates primarily derived from Rortais *et al.* (2005) and Crailsheim *et al.* (1992 and 1993).

Two chronic honeybee larval toxicity tests were available. One test was conducted with pydiflumetofen technical at a single dose of 0.0035 µg a.i./larva/day (limit test). Compared to the controls, there were statistically significant effects on 8-day larval mortality and 22-day adult emergence. Therefore, the acute LD₅₀ for larval mortality and the chronic NOEL for adult emergence were >0.0035 µg a.i./larva/day and <0.0035 µg a.i./larva/day, respectively. The other test was conducted with an end-use product, Pydiflumetofen™ SC, at seven dose levels ranging between 0.016 and 11 µg a.i./larva/day, together with a negative control (untreated diet), a formulant control (equivalent to the highest dose of test item) and a reference control (dimethoate). In comparison with the formulant control and based on a dose-response relationship, the acute LD₅₀ and the NOEL for emergence were determined to be 7.8 µg a.i./larva/day and 0.42 µg a.i./larva/day, respectively. Though the effects in the limit test occurred at a lower concentration than in the multi-concentration study with the end-use product, the results from the test with end-use product were considered more robust as dose-response relationships for mortality and emergence were observed. Therefore, the Tier I risk assessment included endpoints obtained from both studies.

Based on the endpoints obtained from the limit test and an EEC of 2.73 µg a.i./larva, the RQ value for acute oral toxicity to bee larvae was less than 781 and the RQ value for chronic oral toxicity to larvae was greater than 781 (Table 18, Appendix I). Given the study limitations mentioned above, both RQs which exceeded the level of concern are uncertain. Based on the endpoints derived from the multi-dose test with end-use product, RQ values were 0.35 and 6.51, respectively, for the acute oral and chronic oral toxicity on bee larvae (Table 18, Appendix I). In this case, only the RQ for chronic toxicity exceeded the LOC.

Tier I refinement

The Tier I refined risk assessment considered measured residues of pydiflumetofen in nectar, pollen, flowers and leaves following foliar applications of the end-use product Pydiflumetofen SC (a.i.: 18.4% w/w) at 75, 125 and 200 g a.i./ha on *Phacelia tanacetifolia* in full bloom in two semi-field studies. Analysis of residues of pydiflumetofen in pollen and nectar collected by forager bees showed that concentrations in pollen and nectar were the highest on the day of application and declined rapidly thereafter. In pollen samples collected by forager bees from both studies, the peak concentrations were in the range of 7.37-33.3 mg a.i./kg over all treatment levels on the day of application. Residues of pydiflumetofen in pollen decreased to 1.14-2.05 mg a.i./kg, 0.35-0.7 mg a.i./kg and 0.11-0.38 mg a.i./kg (<1.8% of the peak levels) 1, 2 and 4 days after application, respectively. In nectar samples collected by forager bees, the measured residues were in the range of 0.04-0.165 mg a.i./kg on the day of application, one detection at 0.012 mg a.i./kg after 1 day and no detections thereafter. In addition, samples were also collected from combs on Day 37-38 and 52-54 at the monitoring sites. In one study, pollen residues in the range of 0.11-0.56 mg a.i./kg were measured only at the 200 g a.i./ha treatment rate and 10 µg a.i./kg residue in nectar was measured in the Day 37 sample at the 75 g a.i./ha treatment rate. No

residues on Days 38 or 52 were measured in the second study. The residue levels in flowers and leaves were at comparable levels with those measured in the pollen samples from forager bees on the day of application, followed by a rapid decline with calculated DT₅₀ of 0.45-1.72 days in flowers and 2.55-12 days in leaves.

The residues information measured in nectar and pollen from different matrices were converted to a dose (µg a.i./bee/day) based on a combination of pollen and nectar consumption rates of 0.0036 and 0.120 g/day, respectively. The residue levels measured in Day 0-4 samples were used for both acute and chronic risk assessment and the residue levels measured in Day 37-54 samples were used to further assess the chronic risk to bee larvae.

Table 19, Appendix I summarizes results from the Tier I refined risk assessment using measured residues in pollen and nectar. Using the endpoints obtained from the multi-dose test with the end-use product, calculated RQ values were below the level of concern at the highest residue levels. Using the endpoints obtained from the single-dose test with pydiflumetofen technical, calculated RQ values decreased significantly as the measured residue levels declined rapidly. RQ values reduced from 40 on the day of application to 2.3 and 0.9 after 1 and 2 days of application, respectively. Using the residue concentrations measured in the comb during the monitoring period, calculated RQ values for chronic exposure were 0.48-0.76. These results indicated that two days after application, RQ value was below LOC on a chronic basis. Though the RQ value remained above the LOC, the forty-fold reduction within two days suggest that the effects on bee larvae were of a transitory nature.

Tier II Semi-field studies

The potential effects of pydiflumetofen on honeybees were further characterized at the colony level in two semi-field (tunnel) studies. The end-use product, Pydiflumetofen™ SC (a.i.: 18.4% w/w), was sprayed onto full flowering plants (*Phacelia tanacetifolia*) at nominal rates of 75, 125, and 200 g a.i./ha while bees were actively foraging in tunnels. No significant effects on honeybee adult workers, pupae and larvae mortality were observed during the exposure and post-exposure phases at application rates up to 200 g a.i./ha. There were also no significant effects on the brood and compensation indices and termination rates for eggs, young larvae, and old larvae during the exposure and post-exposure phases. In the colony conditions assessments, the number of combs with food was significantly lower in all pydiflumetofen treatment groups for at least one assessment time point when compared to the negative control. While there was a significant (p<0.05) decrease in food stores in the pydiflumetofen treatment groups, there was no dose-response relationship and the observed decrease did not occur over multiple or concurrent time points. Additionally, the transient decreases in food stores did not appear to translate into adverse impacts on brood development or other adverse effects on the honeybee colony population.

There were uncertainties associated with the two studies. One study experienced heavy rainfall during exposure phase and the other study experienced a general declining in total numbers of bees as the colonies were likely preparing for overwintering by the end of the study (mid-October). Furthermore, both studies experienced food shortage during monitoring phase. In both studies, however, the accompanying toxic reference tests conducted with fenoxycarb (Insegar, 25.1%) showed statistically significant (p<0.05) effects included larvae and pupae mortalities,

higher brood termination rates, lower brood index and compensation index, and lower colony strength at 15-30 DAA to 52-63 DAA. In addition, both reference groups showed multiple effects at significant ($p < 0.05$) levels of lower number of eggs, larvae, pupae, capped brood, and total brood compared to the negative control. These effects are consistent with the mode of action for fenoxycarb as an insect growth regulator (juvenile hormone agonist), and thus, suggesting that the weather conditions and the timing of the study did not significantly compromise detection of effects in the studies.

Considering the lack of effects on honeybee colonies across all measured endpoints and dose-response relationships, and in comparison with the toxic reference control and the negative controls, it can be concluded that, on a colony basis, a NOAEC was 200 g a.i./ha and a LOAEC was >200 g a.i./ha.

Results from the semi-field studies suggest that the LOC exceedance seen in the less robust laboratory limit toxicity test with larval bees is unlikely to translate to the population level in the fields. Given that the crop used in the semi-field tests (*Phacelia*) is a representative crop species and the absence of dose-response effects or long-term effects at application rates up to 200 g a.i./ha, application of pydiflumetofen up to 225 g a.i./ha is not expected to adversely impact honeybees at the colony level. Therefore, risks to honeybees from the use of pydiflumetofen are acceptable.

Birds and mammals

Exposure of pydiflumetofen to birds and small wild mammals are estimated through food ingestions. EECs were converted to the estimated daily exposures (EDEs) based on the maximum residue concentrations from the nomogram (maximum residues determined in the Hoerger and Kenaga nomogram) for a set of generic body weights to represent a range of species (20, 100, 1000 g for birds and 15, 35, 1000 g for small mammals). For each size category, one feeding guild that is considered relevant to the specific size is selected. Furthermore, the screening level assessment assumes that exposure occurs entirely through the consumption of food sources contaminated with pydiflumetofen at the maximum nomogram residue levels. However, a diet consisting of 100% plant material is not considered realistic for small and medium sized birds (20 and 100 g) and small mammals (15 g) and, therefore, was not included in the determination of EDE.

Birds: Pydiflumetofen is practically non-toxic to birds on an acute oral or dietary basis. No treatment related mortality was observed for bobwhite quail (*Colinus virginianus*), mallard duck (*Anas platyrhynchos*) and canary (*Serinus canaria*) at the highest test dose. LD₅₀ were >2000 mg a.i./kg bw for oral test and >1258 mg a.i./kg-bw/day for dietary test. The RQ for birds resulting from acute oral or dietary exposure to pydiflumetofen did not exceed the LOC at the screening level (Table 20, Appendix I).

Following chronic exposure to pydiflumetofen, some reproductive effects were observed for both bobwhite quail and the mallard duck at NOELs of 92 and 26.9 mg a.i./kg bw/d, respectively. Using the most sensitive NOEL of 26.9 mg a.i./kg bw/d and assuming the birds were eating 100% contaminated foods that contained maximum amounts of pydiflumetofen residue, the

resulting RQs did not exceed the LOC at the screening level (Table 20, Appendix I) on a chronic basis. Therefore, risks to birds from the use of pydiflumetofen are acceptable.

Small wild mammals: The toxicity of pydiflumetofen to rats was used to determine the risk to small terrestrial mammals. When exposed to pydiflumetofen technical through oral ingestion, no mortality or toxic symptoms were observed at 5000 g a.i./kg bw. However, adverse effects including mortality occurred when rats were exposed to A19649B (EP) containing 18.6% pydiflumetofen (w/w) at 5000 mg EP/kg bw, resulting in a LD₅₀ of 2958 mg EP/kg bw, equivalent to 550 mg a.i./kg bw. Using this endpoint and assuming a diet consisted of 100% contaminated foods at the maximum residue levels, the RQ values did not exceed the LOC on an acute basis at the screening level (Table 20, Appendix I).

In a two-generation study, no treatment-related adverse effects on the parental generation were observed. However, there were reductions in body weight in male and slight delays in sexual maturation in female offspring. The most sensitive NOAEL for the young was 36.1 mg a.i./kg bw/day. When the NOAEL was compared to the most conservative exposure through consumption of 100% contaminated food, the RQ values did not exceed the LOC (Table 20, Appendix I). Therefore, risks to small wild mammals from the use of pydiflumetofen are acceptable.

Non-target terrestrial vascular plants

Seedling emergence: The toxic effects of pydiflumetofen on seedling emergence were tested on 10 plant species (4 monocotyledonous species and 6 dicotyledonous species) at measured application rates of 370-400 g a.i./ha (applied as A19649B). Compared to the negative control, only wheat showed 13% inhibition in seedling dry weight at the highest test rate (370 g a.i./ha). Therefore, the most sensitive IC₂₅ for seedling emergence was > 370 g a.i./ha. Comparing the IC₂₅ values and the EECs presented in Table 13, Appendix I, the only RQ value that slightly exceeded the LOC was for the exposure scenario of in-field over-spray on bare soil surface (Table 21, Appendix I). None of the RQ values calculated for exposure from direct over-spray on plant surface or from spray drift either on soil surface or plant surface exceeded the LOC (Table 21, Appendix I). Therefore, risks to seedling emergence from the use of pydiflumetofen are acceptable.

Vegetative vigour: In a vegetative vigour study, young plants of the same 10 species were exposed to pydiflumetofen at a single application rate of 200 g a.i./ha (applied as A19649B). No statistically significant inhibitions in plant survival and growth (height and dry weight) were observed for any of the ten species tested. Therefore, the IC₂₅ for vegetative vigour was > 200 g a.i./ha. Using this endpoint, the RQs for in-field exposure and for off-field exposure from spray drift during early season airblast application exceeded the LOC (Table 21, Appendix I).

However, it is worth noting that the IC₂₅ for vegetative vigour was derived from a limit test at an application rate of 200 g a.i./ha, half of the maximum application rate of 2x200 g a.i./ha. Since no inhibitions in plant survival and growth were observed at 200 g a.i./ha, the risk to plants may be overestimated by the RQ values. Nonetheless, buffer zones will be required as a risk mitigation measure.

4.2.2 Risks to Aquatic Organisms

A risk assessment of pydiflumetofen was undertaken for freshwater and marine aquatic organisms based on available toxicity data presented in Table 14, Appendix I. When calculating RQ values, acute toxicity endpoints (E_rC_{50} and LC_{50}) are divided by an uncertainty factor of 10 for fish species and 2 for aquatic plants and invertebrates. No uncertainty factors are applied to chronic NOEC endpoints.

At the screening level, EECs in the aquatic environment were calculated based on a cumulative maximum rate of 400 g a.i./ha and directly sprayed on a 15-cm deep water body representing a seasonal pond suitable for amphibians and an 80-cm deep water body representing a permanent pond for aquatic organisms. For marine organisms, the EEC in water was also based on an application rate of 400 g a.i./ha to an 80-cm deep water body. It was assumed that pydiflumetofen was instantaneously and completely mixed within the water body. The resulting EECs were 0.27 mg a.i./L for a water body of 15 cm in depth and 0.05 mg a.i./L for a water body of 80 cm in depth (Table 15, Appendix I).

At a refinement level, exposure resulting from spray drift was considered by applying spray drift factors associated with various application methods as described in Section 4.2.1 and the resulting EECs are summarized in Table 15, Appendix I.

Exposure through surface runoff was estimated using the PWC model. For Level 1 modelling, EECs of pydiflumetofen from runoff into a receiving water body were simulated assuming pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. At this level, the water body consists of a 1 ha wetland with an average depth of 80 cm and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body described above, but having a water depth of 15 cm. Pore water EECs in both 15 and 80 cm wetlands were also generated.

Input fate parameters for the PWC model were provided in Table 12, Appendix I. For ecological modelling, the combined residues of parent and SYN545547 (a major aquatic transformation product) were considered relevant for the 15-cm water bodies because a preliminary assessment identified risks for amphibians from exposure to both parent and SYN545547. However, the screening level risk assessment for SYN545547 did not show a risk to fish and alga, and thus, the 80-cm water bodies were modelled for parent only.

Five standard regional scenarios were modelled to represent different regions of Canada. According to the product labels, maximum application rate of 2×200 g a.i./ha with a 7-d interval was used in Ontario, Quebec and Atlantic regions while a 14-d interval was used in British Columbia and the Prairies. The models were run for various application dates and for 50 years. For each year of the simulation, PWC calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90th percentiles over each averaging period are reported as the EECs for that period.

The highest EECs of all simulation runs for a given use pattern/regional scenario are reported in Table 22, Appendix I. Results showed that water bodies in Prince Edward Island had the highest EECs.

Freshwater fish

Acute toxicity of pydiflumetofen to freshwater fish was determined using three species representing a cold water species (rainbow trout (*Oncorhynchus mykiss*)) and two warm water species (fathead minnow (*Pimephales promelas*) and common carp (*Cyprinus carpio*)). Rainbow trout was the most sensitive species, for which a significant mortality occurred at concentrations above 0.13 mg a.i./L. The acute LC₅₀ was determined to be 0.186 mg a.i./L. Chronic toxicity of pydiflumetofen to fish was determined in an Early-Life-Cycle test with fathead minnow embryos and larvae. Statistically significant effects were observed on hatchability, larval survival, post-hatch survival, and growth, at concentrations of 0.15 mg a.i./L or above, therefore a NOEC was determined to be 0.064 mg a.i./L.

At the screening level, when comparing the most sensitive endpoints with the EEC resulting from a direct overspray on water surfaces, the RQ value for freshwater fish resulting from an acute exposure exceeded the LOC, but the RQ for freshwater fish resulting from a chronic exposure did not exceed the LOC (Table 23, Appendix I). Therefore, risks to freshwater fish from the use of pydiflumetofen are acceptable on a chronic basis.

The risk of acute exposure to fish was further characterized by considering drift-based EECs. For applications using either ground sprayer or aerial application methods, the RQ values were below the LOC (Table 24, Appendix I). However, when the EECs were estimated by assuming pydiflumetofen was applied by airblast, the RQ values exceeded the LOC. Consequently, mitigation measures to protect freshwater fish from spray drift will be required.

To further characterize the risk to freshwater fish, EECs resulting from pesticide runoff into a body of water directly adjacent to the field was determined by the PWC model. The peak EECs and the EECs calculated 96 hours after the application (Table 22, Appendix I) were considered for assessing the risk from acute exposure. The results presented in Table 25, Appendix I showed that RQs were less than 1, indicating risks to freshwater fish due to runoff from the use of pydiflumetofen are acceptable on an acute basis.

Freshwater amphibians

No toxicity data of pydiflumetofen to amphibians were available. Therefore, the most sensitive fish endpoints were used as surrogates. A seasonal 15-cm deep water body was used to represent the most sensitive habitat for this group of organisms. At the maximum annual application rate of 400 g a.i./ha, the EEC for pydiflumetofen in a 15-cm deep body of water was 0.27 mg a.i./L (Table 25, Appendix I). The risk quotients for amphibians were calculated to be 14.5 and 4.2 on acute and chronic bases, respectively (Table 23, Appendix I); both RQs exceeded the level of concern at the screening level.

With refinement, the RQ values calculated with drift-based EECs showed that for airblast and aerial application methods, acute and chronic risks remained for amphibians (Table 24, Appendix I). Therefore, spray buffer zones are required on the label as a mitigation measure to protect amphibians due to spray drift from the use of pydiflumetofen.

For exposure resulting from runoff, the peak EECs and the EECs after 96 hours of application were used for assessing the risk to amphibians from acute exposure and the EECs after 21-day and yearly averages were used for assessing the risk to amphibians from chronic exposure. The resulting RQ values showed the LOC was not exceeded on a chronic basis (Table 25, Appendix I); however, the acute RQs calculated using the peak EEC and 96-hour EEC from runoff continued to slightly exceed the LOC (RQs were 2.31 and 1.34). Therefore, standard recommendations pertaining to runoff are required on the label.

Freshwater algae

The acute toxicity of the technical grade active ingredient pydiflumetofen to freshwater algae was determined on three species under laboratory conditions. In addition, the toxicity of A19649B (containing 18.6% a.i. w/w) and SYN545547 to green algae was also determined. All tests showed that there were statistically significant inhibition effects on algal growth rate, biomass and yield. For pydiflumetofen, the most sensitive species were a diatom (*Navicula pelliculosa*) and green algae (*Pseudokirchneriella subcapitata*) on an acute and chronic basis, respectively (Table 14, Appendix I) and these endpoints were used for the screening level risk assessment. Assuming that pydiflumetofen was applied by direct overspray on water surfaces, the RQ values for freshwater algae did not exceed the LOC (Table 23, Appendix I). Therefore, risks to algae from the use of pydiflumetofen are acceptable.

Freshwater invertebrates

Daphnia magna: The acute toxicity of pydiflumetofen to *Daphnia magna* was determined under static laboratory conditions. Significant mortality was observed at concentrations above 0.22 mg a.i./L. The acute EC₅₀ was determined to be 0.42 mg a.i./L. The chronic toxicity of pydiflumetofen to daphnids was determined under static renewal conditions. A statistically significant inhibitory effect on the reproduction of *D. magna* was observed at concentrations of 0.12 mg a.i./L and above. The NOEC was therefore determined to be 0.064 mg a.i./L.

At the screening level, when pydiflumetofen was assumed to be applied to water by direct overspray, the RQ for *Daphnia magna* resulting from an acute exposure did not exceed the LOC, indicating a negligible risk on an acute basis (Table 23, Appendix I). However, on a chronic basis, the RQ for *Daphnia magna* was 1.2 (Table 23, Appendix I), slightly exceeding the LOC.

Further characterization of the chronic risk was carried out by considering spray drift resulting from the specific application methods and runoff. The results of the assessment showed that none of the refined RQ values exceeded the LOC; therefore, risks to pelagic freshwater invertebrates from the use of pydiflumetofen are acceptable.

Benthic invertebrates: The chronic toxicity of pydiflumetofen to freshwater benthic invertebrates was determined for two species (*Hyalella azteca* and *Chironomus dilutes*) exposed to sediment spiked with the test substance. For both species, significant effects were observed on a number of reproduction parameters. Based on the time-weighted average (TWA) concentrations of pydiflumetofen in the sediment, the most sensitive NOEC was 33 mg a.i./kg sediment; based on the TWA concentrations in the pore water, the most sensitive NOEC was 0.18 mg a.i./L pore water; and based on TWA concentration in the overlying water, the most sensitive NOEC was 0.13 mg a.i./L overlying water. For this group of organisms, the predominant exposure route is from dissolved pesticide in the pore water through runoff. Therefore, the 21-d pore water EEC of 0.0034 mg a.i./L (Table 22, Appendix I) was used in the risk assessment. The resulting RQ was 0.02, did not exceed the LOC. Furthermore, a risk from exposure through spray drift was also assessed using the screening level EECs and the resulting RQ did not exceed LOC (Table 23, Appendix I). Therefore, risks to benthic freshwater invertebrates from the use of pydiflumetofen are acceptable.

Freshwater vascular plant

The toxicity of pydiflumetofen to the aquatic plant *Lemna gibba* was determined in a 7-day semi-static test. At the highest test concentration, 21% inhibition was observed in frond density as compared to the negative control. An IC₅₀ was determined to be >6.3 mg a.i./L and a NOEC was determined to be 0.33 mg a.i./L. Comparing these endpoints with the screening level EEC, the RQ values for freshwater vascular plants did not exceed the LOC (Table 23, Appendix I). Therefore, risks to freshwater aquatic plants from the use of pydiflumetofen are acceptable.

Estuarine and marine fish

Acute and chronic toxicity of pydiflumetofen to saltwater fish was determined on sheepshead minnow (*Cyprinodon variegatus*). In the acute test, no mortalities or sublethal effects were observed at test concentrations up to 0.45 mg a.i./L. A LC₅₀ was determined to be 0.61 mg a.i./L. In the chronic test, several reproduction effects including embryo hatching success, larval survival and post-hatch survival were observed. A NOEC was determined to be 0.090 mg a.i./L. based on these endpoints and the screening level EEC, the RQs were calculated to be 0.82 for acute risk and 0.56 for chronic risk, none exceeded the LOC. Therefore, risks to marine fish from the use of pydiflumetofen are acceptable.

Marine invertebrates

The acute toxicity of pydiflumetofen to saltwater invertebrates was tested on two species (Eastern oyster (*Crassostrea virginica*) and mysid shrimp (*Americamysis bahia*)). Chronic effects on the early life-cycle of mysid shrimp were also examined. In the acute tests, the mysid shrimp was more sensitive to pydiflumetofen than the Eastern oyster (Table 15, Appendix I). For mysid shrimp, the LC₅₀ was 0.127 mg a.i./L. In the chronic test with mysid shrimp, there were no adverse effects on survival, reproduction or growth at the highest test concentration of 76 µg a.i./L. Therefore, the 28-day NOAEC was determined to be 76 µg a.i./L. The risk assessment conducted with these endpoints and the EEC at the screening level showed that the RQ value was less than 1 on both an acute and chronic basis (Table 23, Appendix I), and thus, did not exceed

the level of concern. Therefore, risks to marine invertebrates from the use of pydiflumetofen are acceptable.

Estuarine amphipod

Acute toxicity of pydiflumetofen to estuarine amphipods was tested on *Leptocheirus plumulosus* in sediment spiked with test chemical. A significant effect on survival was observed in the group exposed to the highest concentration of 92 mg a.i./kg dry weight sediment. Based on mean-measured bulk sediment concentrations, the LC₅₀ was determined to be >92 mg a.i./kg sediment dw and the NOAEC was 46 mg a.i./kg sediment dw. These values corresponded to >1.0 and 0.52 mg a.i./L mean-measured pore water, and >0.33 and 0.20 mg a.i./L mean-measured overlying water. The risk to estuarine amphipods from the exposure due to runoff was assessed using the EEC in pore water generated by PWC modelling (Table 22, Appendix I), which resulted in RQ values less than 1 on acute and chronic basis. The estimated RQ from the exposure to spray drift was assessed using the screening level EECs and the resulting RQ did not exceed LOC (Table 23, Appendix I). Therefore, risks to estuarine benthic invertebrates from exposure due to runoff and spray drift resulting from the use of pydiflumetofen are acceptable.

Marine diatom

The acute toxicity of pydiflumetofen to marine algae was tested on marine diatom (*Skeletonema costatum*) under static conditions. Effects on biomass, growth rate and yield were observed at statistically significant levels, resulting in an IC₅₀ of 2.7 mg a.i./L. At the screening level, the RQ value was calculated to be 0.04, which did not exceed the LOC (Table 23, Appendix I). Therefore, risks to marine algae from the use of pydiflumetofen are acceptable.

Risk assessment for SYN545547

Laboratory studies showed that SYN545547 was formed as a major transformation product in aerobic and anaerobic water-sediment systems, therefore, a risk assessment for SYN545547 on aquatic organisms was performed based on the available data. At the screening level, it was assumed that 100% of the applied pydiflumetofen was transformed to SYN545547. Therefore, an application rate of 400 g/ha pydiflumetofen was found to be equivalent to 372 g/ha SYN545547, resulting in an EEC of 0.25 mg/L in a 15-cm deep water body and an EEC of 0.046 mg/L in an 80-cm deep water body.

Comparing the endpoints presented in Table 14, Appendix I, SYN545547 appeared to be less toxic than the parent compound to freshwater organisms. At the screening level, the calculated RQ values for fish, water flea and algae were all less than 1 (Table 23, Appendix I), which is below the level of concern. Therefore, risks to freshwater fish, invertebrates and algae from SYN545547, a major aquatic transformation product of pydiflumetofen, are acceptable.

However, using fish endpoint as a surrogate for amphibians, the screening level RQ was 1.88, which exceeds the LOC. Subsequently, a further refinement to the assessment was performed by considering the risk from spray drift and run-off. When considering the acute exposure from run-off, the peak EEC and the 96-hour EEC were used to calculate RQs, and the resulting RQ values

were < 1 (Table 25, Appendix I), indicating that risks to amphibians from exposure to SYN545547 through runoff are acceptable.

When spray drift was considered for all proposed application methods, all RQs were below the level of concern with the exception of the airblast application method which exceeded the LOC. As the RQs are less than those calculated for the parent compound, the pydiflumetofen spray buffer zones are expected to adequately mitigate the risk of the transformation product SYN545547.

4.2.3 Incident Reports

Pydiflumetofen is a new active ingredient that has not previously been used in Canada. As of 2 November 2017, no incident reports had been submitted to the PMRA. Once products containing pydiflumetofen are registered, the PMRA will monitor for incident reports.

5.0 Value

5.1 Consideration of Benefits

Canadian growers have indicated a need for additional fungicide products to address supported diseases for greenhouse cucumber, ornamental plants, potato, fruiting vegetables, cucurbit vegetables, lettuce, grape, celery, Belgian endive, and spinach. Alternative fungicides from different mode of action groups, including Group 7 Fungicides, are already registered for most of the diseases reviewed (Table 27, Appendix I). Pydiflumetofen represents a new mode of action for Fusarium head blight on wheat and barley, Gibberella ear rot in corn, grey mould of greenhouse cucumber, powdery mildew of ornamentals, brown spot of potato, anthracnose and white mould of fruiting vegetables, and alternaria leaf spot and cercospora leaf spot of cucurbit vegetables. The co-formulated mixtures of pydiflumetofen with other active ingredients offer different modes of action targeting multiple diseases that occur at the same time. In addition, the combination of pydiflumetofen with other active ingredients targets the same pathogens in some cases with the added benefit of managing potential resistance within the pathogen population to either fungicide.

Common cultural methods used by growers to manage diseases include removing inoculum sources (good sanitation, removal of weeds that can act as alternate hosts), management of the environment to favour the host (manage air flow, good nutrient and irrigation management), monitoring fields and greenhouses for early signs of disease, the use of predictive models, and the use of resistant cultivars. Monitoring and predictive models help inform the grower as to when to apply fungicides. Fungicides containing pydiflumetofen are easily integrated into an Integrate Pest Management program to manage important diseases.

The diseases controlled or suppressed by pydiflumetofen and its co-formulants can affect the yield and quality of field crops, fruit crops, and vegetables. Blemished fruit or infected grain can be downgraded, leading to reduced returns for growers. Ornamentals and sod, as well as golf course turf, require high levels of aesthetic value to attract buyers or golfers in a competitive industry. The registration of pydiflumetofen and the associated end-use products provide growers

with an additional tool to protect their crops from disease and to manage the development of resistance.

5.2 Effectiveness Against Pests

Value information in the form of efficacy data and scientific rationales were reviewed in support of the use claims. Extrapolations were also made from other pydiflumetofen products with the same claim whenever possible. The submitted value information supported most of the uses as proposed. The supported claims are summarized in Table 28, 29, 30, 31 and 32, Appendix 1.

5.3 Non-Safety Adverse Effects

Pydiflumetofen and other active ingredients in the co-formulations were tested alone and in combination at the proposed rates in efficacy trials on the labelled crops or representative crops from crop groups. No phytotoxic effects were recorded for food crops or turf. Minor phytotoxicity was detected in trials on ornamental crops, but the effects disappeared as the plants matured. The A19649TO Fungicide label includes a warning to the user that indicates that not all species, varieties, and growing conditions have been tested for ornamentals and greenhouse cucumber and it is advised to test a small portion of the crop to ensure a phytotoxic response will not occur.

5.4 Supported Uses

The reviewed value information was sufficient to support the majority of the proposed use claims. Details of the supported uses are summarized in tables 28, 29, 30, 31 and 32 in Appendix 1.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [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*].

During the review process, pydiflumetofen and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Pydiflumetofen and its transformation product do not meet all Track 1 criteria, and are not considered Track 1 substances. See Table 26, Appendix I for comparison with Track 1 criteria.

Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade pydiflumetofen and its end-use products do not contain any formulants or contaminants identified in the Canada Gazette list of pest control product formulants and contaminants of health or environmental concern.

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

7.0 Summary

7.1 Human Health and Safety

The scientific quality of the data is high and the database is considered adequate to characterize the potential health hazards associated with this active ingredient. In short-term and chronic studies on laboratory animals, the primary target of toxicity was the liver. Pydiflumetofen was not selectively neurotoxic. There was no evidence of oncogenicity in rats after long-term dosing. Pydiflumetofen did not damage genetic material. Liver tumors in male mice were considered to be a threshold effect, therefore, a threshold approach to cancer risk assessment was considered appropriate. Pydiflumetofen did not cause developmental effects in rats or rabbits, and did not cause any adverse effects on reproduction in rats. There was some evidence of increased sensitivity of the offspring; however, concern is low due to the nature of the observed effects. 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 pydiflumetofen and workers re-entering treated areas are not expected to be exposed to levels of pydiflumetofen that will result in an unacceptable risk when pydiflumetofen is used according to label directions. The personal protective equipment on the product labels is long-sleeved shirt, long pants, chemical resistant gloves, and shoes plus socks during mixing, loading, application, clean up and repair. Additionally, A19649TO Fungicide requires chemical resistant headgear for airblast application, while goggles or face shield are required for A21461 Fungicide.

Residential exposure to individuals contacting treated turf is not expected to result in unacceptable risk when pydiflumetofen is used according to label directions.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is pydiflumetofen in plant products and in animal matrices. The proposed use of pydiflumetofen on various crops does not constitute a risk of concern for chronic or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs (See table below). The PMRA recommends that the following MRLs be specified for residues of pydiflumetofen.

Recommended MRLs

Commodity	Recommended MRL (ppm)
Crop Subgroup 4-13A, Leafy Greens	40
Crop Subgroup 22B, Leaf Petioles Vegetables	15
Barley	4
Quinoa	4
Dried tomatoes	3
Oats	3
Raisins	2
Crop Subgroup 13-07F, Small fruits vine climbing , except fuzzy kiwifruit	1.5
Crop Subgroup 20A, Rapeseeds (Revised)	0.9
Wheat bran	0.6
Crop Group 8-09, Fruiting Vegetables	0.6
Crop Group 9, Cucurbit Vegetables	0.5
Dry soybeans	0.4
Wheat germ	0.4
Crop Subgroup 6C, Dried shelled pea and bean (except soybean)	0.4
Rye	0.3
Triticale	0.3
Wheat	0.3
Peanut oil (refined)	0.05
Fat of cattle, goat, horse and sheep	0.03
Meat byproducts of cattle, goat, horse and sheep	0.03
Milk	0.03
Peanuts	0.02
Field corn flour	0.02
Crop Subgroup 1C, Tuberous and Corm Vegetables	0.015
Field corn	0.015
Popcorn grain	0.015
Eggs	0.01
Fat, meat, meat byproducts of hogs	0.01
Fat, meat, meat byproducts of poultry	0.01
Meat of cattle, goat, horse and sheep	0.01
Sweet corn kernels plus cob with husks removed	0.01

7.2 Environmental Risk

Pydiflumetofen is persistent in the terrestrial environment and in the aquatic environment. However, it is moderately persistent in the anaerobic sediments. Pydiflumetofen has low mobility, however, due to its persistence and ability to adsorb to soil organic matter, it has a potential to move to aquatic environments through surface runoff and leach to groundwater in areas vulnerable to leaching. Pydiflumetofen used as a foliar spray may pose a potential risk to non-target terrestrial plants and freshwater fish and amphibians. The identified risks can be mitigated with spray buffer zones to protect sensitive aquatic habitats.

7.3 Value

Pydiflumetofen addresses grower identified disease priorities on many minor crops and provides a new mode of action and/or fungicide active ingredient to manage diseases crops as well as on turf and golf courses. When combined with registered active ingredients, pydiflumetofen expands the disease spectrum of co-occurring diseases and contributes to resistance management. The registration of this active ingredient and the associated end-use products provides additional tools to Canadian growers that are easily integrated in Integrated Pest Management programs.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Pydiflumetofen Technical, A19649 Fungicide and A19649TO Fungicide, containing the technical grade active ingredient Pydiflumetofen to manage certain important diseases on both major and minor crops in Canada. Also being registered are A20259 Fungicide containing pydiflumetofen and difenoconazole, A20560 Fungicide containing pydiflumetofen and fludioxonil and A21461 Fungicide containing pydiflumetofen and azoxystrobin and propiconazole to manage certain diseases on several crops. A19649TO Fungicide is also proposed for use turf and golf courses in Canada.

A number of these pydiflumetofen end-use products are formulated with the active ingredients fludioxonil, difenoconazole, azoxystrobin or propiconazole. These active ingredients are currently registered for the proposed uses in Canada and there are no major new uses for any of these active ingredients.

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

List of Abbreviations

µg	micrograms
AD	administered dose
ADI	acceptable daily intake
<i>A.f.:</i>	<i>Ascochyta fabae</i>
AHETF	Agricultural Handler Exposure Task Force
a.i.	active ingredient
ALP	alkaline phosphatase
ALT	alanine aminotransferase
ARfD	acute reference dose
<i>A.r.:</i>	<i>Ascochyta rabiei</i>
AR	applied radioactivity
AR	anticipated residues
ARfD	acute reference dose
ARTF	Agricultural Reentry Task Force
a.s.	active substance
ASAE	American Society of Agricultural Engineers
AUC	area under the curve
AZY:	azoxystrobin
BAF	bioaccumulation factor
BBCH	Biologische Bundesanstalt, Bundessortenamt and Chemical industry
BCF	bioconcentration factor
BCF _{k,L}	lipid normalized kinetic bioconcentration factor
BQ	7-benzyloxyquinoline
BROD	benzyloxyresorufin O-dealkylase
BM:	biologicals with multi-site mode of action
bw	body weight
bwg	bodyweight gain
CAF	composite assessment factor
CAR	constitutive androstane receptor
CAS	Chemical Abstracts Service
<i>C.l.:</i>	<i>Colletotrichum lindemuthianum</i>
cm	centimetres
C _{max}	maximum concentration
<i>C.t.:</i>	<i>Colletotrichum truncatum</i>
d	day
DAA	days after application
DALA	days after last application
DAT	days after treatment
DB	dietary burden
DFOP	double first-order in parallel
DNA	deoxyribonucleic acid
DON:	deoxynivalenol
DT50	dissipation time 50% (dose required to note 50% decline in concentration)
DT90	dissipation time 90% (dose required to 90% decline in concentration)

dw	dry weight
<i>E.p.:</i>	<i>Erysiphe pisi</i>
EC	Emulsifiable concentrate
EC50	effective concentration on 50% of the population
EDD	estimated daily dose
EDE	estimated dietary exposure
EEC	estimated environmental concentration
ELS	early life stage
EP	end-use product
ER50	effective rate on 50% of the population
EROD	ethoxyresorufin O-deethylase
ErC50	effective concentration on 50% of the population, based on growth rate
F1	first generation
F2	second generation
fc	food consumption
fe	food efficiency
FIR	food ingestion rate
FMF:	pydiflumetofen
g	gram
GUS	groundwater ubiquity score
h	hour
ha	hectare
HAFT	highest average field trial
HDPE	high-density polyethylene
HDT	highest dose tested
HPLC-MS/MS	High-performance liquid chromatography with tandem mass spectrometry
HPLC	high performance liquid chromatography
IC50	inhibition concentration, 50%
IC25	inhibition concentration, 25%
ILV	independent laboratory validation
IORE	indeterminate order rate equation
IUPAC	International Union of Pure and Applied Chemistry
IV	intravenous
kg	kilogram
Kd	soil-water partition coefficient
Kdes	soil-water desorption coefficient
Kdesoc	soil-water desorption coefficient adjusted to organic carbon content
Kdoc	soil-water partition coefficient adjusted to organic carbon content
Koc	soil organic carbon partition coefficient
Kow	n-octanol-water partition coefficient
L	litre
LAFT	lowest average field trial
LC	liquid chromatography
LC50	lethal concentration 50%
LD50	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level

LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR50	lethal rate 50%
LSC	liquid scintillation counting
m	metre
mg	milligram(s)
MAS	maximum average score for 24, 48 and 72 hours
MOA	mode of action
MOE	margin of exposure
mL	millilitre
M/L	Mix/Load
M/L/A	Mixer/Loader/Applicator
mPa	milliPascals
MRL	maximum residue limit
MRM	multiresidue method
MS/MS	tandem mass spectrometry
m/z	mass-to-charge ratio of an ion
NAFTA	North American Free Trade Agreement
NC:	not classified
NIS:	non-ionic surfactant
nm	nanometre
NMR	nuclear magnetic resonance
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NOER	no observed effect rate
NR	not reported
OC	organic carbon content
OCSPP	Office of Chemical Safety and Pollution Prevention
ORETF	Outdoor Residential Exposure Task Force
P:	host plant defense induction
Pa	Pascals
Paper/PETP/Al/PE	paper/polyethylene-pack with additional barrier material (polyethylene terephthalate/aluminum)
PBI	plant-back interval
PCPA	<i>Pest Control Product Act</i>
PET	polyethylene terephthalate
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PON:	propiconazole
ppb	parts per billion
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
ppm	parts per million
PROD	pentoxyresorufin O-dealkylase
PWC	pesticide in water calculator model

PXR	pregnane X receptor
R _{ac}	mean accumulation ratios
RAC	raw agricultural commodity
RD	residue definition
RQ	risk quotient
SC	Suspension concentrate
SDHI	succinate dehydrogenase inhibitors
SFO	single first-order kinetic model
STMR	supervised trial mean residue
STMdR	supervised trial median residue
SYN545974	Pydiflumetofen; 3-(difluoromethyl)- <i>N</i> -methoxy-1-methyl- <i>N</i> -[1-methyl-2-(2,4,6 trichlorophenyl)ethyl]-1 <i>H</i> -pyrazole-4-carboxamide
SYN545547	3-(difluoromethyl)-1-methyl- <i>N</i> -[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1 <i>H</i> -pyrazole-4-carboxamide
t _{1/2} -rep	representative half-life
TC	Transfer Coefficient
TCP	trichlorophenol
TGAI	technical grade active ingredient
TP	transformation products
TRRs	total radioactive residues
TSMP	Toxic Substances Management Policy
U:	unclassified
UDPGT	uridine diphosphate glucuronyltransferase
UF	uncertainty factor
UV	ultraviolet
US	United States
USEPA	United States Environmental Protection Agency
wt	weight
v/v	volume per volume dilution
μmol	micromolar

Appendix I Tables and Figures

Table 1 Residue Analysis in Soil and Water

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Soil	GRM061.04A	SYN545974	HPLC-MS/MS	0.5 µg/kg		2571051, 2608338 2570961, 2608339
	GRM061.02A	SYN545547	<i>m/z</i> 426→193 <i>m/z</i> 396→376			
Water	GRM061.01A	SYN545974	HPLC-MS/MS <i>m/z</i> 426→193	0.05 µg/L		2571049, 2570960, 2638794
Plant	QuEChERS	Pydiflumetofen	LC-MS/MS	0.01 ppm	Dry bean, wheat grain, lettuce, rapeseed, coffee bean and orange	2571076, 2571077
Animal	QuEChERS	Pydiflumetofen	LC-MS/MS	0.01	Milk, liver, muscle, fat, blood and eggs	2571069, 2571035, 2815467

Table 2 Toxicity Profile of End-use Products Containing Pydiflumetofen

(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 Toxicity Studies, A19649TO Fungicide	
Acute Oral Toxicity (gavage)	LD ₅₀ = 2958 mg/kg bw
Wistar rats	1750 mg/kg bw: hunched back, incoordination, piloerection, ↓ activity
PMRA 2569932	5000 mg/kg bw: hunched back, incoordination, piloerection, prone position, dyspnea
	Low toxicity
Acute Dermal Toxicity	LD ₅₀ > 5000 mg/kg bw
Wistar rats	Low toxicity
PMRA 2569933	
Acute Inhalation Toxicity	LC ₅₀ > 3.50 mg/L
Wistar rats	3.50 mg/L: laboured respiration, incoordination, hunched posture, ↓ activity
PMRA 2569934	Low toxicity

Study Type/Animal/PMRA #	Study Results
Eye Irritation New Zealand White rabbits PMRA 2569936	MAS = 0/110 Non-irritating
Dermal Irritation New Zealand White rabbits PMRA 2569935	MAS = 0/8 Non-irritating
Skin Sensitization, Local Lymph Node CBA/J Rj mice PMRA 2569937	Not a potential skin sensitizer
Acute Toxicity Studies, A20259 Fungicide	
Acute Oral Toxicity (gavage) Wistar rats PMRA 2570114	LD ₅₀ = 5000 mg/kg bw 1750 mg/kg bw: hunched back, incoordination, piloerection, prone position, ↓ activity 5000 mg/kg bw: hunched back, piloerection, prone position, dyspnea, cold to touch, ↓ respiration rate, ↓ activity Low toxicity
Acute Dermal Toxicity Wistar rats PMRA 2570115	LD ₅₀ > 5000 mg/kg bw Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA 2570116	LC ₅₀ > 4.43 mg/L 4.43 mg/L: laboured respiration and ↓ activity Low toxicity
Eye Irritation New Zealand White rabbits PMRA 2570118	MAS = 0/110 Non-irritating
Dermal Irritation New Zealand White rabbits PMRA 2570117	MAS = 0/8 Non-irritating
Skin Sensitization, Local Lymph Node CBA/Ca mice PMRA 2570119	Not a potential skin sensitizer

Study Type/Animal/PMRA #	Study Results
Acute Toxicity Studies, A20560 Fungicide	
Acute Oral Toxicity (gavage) Wistar rats PMRA 2570561	LD ₅₀ = 2958 mg/kg bw 1750 mg/kg bw: hunched back, incoordination, piloerection, ↓ activity 5000 mg/kg bw: hunched back, piloerection, prone position, incoordination, dyspnea Low toxicity
Acute Dermal Toxicity Wistar rats PMRA 2570562	LD ₅₀ > 5000 mg/kg bw Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA 2570563	LC ₅₀ > 3.10 mg/L 3.10 mg/L: laboured respiration, hunched posture, incoordination, ↓ activity Low toxicity
Eye Irritation New Zealand White rabbits PMRA 2570565	MAS = 0/110 Non-irritating
Dermal Irritation New Zealand White rabbits PMRA 2570564	MAS = 0/8 Non-irritating
Skin Sensitization, Local Lymph Node CBA/Ca mice PMRA 2570566	Not a potential skin sensitizer
Acute Toxicity Studies, A21461 Fungicide	
Acute Oral Toxicity (gavage) Sprague-Dawley rats PMRA 2571469	LD ₅₀ = 550 mg/kg bw 175 mg/kg bw: irregular respiration, hunched posture, ↓ activity 550 mg/kg bw: irregular respiration, hunched posture, ↓ activity 2000 mg/kg bw: irregular respiration, prone posture Moderate toxicity
Acute Dermal Toxicity Sprague-Dawley rats PMRA 2571471	LD ₅₀ > 5000 mg/kg bw 5000 mg/kg bw: ano-genital staining and nasal discharge Low toxicity

Study Type/Animal/PMRA #	Study Results
Acute Inhalation Toxicity Sprague-Dawley rats PMRA 2571472	$LC_{50} > 2.08 \text{ mg/L}$ 0.51 mg/L: ano-genital staining 2.08 mg/L: abnormal respiration, prone posture, abdominal distention, ↓ activity Low toxicity
Eye Irritation New Zealand White rabbits PMRA 2571474	$MAS = 25.2/110$ Moderately irritating
Dermal Irritation New Zealand White rabbits PMRA 2571473	$MAS = 0.2/8$ Minimally irritating
Skin Sensitization, Local Lymph Node CBA/J mice PMRA 2571475	Not a potential skin sensitizer
Acute Toxicity Studies, A19649 Fungicide	
Acute Oral Toxicity (gavage) Wistar rats PMRA 2569932	$LD_{50} = 2958 \text{ mg/kg bw}$ 1750 mg/kg bw: hunched back, incoordination, piloerection, ↓ activity 5000 mg/kg bw: hunched back, piloerection, prone position, incoordination, dyspnea Low toxicity
Acute Dermal Toxicity Wistar rats PMRA 2569933	$LD_{50} > 5000 \text{ mg/kg bw}$ Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA 2569934	$LC_{50} > 3.50 \text{ mg/L}$ 3.50 mg/L: Laboured respiration, incoordination, hunched posture, ↓ activity Low toxicity
Eye Irritation New Zealand White rabbits PMRA 2569936	$MAS = 0/110$ Minimally irritating
Dermal Irritation New Zealand White rabbits PMRA 2569935	$MAS = 0/8$ Non-irritating

Study Type/Animal/PMRA #	Study Results
Skin Sensitization, Local Lymph Node CBA/J mice PMRA 2569937	Not a potential skin sensitizer

Table 3 Toxicity Profile of Technical Pydiflumetofen

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Dose levels separated by a / symbol signifies dosing for ♂/♀. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Toxicokinetic Studies	
Toxicokinetics, absorption, metabolism and excretion, PMRA 2571078 radiolabeled at [pyrazole-5- ¹⁴ C]- and [phenyl-U- ¹⁴ C]-rings gavage doses of 5 or 1000 mg/kg bw or IV dose 1 mg/kg bw	The oral absorption of total radioactivity from a single 5 mg/kg bw oral gavage dose of [¹⁴ C]-pydiflumetofen was 85-90% AD, in ♂ and ♀ rats. Absorption became limited as the dose increased, where absorption in 100 mg/kg bw to ♀ and 300 mg/kg bw to ♂ equated to 50-55% AD and 19-24% AD absorption, respectively. At these doses, unchanged pydiflumetofen was the major component in feces at up to 63% AD of the dose, but with less than 0.2% AD in bile. Repeat dosing lowered systemic exposure to pydiflumetofen as % administered dose by 37/54% ♂/♀ between days 1 and 7.
Absorption and excretion, PMRA 2570987 radiolabeled at [pyrazole-5- ¹⁴ C]- and [phenyl-U- ¹⁴ C]-rings gavage doses of 5 or 300♂/100♀ mg/kg bw	In mice, dose-limited absorption was also evident. At 10 mg/kg bw, unchanged SYN545974 was only detected in feces at less than 4.4% of the dose; however, at 300 mg/kg bw, SYN545974 accounted for up to 49% of the administered dose. In rats, the tissue distribution of dose-related radioactivity over time was similar, irrespective of dose, label or sex, following single oral doses. Radioactivity was widely distributed, with the highest concentrations observed in the liver and kidney at all sampling time points up to 120 hours, consistent with the excretion profile. The depletion profile of radioactivity from all tissues mirrored depletion in blood/plasma. At termination (96 or 120 h post dose), total tissue and carcass residues accounted for ≤ 3.0% of the administered dose. In a preliminary study, residues continued to decline and at seven days after a single oral dose (5-1000 mg/kg bw), residues of radioactivity remaining in the carcass of both ♂ and ♀ were ≤ 0.1% of the administered dose. The highest tissue concentrations were observed in liver and to a lesser extent the kidneys. Concentrations of radioactivity in the remaining tissues were either below that observed in blood or not reliably detected.
Tissue depletion, PMRA 2570990 radiolabeled at [pyrazole-5- ¹⁴ C]- and [phenyl-U- ¹⁴ C]-rings gavage doses of 5 or 300♂/100♀ mg/kg bw	
Blood and plasma toxicokinetics, PMRA 2570986 radiolabeled at [pyrazole-5- ¹⁴ C]- and [phenyl-U- ¹⁴ C]-rings gavage doses of 5 or 300♂/100♀ mg/kg bw or IV dose 1 mg/kg bw	In rats, following repeat dosing, systemic exposure to pydiflumetofen (based on geometric mean C _{max} and AUC _(0-t) estimates) was generally comparable between Days 1 and 7 at the 3 and 10 mg/kg bw/day doses in both sexes. Mean accumulation ratios (R _{ac}) were 0.9 and 1.1 for 3 and 10 mg/kg bw/day, respectively (derived for ♀ only). However, systemic exposure was appreciably reduced by Day 7 compared to Day 1 for all subsequent doses, (mean R _{ac} estimates were 0.1 and 0.4 for all doses greater than 10 mg/kg bw/day) with the decrease more marked in ♂. Overall, total systemic exposure (AUC _(0-t)) to pydiflumetofen increased in a sub-proportional manner across the dose range in ♂ and ♀. In ♂, a 33-fold increase in dose from 30 to 1000 mg/kg bw/day resulted in a 7.6-fold increase in exposure. In ♂, there are difficulties associated with assessing linearity with a sparse data set, especially at those doses below 30 mg/kg bw/day. In ♀, a 167-fold increase in dose from 3 to 500 mg/kg bw/day resulted in a 12-fold increase in exposure.
Biotransformation, PMRA 2570988, using animals from PMRA 2570987 and 2570990	

Study Type/Animal/PMRA #	Study Results
<p>Toxicokinetics, single and multiple dose, PMRA 2570981 not radiolabeled 7 daily gavage doses of 3, 10, 30, 100, 300, 500 or 1000 (♂ only) mg/kg bw/day or single IV dose 1 mg/kg bw</p> <p>Pharmacokinetics, single and multiple dose, PMRA 2570980 not radiolabeled 7 daily gavage doses of 10, 30, 100, 200, 300, 500, 750 or 1000 mg/kg bw/day or a single IV dose 1 mg/kg bw</p> <p>Excretion and biotransformation, PMRA 2570995 radiolabeled at [pyrazole-5-¹⁴C]- and [phenyl-U-¹⁴C]-rings gavage doses of 10 or 300 mg/kg bw</p> <p>Toxicokinetics in the pregnant rabbit, PMRA 2571031 not radiolabeled daily gavage doses of 100, 300, 750 or 1000 mg/kg bw/day over gestation days 6 to 27</p>	<p>Following single gavage doses, peak concentrations in rat blood and plasma were observed at 0.5-2 hours (5 mg/kg bw) and at 8 hours (100/300 mg/kg bw).</p> <p>Systemic exposure in mice tended to be proportional to supra-proportional between 10 and 100 mg/kg bw/day in ♂ and ♀, but generally sub-proportional above 300 mg/kg bw/day. Absolute oral bioavailability was 3.6-10% in ♂ and 3.1-7.9% in ♀. Following repeat dosing, systemic exposure based on C_{max} and AUC_(0-t) was reduced on day 7 compared to day one with ratios ranging from 0.1 to 0.4 for all doses. Systemic exposure tended to be higher in ♀ following repeat dosing at 200-1000 mg/kg bw/day.</p> <p>Pregnant rabbits showed a sub-proportional increase in systemic exposure with dose; with a small increase beyond 300 mg/kg bw/day and a minimal increase in systemic exposure between 750 and 1000 mg/kg bw/day. Reduced systemic concentrations over time suggested increased metabolic induction.</p> <p>Following oral or IV administration of [¹⁴C]-pydiflumetofen to rats, > 91% of radioactivity was eliminated by 48 hours post-dose and excretion was essentially complete by 168 h, irrespective of radiolabel position, dose or sex. The predominant route of excretion was the feces with the majority of the absorbed dose eliminated via bile. The remainder of the dose was recovered from urine, with < 0.1% of dose recovered in expired air or in the carcass. After a 5 mg/kg bw oral dose, up to 81% of the administered dose was excreted in bile, however, the percentage of dose recovered in bile decreased to < 41% in ♀ at 100 mg/kg bw and 18% in ♂ at 300 mg/kg bw. This decreased biliary excretion was associated with a concomitant increased radioactivity recovered in feces. There is also evidence of enterohepatic recirculation, with lower recovery in the urine in bile duct cannulated animals (10-15% AD) compared to non-cannulated animals (18-26%) administered 5 mg/kg bw [¹⁴C]-pydiflumetofen.</p> <p>In mice, excretion of the administered dose was essentially complete after seven days, irrespective of dose (single gavage doses of 10 and 300 mg/kg bw) or radiolabel following a single oral administration of [¹⁴C]-pydiflumetofen. The majority of administered radioactivity (> 87%) was excreted in the first 24 hours. The routes and rates were similar for both radiolabels and for ♂ and ♀, with the majority of the dose excreted in the feces (63-79% at 10 mg/kg bw and 76-94% at 300 mg/kg bw). Urinary excretion accounted for the remainder of the dose.</p> <p>In rats, following a single gavage administration of pydiflumetofen, the majority of the absorbed dose underwent extensive first pass metabolism and was excreted in feces via biliary elimination, with urine as a minor route. In both rats and mice, the major metabolites were qualitatively and quantitatively similar irrespective of dose and sex. Pydiflumetofen was extensively metabolised in rats and mice via demethylation, hydroxylation, and dechlorination together with glucuronide and sulphate conjugation with the potential for multiple isomers within most types. The molecule also cleaves at the benzylic carbon to yield 2,4,6-trichlorophenol (TCP) and SYN548263, which were further metabolised via direct glucuronidation and sulphation and also following hydroxylation and sulphation to 3-hydroxy-TCP sulphate. In rat, of the absorbed dose, only TCP sulphate and SYN548263, individually accounted for >10% of the administered dose in excreta.</p>
Acute Toxicity Studies	
<p>Acute Oral Toxicity (gavage)</p> <p>Wistar rats</p> <p>PMRA 2570916</p>	<p>LD₅₀ > 5000 mg/kg bw</p> <p>Slightly decreased activity until 4 hours post-dosing</p> <p>Low toxicity</p>

Study Type/Animal/PMRA #	Study Results
Acute Dermal Toxicity Wistar rats PMRA 2570917	LD ₅₀ > 5000 mg/kg bw Decreased activity, Day 1 only Low toxicity
Acute Inhalation Toxicity Wistar rats PMRA 2570918	LC ₅₀ > 5.11 mg/L One ♀ was found dead following exposure Laboured, gasping, and noisy respiration, sneezing, decreased activity, prostration and ataxia were observed on Day 1; noisy respiration or weak condition persisted in some animals until Day 3 Low toxicity
Eye Irritation New Zealand White rabbits PMRA 2570919	MAS = 0.4/110 Minimally irritating
Dermal Irritation New Zealand White rabbits PMRA 2570920	MAS = 0/8 Non-irritating
Skin Sensitization, Local Lymph Node CBA/J Rj mice PMRA 2570921	Not a potential skin sensitizer
Short-Term Toxicity Studies	
28-Day Dermal Toxicity Wistar rats PMRA 2571042	NOAEL = 1000 mg/kg bw/day
28-Day Oral Toxicity (Diet) CD-1 mice PMRA 2570971	NOAEL = 612/1312 mg/kg bw/day LOAEL = 1115/1312 mg/kg bw/day Effects at the LOAEL: ↓ bw, bwg ♂
90-Day Oral Toxicity (Diet) CD-1 mice PMRA 2570974	NOAEL = 630/846 mg/kg bw/day LOAEL = 1158/1483 mg/kg bw/day Effects at the LOAEL: ↑ liver wt, hepatocyte hypertrophy, cholesterol, triglycerides
28-Day Oral Toxicity (Diet) Wistar rats PMRA 2570973	NOAEL = 343/322 mg/kg bw/day LOAEL = 677/619 mg/kg bw/day Effects at the LOAEL: ↓ bwg, fc (first 1-3 days), ↑ liver wt, ↑ centrilobular hepatocellular hypertrophy; ↓ ALT, ↓ glutamate dehydrogenase ♀
90-Day Oral Toxicity (Diet) Wistar rats	NOAEL = 111/127 mg/kg bw/day LOAEL = 587/727 mg/kg bw/day Effects at the LOAEL: ↓ bwg, fc, fe, urinary pH, ↑ liver wt, ↑ thyroid follicular cell

Study Type/Animal/PMRA #	Study Results
PMRA 2570976	hypertrophy, ↑ hepatocellular hypertrophy, ↓ ALP; ↓ bw ♂; ↑ cholesterol ♀
90-Day Oral Toxicity (Capsule) Beagle dogs PMRA 2571025	NOAEL = 30 mg/kg bw/day LOAEL = 300 mg/kg bw/day Effects at the LOAEL: ↑ ALP, triglycerides, liver wt; slight ↓ bwg ♀
1-Year Oral Toxicity (Capsule) Beagle dogs PMRA 2571026	NOAEL = 100 mg/kg bw/day LOAEL = 300 mg/kg bw/day Effects at the LOAEL: ↑ ALP, liver wt, thyroid wt
Chronic Toxicity/Oncogenicity Studies	
1.5-Year Carcinogenicity (Diet) CD-1 mice PMRA 2638786	NOAEL = 9/48 mg/kg bw/day LOAEL = 45/306 mg/kg bw/day Effects at the LOAEL: ↑ liver masses, liver adenomas, centrilobular hepatocellular hypertrophy, eosinophilic focus of hepatocellular alteration ♂; ↓ bw, bwg, fc ♀ Evidence of oncogenicity % tumour incidence in ♂ liver at 0, 9, 45, 288 mg/kg bw/day, respectively: Adenomas: 8, 12, 18, 44 Multiple adenomas in an individual animal: 0, 0, 14, 28 Carcinomas: 2, 3, 4, 10 Combined adenomas and carcinomas: 10, 16, 20, 52
2-Year Carcinogenicity with 1-Year Chronic Toxicity (Diet) Wistar rats PMRA 2638785	NOAEL = 10 mg/kg bw/day LOAEL = 51/31 mg/kg bw/day Effects at the LOAEL: ↓ bw, bwg, fc, ↑ liver wt; ↓ fe, ↑ hepatocellular hypertrophy associated with cytoplasmic eosinophilic inclusions ♂ No evidence of oncogenicity
Developmental/Reproductive Toxicity Studies	
2 Generation Reproductive Toxicity (Diet) Wistar rats PMRA 2571022	Parental NOAEL = 277/116 mg/kg bw/day Parental LOAEL = undetermined Reproductive NOAEL = 277/116 mg/kg bw/day Reproductive LOAEL = undetermined Offspring NOAEL = 36 mg/kg bw/day Offspring LOAEL = 116 mg/kg bw/day Effects at the LOAEL: ↓ bw post-natal days 4-21 F ₁ only Evidence of sensitivity of the young
Developmental Toxicity (Gavage) Sprague Dawley rats PMRA 2571023	Supplementary range-finding study ≥ 500 mg/kg bw/day ↓ bwg on first day of dosing 1000 mg/kg bw/day Body weight loss on first day of dosing

Study Type/Animal/PMRA #	Study Results
Developmental Toxicity (Gavage) Sprague Dawley rats PMRA 2571029	Maternal NOAEL = 100 mg/kg bw/day Maternal LOAEL = undetermined Developmental NOAEL = 100 mg/kg bw/day Developmental LOAEL = undetermined No evidence of sensitivity of the young or malformations
Developmental Toxicity (Gavage) New Zealand White rabbits PMRA 2571024	Supplementary range-finding study 1000 mg/kg bw/day ↓ bwg during gestation, ↑ pre-implantation loss, one mortality and one dam with total resorption
Developmental Toxicity (Gavage) New Zealand White rabbits PMRA 2571027	Maternal NOAEL = 500 mg/kg bw/day Maternal LOAEL = undetermined Developmental NOAEL 500 mg/kg bw/day Developmental LOAEL undetermined Toxicokinetics Decrease in absorption as dose increases. No apparent increase in systemic exposure for either sex as study progressed. No evidence of sensitivity of the young or malformations
Genotoxicity Studies	
Bacterial reverse mutation S typhimurium strains TA1535, TA1537, TA98 and TA100, and E coli strains WP2uvrApKM101 and WP2pKM101 PMRA 2570926	Negative
Bacterial reverse mutation S typhimurium strains TA1535, TA1537, TA98 and TA100, and E coli strains WP2uvrApKM101 and WP2pKM101 PMRA 2570931	Negative
Chromosome aberration Human lymphocytes in vitro PMRA 2570927	Positive in the absence of S9 at cytotoxic dose levels
Gene mutation Mouse lymphoma L5178Y cells in vitro PMRA 2570928	Negative
Micronucleus	Negative

Study Type/Animal/PMRA #	Study Results
Mouse bone marrow in vivo PMRA 2570929	Same batch as used in PMRA 2570927
Micronucleus Mouse bone marrow in vivo PMRA 2570932	Negative
Neurotoxicity Studies	
Acute Neurotoxicity (Gavage) Wistar rats PMRA 2571045	NOAEL = 2000/100 mg/kg bw LOAEL = undetermined/1000 mg/kg bw Effects at the LOAEL: ↑ lateral recumbency, hunched posture, piloerection, reduced muscle tone, reduced activity, abnormal gait, eyes closed, impaired pupil reflex, mydriasis, laboured breathing, pale, ruffled fur, repetitive chewing, ↓ locomotor activity, ↓ mean body temperature one euthanized ♀ at 1000 mg/kg bw with marked convulsions and cold skin ♀ All effects confined to first day of dosing
Acute Neurotoxicity (Gavage) Wistar rats PMRA 2571047	NOAEL = 100 mg/kg bw ♀ LOAEL = 300 mg/kg bw ♀ Effects at the LOAEL: ↑ clinical signs consistent with previous study, though lacking dose-response relationships: piloerection, reduced activity, cold to touch, ruffled fur, ventral recumbency, impaired pupil reflex, ↓ locomotor activity, ↓ mean body temperature All effects confined to first day of dosing
Special Studies (non-guideline)	
28-Day Oral Liver MOA (Diet) Sacrifices on days 2, 7, and 28 CD-1 Mice PMRA 2571041	Supplementary ≥ 10 mg/kg bw/day ↑ hepatocyte proliferation (DNA synthesis) 324 mg/kg bw/day ↑ liver wt (7 and 28 d), ↑ total cytochrome P450 levels and PROD activity, ↑ centrilobular hepatocellular hypertrophy, ↑ mitosis (2 d)
Hepatocyte proliferation indexing MOA CD-1 Mouse hepatocyte cultures in vitro PMRA 2571039	Supplementary 5 µM ↑ PROD, BROD activities 25 µM ↓ PROD, BROD activities (believed to be due to substrate competition between the test substance and pentoxyresorufin and benzyloxyresorufin) ↑ hepatocyte proliferation (DNA synthesis) Positive controls yielded expected results
Hepatocyte proliferation indexing MOA Human hepatocyte cultures in vitro	Supplementary 5 µM ↑ PROD, BROD activities

Study Type/Animal/PMRA #	Study Results
PMRA 2571040	No effect on cell proliferation (DNA synthesis) Positive controls yielded expected results
CAR3 transactivation MOA Mouse, Rat and Human CAR in vitro	Supplementary Pydiflumetofen activated mouse, rat, and human CAR Positive controls yielded expected results
PMRA 2571118	Supplementary
Enzyme analysis of liver samples following 28 day oral toxicity MOA (Diet) Sacrifices on days 3, 7, and 28 CD-1 mice	Supplementary Pydiflumetofen is not a peroxisome proliferator 500 ppm ↑ total cytochrome P450, PROD; ↑ BQ ♂
PMRA 2571038	4000 ppm ↑ BQ ♀ 7000 ppm ↑ EROD (slight); ↑ lauric acid 12-hydroxylation ♂ The effects observed were largely consistent when observed across the three sacrifice days
UDPGT activity (Diet) Liver samples taken from ♂ Wistar rats in 90 day study (2570976)	Supplementary 19 mg/kg bw/day ↑ induction of hepatic microsomal UDPGT activity towards thyroxine expressed as specific activity and per gram of liver
PMRA 2571014	111 mg/kg bw/day ↑ induction of hepatic microsomal UDPGT activity towards thyroxine expressed as per total liver and per relative liver weight ↑ hepatic microsomal protein content
Thyroid peroxidase inhibition, in vitro Wistar rats	Supplementary Negative Positive control yielded expected results
PMRA 2571015	

Table 4 Toxicology Reference Values for Use in Health Risk Assessment for Pydiflumetofen

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Acute dietary	Rat acute neurotoxicity study	NOAEL = 100 mg/kg bw based on clinical signs, decreased activity, and body temperature	100
	ARfD = 1.0 mg/kg bw		

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Repeated dietary	Mouse carcinogenicity study	NOAEL = 9 mg/kg bw/day based on liver pathology supported by a NOAEL of 10 mg/kg bw/day in the rat carcinogenicity study	100
	ADI = 0.09 mg/kg bw/day		
Short-term to intermediate-term inhalation ²	Rat reproductive toxicity study	Offspring NOAEL = 36 mg/kg bw/day based on decreased pup body weights	100
Short-term to intermediate-term dermal ³	Rat reproductive toxicity study	Offspring NOAEL = 36 mg/kg bw/day based on decreased pup body weights	100
Long-term inhalation ²	Mouse 1.5-year carcinogenicity study	NOAEL = 9 mg/kg bw/day based on liver pathology supported by a NOAEL of 10 mg/kg bw/day in the rat carcinogenicity study	100
Long-term dermal ³	Mouse 1.5-year carcinogenicity study	NOAEL = 9 mg/kg bw/day based on liver pathology supported by a NOAEL of 10 mg/kg bw/day in the rat carcinogenicity study	100
Short-term aggregate of oral, dermal and inhalation routes	Rat reproductive toxicity study	Offspring NOAEL = 36 mg/kg bw/day based on decreased pup body weights	100
Cancer	There were increased incidences of hepatocellular adenomas and carcinomas in male mice. The proposed MOA was accepted and a threshold approach was used for the cancer risk assessment. The endpoints selected for non-cancer risk assessment are considered protective of these oncogenic findings.		

¹ CAF (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, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

³ Since an oral NOAEL was selected, a dermal absorption factor (30%) was used in a route-to-route extrapolation

Table 5 Integrated Food Residue Chemistry Summary

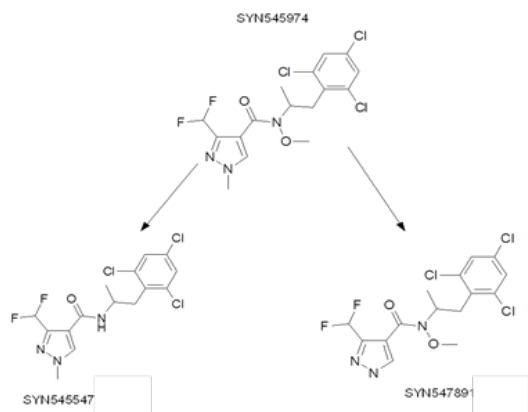
NATURE OF THE RESIDUE IN Wheat			PMRA # 2570982
Radiolabel Position	[14C- phenyl-U] and [14C- pyrazole-5]		
Test Site	Outdoors		
Treatment	Foliar treatment		
Total Rate	2 × 125 g a.i./ha; total rate of 250 g a.i./ha		
Formulation	SC formulation		
Preharvest interval	Forage: 10 days after single application; Hay: 29 days after two applications; Straw and grain: 50 days after 2 applications.		
Matrices	PHI	[14C- phenyl-U]	[14C- pyrazole-5]

	(days)	TRRs (ppm)	TRRs (ppm)	
Forage	10	0.320	0.456	
Hay	29	1.138	1.312	
Straw	50	1.250	1.548	
Grain	50	0.036	0.055	
Metabolites Identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	[14C- phenyl-U]	[14C- pyrazole-5]	[14C- phenyl-U]	[14C- pyrazole-5]
Forage	SYN545974	SYN545974	SYN545547 and SYN547891	SYN545547 and SYN547891
Hay				
Straw				
Grain				

NATURE OF THE RESIDUE IN Tomato			PMRA # 2570991	
Radiolabel Position	[14C- phenyl-U] and [14C- pyrazole-5]			
Test Site	Glasshouse			
Treatment	Foliar treatment or soil treatment			
Total Rate	Foliar: 2 × 200 g a.i./ha; total rate of 400 g a.i./ha, or Soil: 1 × 20 mg a.i./plant			
Formulation	SC formulation			
Preharvest interval	For foliar treatment: 1 day and 14 days. For soil treatment: maturity (103 days).			
Matrices	PHI	[14C- phenyl-U]	[14C- pyrazole-5]	
	(days)	TRRs (ppm)	TRRs (ppm)	
Tomato (Foliar application)	1	0.519	0.481	
Tomato (Foliar application)	14	0.638	0.633	
Tomato (soil application)	103	0.007	0.013	
Metabolites Identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	[14C- phenyl-U]	[14C- pyrazole-5]	[14C- phenyl-U]	[14C- pyrazole-5]
Tomato (Foliar application)	SYN545974	SYN545974	SYN545547 and	SYN545547 and
Tomato (Foliar application)			SYN547891	SYN547891
Tomato (soil application)	-	-	-	SYN545974 and SYN545547
NATURE OF THE RESIDUE IN Canola			PMRA # 2570983	
Radiolabel Position	[14C- phenyl-U] and [14C- pyrazole-5]			
Test Site	Outdoors			
Treatment	Foliar treatment			
Total Rate	Foliar: 1 × 134-147 g a.i./ha			
Formulation	SC formulation			
Preharvest interval	Seed and trash at 62 days			
Matrices	PHI	[14C- phenyl-U]	[14C- pyrazole-5]	
	(days)	TRRs (ppm)	TRRs (ppm)	
Seed	62	0.018	0.014	
Trash	62	0.059	0.062	
Metabolites Identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	[14C- phenyl-U]	[14C- pyrazole-5]	[14C- phenyl-U]	[14C- pyrazole-5]
Canola seed	SYN545974	SYN545974	SYN547891	SYN545547
Trash			SYN545547 and SYN547891	SYN545547 and SYN547891
Proposed Metabolic Scheme in Plants				

	270		SYN545974		SYN547891
Wheat hay	30	SYN545974	SYN545974	SYN547891 and SYN545547	SYN547891 and SYN545547
	120		SYN545974 and SYN547891		SYN545547
	270				
Wheat straw	30	SYN545974	SYN545974	SYN547891 and SYN545547	SYN547891 and SYN545547
	120				
	270				
Immature lettuce	30	SYN545974 and SYN547891	SYN545974	SYN545547	SYN547891 and SYN545547
Turnip foliage	30	SYN545974	SYN545974	SYN547891	SYN547891 and SYN545547

Proposed Metabolic Scheme in Rotational Plants



NATURE OF THE RESIDUE IN LAYING HEN

PMRA # 2570985

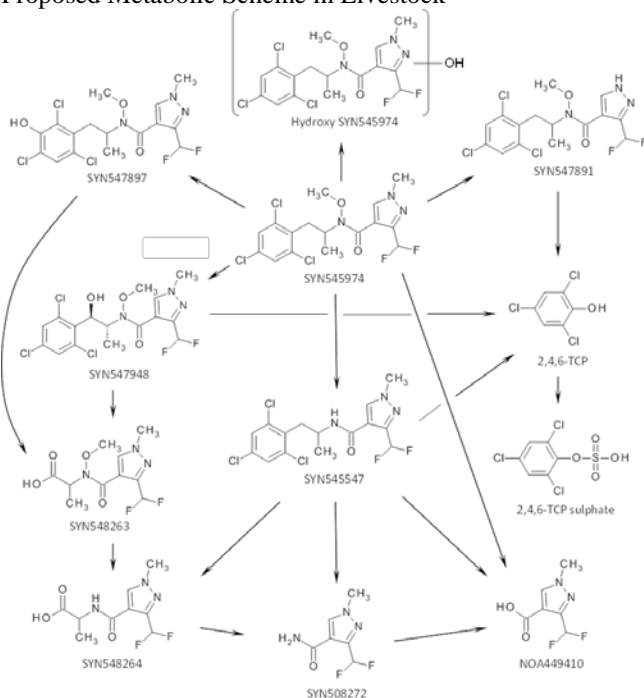
Six laying hens per radiolabel were dosed orally with ¹⁴C-phenyl and ¹⁴C-pyrazole pydiflumetofen at 56 ppm in dry feed (corresponding to 3.3-3.6 mg/kg bw) by gelatin capsule once daily for 14 days. Samples of excreta and eggs were collected daily. Eggs were separated into egg white and yolk. The hens were euthanized 11 hours after administration of the final dose.

Matrices	[¹⁴ C- phenyl-U]		[¹⁴ C- pyrazole-5]	
	TRRs (ppm)	% of Administered Dose	TRRs (ppm)	% of Administered Dose
Excreta	-	99.1	-	84.3
Liver	0.374	<0.1	0.203	<0.1
Egg yolk	0.353	<0.1	0.103	<0.1
Egg white	0.055	<0.1	0.051	<0.1
Muscle	0.028	<0.1	0.022	<0.1
Skin and fat	0.090	<0.1	0.028	<0.1
Peritoneal Fat	-	<0.1	-	<0.1
GI Contents	-	0.5	-	0.3
GI Tract	-	0.2	-	0.2
Cage Wash	-	3.6	-	3.2
Blood	-	<0.1	-	<0.1
Metabolites identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	[¹⁴ C- phenyl-U]	[¹⁴ C- pyrazole-5]	[¹⁴ C- phenyl-U]	[¹⁴ C- pyrazole-5]
Liver	-	-	SYN545974, SYN547897, SYN545547, SYN547891, SYN547948	SYN545974, SYN547897, SYN545547, SYN508272, SYN547948
Egg yolk	2,4,6-TCP	SYN545974	SYN545974, SYN547897	SYN547897, SYN545547,

				SYN547891, SYN508272, SYN547948, NOA449410
Egg white	SYN545974, 2,4,6-TCP	SYN545974, SYN508272, NOA449410	SYN547948	SYN547948
Muscle	2,4,6-TCP	SYN508272	SYN545974, SYN547948	SYN545974, SYN547897, SYN547948
Fat	SYN545974, 2,4,6-TCP	SYN545974	SYN547897, SYN547948	SYN547897, SYN547948, SYN508272, NOA449410
NATURE OF THE RESIDUE IN LACTATING GOAT			PMRA # 2570984	
Two lactating goats, one per radiolabel, were dosed orally with 14C-phenyl and 14C-pyrazole at 143-205 ppm in dry feed (corresponding to 4.6 mg/kg bw) by gelatin capsule once daily for 7 days. Milk, urine and faeces were collected daily. The goats were euthanized 11 hours after administration of the final dose.				
Matrices	[14C- phenyl-U]		[14C- pyrazole-5]	
	TRRs (ppm)	% of Administered Dose	TRRs (ppm)	% of Administered Dose
Milk	0.132	<0.1	0.140	<0.1
Liver	6.967	0.4	9.372	0.4
Kidney	1.701	<0.1	2.280	<0.1
Muscle	0.101	<0.1	0.117	<0.1
Flank Muscle	0.146	<0.1	0.144	<0.1
Lion Muscle	0.074	<0.1	0.097	<0.1
Fat5	0.205	<0.1	0.240	<0.1
Peritoneal Fat	0.252	<0.1	0.354	<0.1
Perirenal Fat	0.218	<0.1	0.252	<0.1
Subcutaneous Fat	0.188	<0.1	0.172	<0.1
Urine	-	31.5	-	29.9
Faeces	-	52.7	-	46.4
Bile	-	0.1	-	0.1
Cage Wash	-	1.4	-	1.3
GI Content	-	9.9	-	16.6
Metabolites identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	[14C- phenyl-U]	[14C- pyrazole-5]	[14C- phenyl-U]	[14C- pyrazole-5]
Milk	SYN545974, 2,4,6-TCP	SYN548263, SYN548264, SYN508272	SYN547948	SYN545974, SYN547948, NOA449410
Liver	-	-	SYN545974, 2,4,6-TCP, SYN547897, SYN545547, SYN547891, SYN547948	SYN545974, SYN547897, SYN545547, SYN547891, SYN547948, NOA449410
Kidney	-	SYN548263, NOA449410	SYN545974, 2,4,6-TCP, SYN547897, SYN545547, SYN547948	SYN545974, SYN547897, SYN547948, SYN548264, SYN508272

Muscle	SYN545974	SYN545974, SYN508272	2,4,6-TCP, SYN547897, SYN547948	SYN547897, SYN547948, SYN548263, SYN548264 NOA 449410
Fat	SYN545974	SYN545974, Hydroxy SYN547974	SYN547948, Hydroxy SYN547974	SYN547948, SYN548263, SYN508272

Proposed Metabolic Scheme in Livestock



FREEZER STORAGE STABILITY

PMRA # 2571074, 2570914, 2638793, 2571075 for plants; 2571002, 2608337, 2638788, 2571071, 2593764, 2638791, 2571036, 2593763, 2638792, 2571126, 2571070 and 2570997 for livestock

Plant matrices: in orange (whole fruit), wheat (grain), wheat (straw), potato (tuber), oilseed rapeseed, Adzuki bean (dried), lettuce, and corn (flour, meal and oil), soybean (flour, milk and oil), apple (juice and dried fruit), and grape (raisin) at ~ -18°C.

Pydiflumetofen – 23 months.

Animal matrices: in muscle, liver, kidney, fat, milk and eggs at ~ -20°C

Pydiflumetofen - 12 months;

2,4,6-TCP - 11 months;

SYN508272 and SYN548264 in milk - 11 months;

SYN547897 and SYN548264 in kidney and liver - 11 months.

CROP FIELD TRIALS & RESIDUE DECLINE ON Grape

PMRA # 2571094

Field trials were conducted in 2013 in the United States. Trials were conducted in NAFTA Growing Regions 1 (NY, 1 trial; PA, 1 trial), 10 (CA, 8 trials), and 11 (WA, 2 trials) for a total of 12 trials. A19649B (SC formulation) was applied twice as foliar broadcast sprays at a rate of 195-215 g a.i./ha/application for a seasonal application rate of 390-424 g a.i./ha. Adjuvant was included in the spray mixture at 0.09-0.83% (v/v). The applications were made at 13- to 15-day intervals with the last application occurring approximately 13-15 days before harvest.

Residue decline data show that residues of pydiflumetofen decreased in grapes with increasing preharvest intervals (PHIs) from 7 to 21 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD

Grapes	390-424	13-15	12	<0.01	0.769	0.333	0.324	0.23
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								
CROP FIELD TRIALS & RESIDUE DECLINE ON Potato						PMRA # 2571093 and 2571104		
A total of 10 independent field trials on potatoes were conducted in Canada in the 2013 growing season, encompassing Zones 1 (PE, 4 trials; NS; 1 trial), 5 (ON, 1 trial), 7A (AB, 2 trials) and 14 (MB, 2 trials). A total of 16 independent field trials on potatoes were conducted in the United States in the 2013 growing season, encompassing Zones 1 (NY, 2 trials), 2 (NC, 1 trial), 3 (FL, 1 trial), 5 (ND and IA, 1 trial each, and MN, 2 trials), 10 (CA, 1 trial) and 11 (ID, 6 trials, WA, 1 trial). A19649B (SC formulation) was applied 3 times as foliar broadcast sprays at a rate of 119-139 g a.i./ha/application for a seasonal application rate of 366-392 g a.i./ha. Adjuvant was included in the spray mixture at 0.12-2.5% (v/v). The applications were made at 6-8 day intervals with PHIs of 6-8 days.								
Residue decline data show that residues of pydiflumetofen decreased in potato with increasing PHIs from 0 to 14 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Potato	366-392	6-8	26	<0.01	0.014	0.010	0.010	0.00
CROP FIELD TRIALS & RESIDUE DECLINE ON Tomato, peppers (bell and non-bell)						PMRA # 2571103		
A total of 21 independent field trials on tomato (12 trials including two trials using small size tomatoes), bell pepper (6 trials) and non-bell pepper (3 trials) were conducted in the United States in the 2013 growing season, encompassing Zones 1 (NY, 1 trial), 2 (GA, 1 trial), 3 (FL, 2 trials), 5 (WI, 1 trial) and 10 (CA, 7 trials) for tomato, Zones 2 (GA, 1 trial), 3 (FL, 1 trial), 5 (WI, 1 trial), 6 (TX, 1 trial) and 10 (CA, 2 trials) for bell pepper, and Zones 8 (KS and TX, 1 trial each) and 10 (CA, 1 trial) for non-bell pepper. A19649B (SC formulation) was applied 2 times as foliar broadcast sprays at a rate of 122-129 g a.i./ha/application for a seasonal application rate of 245-257 g a.i./ha. Adjuvant was included in the spray mixture at 0.03-1.28% (v/v). The applications were made at 6-8 day intervals with PHI of 0 day.								
Residue decline data show that residues of pydiflumetofen decreased in tomato and peppers with increasing PHIs from 0 to 14 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Tomato	246-253	0	12	0.03	0.267	0.097	0.12	0.07
Bell Pepper	245-257	0	6	0.062	0.366	0.125	0.169	0.12
Non-bell Pepper	247-249	0	3	0.088	0.257	0.136	0.16	0.09
CROP FIELD TRIALS & RESIDUE DECLINE ON Cucumber, Muskmelon and summer squash						PMRA # 2571059, 2571058 and 2571057		
A total of 22 independent field trials on cantaloupe (6 trials), summer squash (6 trials) and field/greenhouse cucumber (10 trials) were conducted in the United States in the 2013-2014 growing season, encompassing Zones 2 (MD, 1 trial), 5 (MI, 1 trial), 6 (TX, 1 trial) and 10 (CA, 3 trials) for cantaloupe, Zones 1 (NY, 1 trial), 2 (GA and NC, 1 trial each), 3 (FL, 1 trial), 5 (WI, 1 trial) and 10 (NC, 1 trial) for summer squash, and Zones 2 (GA, NC and MD, 1 trial each), 3 (FL, 1 trial), 5 (MI and WI, 1 trial each) and 6 (TX, 1 trial) for field cucumber, and Zones 2, 4, and 10 (1 trial each) for greenhouse cucumber. A19649B (SC formulation) was applied twice as foliar broadcast sprays at a rate of 120-137 g a.i./ha/application for a seasonal application rate of 246-266 g a.i./ha. Adjuvant was included in the spray mixture at 0.04-2.4% (v/v). The applications were made at 6-8 day intervals with PHI of 0 day.								
Residue decline data show that residues of pydiflumetofen decreased in cantaloupe, summer squash and cucumber with increasing PHIs from 0 to 9 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Cantaloupe	247-265	0	6	0.067	0.168	0.131	0.123	0.04
Summer Squash	246-254	0	6	0.056	0.212	0.129	0.128	0.06
Cucumber (field)	251-257	0	7	0.109	0.190	0.117	0.134	0.03
Cucumber (greenhouse)	249-266	0	3	0.114	0.264	0.23	0.203	0.08
Cucumber (field and greenhouse)	249-266	0	10	0.109	0.264	0.129	0.155	0.06

CROP FIELD TRIALS & RESIDUE DECLINE ON Lettuce (head and leaf), Spinach and Celery						PMRA # 2571110		
A total of 32 independent field trials on leaf lettuce (7), head lettuce (8), spinach (8) and celery (8) were conducted in the United States in the 2013-2014 growing season, encompassing Zones 1 (NY, 1 trial), 3 (FL, 1 trial) and 10 (CA, 6 trials) for leaf lettuce, Zones 1 (NY, 1 trial), 3 (FL, 1 trial) and 10 (CA, 6 trials) for head lettuce, Zones 1 (NY, 1 trial), 2 (GA and SC, 1 trial each), 6 (TX, 1 trial), 8 (TX, 1 trial), 10 (CA, 2 trials) and 11 (ID, 1 trial) for spinach, and Zones 3 (FL, 2 trials), 5 (WI, 1 trial) and 10 (CA, 5 trials) for celery. A19649B (SC formulation) was applied twice as foliar broadcast sprays at a rate of 195-214 g a.i./ha/application for a seasonal application rate of 393-426 g a.i./ha. Adjuvant was included in the spray mixture at 0.06-1.73% (v/v). The applications were made at 6-8 day intervals with PHI of 0 day.								
Residue decline data show that residues of pydiflumetofen decreased in leaf lettuce and spinach with increasing PHIs from 0 to 10 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Leaf Lettuce	403-426	0	7	1.67	12.3	5.54	6.81	3.7
Head Lettuce with wrapper	401-419	0	8	0.513	4.52	2.32	2.16	1.3
Head Lettuce without wrapper	401-419	0	8	<0.01	0.486	0.068	0.140	0.16
Spinach	393-412	0	8	7.53	15.6	12.4	11.8	2.8
Celery	402-411	0	8	2.59	8.12	4.39	4.53	1.7
CROP FIELD TRIALS & RESIDUE DECLINE ON Dry Bean and Dry Pea						PMRA # 2571094		
A total of 10 independent field trials on dry pea and dry bean were conducted in the United States in the 2013 growing season, encompassing Zones 11 (ID, 4 trials, OR, 1 trial) for dry pea, and Zones 5, 8, 9, 10 and 11 (MN, CO, UT, CA and ID, 1 trial each). A total of 10 independent field trials on dry pea and dry bean were conducted in Canada in the 2013 growing season, encompassing Zones 7 (SK, 3 trials) and 14 (MB, 2 trials) for dry pea, and Zones 5 (ON, 2 trials, QC, 1 trial) and 7/7A (AB/AB, 1 trial each). In these trials SYN545974 formulated as products A19649B (SC formulation) and A17573 (EC formulation) were applied side-by-side. For each formulation in the dry pea trials in the United States, two separate plots were established at each site, one for early application to facilitate sampling of pea vine and pea hay and a second plot for later application to facilitate sampling of pea seed. For each formulation in all trials, two applications were made as foliar treatments at a rate of 187-216 g a.i./ha/application, for a seasonal application rate of 381-423 g a.i./ha. Adjuvant was included in the spray mixture at 0.13-5.0% (v/v). The applications were made at 13-15 day intervals with PHIs of 11-15 days.								
Residue decline data show that residues of pydiflumetofen were relatively unchanged in seeds of dry bean and dry pea with increasing PHIs from 7 to 21 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Dry Bean Seed (SC formulation)	400-423	11-15	9	<0.01	0.238	<0.01	0.049	0.07
Dry Bean Seed (EC formulation)	399-415	11-15	9	<0.01	0.213	<0.01	0.046	0.07
Dry Pea Seed (SC formulation)	381-415	13-15	10	0.023	0.088	0.050	0.048	0.02
Dry Pea Seed (EC formulation)	382-410	13-15	10	0.011	0.096	0.031	0.039	0.03
Dry Pea Vine (SC formulation)	402-409	14	5	0.231	2.82	0.884	1.01	1.1
Dry Pea Vine (EC formulation)	394-409	14	5	0.357	1.60	0.471	0.714	0.51
Dry Pea Hay (SC formulation)	402-409	14	5	1.53	17.0	3.38	5.88	6.4
Dry Pea Hay (EC formulation)	394-409	14	5	1.84	10.1	3.02	4.16	3.4
CROP FIELD TRIALS & RESIDUE DECLINE ON Peanut						PMRA # 2571102		

A total of 12 independent field trials on peanut were conducted in the United States in the 2013 growing season, encompassing Zones 2 (GA, 5 trials, NC, 2 trials and SC, 1 trial), 3 (FL, 1 trial), 6 (OK, 2 trials, TX, 1 trial) and 8 (OK, 1 trial). In these trials SYN545974 formulated as products A19649B (SC formulation) and A17573 (EC formulation) were applied side-by-side. For each formulation, four applications at a rate of 48-53 g a.i./ha/application were made, for a seasonal application rate of 199-209 g a.i./ha. Adjuvant was included in the spray mixture at 0.07-1.0% (v/v). The applications were made at 14 day intervals with PHI of 14 days.

Residue decline data show that residues of pydiflumetofen were <LOQ (0.01 ppm) in peanut nutmeat at all PHIs of 7-21 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Peanut Nutmeat (SC formulation)	199-207	14	12	<0.01	0.018	<0.01	0.011	0.002
Peanut Nutmeat (EC formulation)	200-209	14	12	<0.01	0.018	<0.01	0.011	0.002
Peanut Hay (SC formulation)	199-207	14	12	0.018	15.1	4.20	4.69	3.8
Peanut Hay (EC formulation)	200-209	14	12	0.038	14.9	6.14	7.16	4.9

CROP FIELD TRIALS & RESIDUE DECLINE ON Canola PMRA # 2571091 and 2571111

A total of 21 independent field trials on canola were conducted in the United States and Canada in the 2013-2014 growing seasons, encompassing Zones 5 (MB, WI and MN, 1 trial each, ND, 2 trials), 7 (SK and ND, 2 trials each and SC, 1 trial), 11 (ID and WA, 1 trial each) and 14 (SK, 3 trials, MB, 4 trials, AB, 2 trials). In these trials SYN545974 formulated as products A19649B (SC formulation) and A17573 (EC formulation) were applied side-by-side. For each formulation, one application at a rate of 117-134 g a.i./ha was made, followed by a second application at a rate of 191-217 g a.i./ha, for a seasonal application rate of 308-349 g a.i./ha. Adjuvant was included in the spray mixture at 0.1-1.45% (v/v). The applications were made at 13-15 day intervals with PHIs of 25-32 days.

Residue decline data show that residues of pydiflumetofen were relatively unchanged in canola seeds at the PHIs of 20-40 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Canola Seed (SC formulation)	308-349	25-32	21	0.016	0.685	0.087	0.141	0.17
Canola Seed (EC formulation)	309-345	25-32	21	0.013	0.325	0.050	0.082	0.08

CROP FIELD TRIALS & RESIDUE DECLINE ON Soybean PMRA # 2571095

A total of 21 independent field trials on soybean were conducted in the United States during the 2013 growing season, encompassing Zones 2 (GA and NC, 1 trial each), 4 (AR, 2 trials, MO, 1 trial), 5 (IA, 5 trial, KS and MN, 3 trials each, NE, 2 trials, ND, WI and MS, 1 trial each). For each formulation of SC and EC, two separate plots were established at each site, one for application to facilitate sampling of forage and hay and a second plot for later application to facilitate sampling of seed. For forage and hay, two applications at a rate of 139-151 g a.i./ha/application were made, for a seasonal rate of 284-304 g a.i./ha. For seed, two applications at a rate of 189-212 g a.i./ha/application were made, for a seasonal rate of 387-420 g a.i./ha. Adjuvant was included in the spray mixture at 0.25-1.0% (v/v). The applications were made at 6-8 day intervals with a PHI of 0 day for forage and hay and a PHI of 14 days for seeds.

Residue decline data show that residues of pydiflumetofen were relatively unchanged in soybean seeds at the PHIs of 7-21 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Soybean Seed (SC formulation)	387-420	14	21	<0.01	0.286	0.027	0.050	0.07
Soybean Seed (EC formulation)	387-416	14	21	<0.01	0.168	0.014	0.032	0.04

Soybean Forage (SC formulation)	284-304	0	21	3.19	24.4	8.85	9.93	4.9
Soybean Forage (EC formulation)	286-302	0	21	2.90	17.3	9.00	9.43	3.5
Soybean Hay (SC formulation)	284-304	0	21	11.1	90.6	39.6	10.7	18.3
Soybean Hay (EC formulation)	286-302	0	21	13.7	78.5	39.6	19.5	17.1
CROP FIELD TRIALS & RESIDUE DECLINE ON Barley						PMRA # 2571100 and 2571108		
A total of 9 independent field trials on barley were conducted in Canada during the 2013 growing season, encompassing Zones 7A (AB, 1 trial) and 14 (MB, 5 trials, SK, 2 trials and AB, 1 trial). A total of 12 independent field trials on barley were conducted in the United States during the 2013 growing seasons, encompassing Zones 2 (VA, 1 trial), 5 (IA, 2 trials, NE, 1 trial), 7 (NE and ND, 2 trials each), 9 (IA, 1 trial), 10 (CA, 1 trial) and 11 (OR, ID, 1 trial each).								
In each of these trials SYN545974 was applied to barley as a foliar treatment using A17573A (EC formulation) and A19649B (SC formulation) side-by-side. For each formulation, two separate plots were established at each site, one for early application to facilitate sampling of hay and a second plot for later application to facilitate sampling of grain and straw. For hay, a single application at a rate of 140-164 g a.i./ha was made at target BBCH 31, 7±1 days prior to harvest. For grain and straw, one application at a rate of 150 g a.i./ha was followed by a second application at a rate of 200 g a.i./ha, for a seasonal rate of 336-378 g a.i./ha. The first application was made 14±1 days prior to the second application, and the second application was made at target BBCH 71 (PHIs of 16-59 days). All applications were made in tank-mix with a NIS or COC (0.03-1.25%, v/v).								
Residue decline data show that residues of pydiflumetofen decreased in barley hay with increasing PHIs from 0 to 15 days, residues of pydiflumetofen were relatively unchanged in barley grain with increasing PHIs from 31-68 days. The trend for pydiflumetofen residues in barley straw varied among 4 residue decline trials.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Barley Grain (SC formulation)	345-378	16-59	21	0.044	2.56	0.263	0.582	0.68
Barley Grain (EC formulation)	336-369		21	0.044	3.00	0.216	0.602	0.80
Barley Straw (SC formulation)	345-378	16-59	21	1.13	15.0	4.80	5.52	3.9
Barley Straw (EC formulation)	336-369		21	0.985	18.0	3.72	5.68	5.0
Barley Hay (SC formulation)	142-160	6-8	21	1.42	17.0	5.06	6.31	3.8
Barley Hay (EC formulation)	140-164		21	0.808	26.0	4.93	7.34	5.7
CROP FIELD TRIALS & RESIDUE DECLINE ON Oat						PMRA # 2571101 and 2571107		
A total of 12 independent field trials on oats were conducted in Canada during the 2013 and 2014 growing seasons, encompassing Zones 5 (ON and QC, 1 trial each), 7 (SK, 2 trials) and 14 (MB, 4 trials, SK, 3 trials and AB, 1 trial). A total of 17 independent field trials on oats were conducted in the United States during the 2013 and 2014 growing seasons, encompassing Zones 1 (NY, 1 trial), 2 (GA, 1 trial), 5 (IA, 3 trials, ND, 2 trials, MN, 2 trials, WI, 2 trials, and MO, 1 trial), 6 (TX, 1 trial), 7 (ND, 2 trials, NE, 1 trial) and 8 (TX, 1 trial).								
In each of these trials SYN545974 was applied to oats as a foliar treatment using A17573A (EC formulation) and A19649B (SC formulation) side-by-side. For each formulation, two separate plots were established at each site, one for early application to facilitate sampling of forage and hay and a second plot for later application to facilitate sampling of grain and straw. For forage and hay, a single application at a rate of 139-165 g a.i./ha was made at target BBCH 31, 7±1 days prior to harvest. For grain and straw, one application at a rate of 141-158 g a.i./ha was followed by a second application at a rate of 183-212 g a.i./ha at target BBCH 71 (PHIs of 16-61 days), for a seasonal rate of 332-363 g a.i./ha. All applications were made in tank-mix with a NIS or COC (0.06-1.0%, v/v).								

Residue decline data show that residues of pydiflumetofen decreased in oat forage and hay with increasing PHIs from 0 to 15 days, residues of pydiflumetofen were relatively unchanged in oat straw and grain with increasing PHIs from 7-56 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Oat Grain (SC formulation)	336-362	16-61	28	<0.01	2.08	0.202	0.347	0.43
Oat Grain (EC formulation)	332-363		28	0.056	1.50	0.231	0.374	0.38
Oat Straw (SC formulation)	336-362	16-61	28	0.310	17.0	2.81	3.61	3.7
Oat Straw (EC formulation)	332-363		28	0.108	13.0	2.00	3.31	3.1
Oat Hay (SC formulation)	140-165	6-9	28	0.54	23.0	5.31	7.93	6.7
Oat Hay (EC formulation)	139-160		28	0.493	25.1	5.53	7.14	6.4
Oat Forage (SC formulation)	140-165	6-9	28	0.395	6.55	1.94	2.36	1.7
Oat Forage (EC formulation)	139-160		28	0.340	6.96	1.85	2.28	1.6

CROP FIELD TRIALS & RESIDUE DECLINE ON Wheat

PMRA # 2571090 and 2571106

A total of 13 independent field trials on spring wheat were conducted in Canada the 2013/2014 growing seasons, encompassing Zones 7 (SK, 2 trials), 7A (AB, 1 trial) and 14 (MB, 5 trials, SK, 2 trials and AB, 3 trials). A total of 20 independent field trials on spring wheat were conducted in the United States the 2013/2014 growing seasons, encompassing Zones 2 (NC, 1 trial), 4 (AR, 1 trial), 5 (IA, 2 trials, KS, MN and MO, 1 trial each), 6 (TX, 1 trial), 7 (ND, 3 trials, NE, 2 trials), 8 (KS, TX and OK, 2 trials each) and 11 (ID, 1 trial).

In each of these trials SYN545974 was applied to wheat as a foliar treatment using A17573A (EC formulation) and A19649B (SC formulation) side-by-side. For each formulation, two separate plots were established at each site, one for early application to facilitate sampling of forage and hay and a second plot for later application to facilitate sampling of grain and straw. For forage and hay, a single application at a nominal rate of 116-160 g a.i./ha was made at target BBCH 31, 7±1 days prior to harvest. For grain and straw, one application at a nominal rate of 140-164 g a.i./ha was followed by a second application at a nominal rate of 195-216 g a.i./ha, for a seasonal rate of 340-374 g a.i./ha. The first application was made 14±1 days prior to the second application, and the second application was made at target BBCH 71 (PHIs of 16-74 days). All applications were made in tank-mix with a NIS or COC (0.03-2.8%, v/v).

Residue decline data show that residues of pydiflumetofen decreased in wheat forage and hay with increasing PHIs from 0 to 14 days, residues of pydiflumetofen were relatively unchanged in wheat grain with increasing PHIs from 21-62 days. The trend for pydiflumetofen residues in wheat straw varied among 4 residue decline trials.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Wheat Grain (SC formulation)	341-374	16-74	32	0.015	0.216	0.063	0.076	0.05
Wheat Grain (EC formulation)	340-364		33	0.010	0.234	0.062	0.080	0.05
Wheat Forage (SC formulation)	140-157	6-8	33	0.240	10.51	2.36	3.20	2.6
Wheat Forage (EC formulation)	142-160		33	0.140	10.61	2.53	3.16	2.3
Wheat Hay (SC formulation)	140-157	6-8	33	0.983	39.8	11.8	12.6	9.4
Wheat Hay (EC formulation)	142-160		33	0.594	34.7	9.36	11.2	7.9
Wheat Straw (SC formulation)	341-374	16-74	32	1.09	18.0	4.30	5.23	1.0

Wheat Straw (EC formulation)	340-364		33	0.770	29.8	3.80	5.60	5.7
CROP FIELD TRIALS & RESIDUE DECLINE ON Corn (field, popcorn and sweet)						PMRA # 2571105 and 2571119		
A total of 35 independent field trials on field corn (20 trials; 1 trial in each of Zones 1, 2 and 6, 17 trials in Zone 5), popcorn (3 trials; 1 trial in Zone 8, 2 trials in Zone 5) and sweet corn (12 trials; 2 trials in Zone 1, 1 trial in each of Zones 2, 3, 10, 11 and 12, 5 trials in Zone 5) were conducted in the United States during the 2014 growing season.								
In each of the field corn or popcorn trials SYN545974 was applied as A17573A (EC formulation) and A19649B (SC formulation) side-by-side. SYN545974 was applied to sweetcorn as A19649B (SC formulation) only. In the field corn trials, for each formulation two separate plots were established at each site, one for application to facilitate sampling of forage and a second plot for later application to facilitate sampling of grain and stover. In the popcorn trials, for each formulation there was only a single plot. For forage harvest, one application at a rate of 242-272 g a.i./ha was made 7±1 days prior to harvest. For grain and stover, two applications at a rate of 119-134 g a.i./ha/application were made, for a seasonal rate of 248-260 g a.i./ha. The first application was made 7±1 days prior to the second application, and the second application was made 30±2 days prior to harvest. In the sweet corn trials two applications as foliar treatments at a rate of 119-134 g a.i./ha/application were made, for a seasonal rate of 240-260 g a.i./ha. The initial application was made 14±1 days prior to normal harvest and the final application was made 7 days prior to normal harvest. All applications were made in tank-mix with a NIS or COC (0.03-1.25%, v/v).								
Residue decline data show that residues of pydiflumetofen decreased in field corn forage with increasing PHIs from 0 to 14 days and remained unchanged with increasing PHIs from 14 to 28 days. Residues of pydiflumetofen were relatively unchanged in corn stover from one trial with increasing PHIs from 20-40 days, but decreased in corn stover from two trials with increasing PHIs from 20-42 days. Residues of pydiflumetofen in field corn grain were all <LOQ at PHIs of 19-42 days.								
Residue decline data show that residues of pydiflumetofen decreased in sweet corn forage and stover samples with increasing PHIs from 7 days to 14 days. Residues of pydiflumetofen in K+CWHR were all <LOQ at PHIs of 0-14 days.								
Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Field Corn Grain (SC formulation)	248-260	28-32	20	<0.01	0.012	<0.01	<0.01	0.0004
Field Corn Grain (EC formulation)			20	<0.01	<0.01	<0.01	<0.01	0.00
Field Corn Forage (SC formulation)	242-272	6-7	20	0.332	4.87	0.971	1.23	1.0
Field Corn Forage (EC formulation)	248-270		20	0.168	4.43	1.03	1.27	0.9
Field Corn Stover (SC formulation)	248-260	28-32	20	0.442	12.76	2.03	2.82	2.6
Field Corn Stover (EC formulation)			20	0.559	11.54	2.47	2.98	2.3
Popcorn Grain (SC formulation)	252-254	28-31	3	<0.01	<0.01	<0.01	<0.01	-
Popcorn Grain (EC formulation)	251-253		3	<0.01	<0.01	<0.01	<0.01	-
Popcorn Stover (SC formulation)	252-254	28-31	3	1.25	4.71	2.45	2.80	1.8
Popcorn Stover (EC formulation)	251-253		3	1.57	4.95	3.42	3.31	1.7
Sweetcorn (K+CWHR) (SC formulation)	240-260	6-8	12	<0.01	<0.01	<0.01	<0.01	-
Sweetcorn Forage (SC formulation)			12	0.438	3.93	0.774	1.07	0.93

Sweetcorn Stover (SC formulation)			12	0.791	6.62	1.87	2.28	1.6
RESIDUE DATA IN ROTATIONAL CROPS Radish, Spinach (or lettuce) and Wheat						PMRA # 2571089		
Thirty-six rotational crop field trials were conducted in 2013 growing season in the USA, encompassing Zones 2, 6 and 10. Three trials were established for each of three rotational crop types (leafy vegetable, root crop, and small grain crop) at each of four PBIs (30, 60, 90, and 150 days).								
In each trial SYN545974 SC (A19649B), a 200 g/L (20% w/v) suspension concentrate formulation was applied to bare ground by broadcast spray applications. Two applications, each at the rate of 202 g SYN545974/ha/application, were made at 7-day intervals for a total of 404 g a.i./ha. Rotational crops of radish (root crop), spinach or lettuce (leafy vegetable crop) and wheat (small grain crop) were planted at 30, 60, 90, and 150 days after the last application.								
Commodity	Total Application Rate (g a.i./ha)	PBI (days)	Residue Levels (ppm)					
			n	LAFT	HAFT	Median	Mean	SD
Spinach/Lettuce leaf	404	30	3	<0.01	<0.01	<0.01	<0.01	0
Radish roots				<0.01	<0.01	<0.01	<0.01	0
Radish tops				<0.01	<0.01	<0.01	<0.01	0
Wheat grain				<0.01	<0.01	<0.01	<0.01	0
Wheat forage				<0.01	0.011	0.011	0.011	0
Wheat hay				0.018	0.033	0.022	0.024	0.004
Wheat straw				0.031	0.043	0.033	0.036	0.004
Spinach/Lettuce leaf	404	60	3	<0.01	<0.01	<0.01	<0.01	0
Radish roots				<0.01	<0.01	<0.01	<0.01	0
Radish tops				<0.01	<0.01	<0.01	<0.01	0
Wheat grain				<0.01	<0.01	<0.01	<0.01	0
Wheat forage				<0.01	<0.01	<0.01	<0.01	0
Wheat hay				0.018	0.038	0.028	0.028	0.006
Wheat straw				0.018	0.057	0.029	0.035	0.01
Spinach/Lettuce leaf	404	90	3	<0.01	<0.01	<0.01	<0.01	0
Radish roots				<0.01	<0.01	<0.01	<0.01	0
Radish tops				<0.01	<0.01	<0.01	<0.01	0
Wheat grain				<0.01	<0.01	<0.01	<0.01	0
Wheat forage				<0.01	0.011	0.011	0.011	0
Wheat hay				0.012	0.045	0.037	0.031	0.01
Wheat straw				0.017	0.113	0.043	0.058	0.03
Spinach/Lettuce leaf	404	150	3	<0.01	<0.01	<0.01	<0.01	0
Radish roots				<0.01	<0.01	<0.01	<0.01	0
Radish tops				<0.01	<0.01	<0.01	<0.01	0
Wheat grain				<0.01	<0.01	<0.01	<0.01	0
Wheat forage				<0.01	<0.01	<0.01	<0.01	0
Wheat hay				0.011	0.029	0.014	0.018	0.006
Wheat straw				0.015	0.057	0.023	0.032	0.013
Based on the results of the field accumulation study, a plant-back interval of 30 days is required for all other crops not on the label.								
PROCESSED FOOD AND FEED - Grapes						PMRA # 2571094		
Test Site	Two trials in the US							
Treatment	Broadcast foliar applications							
Rate	2 applications with the total rate of 2016 g a.i./ha/season							
End-use product/formulation	A19649B/SC							
Preharvest interval	14 days							
Processed Commodity	Average Processing Factor							
Wet pomace	1.7-fold							
Juice	0.6-fold							

Raisins	2.4-fold	
PROCESSED FOOD AND FEED - Potatoes		PMRA # 2571104
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	3 applications with the total rate of 1848 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	7 days	
Processed Commodity	Average Processing Factor	
Flakes	0.7	
Peeled and fried (chips)	0.7	
Wet peel	1.6	
Peeled	0.7	
Peeled and boiled	0.7	
Unpeeled and boiled	0.7	
Unpeeled and baked	0.7	
Chips (crisps)	0.7	
Cooking liquid (water)	0.7	
Starch	0.7	
Dried pulp	2.7	
Protein	2.6	
PROCESSED FOOD AND FEED - Tomatoes		PMRA # 2571103
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1235-1241 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	0 day	
Processed Commodity	Average Processing Factor	
Tomato paste	0.69	
Tomato puree	0.34	
Washed and peeled tomatoes	0.07	
Canned tomatoes	0.07	
Sun-dried tomatoes	10	
Tomato juice	0.07	
Wet pomace	3.9	
Dried pomace	40	
PROCESSED FOOD AND FEED - Peanuts		PMRA # 2571102
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	4 applications with the total rate of 1008-1009 g a.i./ha/season	
End-use product/formulation	A19649B/SC and A17573A/EC	
Preharvest interval	14 days	
Processed Commodity	Average Processing Factor	
Meal	0.85	
Refined oil	2.3	
PROCESSED FOOD AND FEED - Rapeseeds		PMRA # 2571111
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1604-1614 g a.i./ha/season	
End-use product/formulation	A19649B/SC and A17573A/EC	
Preharvest interval	30 days	
Processed Commodity	Average Processing Factor	
Meal	0.09	
Refined oil	0.37	

PROCESSED FOOD AND FEED - Soybeans		PMRA # 2571095
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1200-1206 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	14 days	
Processed Commodity	Average Processing Factor	
Meal	0.08	
Hulls	3.3	
Refined oil	0.19	
Flour	0.06	
Soy milk	<0.07	
Tofu	0.15	
Soy sauce	<0.07	
Miso	0.13	
Pollard	0.31	
Crude oil	0.70	
AGF	139	
PROCESSED FOOD AND FEED - Barley		PMRA # 2571108
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1736 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	28 to 52 days	
Processed Commodity	Average Processing Factor	
Pearled barley	0.04	
Bran	0.36	
Flour	0.23	
PROCESSED FOOD AND FEED - Oats		PMRA # 2571107
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1736 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	18 or 28 days	
Processed Commodity	Average Processing Factor	
Rolled oats	0.01	
Bran	0.02	
Flour	0.05	
Husks	3.5	
PROCESSED FOOD AND FEED – Field corn		PMRA # 2571105
Test Site	Two trials in the US	
Treatment	Broadcast foliar applications	
Rate	2 applications with the total rate of 1232 g a.i./ha/season	
End-use product/formulation	A19649B/SC	
Preharvest interval	30 days	
Processed Commodity	Average Processing Factor	
AGF	71	
Milled by-products	2	
Wet-milled germ	2.3	
Wet-milled starch	<0.8	
Wet-milled gluten	1.5	
Wet-milled gluten meal	3.2	
Wet-milled refined oil	2	

Dry-milled grits	<0.8					
Dry-milled meal	1					
Dry-milled flour	1.5					
Dry-milled hulls	4.8					
Dry-milled germ	1					
Dry-milled refined oil	<0.8					
Wet milled flour (masa)	<0.8					
PROCESSED FOOD AND FEED – Sweet corn		PMRA # 2571119				
Test Site	Two trials in the US					
Treatment	Broadcast foliar applications					
Rate	2 applications with the total rate of 1232 g a.i./ha/season					
End-use product/formulation	A19649B/SC					
Preharvest interval	7 days					
Processed Commodity	Average Processing Factor					
Canned corn	1					
Cannery waste	1.8					
Frozen corn	1					
Cream corn	1					
PROCESSED FOOD AND FEED – Wheat		PMRA # 2571106				
Test Site	Two trials in the US					
Treatment	Broadcast foliar applications					
Rate	2 applications with the total rate of 1736 g a.i./ha/season					
End-use product/formulation	A19649B/SC					
Preharvest interval	21 or 33 days					
Processed Commodity	Average Processing Factor					
AGF	363					
Bran	2.3					
Flour	0.3					
Middlings	0.55					
Shorts	0.75					
Germ	1.5					
Gluten	1.7					
Starch	0.15					
Gluten feed meal	1.9					
Milled by-products	6.1					
Wholemeal flour	0.75					
Wholemeal bread	0.50					
LIVESTOCK FEEDING – Dairy cattle		PMRA # 2570997				
Dairy cows were administered pydiflumetofen at dose levels of 15 ppm, 45 ppm and 150 ppm in the feeds for 28 consecutive days. The dose levels of 15, 45 and 150 ppm represent ~2.1x, 6.3x, and 21x, respectively, the estimated more balanced diet (MBD) for beef cattle and ~0.8x, 2.3x, and 7.7x, respectively, for dairy cattle.						
Commodity	Dose (ppm)	Highest Pydiflumetofen Residues (ppm)	Langmuir	DB (ppm)	Anticipated residues at DB (ppm)	
Whole milk	150	0.02	y = 0.029 * x / (x + 76.2)	19.41	0.006	
	45	<0.01				
	15	NA				
Skim milk	150	<0.01	-		19.41	<0.01
	45	NA				
	15	NA				
Cream	150	0.20	y = 0.0013x		19.41	0.025
	45	0.04				
	15	0.01				

Liver	150	0.12	y = 0.311 * x / (x + 242)		0.023
	45	0.05			
	15	0.02			
Kidney	150	0.02	y = 0.029 * x / (x + 76.2)		0.006
	45	<0.01			
	15	na			
Muscle	150	<0.01	-		<0.01
	45	<0.01			
	15	NA			
Subcutaneous Fat	150	0.11	y = 0.381 * x / (x + 376)		0.019
	45	0.04			
	15	0.02			
Perirenal Fat	150	0.11	y = 0.218 * x / (x + 146)		0.026
	45	0.06			
	15	0.01			
Mesenterial Fat	150	0.17	y = 0.994 * x / (x + 738)		0.025
	45	0.06			
	15	0.02			
LIVESTOCK FEEDING – Laying hen				PMRA # 2570997	
Laying hens were administered pydiflumetofen at dose levels of 3 ppm, 9 ppm and 30 ppm in the feeds for 28 consecutive days. The dose levels of 3, 9 and 30 ppm represent ~9x, 28x, and 93x, respectively, the estimated more balanced diet (MBD) for poultry.					
Commodity	Dose (ppm)	Highest Pydiflumetofen Residues (ppm)	Langmuir	DB (ppm)	Anticipated residues at DB (ppm)
Whole eggs	30	0.027	y = 0.04 * x / (x + 15.1)	0.32	0.001
	9	0.011			
	3	<0.01			
Muscle	30	<0.01	-		<0.01
Liver	30	<0.01	-		<0.01
Kidney	30	<0.01	-		<0.01
	9	<0.01			
	3	<0.01			
Fat	30	<0.01	-		<0.01

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops and Rotational crops	Pydiflumetofen
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops and Rotational crops	Pydiflumetofen
METABOLIC PROFILE IN DIVERSE CROPS	Similar in canola, wheat and tomato.
ANIMAL STUDIES	
ANIMALS	Ruminant and Poultry
RESIDUE DEFINITION FOR ENFORCEMENT	Pydiflumetofen
RESIDUE DEFINITION FOR RISK ASSESSMENT	-
Ruminant	Pydiflumetofen and the metabolites 2,4,6-Trichlorophenol (free and conjugated), plus SYN547897 in liver and kidney, plus SYN548263 in kidney, expressed as parent equivalents
Poultry	Pydiflumetofen and the metabolite 2,4,6-Trichlorophenol (free and conjugated), expressed as parent equivalents

SIMILAR METABOLIC PROFILE IN ANIMALS (goat, hen, rat)		Yes	
FAT SOLUBLE RESIDUE		No	
DIETARY RISK FROM FOOD AND WATER			
Basic chronic non-cancer dietary exposure analysis ADI = 0.09 mg/kg bw/day Estimated chronic drinking water concentration = 152 µg/L	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Alone	Food and Water
	All infants < 1 year	9.2	21.9
	Children 1–2 years	25.0	29.7
	Children 3 to 5 years	22.7	26.5
	Children 6–12 years	15.9	18.7
	Youth 13–19 years	13.3	15.7
	Adults 20–49 years	18.1	21.5
	Adults 50+ years	18.2	21.5
	Females 13-49 years	18.4	21.7
	Total population	17.7	21.1
Basic acute dietary exposure analysis, 95th percentile ARfD = 1.0 mg/kg bw Estimated acute drinking water concentration = 152 µg/L	POPULATION	ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)	
		Food Alone	Food and Water
	All infants < 1 year	3.67	4.95
	Children 1–2 years	7.37	7.99
	Children 3 to 5 years	7.97	8.46
	Children 6–12 years	5.82	6.06
	Youth 13–19 years	5.23	5.59
	Adults 20–49 years	6.83	7.21
	Adults 50+ years	6.74	7.12
	Females 13-49 years	7.14	7.55
	Total population	6.63	7.04

Table 7 Mixer/Loader/Applicator Exposure estimates and MOE

Crop	Application Method	Total Unit Exposure (µg/kg ai handled)	Rate (kg a.i./ha)	Area Treated per Day (ha/day)	Exposure Estimate (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)
A19649 Fungicide (PPE: single layer plus chemical resistant gloves)						
Dried Shelled Peas and Beans	Open Mix/Load	59.13	0.2	400	0.02988	1208
	Aerial	2.68		400	0.001345	26846
	Open Mix/Load + Groundboom, Custom App. ¹	86.21		360	0.039834	906
Soybeans	Open Mix/Load	59.13	0.2	400	0.02988	1208
	Aerial	2.68		400	0.00134469	26846
	Open Mix/Load + Groundboom, Custom App.	86.21		360	0.039834	906
Wheat and Barley	Open Mix/Load	59.13	0.2	400	0.02988	1208
	Aerial	2.68		400	0.00134469	26846
	Open Mix/Load + Groundboom, Custom App.	86.21		360	0.039834	906
Canola	Open Mix/Load	59.13	0.2	400	0.02988	1208
	Aerial	2.68		400	0.00134469	26846
	Open Mix/Load +	86.21		360	0.039834	906

Crop	Application Method	Total Unit Exposure (µg/kg ai handled)	Rate (kg a.i./ha)	Area Treated per Day (ha/day)	Exposure Estimate (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)
	Groundboom, Custom App.					
Corn	Open Mix/Load	59.13	0.1	400	0.01494	2416
	Aerial	2.68		400	0.000672345	53693
	Open Mix/Load + Groundboom, Custom App.	86.21		140	0.0077455	4661
Peanuts	Open Mix/Load	59.13	0.05	400	0.00747	4833
	Aerial	2.68		400	0.000336173	107385
	Open Mix/Load + Groundboom, Custom App.	86.21		360	0.0099585	3625
A19649TO Fungicide (PPE: single layer plus chemical resistant gloves)						
Turf	Open M/L + GB	86.21	0.2	30 ²	0.00332	10875
	Handgun Lawn Sprayer	1106.04		2	0.002773	13020
Greenhouse Ornamentals	Mechanically Pressurized Handgun	5736.49	0.00015 kg a.i./L	3800L/day	0.020974	439
	Manually Pressurized Handwand	988.57		150L/day	0.000145	63285
	Backpack	5507.95		150L/day	0.000783	11745
Greenhouse Cucumbers	Mechanically Pressurized Handgun	5736.49	0.0001 kg a.i./L	3800L/day	0.013983	658
	Manually Pressurized Handwand	988.57		150L/day	9.69E-05	94928
	Backpack	5507.95		150L/day	0.000522	17618
Outdoor Ornamentals	Open M/L + Airblast without chemical resistant headgear	3837.51	0.225 ³	20	0.108203	74
	Open M/L + Airblast with chemical resistant headgear	483.14			0.027177	577
	Mechanically Pressurized Handgun	5736.49	0.00015 kg a.i./L	3800L/day	0.020974	1721
	Manually Pressurized Handwand	988.57		150L/day	0.000145	248325
	Backpack	5507.95		150L/day	0.000783	46088
A20259 Fungicide (PPE: single layer plus chemical resistant gloves)						
Potatoes	Open M/L	59.13	0.075	400	0.011205	3222
	Aerial	2.68		400	0.000504	71590
	Open M/L + Groundboom, Custom App.	86.21		360	0.014938	2417
Tuberous & Corm Vegetables (except potatoes)	Open M/L + Groundboom, Custom App.	86.21	0.075	360	0.014938	2417
Fruiting Vegetables	Open M/L + Groundboom, Custom App.	86.21	0.075	26	0.001079	33462
Cucurbit Vegetables	Open M/L + Groundboom, Custom App.	86.21	0.075	26	0.001079	33462
A20560 Fungicide (PPE: single layer plus chemical resistant gloves)						
Leafy Greens	Open M/L + Groundboom	86.21	0.15	26	0.002158	16731
Leaf Petiole Vegetables	Open M/L + Groundboom	86.21	0.15	26	0.002158	16731
Small Fruit Vine	Open M/L + Airblast (without	3837.51	0.15	20	0.072135	500

Crop	Application Method	Total Unit Exposure (µg/kg ai handled)	Rate (kg a.i./ha)	Area Treated per Day (ha/day)	Exposure Estimate (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)
Climbing	chemical resistant headgear)					
A21461 Fungicide (PPE: Single layer plus chemical resistant gloves)						
Dried Shell Peas and Beans	Open M/L	59.13	0.09375	400	0.014006	2577
	Aerial	2.68		400	0.00063	57272
	Open M/L + GB	86.21		360	0.018672	1933
Soybeans	Open M/L	59.13	0.09375	400	0.014006	2577
	Aerial	2.68		400	0.00063	57272
	Open M/L + GB	86.21		360	0.018672	1933
Cereal Grains	Open M/L	59.13	0.05625	400	0.008404	4296
	Aerial	2.68		400	0.000378	95454
	Open M/L + GB	86.21		360	0.011203	3222
Corn	Open M/L	59.13	0.09375	400	0.014006	2577
	Aerial	2.68		400	0.00063	57272
	Open M/L + GB	86.21		140	0.007261	4971

‡Exposure Estimate = ((Dermal Unit Exposure × Dermal Absorption Value + Inhalation Unit Exposure) × ATPD × Rate) / (80 kg bw × 1000 µg/mg)

¶Based on NOAEL = 36.1 mg/kg bw/day, target MOE = 100

¹Groundboom Farmer Application is expected to be covered by Groundboom Custom Application based on lower area treated per day

²As golf courses are expected to have a lower area treated per day (ATPD) than sod farms, the ATPD for sod farms was used in the risk assessment

³Application Rate (kg a.i./ha) = 15 g a.i./100 L (application rate) × 1500 L/ha (dilution rate) × 0.001 kg/g

Table 8 Postapplication Exposure Estimates and Margins of Exposure (MOE)

Crop	Peak DFR/TTR (µg/cm ²) *	Activity	Transfer Coefficient (cm ² /hr)	Exposure (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)	REI◇ (hours)
A19649 Fungicide						
Dried Shelled Peas and Beans	0.61	Irrigation	1750	0.053759	672	12
Soybeans	0.74	Scouting	1100	0.040653165	888	12
Wheat & Barley	0.50	Scouting	1100	0.0275	1313	12
Canola	0.95	Scouting	1100	0.05225	691	12
Corn	0.48	Detasseling	8800	0.209	173	12
Peanuts	0.14	Scouting	210	0.001473546	24499	12
A19649TO Fungicide						
Turf	0.022	Transplanting/Planting/Harvesting	6700	0.007433107	4857	0
Greenhouse Ornamentals <i>Cut Flowers</i>	0.38	Hand Harvest/Disbudding/Pruning	4000	0.075	123†	12
Greenhouse Ornamentals <i>Potted Flowers</i>	1.04	All Activities	230	0.0119652	769†	12

Crop	Peak DFR/TTR (µg/cm ²) *	Activity	Transfer Coefficient (cm ² /hr)	Exposure (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)	REI◇ (hours)
Greenhouse Cucumbers	1.25	All Activities	1400	0.0875	105†	12
Outdoor Ornamentals	0.83	Irrigation	1750	0.072759926	496	12
A20259 Fungicide						
Turberous & Corm Vegetables including potatoes	0.32	Irrigation	1750	0.028006532	1289	12
Fruiting Vegetables	0.28	Irrigation	1750	0.024253309	1488	12
Cucurbit Vegetables	0.23	Irrigation	1750	0.020159	1791	12
A20560 Fungicide						
Leafy Greens & Leaf Petiole Vegetables	0.55	Irrigation	1750	0.048506617	744	12
Small Fruit, Vine Climbing	0.42	Turning/Girdling	19300	0.401470997	90	12
	0.37			0.361323897	100	1 Day
A21461 Fungicide						
Dried Shelled Peas and Beans	0.29	Irrigation	1750	0.025269	1429	12
Soybeans	0.29	Scouting	1100	0.015882	2273	12
Cereal Grains	0.17	Scouting	1100	0.009462	3815	12
Corn	0.45	Detasseling	8800	0.19646	184	12

* Calculated using the default 25% or 1% dislodgeable on the day of application and 10% dissipation per day

‡ Exposure = (Peak DFR/TTR [µg/cm²] × TC [cm²/hr] × 8 hours × 50% dermal absorption) / (80 kg bw × 1000 µg/mg)

¶ Based on a NOAEL of 36.1 mg/kg bw/day, target MOE = 100

† Based on a NOAEL of 9.2 mg/kg bw/day, target MOE = 100

◇ Minimum REI is 12 hours to allow residues to dry, except golf courses where it specifies until sprays have dried

Table 9 Postapplication Exposure to Golfers

Lifestage	Peak TTR (µg/cm²)*	Exposure (mg a.i./kg bw/day) ‡	MOE¶ (Target = 100)
Adults	0.02	0.00293996	12279
Youth (11 to <16)		0.003425574	10538
Child (6 to <11)		0.004021644	8976

* Calculated using the default 1% dislodgeable on the day of application and 10% dissipation per day

‡ Transfer coefficients obtained from USEPA Residential SOP (2012)

‡ Exposure = (Peak TTR [µg/cm²] × TC [cm²/hr] × 4 hours × 50% dermal absorption) / (kg bw × 1000 µg/mg) (80 kg adults; 57 kg youth; 32 kg child)

¶ Based on a NOAEL of 36.1 mg/kg bw/day, target MOE = 100

Table 10 Postapplication Aggregate Exposure and Risk

Lifestage	Postapplication (Golfing) Dermal Exposure (mg a.i./kg bw/day)	Dietary Exposure (mg a.i./kg bw/day)	Aggregate Exposure (mg a.i./kg bw/day) ^a	MOE (Target = 100)
Adults	0.00293996	0.019134	0.022074	1635
Youth (11 to <16)	0.003425574	0.013494	0.01692	2134
Child (6 to <11)	0.004021644	0.017872	0.021894	1649

^aAggregate Exposure (mg/kg bw/day) = sum of exposures / kg bw (80 kg adults; 57 kg youth; 32 kg child)

^bBased on a NOAEL of 36.1 mg/kg bw/day; MOE = 100 (Table 3)

Table 11 Physical and chemical properties of the active ingredient relevant to the environment

Property	Value	Comment
Water Solubility (25°C)	1.5 mg/L	Low aqueous solubility
Vapour pressure	1.849 × 10 ⁻⁷ Pa at 20°C 5.30 × 10 ⁻⁷ Pa at 25°C	Low potential for residues on fruits and foliage to decrease as a result of volatilization
Henry's law constant at 25°C (reviewer calculated)	1.49 × 10 ⁻¹⁰ atm·m ³ /mol 6.09 × 10 ⁻⁸ (unitless)	Low potential for residues to volatilize from moist soil and water surface to atmosphere
Dissociation constant, pKa	Not applicable; does not dissociate in the pH range of 2.0-12.0	Found in neutral form in the environment
Log K _{ow}	3.8	Potential concern for bioaccumulation
UV/visible absorption spectrum	Max at 230 nm	Not expected to absorb light at λ > 300 nm
Stability (temperature, metal)	Stable for 2 weeks at 54°C; stable for 2 weeks in the presence of metals (aluminum flakes, iron granules) and metal ions (aluminum acetate and iron acetate) at 20°C and 40°C.	

Table 12 Summary of fate and behaviour of pydiflumetofen in the environment

Property	Test substance	DT ₅₀ /t _{1/2-rep} (days)	Transformation products	Comments/classification	PMRA#
Abiotic transformation					
Hydrolysis	a.i.	stable at 50°C pH 4 - 9	None	Not an important route of dissipation	2570965
Phototransformation on soil (summer light, 30-50°N)	a.i.	t _{1/2,rep} : >150 d	SYN545574, minor	Not an important route of dissipation	2570968
Phototransformation in water (summer light at 30- 55°N)	a.i.	99 d (pH 7 buffer) 118 d (natural water)	SYN548261, SYN548262, NOA449410 and Unk AP2, all minor; CO ₂ up to 12.6% AR	Not an important route of dissipation	2570967
Phototransformation in air	NA	NA	NA	Not expected to be a route of dissipation	NA
Volatilization	NA	NA	NA	Not expected based on vapour pressure and Henry's law constant	NA
Biotransformation in soil					

Property		Test substance	DT ₅₀ /t _{1/2-rep} (days)	Transformation products	Comments/classification	PMRA#
Biotransformation in aerobic soil		a.i.	474-4505 (t _{1/2,rep} 90% upper bound on the mean: 3118 d; n=5)	SYN545547 – minor CO ₂ 0.2-16.5% AR	Persistent	2570966
			Combined pydiflumetofe n + SYN545547: 422-4110 (t _{1/2,rep} 90% upper bound of the mean: 2783 d; n=5)		Half-lives for combined residues of parent and SYN545547 were used for water modelling.	
Biotransformation in anaerobic soil		a.i.	960 d – stable (n=4)	No major transformation products Minor transformation products: SYN545547 and CO ₂ < 1% AR	Persistent	2570970
			Combined pydiflumetofe n + SYN545547: 1053 – stable		Half-lives for combined residues of parent and SYN545547 were used for water modelling.	
Mobility						
Property		Test substance	Mean K _a /K _{oc} (L/g)	Comment	Mobility classification	PMRA#
Adsorption in soil		a.i.	30.23±12.77 (13.5-44.22) / 2065±396 (1383 - 2247)	Linear adsorption, 6 soils	Low to slight mobility	2571020
		SYN545547	12.13±4.24 (6.2-16.92)/ 703±203(360 - 860)	Linear adsorption, 5 soils	Medium to low mobility	2571079
Soil leaching		a.i.	Borderline leacher (according to criteria of Cohen <i>et al.</i> and GUS index)			
		SYN545547	NA			
Field dissipation						
Test site		Test item and rate	DT ₅₀ /t _{1/2-rep} (days)	Major transformation products	Classification/comments	PMRA#
Field dissipation	AB – bare soil	SYN54597 4 SC 200 (A16946B) @ 2×220 g a.i./ha (nominal)	357 / 357	NA	Persistent, max. depth <15 cm, 23% carry-over	2571098
	PEI – bare soil		> 356 / NA		Persistent, max. depth <75 cm, 65% carry-over, half-life cannot be calculated.	2571112
	Iowa – bare soil		57 / 155		Moderately persistent, max. depth <30 cm, 18% carry-over	2571086
	WA – bare		594 / 1390		Persistent, max. depth <30 cm, 47% carry-over	2571096

Property		Test substance	DT ₅₀ /t _{1/2-rep} (days)	Transformation products	Comments/classification	PMRA#
	soil					
	GA – bare soil		260 / 811		Persistent, max. depth <30 cm, 21% carry-over	2571016
	CA – bare soil		666 / 666		Persistent, max. depth <75 cm, 37% carry-over	2571018
	PEI – turf		240 / 658		Persistent, max. depth <60 cm, 46% carry-over	2571112
	WA – wheat		>600 / NA		Persistent, max. depth <30 cm, >53% carry-over, half-life cannot be calculated.	2571096
	GA – peanut		611 / 611		Persistent, max. depth <30 cm, 22% carry-over	2571016
	GA – turf		63.7 / 126		Moderately persistent, max. depth <60 cm, 4.5% carry-over	2571114
	CA – turf		17.7 / 84		Moderately persistent, max. depth <15 cm, 5.3% carry-over	2571116
Biotransformation in aquatic environment						
Property	Test substance	DT ₅₀ /t _{1/2-rep} (days)	Major transformation products	Comments/classification	PMRA#	
Biotransformation in aerobic water systems	a.i.	Water: 4.83-13.7 / 9.95-35 Total system: 238-278 / 238-278	SYN545574 up to 13% CO ₂ < 1% AR	Persistent in whole system	2570969	
		Combined pydiflumetofen + SYN545547 in the total system: 371-552		Half-lives for combined residues of parent and SYN545547 were considered for water modelling.		
Biotransformation in anaerobic water systems		Water: 33.2-39.3 / 33.2-52.4 Total system: 162-174 / 162-174		Moderately persistent in whole system		
Combined pydiflumetofen + SYN545547 in the total system: 433-1185		Persistent when considers half-lives for combined residues of parent and SYN545547. The longer of the two was used for water modelling.				
Partitioning						
Primarily in the sediment layer.						

Table 13 Summary of toxicity effects of pydiflumetofen on terrestrial organisms

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
Invertebrates							
<i>Eisenia fetida</i> (Earthworm)	Pydiflumetofen	14 days, mortality	LC ₅₀	>1000 mg a.i./kg soil dw	NA	2570915	Fully reliable
			NOEC	1000 mg a.i./kg soil dw	NA		
	A19649B (SYN545974 200 SC)	14 days, mortality	LC ₅₀	>1000 mg product/kg soil dw (>186 mg a.i./kg soil dw)	NA	2570924	Fully reliable
			NOEC	1000 mg product/kg soil dw (186 mg a.i./kg soil dw)	NA		
		56 days, reproduction	NOEC	171 mg product/kg soil dw (31.8 mg a.i./kg soil dw)	NA	2570925	Fully reliable
<i>Apis mellifera</i> (Honeybee)	Pydiflumetofen	48-h acute oral (limit test) adult	LD ₅₀ :	> 116 µg a.i./bee	Relatively non-toxic	2571073	Fully reliable
		48-h acute contact (limit test), adult	LD ₅₀ :	> 100 µg a.i./bee	Relatively non-toxic		
		22-d chronic (limit test), brood	LD ₅₀ : (8-d mortality)	>0.0035 µg a.i./larvae/day	NA	2570912	Reliable with restrictions
			NOEL: (22-d adult emergence)	<0.0035 µg a.i./larvae/day			
	A19649B (SYN545974 SC 200)	10-dd continuous feeding, adult	LD ₅₀ :	>141 µg a.i./bee/day	NA	2570922	Fully reliable
			NOEL:	141 µg a.i./bee/day			
		22-d chronic, brood	LD ₅₀ : (8-d mortality)	7.8 µg a.i./larvae/day	Moderately toxic	2767154	Fully reliable
			NOEL: (22-d adult emergence)	0.42 µg a.i./larvae/day	NA		
	Pydiflumetofen™ SC (a.i.: 18.4%)	Semi-field study: spay application	There were no significant effects on honeybee worker mortality or pupae		NA	2763319	

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
	pydiflumetofen)	<p>at nominal rates of 75, 125 and 200 g a.i./ha to flowering <i>Phacelia tanacetifolia</i> while bees were actively foraging. 7 d exposure followed by 56 d monitoring.</p> <p>Additional tunnels were set up at each treatment level for residue analysis in bee-collected pollen and nectar samples, as well as flowers and leaves (-2, 0, 1, 4 and 6 DAA). Pollen from comb was collected on 38 and 52 DAA.</p>	<p>and larvae mortality during the exposure and post-exposure phases for pydiflumetofen applications up to 200 g a.i./ha. There were also no significant effects on the brood and compensation indices and termination rates for eggs, young larvae, and old larvae during the exposure and post-exposure phases. In the colony conditions assessments, none of the parameters assessed showed a dose-response relationship. Overall, based on a weight-of-evidence approach and considering the results across all measured endpoints, dose-response relationships, adverse impacts to brood and honeybee colonies, pydiflumetofen applications up to 200 g a.i./ha do not appear to adversely impact honeybees at the colony level under semi-field conditions. There may be some transitory behavioural effects in a small number of individual bees at the 200 g a.i./ha treatment level, but no effect on the colony development is expected.</p> <p>On colony basis, NOAEC: 200 g a.i./ha; LOAEC: >200 g a.i./ha</p> <p>Measured residues on the day of application:</p> <p>Nectar (foraging bees): 0.107 mg/kg Pollen (foraging bees): 33.3 mg/kg Flowers: 30.6 mg/kg Leaves: 33.4 mg/kg</p> <p>Measured residues 1 day after application:</p> <p>Nectar (foraging bees): 0.012 mg/kg Pollen (foraging bees): 2.05 mg/kg Flowers: 21.9 mg/kg Leaves: 34.5 mg/kg</p>				

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
			38 DAA combs: Nectar: <LOD; Pollen: <LOD 52 DAA combs: Nectar: <LOD; Pollen: <LOD Residue in all matrices declined rapidly The study experienced heavy rainfall during exposure and food scarcity during monitoring. Artificial nectar was provided. However, the reference chemical information showed effects as expected, suggesting that the timing of the study and food shortage did not prevent detection of effects.				
		Semi-field study: spray application at nominal rates of 75, 125 and 200 g a.i./ha to flowering <i>Phacelia tanacetifolia</i> while bees were actively foraging. 7 d exposure followed by 56 d monitoring. Additional tunnels were set up at each treatment level for residue analysis in bee-collected pollen and nectar samples, as well as flowers and leaves (-3, 0, 2, 4 and 6 DAA). Pollen from comb	There were no significant effects on worker bee mortality or pupae and larvae mortality during the exposure and post-exposure phases for pydiflumetofen applications up to 200 g a.i./ha. In the colony condition assessments, there were a few statistically significant (p<0.05) differences in the number of cells with food and cells and combs with brood. However, these differences occurred in different treatment groups and at different times with no apparent dose-response relationships across treatments. No treatment-related effects on brood were observed during the 22-day development cycle. Based on a weight of evidence approach and in comparison with control treatments, the results across all measured parameters, including colony conditions, brood development and dose-response relationships, pydiflumetofen applications up to 200 g a.i./ha do not appear to adversely impact honeybee colony under the semi-field conditions.		NA	2763321	

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
		was collected on 37 and 54 DAA.	<p>On colony basis, NOAEC: 200 g a.i./ha; LOAEC: >200 g a.i./ha</p> <p>Measured residues on the day of application:</p> <p>Nectar (foraging bees): 0.165 mg/kg</p> <p>Pollen (foraging bees): 29.5 mg/kg</p> <p>Flowers: 31.8 mg/kg (0 DAA)</p> <p>Leaves: 41.4 mg/kg (0 DAA)</p> <p>Measured residues 2 days after application:</p> <p>Nectar (foraging bees): < LOQ (0.005 mg/kg)</p> <p>Pollen (foraging bees): 0.697 mg/kg</p> <p>Flowers: 15.2 mg/kg</p> <p>Leaves: 24.6 mg/kg</p> <p>37 DAA combs: Nectar: 0.01 mg/kg; Pollen: 0.108 mg/kg</p> <p>54 DAA combs: Nectar: < LOD; Pollen: 0.56 mg/kg</p> <p>Residue in all matrices declined rapidly</p> <p>The study was conducted late in the season when colonies were general declining in total numbers of bees and were likely preparing for overwintering by the end of the study (mid-October). Also, food was scarce during monitoring. Artificial nectar was provided. However, the test with toxic reference showed effects as expected, suggesting that the rainfall and food shortage did not prevent detection of effects.</p>				
<i>Typhlodromus pyri</i> (Predatory mite)	A19649B (SYN545974 SC 200)	7-d contact glass plate (Tier I) Proto-nymphs	LR ₅₀ mortality	> 2000 mL/ha (> 400 g a.i./ha)	NA	2571081	Fully reliable
			NOER mortality	2000 mL/ha (> 400 g a.i./ha)	NA		

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
		14-d reproduction glass plate Proto-nymphs	ER ₅₀ reproduction	> 2000 mL/ha (> 400 g a.i./ha)	NA	2571083	Fully reliable
			NOER reproduction	250 mL/ha (50 g a.i./ha)	NA		
		7-d contact leaf discs (Tier II) Proto-nymphs	LR ₅₀	> 4000 mL/ha (> 800 g a.i./ha)	NA		
			NOER mortality	4000 mL/ha (800 g a.i./ha)	NA		
		14-d reproduction leaf discs (Tier II) Proto-nymphs	ER ₅₀ reproduction	> 4000 mL/ha (> 800 g a.i./ha)	NA		
			NOER reproduction	4000 mL/ha (800 g a.i./ha)	NA		
<i>Aphidius rhopalosiphi</i> (Parasitoid wasp)	A19649B (SYN545974 SC 200)	48-h contact glass plate (Tier I) Female adult	48 hr LR ₅₀	> 2000 mL/ha (> 400 g a.i./ha)	NA	2571080	Fully reliable
			48 hr NOER mortality	500 mL/ha (100 g a.i./ha)	NA		
			ER ₅₀ parasitisation	> 2000 mL/ha (>400 g a.i./ha)	NA		
			NOER parasitisation	1000 mL /ha (200 g a.i./ha)	NA		
		48-h contact Barley seedlings (Tier II) Female adult	LR ₅₀	> 4000 mL/ha (> 800 g a.i./ha)	NA	2571082	Fully reliable
			NOER mortality	4000 mL/ha	NA		

Test organism	Test substance	Exposure	Endpoint	Value		Degree of toxicity	PMRA #	Study acceptability
					(800 g a.i./ha)			
			ER ₅₀ parasitisation		> 4000 mL/ha (> 800 g a.i./ha)	NA		
			NOER parasitisation		4000 mL/ha (800 g a.i./ha)	NA		
Birds								
<i>Colinus virginianus</i> Northern Bobwhite quail	Pydiflumetofen	Acute oral (limit test)	LD ₅₀ :		> 2000 mg a.i./kg bw	Practically non-toxic	2571005	Fully reliable
<i>Serinus canaria</i> Canary		Acute oral (limit test)	LD ₅₀ :		> 2000 mg a.i./kg bw	Practically non-toxic	2571006	Fully reliable
<i>Colinus virginianus</i> Northern Bobwhite		Acute Dietary	LC ₅₀ :		> 5919 mg a.i./kg diet (> 1258 mg a.i./kg bw/d)	Practically non-toxic	2571003	Fully reliable
			NOEC:		1024 mg a.i./kg diet (199 mg a.i./kg bw/d)	NA		
<i>Anas platyrhynchos</i> Mallard duck		Acute Dietary	LC ₅₀ :		> 5823 mg a.i./kg diet (> 2437 mg a.i./kg bw/d)	Practically non-toxic	2571004	Fully reliable
<i>Colinus virginianus</i> Northern Bobwhite		Reproduction	NOEC:		1035 mg a.i./kg diet (92 mg a.i./kg bw/day)	NA	2571007/ 2571008	Fully reliable
			LOEC:		5191 mg a.i./kg diet (465 mg a.i./kg bw/day)			
<i>Anas platyrhyn-</i>		Reproduction	NOEC:		200 mg	NA	2571009/	Fully reliable

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
<i>chos</i> Mallard duck				a.i./kg diet (26.9 mg a.i./kg bw/day)		2571010	
			LOEC:	1024 mg a.i./kg diet (144 mg a.i./kg bw/day)			
Small wild mammals							
Wistar rats	Pydiflumetofen	Acute oral (gavage)	LD ₅₀ :	> 5000 mg a.i./kg bw	Practically non- toxic	2570916	
	A19649TO (same as A19649B) (18.6% a.i.)		LD ₅₀ :	2958 mg EP/kg bw (550 mg a.i./kg bw)	Slightly toxic	2569932	
Wistar rats	Pydifumetofen	2 generation reproduction	NOEL: (reproductive)	116.2 mg a.i./kg bw/day	NA	2571022	
			NOEL (offspring)	36.1 mg a.i./kg bw/day	NA		
Vascular plants							
Four monocot species: corn, onion, ryegrass and wheat	A19649B (18.6% a.i.)	Seedling emergence Limit test (Sprayed on planted seeds at 200 g a.i./ha)	IC ₂₅ :	> 200 g a.i./ha	NA	2571011	Fully reliable
			NOEC:	200 g a.i./ha	NA		
Six dicot species: cabbage, lettuce, oilseed rape, soybean, sugar beet and tomato			IC ₂₅ :	> 200 g a.i./ha	NA		
			NOEC:	200 g a.i./ha	NA		
Four monocot species: corn, onion, ryegrass and wheat	A19649B (18.6% a.i.)	Seedling emergence Definite test (Sprayed on	IC ₂₅ :	> 370 g a.i./ha	NA	2571013	Fully reliable
			NOEC:	200 g a.i./ha	NA		

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
Six dicot species: cabbage, lettuce, oilseed rape, soybean, sugar beet and tomato		planted seeds at 5 dose levels between 50-370 g a.i./ha)	IC ₂₅ :	> 370 g a.i./ha	NA		
			NOEC:	370 g a.i./ha	NA		
Four monocot species: corn, onion, ryegrass and wheat	A19649B (18.6% a.i.)	Vegetative vigour Limit test (Sprayed on young plants at 200 g a.i./ha)	IC ₂₅ :	> 200 g a.i./ha	NA	2571012	Fully reliable
NOEC:			200 g a.i./ha				
Six dicot species: cabbage, lettuce, oilseed rape, soybean, sugar beet and tomato			IC ₂₅ :	> 200 g a.i./ha	NA		
			NOEC:	200 g a.i./ha	NA		

Table 14 Summary of toxicity effects of pydiflumetofen, SYN545547 (TP) and its associated end-use product on aquatic organisms

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
Freshwater Invertebrates							
Daphnia magna	Pydiflumetofen (TGAI)	48-h Acute (static)	EC ₅₀ :	0.421 mg a.i./L	Highly toxic	2570934	Fully reliable
			NOEC:	0.057 mg a.i./L	NA		
		Full Life-Cycle (static renewal)	NOEC:	0.042 mg a.i./L	NA	2570937	Fully reliable
	SYN545547 (TP)	48-h Acute (static)	EC ₅₀ :	7.53 mg/L	Moderately toxic	2570956	Fully reliable
			NOEC:	2.5 mg/L	NA		
Chironomus riparius Midge	Pydiflumetofen (TGAI)	Life-cycle (spiked sediment)	NOEC _{bulk sediment} :	14 mg a.i./kg	NA	2570948/2570949	Fully reliable
			NOEC _{pore water} :	0.18 mg a.i./L	NA		
Hyalella Azteca amphipod	Pydiflumetofen (TGAI)	42-day (spiked sediment)	NOEC _{bulk sediment} :	33 mg a.i./kg	NA	2570950/2570951	Fully reliable
			NOEC _{pore water} :	1.2 mg a.i./L	NA		
			NOEC _{overlying water} :	0.13 mg a.i./L	NA		
Fish							
Oncorhynchus mykiss	Pydiflumetofen	96-h acute	LC ₅₀ :	0.186 mg a.i./L	Highly toxic	2570935	Fully reliable

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
Rainbow Trout	(TGAI)	Flow-through	NOEC:	0.13 mg a.i./L	NA	2570944	Fully reliable
<i>Pimephales promelas</i>		96-h acute	LC ₅₀ :	0.346 mg a.i./L	Highly toxic		
Fathead Minnow		Flow-through	NOEC:	0.24 mg a.i./L	NA		
<i>Cyprinus carpio</i> common carp		96-h acute	LC ₅₀ :	0.335 mg a.i./L	Highly toxic	2570943	Fully reliable
		Flow-through	NOEC:	0.13 mg a.i./L	NA		
<i>Pimephales promelas</i> Fathead Minnow		35-d ELS flow-through	NOEC:	0.064 mg a.i./L	NA	2570938	Fully reliable
<i>Oncorhynchus mykiss</i> Rainbow Trout	SYN545547 (TP)	96-h acute static	LC ₅₀ :	1.32 mg/L	Moderately toxic	2570957	Fully reliable
			NOEC	0.92 mg/L	NA		
Vascular plants							
<i>Lemna gibba</i> Duckweed	Pydiflumetofen (TGAI)	7-d semi-static	IC ₅₀ :	> 6.3 mg a.i./L	NA	2570939	Fully reliable
			NOEC:	0.33 mg a.i./L	NA		
Freshwater alga							
<i>Pseudokirchneriella subcapitata</i> Green Alga	Pydiflumetofen (TGAI)	96 h-Acute + 96 h- recovery static	IC ₅₀ :	1.5 mg a.i./L	NA	2570936	Fully reliable
			NOEC:	0.093 mg a.i./L	NA		
<i>Anabaena flos-aquae</i> Blue-green alga	Pydiflumetofen (TGAI)	96 h-acute static	IC ₅₀ :	>2.7 mg a.i./L	NA	2570942	Reliable with restrictions
			NOEC:	0.28 mg a.i./L	NA		
<i>Pseudokirchneriella subcapitata</i> Green Alga	A19649B (18.6% a.i.)	96 h-acute continuously stirred	IC ₅₀ :	6.87 mg a.i./L (36.93 mg EP/L)	NA	2608340	Reliable with restrictions
			NOEC:	0.0505 mg a.i./L (0.27 mg EP/L)	NA		
<i>Navicula pelliculosa</i> Freshwater diatom	Pydiflumetofen (TGAI)	96 h-acute static	IC ₅₀ :	1.1 mg a.i./L	NA	2570940	Reliable with restrictions
			NOEC:	0.31 mg a.i./L	NA		
<i>Pseudokirchneriella subcapitata</i> Green Alga	SYN545547 (TP)	96 h-acute static	IC ₅₀ :	2.55 mg/L	NA	2570955	Fully reliable
			NOEC:	1.0 mg/L	NA		
Marine species							
<i>Skeletonema costatum</i> Marine diatom	Pydiflumetofen (TGAI)	96 h-acute static	IC ₅₀ :	2.7 mg a.i./L	NA	2570941	Reliable with restrictions
			NOEC:	2.4 mg a.i./L	NA		
<i>Americamysis bahia</i> mysid shrimp	Pydiflumetofen (TGAI)	96 h-acute static	LC ₅₀ :	0.127 mg a.i./L	Highly toxic	2570933	Fully reliable
		Life-cycle Flow-through	NOEC:	0.076 mg a.i./L	NA	2570947	Fully reliable

Test organism	Test substance	Exposure	Endpoint	Value	Degree of toxicity	PMRA #	Study acceptability
<i>Crassostrea virginica</i> Eastern oyster	Pydiflumetofen (TGAI)	96 h-acute Flow-through	EC ₅₀ :	0.297 mg a.i./L	Highly toxic	2570946	Reliable with restrictions
<i>Cyprinodon variegatus</i> Sheepshead Minnow	Pydiflumetofen (TGAI)	96 h-acute Flow-through	LC ₅₀ :	0.61 mg a.i./L	Highly toxic	2570945	Fully reliable
			NOEC:	0.45 mg a.i./L	NA		
		35 d Life-cycle Flow-through	NOEC:	0.090 mg a.i./L	NA	2570953	Fully reliable
<i>Leptocheirus plumulosus</i> Estuarine Amphipods	Pydiflumetofen (TGAI)	10-d acute static	LC ₅₀ -sediment:	> 92 mg a.i./kg dw sed	NA	2570954	Fully reliable
			LC ₅₀ -pore water:	> 1.0 mg a.i./L	NA		
			LC ₅₀ -overlying water:	> 0.33 mg a.i./L	NA		
			NOEC _{sediment} :	46 mg a.i./kg dw sed	NA		
			NOEC _{pore water} :	0.52 mg a.i./L	NA		
			NOEC _{overlying water} :	0.20 mg a.i./L	NA		

Table 15 Summary of EECs resulting from direct application and spray drifts

Product	Maximum seasonal rate (g a.i./ha)	Application method	Spray drift (%)	Terrestrial EEC (g a.i./ha)		Aquatic EEC (mg a.i./L)	
				Soil exposure ¹	Foliar exposure ²	15 cm water ³	80 cm water ³
A16946B/ A16946TO	2 × 200 (7 day interval)	Direct over spray	100	0.18 mg a.i./kg ⁴	NA	NA	NA
				400	323	0.27	0.05
		Ground spray	11	44	35.5	0.016	0.003
		Early airblast	74	296	239	0.2	0.037
		Late season airblast	59	236	191	0.16	0.03
		Aerial	23	92	74.3	0.06	0.011

¹ Calculated using a soil half-life of 3118 days.

² Calculated using a default foliar half-life of 10 days.

³ Aquatic EECs were calculated using an aerobic half-life of 278 days for pydiflumetofen and considered direct over spray on water bodies of different depths.

⁴ Calculated assuming direct application to the top 15 cm soil layer with a bulk density of 1.5 g/cm³ and homogeneously mixed instantaneously.

Table 16 Risk to earthworms as a result of direct in-field exposure at a maximum annual application rate of 400 g a.i./ha

Test substance	Exposure	Endpoint value	EEC	RQ	LOC exceeded?
Pydiflumetofen	Acute	LC ₅₀ : > 1000 mg a.i./kg dw soil	0.18 mg a.i./kg soil	< 0.01	No
A19649B	Acute	LC ₅₀ : > 186 mg a.i./kg dw soil	0.18 mg a.i./kg soil	< 0.01	No
	Chronic	NOEC: 31.8 mg a.i./kg dw soil	0.18 mg a.i./kg soil	< 0.01	No

Table 17 Risk to beneficial arthropods as a result of direct in-field and off-field exposure to A19649B applied at 2 × 200 g a.i./ha with 7-d interval and a default forliar half-life of 10 days.

Organisms	Study type	Endpoints	Exposure scenario	EEC (g a.i./ha)	RQ	LOC exceeded?
Acute effects						
parasitoid wasp <i>A. rhopalosiphi</i>	48-h contact, glass plate	LR ₅₀ : >400 g a.i./ha	In-field over-spray (100%)	323	<1.6	No
predatory mite <i>T. pyri</i>	7-d contact, glass plate	LR ₅₀ : >400 g a.i./ha	In-field over-spray (100%)	323	<1.6	No
Effects on reproduction						
parasitoid wasp <i>A. rhopalosiphi</i>	10-d parasitisation glass plate	NOER: 200 a.i./ha	In-field over-spray (100%)	323	1.6	Yes
			Ground spray drift, medium droplets (11%)	35.5	0.2	No
			Airblast, early season (74%)	239	1.2	Yes
			Airblast, late season (59%)	191	0.95	No
			Aerial, medium droplets (23%)	74.3	0.37	No
predatory mite <i>T. pyri</i>	14-d reproduction Glass plate	NOER: 50 g a.i./ha	In-field over-spray (100%)	323	6.5	Yes
			Ground spray drift, medium droplets (11%)	35.5	0.7	No
			Airblast, early season (74%)	239	4.8	Yes
			Airblast, late season (59%)	191	3.8	Yes
			Aerial, medium droplets (23%)	74.3	1.5	Yes
Effects on reproduction						
parasitoid wasp <i>A. rhopalosiphi</i>	Barley seedlings	NOER: 800 g a.i./ha	In-field over-spray (100%)	323	0.4	No
			Ground spray drift, medium droplets (11%)	35.5	0.04	No
			Airblast, early season (74%)	239	0.3	No
			Airblast, late season (59%)	191	0.2	No
			Aerial, medium droplets (23%)	74.3	0.1	No
predatory mite <i>T. pyri</i>	14-d reproduction Leave discs	NOER: 800 g a.i./ha	In-field over-spray (100%)	323	0.4	No
			Ground spray drift, medium droplets (11%)	35.5	0.04	No
			Airblast, early season (74%)	239	0.3	No
			Airblast, late season (59%)	191	0.2	No
			Aerial, medium droplets (23%)	74.3	0.1	No

Table 18 Screening level risk assessment of pydiflumetofen and its end-use product A19649B for honeybee, *Apis mellifera*.

Test substance	Exposure	Endpoint value	EEC ¹	RQ	LOC exceeded? ²
Pydiflumetofen	Acute oral, adults	LD ₅₀ : >116 µg a.i./bee	6.44 µg a.i./bee	<0.055	No
	Acute contact, adults	LD ₅₀ : > 100 µg a.i./bee	0.54 µg a.i./bee	<0.005	No
	Acute oral, larvae	LD ₅₀ : >0.0035 µg a.i./larva/d	2.73 µg a.i./larva	< 781	Yes
	Chronic oral, larvae	NOEL: <0.0035 µg a.i./larva/d	2.73 µg a.i./larva	> 781	Yes
A19649B	Chronic oral, adults	NOEL: 141 µg a.i./bee/d	6.44 µg a.i./bee	0.046	No
	Acute oral, larvae	LD ₅₀ : 7.8 µg a.i./larva/d	2.73 µg a.i./larva	0.35	No
	Chronic oral, larvae	NOEL: 0.42 µg a.i./larva/d	2.73 µg a.i./larva	6.51	Yes

¹ Exposure estimate for bees = application rate (kg a.i./ha) × adjustment factor (2.4 µg a.i./bee per kg a.i./ha for adult bee contact exposure; 28.6 µg a.i./bee per kg a.i./ha for adult bee oral exposure; and 12.15 µg a.i./bee per kg a.i./ha for larvae)

² LOC for bees is set at 0.4 for acute endpoints and 1.0 for chronic endpoints.

Table 19 Tier I refinement for honeybee larvae using empirical residue data

EEC-Maximum Residue ¹			Toxicity endpoint	RQ ^{2, 3}		LOC exceeded?
Multi-dose test with end-use product						
Pollen	Maximum at Day 0	33300 ppb	LD ₅₀ : 7.8 µg a.i./larva/d	Acute	0.02	No
Nectar		165 ppb	NOEL: 0.42 µg a.i./larva/d	Chronic	0.34	No
Single-dose test with pydiflumetofen technical (TGAI)						
Pollen	Maximum at Day 0	33300 ppb	LD ₅₀ : >0.0035 µg a.i./larva/d NOEL: <0.0035 µg a.i./larva/d	Acute	<40.38	Yes
Nectar		165 ppb		Chronic	>40.38	Yes
Pollen	Maximum at Day 1	2050 ppb		Acute	<2.29	Yes
Nectar		5 ppb		Chronic	>2.29	Yes
Pollen	Maximum at Day 2	697 ppb		Acute	<0.90	Yes
Nectar		5 ppb		Chronic	>0.90	No
Pollen	Maximum at Day 4	383 ppb		Acute	<0.58	Yes
Nectar		5 ppb		Chronic	>0.58	No
Pollen	Maximum at Day 37	108 ppb		Chronic	>0.48	No
Nectar		10 ppb				
Pollen	Maximum at Day 54	560 ppb		Chronic	>0.76	No
Nectar		5 ppb				

¹ Maximum residue levels measured in samples taken at the same sampling intervals from all treatments in both residue studies. A LOQ of 5 ppb was used for reported values of <LOQ.

² Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint; Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 10⁶] + pollen dose [pollen consumption rate

(mg/day) × maximum pollen residue (µg/kg)/ 1.0×10^6]; Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total.

³ Chronic RQ = Chronic estimated daily dose (EDD)/chronic toxicity endpoint; Chronic EDD = nectar dose [nectar consumption rate (mg/day) × highest mean nectar residue (µg/kg)/ 1.0×10^6] + pollen dose [pollen consumption rate (mg/day) × highest mean pollen residue (µg/kg)/ 1.0×10^6]; Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total. Note, in this case, the maximum residues and the mean daily residues are the same as only one sample at each sampling time was taken.

Table 20 Screen Risk assessment to birds and small mammals as a result of direct in-field exposure at an application rate of 2×200 g a.i./ha and a foliar half-life of 10 days

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw) ^a	RQ
Small Bird (0.02 g)				
Acute	>200.0	Insectivore	26.30	<0.13
Reproduction	26.9	Insectivore	26.30	0.98
Medium Sized Bird (0.1 kg)				
Acute	>200.0	Insectivore	20.53	<0.10
Reproduction	26.9	Insectivore	20.53	0.76
Large Sized Bird (1 kg)				
Acute	>200.0	Herbivore (short grass)	13.26	<0.07
Reproduction	26.9	Herbivore (short grass)	13.26	0.49
Small Mammal (0.015 kg)				
Acute	55.0	Insectivore	15.13	0.28
Reproduction	36.1	Insectivore	15.13	0.42
Medium Sized Mammal (0.035 kg)				
Acute	55.0	Herbivore (short grass)	29.34	0.53
Reproduction	36.1	Herbivore (short grass)	29.34	0.81
Large Sized Mammal (1 kg)				
Acute	55.0	Herbivore (short grass)	15.68	0.29
Reproduction	36.1	Herbivore (short grass)	15.68	0.43

^a EDE = Estimated daily exposure; is calculated using the following formula: (FIR/BW) × EEC. Where FIR is Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the “passerine” equation was used; for generic birds with body weight greater than 200 g, the “all birds” equation was used:

Passerine Equation (body weight < or =200 g): $\text{FIR (g dry weight/day)} = 0.398(\text{BW in g})^{0.850}$

All birds Equation (body weight > 200 g): $\text{FIR (g dry weight/day)} = 0.648(\text{BW in g})^{0.651}$.

For mammals, the “all mammals” equation was used: $\text{FIR (g dry weight/day)} = 0.235(\text{BW in g})^{0.822}$

At the screening level, food items representing the most conservative EEC for each size guild are used.

Table 21 Risk to non-target terrestrial vascular plants as a result of direct in-field and off-field exposure

Effects	Endpoints	Exposure scenario	EEC (g a.i./ha)	RQ	LOC exceeded?
On soil surface					
Seedling emergence	21-d ER ₂₅ : > 370 g a.i./ha	In-field over-spray (100%)	400	<1.1	Yes
		Ground spray drift, medium droplets (11%)	44	<0.1	No
		Airblast, early season (74%)	296	<0.8	No
		Airblast, late season (59%)	236	<0.6	No
		Aerial, medium droplets (23%)	92	<0.3	No
Vegetative vigour	21-d ER ₂₅ : > 200 g a.i./ha	In-field over-spray (100%)	400	<2.0	Yes
		Ground spray drift, medium droplets (11%)	44	<0.2	No
		Airblast, early season (74%)	296	<1.5	Yes
		Airblast, late season (59%)	236	<1.2	Yes
		Aerial, medium droplets (23%)	92	<0.5	No
On plant surface					
Seedling emergence	21-d ER ₂₅ : > 370 g a.i./ha	In-field over-spray (100%)	323	<0.9	No
		Ground spray drift, medium droplets (11%)	35.5	<0.1	No
		Airblast, early season (74%)	239	<0.6	No
		Airblast, late season (59%)	191	<0.5	No
		Aerial, medium droplets (23%)	74.3	<0.2	No
Vegetative vigour	21-d ER ₂₅ : > 200 g a.i./ha	In-field over-spray (100%)	323	<1.6	Yes
		Ground spray drift, medium droplets (11%)	35.5	<0.2	No
		Airblast, early season (74%)	239	<1.2	Yes
		Airblast, late season (59%)	191	<0.95	No
		Aerial, medium droplets (23%)	74.3	<0.4	No

Table 22 Summary of EECs from Level 1 aquatic ecoscenario modelling for pydiflumetofen in water bodies, excluding spray drift.

Region	EEC (µg a.i./L)							
	Peak	96-hour	21-day	60-day	90-day	Yearly	Peak (in pore water)	21-day (in pore water)
15-cm water body								
2 × 200 g a.i./ha, at 7-day intervals								
ON	23	15	11	11	11	10	10	10
QC	30	20	16	15	15	15	15	15
PEI	43	25	17	16	16	15	15	15
2 × 200 g a.i./ha, at 14-day intervals								
BC	6.3	3.5	2.3	2.1	2.0	1.9	1.9	1.9
Prairies	33	21	15	14	14	13	14	14
80-cm water body								
2 × 200 g a.i./ha, at 7-day intervals								
ON	4.8	4.2	3.1	2.6	2.4	2.1	2.1	2.1
QC	5.5	5.1	4.3	3.6	3.4	2.7	2.9	2.9
PEI	8.1	7.0	4.9	4.2	4.2	3.0	3.4	3.4
2 × 200 g a.i./ha, at 14-day intervals								
BC	1.2	1.0	0.70	0.57	0.54	0.38	0.44	0.43
Prairies	7.4	6.3	4.6	3.8	3.5	2.6	3.2	3.2

Table 23 Screening level risk to aquatic organisms

Organism	Exposure	Endpoint value (mg a.i./L)	EECs (mg a.i./L)			RQ	LOC exceeded?
			Fresh water		Marine		
			15 cm	80 cm	80 cm		
Pydiflumetofen							
Water flea	Acute	EC ₅₀ : 0.421	NA	0.05	NA	0.24	No
	Chronic	NOEC: 0.042	NA	0.05	NA	1.19	Yes
Benthic invertebrates	Chronic	0.13 (overlying water)	NA	0.05	NA	0.38	No
Amphibian	Acute	LC ₅₀ : 0.186	0.27	NA	NA	14.52	Yes
	Chronic	NOEC: 0.064	0.27	NA	NA	4.22	Yes
Freshwater fish	Acute	LC ₅₀ : 0.186	NA	0.05	NA	2.69	Yes
	Chronic	NOEC: 0.064	NA	0.05	NA	0.78	No
Freshwater alga	Acute	IC ₅₀ : 1.5	NA	0.05	NA	0.07	No
		NOEC: 0.0505	NA	0.05	NA	0.99	No
Freshwater diatom	Acute	IC ₅₀ : 1.1	NA	0.05	NA	0.09	No
		NOEC: 0.31	NA	0.05	NA	0.16	No
Vascular plant	Acute	IC ₅₀ : > 6.3	NA	0.05	NA	<0.02	No
		NOEC: 0.33	NA	0.05	NA	0.15	No
Crustacean	Acute	LC ₅₀ : 0.127	NA	NA	0.05	0.79	No
	Chronic	NOEC: 0.076	NA	NA	0.05	0.66	No
Mollusk	Acute	LC ₅₀ : 0.297	NA	NA	0.05	0.34	No
Salt water fish	Acute	LC ₅₀ : 0.61	NA	NA	0.05	0.82	No
	Chronic	NOEC: 0.09	NA	NA	0.05	0.56	No
Marine diatom	Acute	IC ₅₀ : 2.7	NA	NA	0.05	0.04	No
Estuary amphipod	Acute	LC ₅₀ : >0.33 (overlying water)	NA	NA	0.05	<0.3	No
SYN545547*							
Rainbow Trout	Acute	LC ₅₀ : 1.32	NA	0.046	NA	0.35	No
Amphibian	Acute	LC ₅₀ : 1.32	0.25	NA	NA	1.88	Yes
Water flea	Acute	EC ₅₀ : 7.53	NA	0.046	NA	0.01	No
Freshwater alga	Acute	LC ₅₀ : 2.55	NA	0.046	NA	0.018	No
		NOEC: 1.0	NA	0.046	NA	0.046	No

NA indicates that the scenario does not apply to the species.

* EECs for the transformation product SYN545547 were calculated for transformation products were based on 100% conversion from the parent compound, the most conservative scenario.

Table 24 Risk to fresh water organisms resulting from spray drift

Organism	Exposure	Endpoint value (mg a.i./L)	Early season airblast 74%		Late season airblast 59%		Aerial 23%		Ground 6%	
			EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
Pydiflumetofen										
Water flea	Chronic	NOEC: 0.042	0.037	0.88	0.03	0.7	0.011	0.27	0.003	0.07
Fresh water fish	Acute	LC ₅₀ : 0.186	0.037	2.0	0.03	1.6	0.011	0.62	0.003	0.16
Amphibian	Acute	LC ₅₀ : 0.186	0.2	10.6	0.16	8.5	0.06	3.3	0.016	0.86
	Chronic	NOEC: 0.064	0.2	3.1	0.16	2.5	0.06	0.96	0.016	0.25
SYN545547										
Amphibian	Acute	LC ₅₀ : 1.32	0.18	1.4	0.15	1.1	0.06	0.43	0.015	0.11

Table 25 Risk to fresh water organisms resulting from runoff

Organism	Exposure	Endpoint value (mg a.i./L)	Peak		96-h		21-d		Year avg	
			EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
Pydiflumetofen										
Water flea	Chronic	NOEC: 0.042	NA	NA	NA	NA	0.005	0.40	0.004	0.36
Fresh water fish	Acute	LC ₅₀ : 0.186	0.008	0.44	0.007	0.38	NA	NA	NA	NA
Amphibian	Acute	LC ₅₀ : 0.186	0.043	2.31	0.025	1.34	NA	NA	NA	NA
	Chronic	NOEC: 0.064	NA	NA	NA	NA	0.017	0.27	0.015	0.23
SYN545547										
Amphibian	Acute	LC ₅₀ : 1.32	0.043	0.33	0.025	0.19	NA	NA	NA	NA

Table 26 Toxic Substances Management Policy considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Pydiflumetofen Endpoints
CEPA toxic or CEPA toxic equivalent ¹	Yes		Yes
Predominantly anthropogenic ²	Yes		Yes
Persistence ³ :	Soil	Half-life ≥ 182 days	Yes (474 – 4505 d)
	Water/ Sediment	Half-life ≥ 365 days	No (238 – 278 d)
	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur.
Bioaccumulation ⁴	Log K _{ow} ≥ 5		3.8
	BCF ≥ 5000		No (189 L/kg)
	BAF ≥ 5000		NA
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.
¹ All pesticides will be considered toxic or toxic equivalent under the <i>Canadian Environmental Protection Act</i> (CEPA) for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).			
² The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, 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.			
⁴ Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K _{ow}).			

Table 27 Registered Alternatives based on mode of action as of May, 2017.

Product	Crop	Pest	Conventional Mode of Action Group No. ^x	Non-Conventional Mode of Action Group No.
A19649 (FMF) **	dried shelled pea and bean*	white mould	1, 2, 3, 7, 11, 29, 3 + 7, 3 + 11, 7 + 11, 9 + 12	~
	soybean	white mould	7, 11, 29, 3 + 7, 3 + 11, 7 + 11, 9 + 12	44, P
	barley	Fusarium head blight	3, 3 + 11	~
		net blotch	3, 7, 11, 3 + 7, 3 + 11, M + 7	~
		scald	3, 7, 11, 3 + 7, 3 + 11, 7 +	~

Product	Crop	Pest	Conventional Mode of Action Group No. ^x	Non-Conventional Mode of Action Group No.
			11	
		spot blotch	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
	wheat	Fusarium head blight	3, M, 3 + 11	NC
		Septoria leaf blotch	3, 7, 11, M, 3 + 4, 3 + 7, 3 + 11, 7 + 11	P
		tan spot	3, 7, 11, M, M, 3 + 11, 7 + 11	~
	corn	Gibberella ear rot	3	~
		reduction of DON levels	3	~
	rapeseeds	Sclerotinia stem rot	2, 3, 7, 11, 3 + 7, 3 + 11, 7 + 11,	44, NC
		blackleg	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
	peanut	early leaf spot	3, 7, 11	44
A19649TO (FMF)	turf	dollar spot	1, 2, 3, 7, 11, M	44,NC, P
		microdochium patch	2, 3, 7, 11, 12	~
	greenhouse ornamentals	grey mould	1, 11, 14, 17, M	NC
		powdery mildew	1, 3, 7, 11, M	NC, P
	outdoor ornamentals	grey mould	7, 14, 17	44, BM02
		powdery mildew	3, 7, 11, 9 + 12, M	NC
	greenhouse cucumber	grey mould	2, 7, M	BM02, NC
		gummy stem blight	3, 7 + 11, M	44, NC
		powdery mildew	3, 7, 7 + 11, 9 + 12, M	44, NC, P
A20259 (FMF + DFZ)	potato	early blight	3, 7, 9, 11, 11 + 27, 11 + M, M	44
		brown spot	3 + 11, 7 + 9	~
		white mould	3, 3 + 11, 7, 7 + 9, 29	44, P
		grey mould	7, 9, 29, M	44, BM02
	tubers and corms	alternaria blight	11 + 3	~
		white mould	~	44
		grey mould	no alternatives	~
	fruiting vegetables	early blight	3 + 11, 7, 9, 11, 11 + 27, M	44
		alternaria canker	7	
		powdery mildew	3, 3 + 11, 7, 11, 46, M, U	44, NC, P
		anthracnose	3, 3 + 11, 11, M	~
		cercospora leaf spot	3 + 7, 3 + 11	~
grey mould		2, 7, 9, 9 + 12, 17, M	44, P, BM01, BM02	

Product	Crop	Pest	Conventional Mode of Action Group No. ^x	Non-Conventional Mode of Action Group No.
	cucurbits	white mould	~	NC
		powdery mildew	3, 7, 7 + 11, 11, 13, 46, M, U	44, NC
		alternaria blight	3 + 11, 7, 7+11, 11, M	~
		alternaria leaf spot	no alternatives	~
		anthracnose	3 + 11, 7, 11, M	~
		cercospora leaf spot	~	44
		gummy stem blight	3, 3 + 11, 7, 7 + 11, 11	44, NC
A20560 (FMF + FLD)	leafy greens / leaf petiole vegetables	grey mould	2, 7, 9 + 12, 17	BM02
		white mould, pink rot	2, 7	44, NC
	grape	grey mould / bunch rot	2, 7, 9, 7 + 9, 9 + 12, 7 + 11, 17	44, P, BM01
A21461 (FMF + AZY + PON) **	Dried Shelled Pea and Bean	powdery mildew (<i>E.p.</i>)	3, 7, 11, M, U, 3 + 7, 3 + 11, 7 + 11,	~
		anthracnose (<i>C.t.</i>)	7, 11, M, 3 + 7, 3 + 11, 7 + 11	~
		anthracnose (<i>C.l.</i>)	7, 11, M, 3 + 7, 3 + 11, 7 + 11	~
		Mycosphaerella blight	7, 11, M, 3 + 7, 3 + 11, 7 + 11,	~
		Asian soybean rust	3, 7, 11, 3 + 7, 7 + 11	~
		Ascochyta blight (<i>A.r.</i>)	3, 7, 11, M, 3 + 7, 3 + 11, 7 + 11	~
		Ascochyta blight (<i>A.f.</i>)	7, 7 + 11	~
		white mold	1, 2, 3, 7, 11, 29, 3 + 7, 3 + 11, 7 + 11, 9 + 12	~
	soybean	powdery mildew	3, 11, M, 3 + 7, 3 + 11, 7 + 11	~
		frogeye leaf spot	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	44, P
		anthracnose (<i>C.t.</i>)	7, 11, 3 + 7, 3 + 11, 7 + 11	~
		Asian soybean rust	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
		white mold	7, 11, 29, 3 + 7, 3 + 11, 7 + 11, 9 + 12	44, P
	barley	scald	3, 7, 11, 3 + 7, 3+11, 7+11	~
		Septoria leaf blotch	3, 7, 11, 3 + 7, 3 + 11	~
		spot blotch	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	
		tan spot	7, 11, 3 + 7, 3 + 11,	~

Product	Crop	Pest	Conventional Mode of Action Group No. ^x	Non-Conventional Mode of Action Group No.
		net blotch	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
		stripe rust	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
	wheat	Septoria leaf blotch	3, 7, 11, M, 3 + 4, 3 + 7, 3 + 11, 7 + 11	~
		spot blotch	3, 7, 11, 3 + 11, 7 + 11	~
		tan spot	3, 7, 11, M, 3 + 11, 7 + 11	~
		leaf rust	3, 7, 11, M, 3 + 11, 7 + 11	~
		stripe rust	3, 7, 11, 3 + 11, 7 + 11	~
		scald	3, 11, 3 + 7, 3 + 11	~
	rye	Septoria leaf blotch	3, 7, 11, 3 + 7, 3 + 11	~
		tan spot	3, 7, 11, 3 + 7, 3 + 11	~
		stripe rust	3, 7, 11, 3 + 7	~
		Septoria leaf blotch	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
	corn	Gibberella ear rot	3	~
		reduction of DON levels	3	~
		common rust	3, 7, 11, M, 3 + 7, 3 + 11, 7 + 11	~
		eye spot	3, 11, 3 + 11, 7 + 11	~
		grey leaf spot	3, 7, 11, 3 + 7, 3 + 11, 7 + 11	~
		northern corn leaf blight	3, 11, 3 + 7, 3 + 11, 7 + 11	~
		southern corn leaf blight	3, 11, 3 + 7, 3 + 11, 7 + 11	~

M=multi-site mode of action; U=unknown; NC=not classified; P=host plant defense induction, BM=biologicals with multi-site mode of action

*: Under the crop groups, the indication of a mode of action alternative may not apply to all the crops in a crop group; i.e. the listing of a mode of action group indicates that this alternative is registered for this claim on at least one crop in the group.

**: seed treatments were not included

Table 28 Supported use claim combinations for A19649 Fungicide

Crops	Supported disease claim	Rates and application interval
Crop Subgroup 6C*: Dried Shelled Pea and Bean - except soybean.	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	Rate: 0.5-1.0 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days
Soybean	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	Rate: 0.5-1.0 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 7-14 days

Crops	Supported disease claim	Rates and application interval
Barley	Suppression of Fusarium head blight (<i>Fusarium graminearum</i>)	Rate: 0.75-1.0 L/ha + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Control of net blotch (<i>Pyrenophora teres</i>)	Rate: <u>0.45 L/ha</u> + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Control of scald (<i>Rhynchosporium secalis</i>)	Rate: <u>0.3-0.45 L/ha</u> + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Control of spot blotch (<i>Cochliobolus sativus</i>)	Rate: <u>0.3-0.45 L/ha</u> + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
Wheat	Suppression of Fusarium head blight (<i>Fusarium graminearum</i>)	Rate: 0.75-1.0 L/ha + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Control of Septoria leaf blotch (<i>Septoria tritici</i>)	Rate: <u>0.3-0.45 L/ha</u> + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Control of tan spot (<i>Pyrenophora tritici-repentis</i>)	Rate: <u>0.3-0.45 L/ha</u> + NIS at 0.125% Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
Corn	Suppression of Gibberella ear rot (<i>Gibberella zeae</i> , <i>Fusarium graminearum</i>)	Rate: 0.5 L/ha Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
	Reduction of levels of deoxynivalenol (DON) in the grain	Rate: 0.5 L/ha Maximum seasonal rate: 1.0 L/ha Appl. interval: Maximum of 1 application then rotate to a non-group 7 product.
Crop Subgroup 20A*— Rapeseeds	Control of Sclerotinia stem rot (<i>Sclerotinia sclerotiorum</i>)	Rate: 1.0 L/ha + NIS at 0.125% v/v Maximum seasonal rate: 1.625 L/ha Appl. timing: Once at the 10-50% bloom stage
	Control of blackleg (<i>Leptosphaeria maculans</i>)	Rate: 0.5-0.625 L/ha Maximum seasonal rate: 1.625 L/ha Appl. timing: Once at the 2-6 leaf stage
	Tank-mixes with labeled herbicides on canola	Rate: labeled rates.

Crops	Supported disease claim	Rates and application interval
Peanut	Control of early leaf spot (<i>Cercospora arachidicola</i>)	Rate: 0.125-0.250 L/ha Maximum seasonal rate: 1.0 L/ha Appl. interval: 14-21 days for the 0.125 L/ha rate; 21-28 days for the 0.250 L/ha rate
Applications methods	Ground and aerial application.	

*: Some crops which belong to the listed crop groups may not be supported for the listed claim. Consult the label for exact list of supported crops.

Table 29 Supported use-claim combinations for A19649TO Fungicide

Crops	Supported disease claim	Rates and application timing
Turf	Control of dollar spot (<i>Sclerotinia sclerotiorum</i>)	2.5 – 5.0 ml/100 m ² (0.5 – 1.0 g a.i./1400 m ²) or 250 – 500 ml/ha (50 – 100 g a.i./ha). Up to four applications may be made on a 21 – 28 day interval.
	Control of microdochium patch (<i>Microdochium nivale</i>)	5.0- 10.0 ml/100 m ² (1.0 – 2.0 g a.i./100 m ²) or 500 – 1000 ml/ha (100 – 200 g a.i./ha) Up to four applications may be made on a 21 – 28 day interval.
	For broad spectrum disease control on turf, tank mix or alternate A19649TO Fungicide with BANNER MAXX, DACONIL 2787 or DACONIL Ultrex.	Labelled rates.
Greenhouse cucumber	Control of gummy stem blight (<i>Didymella bryoniae</i>)	25 – 50 ml/100L water (5 – 10 g a.i./100 L water) on a 7 – 14 day interval. DO NOT use more than 500 litres of spray solution per hectare. A19649TO Fungicide can only be used on plant growth stages for which thorough coverage can be achieved with a maximum spray volume of 500 L/ha. Maximum 2 applications per crop cycle.
	Control of powdery mildew (<i>Erysiphe cichoracearum</i> and <i>Sphaerotheca fuliginea</i>)	25 – 50 ml/100L water (5 – 10 g a.i./100 L water) on a 7 – 14 day interval. DO NOT use more than 500 litres of spray solution per hectare. A19649TO Fungicide can only be used on plant growth stages for which thorough coverage can be achieved with a maximum spray volume of 500 L/ha. Maximum 2 applications per crop

Crops	Supported disease claim	Rates and application timing
		cycle.
	Control of grey mould (<i>Botrytis cinerea</i>)	50 ml/100L water (10 g a.i./100 L water) on a 7 – 14 day interval. DO NOT use more than 500 litres of spray solution per hectare. A19649TO Fungicide can only be used on plant growth stages for which thorough coverage can be achieved with a maximum spray volume of 500 L/ha. Maximum 2 applications per crop cycle.
Ornamentals grown outdoors and in greenhouses	Control of grey mould (<i>Botrytis cinerea</i>)	50 – 75 ml/100 L water (10 – 15 g a.i./100 L water) on a 7 – 14 day interval. For greenhouse cut flowers, apply once per year at 50 ml/100 L water (10 g a.i./100 L water). Use only under low to moderate disease pressure. Apply only once per year for greenhouse cut flowers. Maximum 400 g a.i./ha per season (outdoor) or per greenhouse ornamental crop.
	Control of powdery mildew (<i>Oidium longipes</i> , <i>Podosphaera xanthii</i> , <i>Sphaerotheca pannosa</i>)	25 – 50 ml/100 L water (5 – 10 g a.i./100 L water) on a 7 – 14 day interval. Maximum 400 g a.i./ha per season (outdoor) or per greenhouse ornamental crop. For greenhouse cut flowers, apply only once per year.

Table 30 Supported use-claim combinations for A20259 Fungicide

Crops	Supported disease claim	Rates and application timing
Potato	Control of early blight (<i>Alternaria solani</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 -14 day interval. Maximum seasonal application rate 3 L/ha.
	Control of brown spot (<i>Alternaria alternata</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 -14 day interval. Maximum seasonal application rate 3 L/ha.

Crops	Supported disease claim	Rates and application timing
	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 10 -14 day interval. Maximum seasonal application rate 3 L/ha.
	Suppression of botrytis grey mould (<i>Botrytis cinerea</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 -14 day interval. Maximum seasonal application rate 3 L/ha.
	Aerial application to potato	Spray volume of 50 L/ha.
Tuberous and Corm crops (Artichoke, Chinese; Artichoke, Jerusalem; Canna, edible Chufa; Sweet potato)	Control of leaf spot (<i>Alternaria</i> spp., <i>A. alternata</i>) on sweet potato, Jerusalem artichoke, and canna, alternaria rot (<i>Alternaria</i> spp.) on sweet potato, and alternaria leaf petiole and stem blight (<i>A. tenuissima</i> , <i>A. bataticola</i>) on sweet potato	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 -14 day interval. Maximum seasonal application rate 3 L/ha.
	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>) on Artichoke, Chinese; Artichoke, Jerusalem; Chufa; Sweet potato	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 10 -14 day interval. Maximum seasonal application rate 3 L/ha.
	Suppression of botrytis grey mould (<i>Botrytis cinerea</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 -14 day interval. Maximum seasonal application rate 3 L/ha.
Fruiting vegetable crops (Tomato; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Pepino; Groundcherry; Eggplant)	Control of early blight (<i>Alternaria solani</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of alternaria canker and rot (<i>Alternaria alternata</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of powdery mildew (<i>Leveillula taurica</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of anthracnose (<i>Colletotrichum</i> spp.)	1 L/ha (200 g a.i./ha; 75 g

Crops	Supported disease claim	Rates and application timing
		pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of cercospora leaf spot (<i>Cercospora capsici</i>) on Tomato; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Eggplant	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of botrytis grey mould (<i>Botrytis cinerea</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 7 – 14 day interval. Maximum seasonal application rate 2 L/ha.
Cucurbit Vegetables (Chinese waxgourd; Citron melon; Cucumber (field); Gerkin Gourd, edible; Momordica spp.; Muskmelons (includes cantaloupe); Pumpkin; Squash, Summer (includes zucchini); Squash, winter; Watermelon)	Control of powdery mildew (<i>Sphaerotheca fuliginea</i> , <i>Erysiphe cichoracearum</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 14 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of alternaria blight (<i>Alternaria cucumerina</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of alternaria leaf spot (<i>Alternaria alternata</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of gummy stem blight (<i>Didymella bryoniae</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 14 day interval. Maximum seasonal application rate 2 L/ha.
	Control of anthracnose (<i>Colletotrichum lagenarium</i> syn. <i>C. orbiculare</i>)	1 L/ha (200 g a.i./ha; 75 g pydiflumetofen + 125 g difenoconazole) on a 14 day interval. Maximum seasonal application rate 2 L/ha.

Table 31 Supported use–claim combinations for A20560 Fungicide

Crops	Supported disease claim	Rate and application timing
Leafy Green Vegetable crops (Amaranth, Chinese; Amaranth, leafy; Aster, Indian; Basil; Blackjack; Cat's Whiskers; Chervil, fresh leaves; Cham-chwi; Cham-na-mul; Chipilin; Chrysanthemum, garland; Cilantro, fresh leaves; Corn salad; Cosmos; Dandelion; Dock; Dol-nam-mul; Ebolo; Endive; Escarole; Fameflower; Feather cockscomb; Good King Henry; Huauzontle; Jute leaves; Lettuce, bitter; Lettuce, head; Lettuce, leaf (Romaine) ; Orach; Parsley, fresh leaves; Plantain, buckhorn; Primrose, English; Purslane, garden; Purslane, winter; Radicchio (Red Chicory); Spinach; Spinach, Malabar; Spinach, New Zealand)	Control of sclerotinia rot or sclerotinia drop (<i>Sclerotinia sclerotiorum</i> , <i>Sclerotinia minor</i>) on Amaranth, Chinese; Amaranth, leafy; Aster, Indian; Basil; Blackjack; Chervil, fresh leaves; Cham-chwi; Cham-na-mul; Chipilin; Chrysanthemum, garland; Cilantro, fresh leaves; Cosmos; Dandelion; Dock; Ebolo; Endive; Escarole; Good King Henry; Huauzontle; Jute leaves; Lettuce, bitter; Lettuce, head; Lettuce, leaf (Romaine) ; Orach; Parsley, fresh leaves; Plantain, buckhorn; Primrose, English; Purslane, garden; Radicchio (Red Chicory); Spinach; Spinach, New Zealand.	0.8 – 1.0 L/ha (320 – 400 g a.i./ha; 120 – 150 g pydiflumetofen + 200 – 250 g fludioxonil) on a 7 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of botrytis grey mould (<i>Botrytis cinerea</i>).	0.8 – 1.0 L/ha (320 – 400 g a.i./ha; 120 – 150 g pydiflumetofen + 200 – 250 g fludioxonil) on a 7 – 10 day interval. Maximum seasonal application rate 2 L/ha.
Leaf Petiole	Control of pink rot and watery soft rot	0.8 – 1.0 L/ha (320 – 400 g a.i./ha;

Crops	Supported disease claim	Rate and application timing
Vegetable crops (Cardoon; Celery; Celery, Chinese; Fuki; Rhubarb; Udo; Zuiki)	(<i>Sclerotinia sclerotiorum</i>) on Cardoon; Celery; Celery, Chinese; Fuki; Rhubarb; Udo.	120 – 150 g pydiflumetofen + 200 – 250 g fludioxonil) on a 7 day interval. Maximum seasonal application rate 2 L/ha.
	Suppression of grey mould (<i>Botrytis cinerea</i>).	0.8 – 1.0 L/ha (320 – 400 g a.i./ha; 120 – 150 g pydiflumetofen + 200 – 250 g fludioxonil) on a 7 – 10 day interval. Maximum seasonal application rate 2 L/ha.
Small Fruit Vine Climbing crops (Amur river grape; Grape; Hardy kiwifruit; Maypop; Schisandra berry (excluding fuzzy kiwifruit))	Control of botrytis grey mould (<i>Botrytis cinerea</i>).	0.8 – 1.0 L/ha (320 – 400 g a.i./ha; 120 – 150 g pydiflumetofen + 200 – 250 g fludioxonil) on a 21 day interval. Maximum seasonal application rate 2 L/ha.

Table 32 Supported use-claim combinations for A21461 Fungicide.

Crops	Supported disease claim	Rates and application interval
Crop Subgroup 6C*: Dried Shelled Pea and Bean - except soybean.	Control of powdery mildew (<i>Erysiphe pisi</i>)	Rate: 1.0 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of anthracnose (<i>Colletotrichum truncatum</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of anthracnose (<i>Colletotrichum lindemuthianum</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of Mycosphaerella (<i>Mycosphaerella pinodes</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of Asian soybean rust (<i>Phakopsora pachyrhizi</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of Ascochyta blight (<i>Ascochyta rabiei</i>)	Rate: 1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of Ascochyta blight (<i>Ascochyta fabae</i>)	Rate: 1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days

Crops	Supported disease claim	Rates and application interval
	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	Rate: 1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
Soybean	Control of powdery mildew (<i>Microsphaeria diffusa</i>)	Rate: 0.75-1.0 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of frogeye leaf spot (<i>Cercospora sojina</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of anthracnose (<i>Colletotrichum truncatum</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Control of Asian soybean rust (<i>Phakopsora pachyrhizi</i>)	Rate: 1.0-1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
	Suppression of white mould (<i>Sclerotinia sclerotiorum</i>)	Rate: 1.25 L/ha Maximum seasonal rate: 2.5 L/ha Application interval: 14 days
Barley	Control of scald (<i>Rhynchosporium secalis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of Septoria leaf blotch (<i>Septoria tritici</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of spot blotch (<i>Cochliobolus sativus</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of tan spot (<i>Pyrenophora tritici-repentis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of net blotch (<i>Pyrenophora teres</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of stripe rust (<i>Puccinia striiformis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
Wheat	Control of Septoria leaf blotch (<i>Septoria tritici</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of spot blotch (<i>Cochliobolus sativus</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of tan spot (<i>Pyrenophora tritici-repentis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days

Crops	Supported disease claim	Rates and application interval
	Control of leaf rust (<i>Puccinia triticina</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of stripe rust (<i>Puccinia striiformis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
Rye	Control of scald (<i>Rhynchosporium secalis</i>)	Rate: 0.75 Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of Septoria leaf blotch (<i>Septoria tritici</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of tan spot (<i>Pyrenophora tritici-repentis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
	Control of stripe rust (<i>Puccinia striiformis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
Triticale	Control of Septoria leaf blotch (<i>Septoria tritici</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 1.5 L/ha Application interval: 14 days
Corn	Suppression of Gibberella ear rot (<i>Gibberella zeae</i> , <i>Fusarium graminearum</i>)	Rate: 1.25 L/ha Maximum seasonal rate: 2.0 L/ha Appl. interval: Maximum of one application allowed.
	Reduction of levels of deoxynivalenol (DON) in the grain	Rate: 1.25 L/ha Maximum seasonal rate: 2.0 L/ha Appl. interval: Maximum of one application allowed.
	Control of common rust (<i>Puccinia sorghi</i>)	Rate: 0.75-1.0 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days
	Control of eye spot (<i>Aureobasidium zeae</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days
	Control of grey leaf spot (<i>Cercospora zeae-maydis</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days
	Control of northern corn leaf blight (<i>Setophacteria turcica</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days
	Control of southern corn leaf blight (<i>Cochliobolus heterostrophus</i>)	Rate: 0.75 L/ha Maximum seasonal rate: 2.0 L/ha Application interval: 14 days

Crops	Supported disease claim	Rates and application interval
Applications methods	Ground and aerial application.	

*: Some crops which belong to the listed crop groups may not be supported for the listed claim. Consult the label for exact list of supported crops.

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

Table 1 Differences Between MRLs in Canada and in Other Jurisdictions

Pydiflumetofen is a new active ingredient which is concurrently being registered in Canada and the United States. The MRLs proposed for pydiflumetofen in Canada are the same as corresponding tolerances to be promulgated in the United States, except for certain (livestock) commodities, in accordance with Table 1, for which differences in MRLs/tolerances may be due to different legislative framework.

Once established, the American tolerances for pydiflumetofen will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs⁵ listed for pydiflumetofen in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

Table 1 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Eggs	0.01	Not established	Not established
Fat, meat, meat byproducts of hogs	0.01	0.01 for meat of hogs 0.03 for fat and meat byproducts of hogs	Not established
Fat, meat, meat byproducts of poultry	0.01	Not established	Not established
Wheat bran	0.6	Not established	Not established

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. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

⁵ The [Codex Alimentarius Commission](#) is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

2570894	2011, SYN545974 - Pydiflumetofen - Certificate of Analysis of Analytical Standards, DACO: 2.13.3 CBI
2570964	2015, Analytical Method SA-97/1 - SYN545974 tech. Assay by Liquid Chromatography (UHPLC), DACO: 2.13.1, IIA 4.2.1
2571037	2015, SYN545974 - Validation of Analytical Method SA-97/1, DACO: 2.13.1, IIA 4.2.1
2571065	2015, SYN545974 - Physico-Chemical Studies of the Pure and Technical Substance, DACO: 2.13.2, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.16, 8.2.3.2, 8.2.3.3, IIA 2.1.1, IIA 2.1.2, IIA 2.1.3, IIA 2.10, IIA 2.11.1, IIA 2.11.2, IIA 2.12, IIA 2.13, IIA 2.14, IIA 2.15, IIA 2.16, IIA 2.17.1, IIA 2.17.2, IIA 2.2, IIA 2.3.1, IIA 2.3.2, IIA 2.4.1, IIA 2.4.2, IIA 2.5.1.1, IIA 2.5.1.2, IIA 2.5.1.3, IIA 2.5.1.4, IIA 2.5.1.5, IIA 2.6, IIA 2.7, IIA 2.8.1, IIA 2.8.2, IIA 2.9.5
2571064	2015, SYN545974 - Document MII Section 1 - Identity, Physical and Chemical Properties, Further Information and Proposed Classification, DACO: 0.9.1, 1.1, 10.2.1, 10.2.2, 10.2.3, 10.5.3, 10.6, 12.7.2.1, 2.10, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.2, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.16, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 8.2.3.2, 8.2.3.3, 8.2.3.3.2, 8.2.3.3.3, 8.4.1, 8.6, Document M, IIA 1.1, IIA 1.2, IIA 1.3, IIA 1.4, IIA 1.5.1, IIA 1.5.2, IIA 1.5.3, IIA 1.6, IIA 1.7, IIA 1.8.1, IIA 1.8.2, IIA 1.9.1.1, IIA 1.9.1.2, IIA 1.9.2, IIA 1.9.3, IIA 2.1.1, IIA 2.1.2, IIA 2.1.3, IIA 2.10, IIA 2.11.1, IIA 2.11.2,
2571066	2015, SYN545974 - Document M-II, Section 2 - Analytical Methods, DACO: 12.7.2.13.1, 2.13.4, 2.15, 2.16, 5.10, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 8.2.2.1, 8.2.2.2, 8.2.2.3, 8.2.2.4, 8.6, Document M, IIA 4.1.1, IIA 4.1.2, IIA 4.1.3, IIA 4.1.4, IIA 4.2.1, IIA 4.2.2, IIA 4.2.3, IIA 4.2.4, IIA 4.2.5, IIA 4.2.6, IIA 4.2.7, IIA 4.3, IIA 4.4, IIA 4.5, IIA 4.6, IIA 4.7, IIA 4.8, IIA 4.9
2571067	2015, Pydiflumetofen Technical (SYN545974) - Document J - Confidential Information, DACO: 0.8.11, 0.8.12, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.1, 2.13.3, 2.13.4, 2.16, 2.2, 4.2.9, 4.3.8, 4.4.5, 4.5.8, 4.8, Document J, IIA 1.10.1, IIA 1.10.2, IIA 1.11.1, IIA 1.11.2, IIA 1.12, IIA 1.2, IIA 1.8.1, IIA 1.8.2, IIA 1.9.1.1, IIA 1.9.1.2, IIA 1.9.2, IIA 1.9.3, IIA 4.2.1, IIA 4.2.2, IIA 4.2.3, IIA 5.10 CBI
2571068	2015, PC-15-112 Pydiflumetofen (SYN545974) - OECD Document H (Confidential), DACO: 2.11.2 CBI
2612308	2016, Statement on suitability of Method SD-1901/1, DACO: 2.13.4 CBI
2638782	2016, ADEPIDYNTM (SYN545974) DOCUMENT M-II, Section 1 IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, FURTHER INFORMATION AND PROPOSED CLASSIFICATION, DACO: 0.9.1, 10.2.1, 10.2.2, 10.2.3, 10.5.3, 10.6, 12.7.2.1, 2.10, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.2, 2.13.3, 2.13.4, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.16, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 8.2.3.2, 8.2.3.3, 8.2.3.3.2, 8.2.3.3.3, 8.4.1, 8.6 CBI

2638783	2016, SYN545974 - Physico-Chemical Studies of the Pure and Technical Substance Product Chemistry Volume, DACO: 2.11.1 CBI
2738839	2017, Document J - Amendment 1, DACO: 2.11.2 CBI
2751424	2017, Document J - Addendum 2, DACO: 2.11.2 CBI
2754562	2017, Pydiflumetofen Analytical Method [CBI REMOVED], DACO: 2.13.1 CBI
2754563	2017, SYN545974 - Analysis of Five Representative Batches Produced [PRIVACY INFO REMOVED], DACO: 2.13.3 CBI
2570960	2013, SYN545974 - Independent Laboratory Validation of Residue Method (GRM061.01A) for the Determination of SYN545974 in Water, DACO: 8.2.2.3,IIA 4.5
2570961	2013, SYN545974 - Independent Laboratory Validation of Residue Method (GRM061.02A) for the Determination of SYN545974 and SYN545547 in Soil, DACO: 8.2.2.1,IIA 4.4
2571049	2013, SYN545974 - Residue Method for the Determination of SYN545974 in Water, DACO: 8.2.2.3,IIA 4.5
2571051	2013, SYN545974 - Analytical Method (GRM061.04A) for Determination of SYN545974 in Soil, DACO: 8.2.2.1,IIA 4.4
2608338	2016, SYN545974 - Additional Validation Data Supporting GRM061.04A, DACO: 8.2.2.1,8.2.2.2
2608339	2013, SYN545974 - Analytical Method (GRM061.02A) for Determination of SYN545974 and SYN545547 in Soil, DACO: 8.2.2.1,8.2.2.2
2638794	2016, SYN545974 - Validation of Residue Method (GRM061.01A)for the Determination of SYN545974 in Water Method Validation Report, DACO: 8.2.2.3
2569815	2015, A19649B - Document J - Confidential Information, DACO: 0.1.6003,0.8.11,0.8.12,0.9.1,3.1.2,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,4.8,Document J,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 5.2.4,IIIA 5.2.5,IIIA 7.9.1,IIIA 7.9.2 CBI
2569816	2015, Addendum to Document J-1, DACO: 0.8.11,0.8.12,3.2.1,3.2.2,3.3.1,3.3.2,Document J,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1 CBI
2569817	2015, A19649B - Details of SYN545974 Solo and Pre-mix Formulations Used in Regulatory Studies Submitted in NAFTA Joint Review, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
2569818	2015, PC-15-084 A19649B OECD Document H (Confidential), DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2569820	2015, A19649B - Document MIII, Section 1, DACO: 0.1.6003,1.1,1.1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.3.3,10.6,12.5.7,12.7,3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,5.11,5.13,5.14,5.2,5.6,5.7,5.9,8.4.1,8.5.2,8.6,Document M,IIIA 1.1,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.2.3,IIIA 1.3,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.2,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5,IIIA 1.6,IIIA 1.7,IIIA 11.1,IIIA 11.2,IIIA 11.3,IIIA 11.4,
2569822	2015, A19649B - Document MIII Section 2, DACO: 12.7,3.4.1,3.4.2,3.5.10,3.6,3.7,5.14,5.5,5.7,7.2.1,7.2.2,7.2.3,7.2.4,7.2.5,7.8,8.2.2.4,8.2.3.3,8.2.3.6,8.2.4.6,8.6,Document M,IIIA 5.1.1,IIIA 5.1.2,IIIA 5.1.3,IIIA 5.1.4,IIIA 5.1.5,IIIA 5.2.1,IIIA 5.2.2,IIIA 5.2.3,IIIA 5.2.4,IIIA 5.2.5,IIIA 5.3.1,IIIA 5.3.2,IIIA 5.4,IIIA 5.5,IIIA 5.6,IIIA 5.7,IIIA 5.8,IIIA 5.9

2569893	2015, A19649B - Physico-Chemical Studies of the Formulation, DACO: 12.7.3.5.1,3.5.10.3.5.11,3.5.12.3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,8.2.2.1,8.2.2.2,8.2.3.6,IIIA 2.1,IIIA 2.10.1,IIIA 2.10.2,IIIA 2.11,IIIA 2.12,IIIA 2.13,IIIA 2.14,IIIA 2.15,IIIA 2.16,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.2,IIIA 2.3.3,IIIA 2.4.1,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.6.2,IIIA 2.7.1,IIIA 2.7.2,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5,IIIA 2.7.6,IIIA 2.8.1,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.4,IIIA 2.8.5.1,IIIA 2.8.5.2,IIIA 2.8.6.1,
2569894	2013, Analytical Method SF-636/1 - Content of SYN545974 in Formulation SC (200) by HPLC, DACO: 3.4.1,IIIA 5.2.1
2569895	2013, A19649B - Validation of Analytical Method SF-636/1, DACO: 3.4.1,IIIA 5.2.1
2612334	2016, DACO 3.2.2 - A19649B (A19649 and A19649TO) - Document J - Addendum 1, DACO: 3.2.2 CBI
2570071	2015, Addendum to Document J-1, DACO: 0.8.11,0.8.12,3.2.1,3.2.2,3.3.1,3.3.2,Document J,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1 CBI
2570098	2015, PC-15-098 A20259E OECD Document H (Confidential), DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2570110	2015, A20259E - Document J - Confidential Information, DACO: 0.1.6003,0.8.11,0.8.12,0.9.1,3.1.2,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,4.8,Document J,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 5.2.4,IIIA 5.2.5,IIIA 7.9.1,IIIA 7.9.2 CBI
2570111	2015, A20259E - Physico-Chemical Studies of the Formulation, DACO: 12.7.3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,8.2.2.1,8.2.2.2,8.2.3.6,IIIA 2.1,IIIA 2.10.1,IIIA 2.10.2,IIIA 2.11,IIIA 2.12,IIIA 2.13,IIIA 2.14,IIIA 2.15,IIIA 2.16,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.2,IIIA 2.3.3,IIIA 2.4.1,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.6.2,IIIA 2.7.1,IIIA 2.7.2,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5,IIIA 2.7.6,IIIA 2.8.1,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.4,IIIA 2.8.5.1,IIIA 2.8.5.2,IIIA 2.8.6.1,
2570112	2014, Analytical Method SF-726/1 - Determination of Difenconazole, its cis/trans diastereomers CGA185882/CGA185883 and SYN545974 in Formulation SC (120/075) by HPLC, DACO: 3.4.1,IIIA 5.2.1
2570113	2014, A20259E - Validation of Analytical Method SF-726/1, DACO: 3.4.1,IIIA 5.2.1
2570121	2015, A20259E - Document MIII, Section 1, DACO: 0.1.6003,1.1,1.1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.3.3,10.6,12.5.7,12.7,3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,5.11,5.13,5.14,5.2,5.6,5.7,5.9,8.4.1,8.5.2,8.6,Document M,IIIA 1.1,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.2.3,IIIA 1.3,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5,IIIA 1.6,IIIA 1.7,IIIA 11.1,IIIA 11.2,IIIA 11.3,IIIA 11.4,IIIA 11.5,IIIA 2.1,IIIA 2.
2570122	2015, A20259E - Document MIII Section 2, DACO: 12.7,3.4.1,3.4.2,3.5.10,3.6,3.7,5.14,5.5,5.7,7.2.1,7.2.2,7.2.3,7.2.4,7.2.5,7.8,8.2.2.4,8.2.3.3,8.2.3.6,8.2.4.6,8.6,Document M,IIIA 5.1.1,IIIA 5.1.2,IIIA 5.1.3,IIIA 5.1.4,IIIA 5.1.5,IIIA 5.2.1,IIIA 5.2.2,IIIA 5.2.3,IIIA 5.2.4,IIIA 5.2.5,IIIA 5.3.1,IIIA 5.3.2,IIIA 5.4,IIIA 5.5,IIIA 5.6,IIIA 5.7,IIIA 5.8,IIIA 5.9
2612335	2016, DACO 3.2.2 - A20259E - Document J - Addendum 1, DACO: 3.2.2 CBI
2612309	2016, DACO 3.2.2 - A19649B (A19649 and A19649TO) - Document J - Addendum 1, DACO: 3.2.2 CBI

2570475	2015, A20560C - Document J - Confidential Information, DACO: 0.1.6003,0.8.11,0.8.12,0.9.1,3.1.2,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,4.8,Document J,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 5.2.4,IIIA 5.2.5,IIIA 7.9.1,IIIA 7.9.2 CBI
2570477	2015, Addendum to Document J-1, DACO: 0.8.11,0.8.12,3.2.1,3.2.2,3.3.1,3.3.2,Document J,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1 CBI
2570478	2015, PC-15-106 A20560C OECD Document H (Confidential), DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2570480	2015, A20560C - Document MIII, Section 1, DACO: 0.1.6003,1.1,1.1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.3.3,10.6,12.5.7,12.7,3.1.1,3.1.2,3. 1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3, 3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,5.11,5.13,5.14,5.2,5.6,5.7,5.9,8.4.1,8.5.2,8.6,Document M,IIIA 1.1,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.2.3,IIIA 1.3,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.2,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5,IIIA 1.6,IIIA 1.7,IIIA 11.1,IIIA 11.2,IIIA 11.3,IIIA 11.4,
2570481	2015, A20560C - Document MIII Section 2, DACO: 12.7,3.4.1,3.4.2,3.5.10,3.6,3.7,5.14,5.5,5.7,7.2.1,7.2.2,7.2.3,7.2.4,7.2.5,7.8,8.2.2.4,8.2.3.3,8.2. 3.6,8.2.4.6,8.6,Document M,IIIA 5.1.1,IIIA 5.1.2,IIIA 5.1.3,IIIA 5.1.4,IIIA 5.1.5,IIIA 5.2.1,IIIA 5.2.2,IIIA 5.2.3,IIIA 5.2.4,IIIA 5.2.5,IIIA 5.3.1,IIIA 5.3.2,IIIA 5.4,IIIA 5.5,IIIA 5.6,IIIA 5.7,IIIA 5.8,IIIA 5.9
2570541	2015, A20560C - Physico-Chemical Studies of the Formulation, DACO: 12.7,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,8 .2.2.1,8.2.2.2,8.2.3.6,IIIA 2.1,IIIA 2.10.1,IIIA 2.10.2,IIIA 2.11,IIIA 2.12,IIIA 2.13,IIIA 2.14,IIIA 2.15,IIIA 2.16,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.2,IIIA 2.3.3,IIIA 2.4.1,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.6.2,IIIA 2.7.1,IIIA 2.7.2,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5,IIIA 2.7.6,IIIA 2.8.1,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.4,IIIA 2.8.5.1,IIIA 2.8.5.2,IIIA 2.8.6.1,
2570544	2014, Analytical Method SF-725/1 - Determination of Fludioxonil and SYN545974 in Formulation SC (250/150) by HPLC, DACO: 3.4.1,IIIA 5.2.1
2570545	2014, A20560C - Validation of Analytical Method SF-725/1, DACO: 3.4.1,IIIA 5.2.1
2612336	2016, DACO 3.2.2 - A20560C - Document J - Addendum 1, DACO: 3.2.2 CBI
2571315	2015, PC-15-079 A21461A OECD Document H (Confidential), DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2571317	2015, A21461A - Document J - Confidential Information, DACO: 0.8.11,0.8.12,0.9.1,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,4.8,Document J,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 5.2.4,IIIA 5.2.5,IIIA 7.9.1,IIIA 7.9.2 CBI
2571318	2015, Addendum to Document J-1, DACO: 0.8.11,0.8.12,3.2.2,3.3.1,3.3.2,Document J,IIIA 1.4.2,IIIA 1.4.5.1 CBI
2571324	2015, A21461A - Document MIII Section 1, DACO: 0.1.6003,1.1,1.1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.3.3,10.6,12.5.7,12.7,3.1.1,3.1.2,3. 1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3, 3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,5.11,5.13,5.14,5.2,5.6,5.7,5.9,8.4.1,8.5.2,8.6,Document M,IIIA 1.1,IIIA 1.2.1,IIIA 1.2.2,IIIA 1.2.3,IIIA 1.3,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.2,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 1.5,IIIA 1.6,IIIA 1.7,IIIA 11.1,IIIA 11.2,IIIA 11.3,IIIA 11.4,

2571326	2015, A21461A - Document MIII Section 2, DACO: 12.7,3.4.1,3.4.2,3.5.10,3.6,3.7,5.14,5.5,5.7,7.2.1,7.2.2,7.2.3,7.2.4,7.2.5,7.8,8.2.2.4,8.2.3.3.3,8.2.3.6,8.2.4.6,8.6,Document M,IIIA 5.1.1,IIIA 5.1.2,IIIA 5.1.3,IIIA 5.1.4,IIIA 5.1.5,IIIA 5.2.1,IIIA 5.2.2,IIIA 5.2.3,IIIA 5.2.4,IIIA 5.2.5,IIIA 5.3.1,IIIA 5.3.2,IIIA 5.4,IIIA 5.5,IIIA 5.6,IIIA 5.7,IIIA 5.8,IIIA 5.9
2571406	2015, A21461A - Physico-Chemical Studies of the Formulation, DACO: 12.7,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,3.7,8.2.2.1,8.2.2.2,8.2.3.6,IIIA 2.1,IIIA 2.10.1,IIIA 2.10.2,IIIA 2.11,IIIA 2.12,IIIA 2.13,IIIA 2.14,IIIA 2.15,IIIA 2.16,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.2,IIIA 2.3.3,IIIA 2.4.1,IIIA 2.4.2,IIIA 2.5.1,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.6.2,IIIA 2.7.1,IIIA 2.7.2,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.7.5,IIIA 2.7.6,IIIA 2.8.1,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.4,IIIA 2.8.5.1,IIIA 2.8.5.2,IIIA 2.8.6.1,
2571410	2015, A21461A - SF-779/1 - Determination of ICI5504/CGA64250/SYN545974 in A21461A by UHPLC, DACO: 3.4.1,IIIA 5.2.1
2571411	2015, A21461A - Validation of Analytical Method SF-779/1, DACO: 3.4.1,IIIA 5.2.1
2726172	2017, DACO 3.2.2 - A21461A and B - Document J - Addendum 1, DACO: 3.2.2 CBI

2.0 Human and Animal Health

2570916	2012, SYN545974 - Acute Oral Toxicity Study in the Rat (Up and Down Procedure), DACO: 4.2.1,IIA 5.2.1
2570917	2013, SYN545974 - Acute Dermal Toxicity Study in Rats, DACO: 4.2.2,IIA 5.2.2
2570918	2013, SYN545974 - Acute Inhalation Toxicity Study (Nose-Only) in the Rat, DACO: 4.2.3,IIA 5.2.3
2570919	2012, SYN545974 - Acute Eye Irritation Study in Rabbits, DACO: 4.2.4,IIA 5.2.5
2570920	2012, SYN545974 - Primary Skin Irritation Study in Rabbits, DACO: 4.2.5,IIA 5.2.4
2570921	2013, SYN545974 - Local Lymph Node Assay in the Mouse, DACO: 4.2.6,IIA 5.2.6
2570926	2012, SYN545974 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay, DACO: 4.5.4,IIA 5.4.1
2570927	2013, SYN545974 - Chromosome Aberration Test in Human Lymphocytes In Vitro, DACO: 4.5.6,IIA 5.4.2
2570928	2013, SYN545974 - Cell Mutation Assay at the Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y Cells, DACO: 4.5.5,IIA 5.4.3
2570929	2012, SYN545974 - Micronucleus Assay in Bone Marrow Cells of the Mouse, DACO: 4.5.7,IIA 5.4.4
2570931	2014, SYN545974 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay, DACO: 4.5.4,IIA 5.4.1
2570932	2014, SYN545974 - Micronucleus Assay in Bone Marrow Cells of the Mouse, DACO: 4.5.7,IIA 5.4.4
2570971	2012, SYN545974, SYN546022 - 28 Day Dietary Toxicity Study in Mice, DACO: 4.3.3,IIA 5.3.1

2570973	2012, SYN545974, SYN546022 - 28 Day Dietary Toxicity Study in Rats, DACO: 4.3.3,IIA 5.3.1
2570974	2015, SYN545974 - A 13 Week Toxicity Study of SYN545974 by Oral (Dietary) Administration in Mice, DACO: 4.3.1,IIA 5.3.2
2570976	2015, SYN545974 - A 13 Week Toxicity Study of SYN545974 by Oral (Dietary) Administration in Rats, DACO: 4.3.1,IIA 5.3.2
2570980	2014, SYN545974 - Pharmacokinetics of SYN545974 in the Mouse Following Multiple Oral and Single Intravenous Administration, DACO: 4.5.9,IIA 5.1.3
2570981	2014, SYN545974 - Pharmacokinetics of SYN545974 in the Rat Following Multiple Oral and Single Intravenous Administration, DACO: 4.5.9,IIA 5.1.2
2570986	2015, SYN545974 - Pharmacokinetics of [Phenyl-U-14C] and [Pyrazole-5-14C]-SYN545974 Following Single Oral and Intravenous Administration in the Rat, DACO: 4.5.9,IIA 5.1.1
2570987	2015, SYN545974 - The Absorption and Excretion of [Phenyl-U-14C] and [Pyrazole-5-14C]-SYN545974 Following Single Oral Administration in the Rat, DACO: 4.5.9,IIA 5.1.1
2570988	2015, SYN545974 - Biotransformation of [14C]-SYN545974 in Rat, DACO: 4.5.9,IIA 5.1.1
2570990	2015, SYN545974 - Tissue Depletion of [Phenyl-U-14C] and [Pyrazole-5-14C]-SYN545974 Following Single Oral Administration in the Rat, DACO: 4.5.9,IIA 5.1.1
2570995	2015, SYN545974 - The Excretion and Biotransformation of [Phenyl-U-14C] and [Pyrazole-5-14C]-SYN545974 Following Single Oral Administration in the Mouse, DACO: 4.5.9,IIA 5.1.1
2571014	2015, SYN545974 - Effect on Hepatic UDP-glucuronosyltransferase Activity Towards Thyroxine as Substrate After Dietary Administration for 90 Days to Male Rats, DACO: 4.8,IIA 5.5.4
2571015	2014, SYN545974 - Effect on Rat Thyroid Peroxidase Activity In Vitro, DACO: 4.8,IIA 5.5.4
2571022	2015, SYN545974 - Oral (Dietary) Two-Generation Reproduction Toxicity Study in the Rat, DACO: 4.5.1,IIA 5.6.1
2571023	2011, SYN545974, SYN546022 - Preliminary Oral (Gavage) Prenatal Developmental Toxicity Dose Range Finding Study in the Rat, DACO: 4.5.2,IIA 5.6.10
2571024	2015, SYN545974 - Preliminary Oral (Gavage) Prenatal Developmental Toxicity Study in the Rabbit, DACO: 4.5.3,IIA 5.6.11
2571025	2015, SYN545974 - 90 Day Oral (Capsule) Study in the Dog, DACO: 4.3.2,IIA 5.3.3
2571026	2015, SYN545974 - 52 Week Oral (Capsule) Toxicity Study in the Dog, DACO: 4.3.2,IIA 5.3.4
2571027	2015, SYN545974 - Oral (Gavage) Prenatal Developmental Toxicity Study in the Rabbit, DACO: 4.5.3,IIA 5.6.11

2571029	2015, SYN545974 - Oral (Gavage) Prenatal Developmental Toxicity Study in the Rat, DACO: 4.5.2,IIA 5.6.10
2571031	2015, SYN545974 - Oral (Gavage) Toxicokinetic Study in the Pregnant Rabbit, DACO: 4.5.3,IIA 5.6.11
2571038	2012, Ex-Vivo Enzyme Analysis of Liver Samples Taken at Termination of a 28 Day Dietary Study of SYN545974 and SYN546022 in the Mouse, DACO: 4.8,IIA 5.5.4
2571039	2015, SYN545974 - In Vitro Hepatocyte Proliferation Index and Enzyme Activity Measurements in Male CD-1 Mouse Hepatocyte Cultures, DACO: 4.8,IIA 5.5.4
2571040	2015, SYN545974 - In Vitro Hepatocyte Proliferation Index and Enzyme Activity Measurements in Male Human Hepatocyte Cultures, DACO: 4.8,IIA 5.5.4
2571041	2015, SYN545974 - A 28-Day Dietary Liver Mode of Action Study in Male CD-1 Mice, DACO: 4.8,IIA 5.5.4
2571042	2013, SYN545974 - 28-Day Dermal Toxicity Study in the Wistar Rat, DACO: 4.3.5,IIA 5.3.7
2571045	2015, SYN545974 - Acute Oral (Gavage) Neurotoxicity Study in the Wistar Rat, DACO: 4.5.12,IIA 5.7.1
2571047	2015, SYN545974 - An Abbreviated Acute Oral (Gavage) Neurotoxicity Study in the Female Wistar Rat, DACO: 4.5.12,IIA 5.7.1
2571078	2015, SYN545974 - A Preliminary Study of Pharmacokinetics, Absorption, Metabolism and Excretion in Rats Following Single Oral and Intravenous Administration of ¹⁴ C-SYN545974, DACO: 4.5.9,IIA 5.1.1
2571118	2014, SYN545974 - CAR3 Transactivation Assay with Mouse, Rat and Human CAR, DACO: 4.8,IIA 5.5.4
2638785	2016, SYN545974 - 104 Week Rat Dietary Carcinogenicity Study with a Combined 52 Week Toxicity Study Final Report Amendment 1, DACO: 4.4.1,4.4.2,4.4.4
2638786	2016, SYN545974 - 80 Week Mouse Dietary Carcinogenicity Study Final Report Amendment 2, DACO: 4.4.3

2570914	2015, SYN545974 - Stability of SYN545974 in Processed Commodities of Soybean, Corn, Apple and Grapes Under Freezer Storage Conditions, DACO: 7.3,IIA 6.1.1
2570958	2015, SYN545974 - Independent Laboratory Validation of Analytical Method (GRM061.03A) for the Determination of SYN545974 in Crops by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2570959	2015, SYN545974 - Independent Laboratory Validation of Analytical Method (GRM061.06A) for the Determination of SYN545974 in Bovine Liver by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2570983	2015, SYN545974 - Metabolism of [¹⁴ C]-SYN545974 in Oilseed Rape, DACO: 6.3,IIA 6.2.1
2570984	2015, SYN545974 - Metabolism of [¹⁴ C]-SYN545974 in the Lactating Goat, DACO: 6.2,IIA 6.2.3
2570985	2015, SYN545974 - Metabolism of [¹⁴ C]-SYN545974 in the Laying Hen, DACO: 6.2,IIA 6.2.2
2570989	2015, SYN545974 - Uptake and Metabolism of [¹⁴ C]-SYN545974 in Confined Rotational Crops, DACO: 7.4.4,IIA 6.6.2
2570991	2014, SYN545974 - Metabolism of [¹⁴ C]-SYN545974 in Tomatoes, DACO: 6.3,IIA 6.2.1
2570997	2015, SYN545974 - Magnitude of Residues in Milk and Tissues of Dairy Cows Following Multiple Oral Administrations of SYN545974, DACO: 7.5,7.6,IIA 6.4.2
2571001	2015, SYN545974 - Validation of an Analytical Method for the Determination of SYN545974 in Bovine Meat, Liver, Kidney, Milk, Blood and Chicken Eggs, DACO: 7.2.1,7.2.4,IIA 4.3

2571002	2015, SYN545974 - Storage Stability of SYN545974 in Bovine Muscle, Liver, Milk, Fat and Chicken Eggs, DACO: 7.3,IIA 6.1.1
2571035	2015, SYN545974 - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of SYN545974 in Liver and Milk by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2815467	2017, SYN545974 - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of SYN545974 in Egg and Muscle by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571036	2015, SYN545974 - Frozen Storage Stability of Residues of SYN508272, SYN548264, SYN547897 and SYN548263 in Animal Matrices, DACO: 7.3,IIA 6.1.1
2571050	2015, SYN545974 - Analytical Method for Determination of SYN545974 in Crops by LC-MS/MS with Validation Data, DACO: 7.2.1,7.2.4,IIA 4.3
2571053	2015, SYN545974 - Analytical Method (GRM061.06A) for the Determination of SYN545974 in Bovine Milk, Liver, Kidney, Muscle, Fat, Blood and Hen Eggs by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571054	2015, SYN545974 - Analytical Method (GRM061.07A) for the Determination of Free and Conjugated 2,4,6-trichlorophenol in Bovine Milk, Liver, Kidney, Muscle, Fat, Blood and Hen Eggs by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571055	2015, SYN545974 - Analytical Method (GRM061.08A) for the Determination of SYN548264 and SYN508272 in Bovine Milk by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571056	2015, SYN545974 - Analytical Method (GRM061.09A) for the Determination of Free and Conjugated SYN547897 and SYN548263 in Kidney and Liver by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571057	2015, FTH 545 (SYN545974 SC (200)) - Magnitude of the Residue on Cucumber (Field & Greenhouse), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571058	2015, FTH 545 (SYN545974 SC (200)) - Magnitude of the Residue on Summer Squash, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571059	2015, FTH 545 (SYN545974 SC (200)) - Magnitude of the Residue on Cantaloupe, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571069	2015, SYN545974 - Validation of the QuEChERS Method for the Determination of Residues of SYN545974 in Animal Matrices by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571070	2015, SYN545974 - Validation of the Analytical Method GRM061.07A for the Determination of Residues of Conjugated 2,4,6-Trichlorophenol in Animal Matrices, DACO: 7.2.1,7.2.4,IIA 4.3
2571071	2015, SYN545974 - Storage Stability of Residues of Conjugated 2,4,6 Trichlorophenol in Animal Matrices Stored Frozen for up to Twelve Months, DACO: 7.3,IIA 6.1.1
2571072	2015, SYN545974 - Independent Lab Validation of the Analytical Method for the Determination of Conjugated 2,4,6-Trichlorophenol in Animal Matrices, DACO: 7.2.1,7.2.4,IIA 4.3
2571074	2015, SYN545974 - Storage Stability in Crops Stored Frozen for up to 23 Months, DACO: 7.3,IIA 6.1.1
2571075	2015, SYN545974 - Validation of the Syngenta Method GRM061.03A for the Determination of Residues of SYN545974 in Crop Matrices, DACO: 7.2.1,7.2.4,IIA 4.3
2571076	2015, SYN545974 - Validation of the QuEChERS Method for the Determination of Residues of SYN545974 in Crop Matrices by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571077	2015, SYN545974 - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of SYN545974 in Crop Matrices by LC-MS/MS, DACO: 7.2.1,7.2.4,IIA 4.3
2571088	2015, SYN545974 - Magnitude of the Residues in Tissue and Eggs Resulting from the Feeding of Three Dose Levels to Poultry 2014, DACO: 7.5,7.6,IIA 6.4.1
2571089	2015, SYN545974 SC (A19649B) - Field Accumulation in Rotational Crops (30-, 60-, 90- and 150-day Plant Back Intervals) USA 2013, DACO: 7.4.4,IIA 6.6.3
2571090	2015, SYN545974 EC (A17573A) and SYN545974 SC (A19649B) - Residue Levels on Wheat (Forage, Hay, Grain and Straw) from Trials Conducted in Canada During 2013 and 2014, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1

2571091	2015, SYN545974 EC A17573A and SYN545974 SC A19649B - Residue Levels on Canola Seed from Trials Conducted in Canada During 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571092	2015, SYN545974 EC (A17573A) and SYN545974 SC (A19649B) - Residue Levels on Dry Bean and Pea from Trials Conducted in Canada During 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571093	2015, SYN545974 SC (A19649B) - Residue Levels on Potatoes from Trials Conducted in Canada During 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571094	2015, SYN545974 SC (A19649B) - Magnitude of the Residues in or on Grapes USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571095	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Soybeans USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571100	2015, SYN545974 EC (A17573A) and SYN545974 SC (A19649B) - Residue Levels on Barley (Hay, Grain and Straw) from Trials Conducted in Canada During 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571101	2015, SYN545974 EC (A17573A) and SYN545974 SC (A19649B) - Residue Levels on Oats (Forage, Hay, Grain and Straw) from Trials Conducted in Canada During 2013 and 2014, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571102	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Peanut USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571103	2015, SYN545974 SC (A19649B) - Magnitude of the Residues in or on Tomatoes and Peppers (Representative Commodities of Fruiting Vegetables Crop Group 8) USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571104	2015, SYN545974 SC (A19649B) - Magnitude of the Residues in or on Potato as Representative Crop of Tuberous and Corm Vegetables, Subgroup 1C USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571105	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Field Corn and Popcorn (Maize) USA 2014, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571106	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Wheat USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571107	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Oats USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571108	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Barley USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571109	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Dry Bean and Pea (Representative Commodities for Crop Group 6C) USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571110	2015, SYN545974 SC (A19649B) - Magnitude of the Residues in or on Lettuce (Head and Leaf), Spinach, and Celery (Representative Commodities of Crop Groups 4A & 4B) USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571111	2015, SYN545974 SC (A19649B) and SYN545974 EC (A17573A) - Magnitude of the Residues in or on Canola as Representative Crop of Rapeseed, Subgroup 20A USA 2013, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571119	2015, SYN545974 SC (A19649B) - Magnitude of the Residues in or on Sweet Corn USA 2014, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2571126	2015, SYN545974 - Supplemental Data Demonstrating Stability of Metabolites in Animal Commodities, DACO: 7.3,IIA 6.1.1
2593763	2015, SYN545974 - Frozen Storage Stability of Residues of SYN508272, SYN548264, SYN547897 and SYN548263 in Animal Matrices, DACO: 7.3
2593764	2015, SYN545974 - Storage Stability of Residues of Conjugated 2, 4, 6 Trichlorophenol in Animal Matrices Stored Frozen for up to Twelve Months Storage Stability Report, DACO: 7.3
2608337	2015, SYN545974 - Storage Stability of SYN545974 in Bovine Muscle, Liver, Milk, Fat and Chicken Eggs, DACO: 7.3
2638788	2016, SYN545974 -Storage Stability of SYN545974 in Bovine Muscle, Liver, Milk, Fat and Chicken Eggs, DACO: 7.3

2638791	2016, SYN545974 - Storage Stability of Residues of Conjugated 2, 4, 6 Trichlorophenol in Animal Matrices Stored Frozen for up to Twelve Months Storage Stability Report, DACO: 7.3
2638792	2016, SYN545974 - Frozen Storage Stability of Residues of SYN508272, SYN548264, SYN547897 and SYN548263 in Animal Matrices, DACO: 7.3
2638793	2016, SYN545974 - Stability of SYN545974 in Processed Commodities of Soybean, Corn, Apple and Grapes Under Freezer Storage Conditions Final Report Amendment 1, DACO: 7.3

1563654	1999, Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns. Appendix 4 Exposure Of Professional Lawn Care Workers During The Mixing And Loading Of Dry And Liquid Formulations And The Liquid Application Of Turf Pesticides Utilizing A Surrogate Compound., DACO: 5.3,5.4
1563664	1999, Integrated Report for Evaluation of Potential Exposures to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns. Appendix B Field Phase Report for Exposure of Professional Lawn Care Workers During the Mixing and Loading of Dry and Liquid Formulations and the Liquid Application of Turf Pesticides Utilizing a Surrogate Compound., DACO: 5.3,5.4
1913109	2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO: 5.3,5.4
2115788	2008, Data Submitted by the Agricultural Rentry Task Force (ARTF) to Support Revision of Agricultural Transfer Coefficients., DACO: 5.6
2172938	2012, Agricultural Handler Exposure Scenario Monograph: Closed Cockpit Aerial Application of Liquid Sprays, DACO: 5.3,5.4
2572743	2014, Agricultural Handler Exposure Scenario Monograph: Open Cab Airblast Application of Liquid Sprays, DACO: 5.3,5.4
2572745	2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations, DACO: 5.3,5.4

3.0 Environment

2570965	2015. ¹⁴ C-SYN545974 - Hydrolysis in Sterile Buffer at pH 4, 7 and 9. DACO 8.2.3.2
2570967	2015. SYN545974 - Aqueous Photolysis of [¹⁴ C]SYN545974. DACO 8.2.3.3.2
2570968	2014. SYN545974 - Soil Photolysis of ¹⁴ C-SYN545974. DACO 8.2.3.3.1
2570966	2015. SYN545974 - Aerobic Soil Metabolism of [¹⁴ C]-SYN545974. DACO 8.2.3.4.2
2570970	2015. SYN545974 - Anaerobic Soil Metabolism of ¹⁴ C-SYN545974. DACO 8.2.3.4.4
2570969	2015. SYN545974 - Aerobic and Anaerobic Aquatic Sediment Metabolism of ¹⁴ C-SYN545974. DACO 8.2.3.6
2571020	2013. SYN545974 - Adsorption and Desorption of ¹⁴ C-SYN545974. DACO 8.2.4.2
2571079	2015. SYN545547 - Adsorption and Desorption of [¹⁴ C]-SYN545547 in Five Soils. DACO 8.2.4.2

2571096	2015. SYN545974 SC (A19649B) - Dissipation of SYN545974 in Soil Under Winter Wheat Crop Conditions in the Northwestern United States. DACO 8.3.2
2571097	2015. Supplemental Data to Support SYN545974 SC (A19649B) - Dissipation of SYN545974 in Soil under Winter Wheat Crop Conditions in the Northwestern United States. DACO 8.3.2
2571098	2015. SYN545974 SC (A19649B) - Soil Dissipation Trial to Determine Persistence and Leaching Movement of SYN545974 after Application of SYN545974 200SC Fungicide. DACO 8.3.2
2571099	2015. Supplemental Data to Support SYN545974 SC (A19649B) - Soil Dissipation Trial to Determine Persistence and Leaching Movement of SYN545974 after Application of SYN545974 200SC Fungicide. DACO 8.3.2
2571112	2015. SYN545974 (A19649B) - Field Dissipation of SYN545974 in Soil Under Turf and Bare Soil Conditions in Prince Edward Island, Canada. DACO 8.3.2
2571113	2015. Supplemental Data to Support SYN545974 (A19649B) - Field Dissipation of SYN545974 in Soil Under Turf and Bare Soil Conditions in Prince Edward Island, Canada. DACO 8.3.2
2571086	2015. SYN545974 (A19649B) - Dissipation of SYN545974 (SC 200) in Soil Applied at a Typical Fungicide Application Timing for Soybeans in the Midwestern United States. DACO 8.3.2
2571087	2015. Supplemental Data to Support SYN545974 (A19649B) - Dissipation of SYN545974 (SC 200) in Soil Applied at a Typical Fungicide Application Timing for Soybeans in the Midwestern United States. DACO 8.3.2
2571114	2015. SYN545974 (A19649B) - Dissipation of SYN545974 (SC 200) in a Warm-Season Turf in Southeastern United States. DACO 8.3.2
2571115	2015. Supplemental Data to Support SYN545974 (A19649B) - Dissipation of SYN545974 (SC 200) in a Warm-Season Turf in Southeastern United States. DACO 8.3.2
2571016	2015. SYN545974 - Dissipation of SYN545974 in Soil Under Bare Soil and Peanut Crop Conditions in the Southeastern United States. DACO 8.3.2
2571017	2015. Supplemental Data to Support SYN545974 - Dissipation of SYN545974 in Soil Under Bare Soil and Peanut Crop Conditions in the Southeastern United States. DACO 8.3.2
2571018	2015. SYN545974 SC (A19649B) - Dissipation of SYN545974 in Soil Applied at a Typical Fungicide Application Timing for Fresh Market Tomatoes in the Central Valley of California. DACO 8.3.2
2571019	2015. Supplemental Data to Support SYN545974 SC (A19649B) - Dissipation of SYN545974 in Soil Applied at a Typical Fungicide Application Timing for Fresh Market Tomatoes in the Central Valley of California. DACO 8.3.2
2570963	2015. Stability of SYN545974 in Representative Turfgrass Clippings, Turf Thatch-Sod Layer and Soil Matrices Under Freezer Storage Conditions. DACO 8.3.2
2570915	2012. SYN545974 - Acute Toxicity to the Earthworm <i>Eisenia fetida</i> . DACO 9.2.3.1

2570924	2014. SYN545974 SC (A19649B) - Acute Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil. DACO 9.2.3.1
2570925	2015. SYN545974 SC (A19649B) - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5% Peat. DACO 9.2.3.1
2571073	2015. SYN545974 - Acute Oral and Contact Toxicity to the Honeybee <i>Apis mellifera</i> L. in the Laboratory. DACO 9.2.4.2
2570912	2015. SYN545974 - A Laboratory Study to Determine the Chronic Effects on the Brood of the Honey Bee <i>Apis mellifera</i> L. (Hymenoptera - Apidae) DACO 9.2.4.3
2570913	2015. SYN545974 SC (A19649B) - A Laboratory Study to Determine the Chronic Effects on the Brood of the Honey Bee <i>Apis mellifera</i> L. (Hymenoptera - Apidae) DACO 9.2.4.3
2570922	2014. A19649B - Chronic Toxicity to the Honeybee <i>Apis mellifera</i> L. in a 10 Day Continuous Laboratory Feeding Study. DACO 9.2.4.1, 9.2.4.2, 9.2.4.3
2571122	2015. Acute Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Study with Pydiflumetofen. DACO 9.2.4.3
2763319	2017. Pydiflumetofen SC (A19649B) – A Semi-Field Study to Evaluate Side Effects on Honeybees (<i>Apis mellifera</i> L.) in <i>Phacelia tanacetifolia</i> in Germany 2016. DACO 9.2.4.6, 9.2.4.5
2763321	2017. Pydiflumetofen SC (A19649B) – A Semi-Field Study to Evaluate Side Effects on Honeybees (<i>Apis mellifera</i> L.) in <i>Phacelia tanacetifolia</i> in Germany 2016. DACO 9.2.4.6, 9.2.4.5
2571080	2014. SYN545974 SC (A19649B) - A Rate-Response Laboratory Bioassay of the Effects of Fresh Residues on the Parasitic Wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae). DACO 9.2.6
2571081	2014. SYN545974 SC (A19649B) - A Rate-Response Laboratory Bioassay of the Effects of Fresh Residues on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae). DACO 9.2.5
2571082	2015. SYN545974 SC (A19649B) - A Rate-Response Extended Laboratory Bioassay of the Effects of Fresh Residues on the Parasitic Wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae). DACO 9.2.6
2571083	2015. SYN545974 SC (A19649B) - A Rate-Response Extended Laboratory Bioassay of the Effects of Fresh Residues on the Predatory Mite <i>Typhlodromus pyri</i> (Acari - Phytoseiidae). DACO 9.2.5
2571005	2013. SYN545974 - An Acute Oral Toxicity Study with the Northern Bobwhite Using a Sequential Testing Procedure. DACO 9.6.2.1, 9.6.2.2, 9.6.2.3
2571006	2013. SYN545974 - An Acute Oral Toxicity Study with the Canary Using a Sequential Testing Procedure. DACO 9.6.2.1, 9.6.2.2, 9.6.2.3
2571003	2013. SYN545974 - A Dietary LC ₅₀ Study with the Northern Bobwhite. DACO 9.6.2.6
2571004	2013. SYN545974 - A Dietary LC ₅₀ Study with the Mallard. DACO 9.6.2.4, 9.6.2.5
2571007	2015. SYN545974 - A Reproduction Study with the Northern Bobwhite. DACO 9.6.3.1, 9.6.3.2, 9.6.3.3

2571008	2014. Supplemental Data to Support SYN545974 - A Reproduction Study with the Northern Bobwhite. DACO 9.6.3.1, 9.6.3.2, 9.6.3.3
2571009	2014. SYN545974 - A Reproduction Study with the Mallard. DACO 9.6.3.1, 9.6.3.2, 9.6.3.3
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2571011	2015. SYN545974 SC (A19649B) - Toxicity Effects on the Seedling Emergence of Ten Species of Plants. DACO 9.8.4
2571012	2015. SYN545974 SC (A19649B) - Toxicity Effects on the Vegetative Vigour of Ten Species of Plants. DACO 9.8.4
2571013	2015. SYN545974 SC (A19649B) - Toxicity Effects on the Seedling Emergence of Ten Species of Plants. DACO 9.8.4
2570933	2012. SYN545974 - Acute Toxicity to Mysid (<i>Americamysis bahia</i>), Under Static Conditions DACO 9.3.4
2570934	2012. SYN545974 - Acute Toxicity to Water Fleas (<i>Daphnia magna</i>) Under Static Conditions. DACO 9.3.2
2570935	2012. SYN545974 - Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) Under Flow-Through Conditions. DACO 9.5.2.1, 9.5.2.3
2570936	2013. SYN545974 - 96-Hour Toxicity Test with the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i> . DACO 9.8.2, 9.8.3
2570937	2015. SYN545974 - Full Life-Cycle Toxicity Test with Water Fleas, <i>Daphnia magna</i> , Under Static Renewal Conditions. DACO 9.3.3
2570938	2015. SYN545974 - Early Life-Stage Toxicity Test with Fathead Minnow (<i>Pimephales promelas</i>). DACO 9.5.3.1
2570939	2015. SYN545974 - 7-Day Toxicity Test with Duckweed (<i>Lemna gibba</i>). DACO 9.8.5
2570940	2015. SYN545974 - 96-Hour Toxicity Test with the Freshwater Diatom, <i>Navicula pelliculosa</i> . DACO 9.8.2, 9.8.3
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2570942	2013. SYN545974 - Toxicity Test to the Freshwater Blue-Green Alga, <i>Anabaena flos-aquae</i> . DACO 9.8.2, 9.8.3
2570943	2013. SYN545974 - Acute Toxicity to Carp (<i>Cyprinus carpio</i>) Under Flow-Through Conditions. DACO 9.5.2.2, 9.5.2.3
2570944	2013. SYN545974 - Acute Toxicity to Fathead Minnow (<i>Pimephales promelas</i>) Under Flow-Through Conditions. DACO 9.5.2.2, 9.5.2.3
2570945	2013. SYN545974 - Acute Toxicity to Sheepshead Minnow (<i>Cyprinodon variegatus</i>) Under Flow-Through Conditions. DACO 9.4.2, 9.4.3, 9.4.4
2570946	2014. SYN545974 - Toxicity to Eastern Oyster (<i>Crassostrea virginica</i>) Under Flow-Through Conditions. DACO 9.3.4
2570947	2015. SYN545974 - Life-Cycle Toxicity Test with Mysids (<i>Americamysis bahia</i>). DACO 9.4.2, 9.4.3, 9.4.4
2570948	2015. SYN545974 - Life-Cycle Toxicity Test Exposing Midges (<i>Chironomus dilutus</i>) to Spiked Sediment. DACO 9.9

2570949	2015. Supplemental Data to Support SYN545974 - Life-Cycle Toxicity Test Exposing Midges (<i>Chrionomus dilutes</i>) to Spiked Sediment. DACO 9.9
2570950	2015. SYN545974 - 42-Day Toxicity Test Exposing Freshwater Amphipods (<i>Hyalella azteca</i>) to Spiked Sediment. DACO 9.9
2570951	2015. Supplemental Data to Support SYN545974 - 42-Day Toxicity Test Exposing Freshwater Amphipods (<i>Hyalella azteca</i>) to Spiked Sediment. DACO 9.9
2570952	2014. SYN545974 - Flow-Through Bioconcentration and Metabolism Study with Bluegill Sunfish (<i>Lepomis macrochirus</i>). DACO 9.5.6
2570953	2015. SYN545974 - Early Life-Stage Toxicity Test with Sheepshead Minnow, <i>Cyprinodon variegatus</i> . DACO 9.5.3.1
2570954	2015. SYN545974 - 10-Day Toxicity Test Exposing Estuarine Amphipods (<i>Leptocheirus plumulosus</i>) to a Test Substance Applied to Sediment under Static Conditions. DACO 9.9
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2570956	2015. SYN545547 - Acute Toxicity to Water Fleas (<i>Daphnia magna</i>) Under Static Conditions. DACO 9.3.2
2570957	2015. SYN545547 - Acute Toxicity Test with Rainbow Trout (<i>Oncorhynchus mykiss</i>) Under Static Conditions. DACO 9.5.2.1, 9.5.2.3
2608340	2014. SYN545974 SC (A19649B) - Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 96-Hour Algal Growth Inhibition Test. DACO 9.8.2, 9.8.3

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- 2569827 2015, A19649 - Adepidyn (SYN545974), 200 g/L - Document M-III, Section 7 - Efficacy and Information - Canada, DACO:
1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,12.7,5.2,Document M,IIIA 3.1,IIIA 3.2,IIIA 3.3.1,IIIA 3.3.2,IIIA 3.4,IIIA 3.5,IIIA 3.6,IIIA 3.7.1,IIIA 3.8.1,IIIA 3.8.2,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2569897 2014, CAN14-01 - Evaluate FUSHA LER for the control of Blackleg in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569898 2014, CAN14-02 - Evaluate FUSHA LER for the control of Blackleg in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569899 2014, CAN14-03 - Evaluate FUSHA LER for the control of Sclerotinia in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569900 2014, CAN14-04 - Evaluate FUSHA LER for the control of Sclerotinia in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569904 2013, NUT13-01 - SYN545974: Peanut leafspot and foliar disease efficacy, DACO: 10.2.3.3,IIIA 6.1.2

- 2569906 2015, NUT13-03 - SYN545974: Peanut leafspot and foliar disease efficacy, DACO: 10.2.3.3,IIIA 6.1.2
- 2569907 2013, BEA13-01 - SYN545974: Evaluate formulations and rates for control of White Mold in Drybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569909 2014, NUT14-02 - Developmental Fungicide: Peanut crop tolerance and foliar disease efficacy, DACO: 10.2.3.3,IIIA 6.1.2
- 2569910 2014, NUT14-03 - Developmental Fungicide: Peanut crop tolerance and foliar disease efficacy, DACO: 10.2.3.3,IIIA 6.1.2
- 2569911 2014, NUT14-04 - Developmental Fungicide: Peanut crop tolerance and foliar disease efficacy, DACO: 10.2.3.3,IIIA 6.1.2
- 2569912 2013, SOY13-01 - SYN545974: Evaluate formulations and rates for control of White Mold in Soybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569914 2014, SOY14-01 - Evaluate SYN545974 activity on white mold in soybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569915 2014, SOY14-02 - Evaluate SYN545974 activity on white mold in soybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569916 2014, SOY14-03 - Development Fungicide: Evaluate Formulations and rates for White Mold (Sclerotinia) Control in Soybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569917 2013, WHE13-01 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569919 2014, BEA14-01 - FUSHA vs White Mold (Sclerotinia) in drybeans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569920 2013, WHE13-02 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569922 2013, WHE13-03 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569923 2014, WHE14-01 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569924 2014, WHE14-02 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569925 2014, WHE14-03 - Evaluate FUSHA LER for the control of Fusarium Head Blight in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2569926 2014, BEA14-02 - Evaluate SYN545974 control of white mold in dry beans, DACO: 10.2.3.3,IIIA 6.1.2

-
- 2569927 2014, BEA14-03 - A19649B - 200SC, Efficacy and crop safety registration trials against Sclerotinia and Botrytis in beans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569928 2014, BEA14-04 - A19649B - 200SC, Efficacy and crop safety registration trials against Sclerotinia and Botrytis in beans, DACO: 10.2.3.3,IIIA 6.1.2
- 2569929 2013, CAN13-01 - Evaluate FUSHA LER for the control of Blackleg in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569930 2013, CAN13-02 - Evaluate FUSHA LER for the control of Sclerotinia in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2569931 2013, CAN13-03 - Evaluate FUSHA LER for the control of Sclerotinia in canola, DACO: 10.2.3.3,IIIA 6.1.2
- 2571412 2015, BAR13-04 - F501 -- Argentina Barley STL + PPZ Syn545, DACO: 10.2.3.3,IIIA 6.1.2
- 2571420 2013, WHE13-03 - Evaluate FUSHA LER for the control of cereal leaf diseases in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2571425 2013, WHE13-02 - Evaluate FUSHA LER for the control of cereal leaf diseases in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2571428 2013, WHE13-04 - Evaluate FUSHA LER for the control of cereal leaf diseases in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2571429 2013, BAR13-01 - Evaluate FUSHA LER for the control of cereal leaf diseases in spring and winter wheat, DACO: 10.2.3.3,IIIA 6.1.2
- 2571439 2014, BAR14-05 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571445 2014, WHE14-04 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571446 2014, WHE14-06 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571451 2014, WHE14-05 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571452 2014, BAR14-02 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571453 2014, BAR14-01 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2696143 2014, BEA14-02 - Evaluate SYN545974 control of white mold in dry beans, DACO: 10.2.3.3
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- 2696146 2013, CAN13-02 - Evaluate FUSHA LER for the control of Sclerotinia in canola, DACO: 10.2.3.3
- 2706066 2015, Evaluate SYN545974 control of Fusarium ear rot in corn, DACO: 10.2.3.3
- 2706067 2015, Evaluate Fusha LER for the control of Sclerotinia in lentils, DACO: 10.2.3.3
- 2706068 2015, A19649B - 200SC, Efficacy and crop safety registration trials against Sclerotinia and Botrytis in peas, DACO: 10.2.3.3
- 2706069 2015, A19649B - 200SC Efficacy and crop safety registration trials against Sclerotinia and Botrytis in peas, DACO: 10.2.3.3
- 2706070 2014, Efficacy of A19649B for Sclerotinia control in beans, DACO: 10.2.3.3
- 2706071 2015, Efficacy of A19649B for sclerotinia control in beans , DACO: 10.2.3.3

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- 2569963 2015, A19649TO - Adepidyn (SYN545974), 200 g/L - Document M-III, Section 7 – Efficacy Data and Information - Canada, DACO: 1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4, 10.5.1,10.5.2,10.5.3,10.5.4,10.6,12.7,5.2, Document M,IIIA 3.1,IIIA 3.2,IIIA 3.3.1,IIIA 3.3.2,IIIA 3.4,IIIA 3.5,IIIA 3.6,IIIA 3.7.1,IIIA 3.8.1,IIIA 3.8.2,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2569965 2013, GHORN13-03 - FUSHA: Evaluate the efficacy of a formulated mixture of FUSHA/FDL on *Botrytis cinerea* in ornamentals (GEP), DACO: 10.2.3.3,IIIA 6.1.2
- 2569966 2013, GHORN13-04 - FUSHA: Evaluate the efficacy of a formulated mixture of FUSHA/FDL on *Botrytis cinerea* in ornamentals (GEP), DACO: 10.2.3.3,IIIA 6.1.2
- 2569967 2013, GHORN13-05 - FUSHA: Evaluate the efficacy of a formulated mixture of FUSHA/FDL on *Botrytis cinerea* in ornamentals (GEP), DACO: 10.2.3.3,IIIA 6.1.2
- 2569968 2012, GHORN13-12 - SYN545974: Efficacy against foliar diseases in ornamentals – comparison of EC and SC formulations against powdery mildew in petunia., DACO: 10.2.3.3,IIIA 6.1.2
- 2569969 2014, GHORN14-02 - FTH545: Evaluation of *Botrytis* control in ornamental species - geranium., DACO: 10.2.3.3,IIIA 6.1.2
- 2569970 2014, GHORN14-04 - FTH545: Evaluation of disease control in ornamental species – powdery mildew in petunia., DACO: 10.2.3.3,IIIA 6.1.2
- 2569971 2015, GHORN15-01 - The effect of Fusha against *Botrytis cinerea* on Poinsettia, DACO: 10.2.3.3,IIIA 6.1.2
- 2569972 2014, GHORN15-02 - The effect of Fusha against *Botrytis cinerea* on Poinsettia, DACO: 10.2.3.3,IIIA 6.1.2

- 2569973 2012, GHCUC12-01 - Stage 2: FUSHA - Efficacy and crop safety of SYN545974 against powdery mildew on cucurbits , DACO: 10.2.3.3,IIIA 6.1.2
- 2569974 2012, GHCUC13-01 - Efficacy and crop safety of A19649B against powdery mildew of cucurbits (cucumbers) in South Africa , DACO: 10.2.3.3,IIIA 6.1.2
- 2569975 2014, TUR14-01 - Evaluate SYN545974 for control of dollar spot in turf., DACO: 10.2.3.3,IIIA 6.1.2
- 2569976 2013, GHCUC13-02 - Stage 3: FUSHA - Efficacy and crop safety of SYN545974 against *Cladosporium* and *Didymella* on cucurbits, DACO: 10.2.3.3,IIIA 6.1.2
- 2569977 2013, GHCUC13-03 - Stage 3: FUSHA - Efficacy and crop safety of SYN545974 against *Cladosporium* and *Didymella* on cucurbits, DACO: 10.2.3.3,IIIA 6.1.2
- 2569978 2014, GHCUC14-01 - A19649B 200SC - profiling and rate definition against *Botrytis* and *Sclerotinia* on cucurbits (F and GH), DACO: 10.2.3.3,IIIA 6.1.2
- 2569979 2013, GHCUC14-02 - A19649B 200SC - profiling and rate definition against *Botrytis* and *Sclerotinia* on cucurbits (GH), DACO: 10.2.3.3,IIIA 6.1.2
- 2569980 2014, GHCUC14-05 - A18119A DFZ / Cyflufenamid supporting registration trials for vegetables *Dydymella* on cucurbits (GH)., DACO: 10.2.3.3,IIIA 6.1.2
- 2569981 2014, TUR14-03 - Test Syngenta's FUSHA and potential FUSHA premixes for extended control of dollar spot in fairway height cool-season turfgrass. , DACO: 10.2.3.3,IIIA 6.1.2
- 2569982 2014, TUR14-04 - Test Syngenta's FUSHA and potential FUSHA premixes for extended control of dollar spot in fairway height cool-season turfgrass., DACO: 10.2.3.3,IIIA 6.1.2
- 2569983 2014, TUR14-05 - Test Syngenta's FUSHA and potential FUSHA premixes for extended control of dollar spot in fairway height cool-season turfgrass. , DACO: 10.2.3.3,IIIA 6.1.2
- 2569984 2015, TUR14-07 - Evaluation of A19649B and A19188A fungicidal products for control of Microdochium patch (Fusarium patch; pink snow mould) of turf grass: efficacy and crop tolerance., DACO: 10.2.3.3,IIIA 6.1.2
- 2569985 2014, ORN14-03 - Assessment of FUSHA+FDL to control *Sphaerotheca pannosa* in rose, DACO: 10.2.3.3,IIIA 6.1.2
- 2569986 2014, ORN14-05 - Assessment of FUSHA+FDL to control *Sphaerotheca pannosa* in rose, DACO: 10.2.3.3,IIIA 6.1.2
- 2569987 2014, ORN14-06 - FTH545: Evaluation of disease control in ornamental species., DACO: 10.2.3.3,IIIA 6.1.2

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- 2570074 2006, CAR06-01 - Ortiva Top: registrazione del prodotto su diverse colture orticole, DACO: 10.2.3.3,IIIA 6.1.2
- 2570078 2007, CUC07-01 - Ortive - Registrazione di Ortiva Top su differenti colture e valutazione di Syn 520453 su oidio del melone, DACO: 10.2.3.3,IIIA 6.1.2

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- 2570079 2008, CUC08-01 - HAMBRA: Evaluation of the efficacy of SYN545192 for the control of *Colletotrichum* spp. on peppers/cucurbits, DACO: 10.2.3.3,IIIA 6.1.2
- 2570080 2010, CUC10-01 - Evaluate rate/formulations/spectrum of Hambra on cucurbits, DACO: 10.2.3.3,IIIA 6.1.2
- 2570081 2011, CUC11-01 - DFZ+CYF (A18119A) - registration trials against leaf spots in melons and watermelons in Med EPPO zone, DACO: 10.2.3.3,IIIA 6.1.2
- 2570082 2011, CUC11-02 - DFZ+CYF (A18119A) - registration trials against leaf spots in melons and watermelons in Med EPPO zone, DACO: 10.2.3.3,IIIA 6.1.2
- 2570083 2012, CUC12-05 - INSPIRE SUPER contra *Alternaria cucumerina*) en el cultivo de Pepino . 2012., DACO: 10.2.3.3,IIIA 6.1.2
- 2570084 2012, CUC13-02 - Efficacy and crop safety of A19649B against powdery mildew of cucurbits (SQUASH) in South Africa, DACO: 10.2.3.3,IIIA 6.1.2
- 2570085 2012, CUC13-03 - Efficacy and crop safety of A19649B against powdery mildew of cucurbits (babymarrow) in South Africa, DACO: 10.2.3.3,IIIA 6.1.2
- 2570086 2013, CUC14-01 - Efficacy and crop safety of foliar applications of FUSHA formulations against powdery mildew of cucurbits in South Africa, DACO: 10.2.3.3,IIIA 6.1.2
- 2570087 2014, CUC14-03 - A19649B - 200SC Efficacy and crop safety registration trials against Powdery Mildew in cucurbits (F), DACO: 10.2.3.3,IIIA 6.1.2
- 2570088 2014, CUC14-04 - A19649B - 200SC Efficacy and crop safety registration trials against Powdery Mildew in cucurbits (Melon,F), DACO: 10.2.3.3,IIIA 6.1.2
- 2570089 2014, CUC14-06 - Stage 3 : FUSHA - Efficacy and crop safety of FUSHA mixture formulations against gummy stem blight (GSB) on watermelon, DACO: 10.2.3.3,IIIA 6.1.2
- 2570090 2014, CUC14-07 - Stage 3 : FUSHA - Efficacy and crop safety of FUSHA mixture formulations against gummy stem blight (GSB) on watermelon, DACO: 10.2.3.3,IIIA 6.1.2
- 2570091 2014, CUC14-08 - Stage 3 : FUSHA - Efficacy and crop safety of FUSHA mixture formulations against gummy stem blight, DACO: 10.2.3.3,IIIA 6.1.2
- 2570093 2013, FRU13-02 - FUSHA- A19649B - 200SC crop safety and registration trials against Powdery Mildew in tomato, DACO: 10.2.3.3,IIIA 6.1.2
- 2570094 2013, FRU13-04 - FUSHA- A19649B - 200SC crop safety and registration trials against Powdery Mildew in tomato, DACO: 10.2.3.3,IIIA 6.1.2
- 2570095 2012, FRU13-06 - Stage 3: FUSHA - Efficacy and crop safety of SYN545974 against powdery mildew of peppers, DACO: 10.2.3.3,IIIA 6.1.2
- 2570096 2012, FRU13-07 - Stage 3: FUSHA - Efficacy and crop safety of SYN545974 against anthracnose of chili, DACO: 10.2.3.3,IIIA 6.1.2
- 2570097 2013, FRU13-11 - Stage 3: FUSHA: Efficacy and crop safety of A19649B (SYN545974) against grey mould in tomatoes, DACO: 10.2.3.3,IIIA 6.1.2
- 2570099 2013, POT13-01 - 974 on potato: Evaluate for control of early blight, DACO: 10.2.3.3,IIIA 6.1.2
- 2570100 2014, POT14-01 - Development Fungicide: Evaluate for foliar diseases of potatoes, DACO: 10.2.3.3,IIIA 6.1.2
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- 2570101 2014, POT14-02 - Development Fungicide: Evaluate for foliar diseases of potatoes, DACO: 10.2.3.3, IIIA 6.1.2
- 2570102 2015, POT14-05 - Efficacy and crop safety of foliar applications of FUSHA formulations on early blight (*Alternaria solani*) and Botrytis blight (*Botrytis cinerea*) of potatoes in South Africa, DACO: 10.2.3.3, IIIA 6.1.2
- 2570103 2014, POT14-06 - A19469B- 200SC Registration trials against *Alternaria* in potatoes, DACO: 10.2.3.3, IIIA 6.1.2
- 2570104 2014, POT14-07 - Evaluate 974 for foliar diseases of potatoes, DACO: 10.2.3.3, IIIA 6.1.2
- 2570124 2015, A20259 - Adepidyn (SYN545974) and Difenoconazole, 200 g/L - Efficacy Data and Information – Canada, DACO: 1.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.6, 12.7, 5.2, Document M, IIIA 3.1, IIIA 3.2, IIIA 3.3.1, IIIA 3.3.2, IIIA 3.4, IIIA 3.5, IIIA 3.6, IIIA 3.7.1, IIIA 3.8.1, IIIA 3.8.2, IIIA 6.1.1, IIIA 6.1.2, IIIA 6.1.3, IIIA 6.1.4.1, IIIA 6.1.4.2, IIIA 6.1.4.3, IIIA 6.2.1, IIIA 6.2.2, IIIA 6.2.3, IIIA 6.2.4, IIIA 6.2.5, IIIA 6.2.6, IIIA 6.2.7, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3, IIIA 6.5, IIIA 6.6, IIIA 6.7
- 2612337 2016, T & O Summary, DACO: 10.1
- 2612338 2015, F701 E 32015BR_CP_Efficacy Trials_Wheat_Fusha Solo_Season 2014/15_Field, DACO: 10.2.3.3
- 2612339 2015, Vegetable Trials, DACO: 10.2.3.3
- 2612344 2011, Compare Syngenta early blight and brown spot solutions in potatoes., DACO: 10.2.3.3
- 2612345 2015, 974: Evaluation for control of leaf spot on potato, DACO: 10.2.3.3
- 2612346 2015, Evaluate fungicides for control of white mold in potato - Syngenta-Canada, DACO: 10.2.3.3
- 2612347 2006, Trials on vegetables, DACO: 10.2.3.3
- 2612348 2012, Vegetable Trials, DACO: 10.2.3.3
- 2612330 2016, Syngenta Response, DACO: 0.8
- 2707339 2014, CUC14-09 - Evaluation of fungicide combinations with Actigard for control of anthracnose in cucumber - DIOMEDE, DACO: 10.2.3.3

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- 2570487 2015, A20560 - Adepidyn (SYN545974) and Fludioxonil, 400 g/L - Document M-III, Section 7 - Efficacy Data and Information - Canada, DACO: 1.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.3, 12.7, 5.2, Document M, IIIA 3.1, IIIA 3.2, IIIA 3.3.1, IIIA 3.3.2, IIIA 3.4, IIIA 3.5, IIIA 3.6, IIIA 3.7.1, IIIA 3.8.1, IIIA 3.8.2
- 2570547 2014, LEA14-04 - A19649B - 200SC, Efficacy and crop safety registration trials against *Botrytis* and *Sclerotinia* in lettuce, DACO: 10.2.3.3, IIIA 6.1.2
- 2570548 2014, LEA14-06 - A19649B - 200SC, Efficacy and crop safety registration trials against *Botrytis* and *Sclerotinia* in lettuce (Field), DACO: 10.2.3.3, IIIA 6.1.2
- 2570549 2014, LEA14-07 - Evaluate developmental fungicides for *Sclerotinia* control in lettuce, DACO: 10.2.3.3, IIIA 6.1.2
- 2570550 2014, LEA14-08 - Evaluate developmental fungicides for *Sclerotinia* control in lettuce, DACO: 10.2.3.3, IIIA 6.1.2

- 2570551 2014, LEA15-01 - FS9730A3-2015US974: Evaluation for control of *Sclerotinia* on lettuce, DACO: 10.2.3.3,IIIA 6.1.2
- 2570552 2014, LEA15-02 - FS9730A3-2015US974: Evaluation for control of *Sclerotinia* on lettuce, DACO: 10.2.3.3,IIIA 6.1.2
- 2570553 2015, GRA13-01 - F534. Fusha Grapes. Evaluate control of *Botrytis cinerea*, DACO: 10.2.3.3,IIIA 6.1.2
- 2570554 2015, GRA13-02 - Evaluate 974 for *Botrytis* control in grape, DACO: 10.2.3.3,IIIA 6.1.2
- 2570555 2015, GRA13-04 - FUSHA- A19649B - 200SC crop safety and registration trials against *Botrytis* in grapes, DACO: 10.2.3.3,IIIA 6.1.2
- 2570556 2015, GRA13-06 - A19649B - 200SC crop safety and registration trials against *Botrytis* in grapes, DACO: 10.2.3.3,IIIA 6.1.2
- 2570557 2008, GRA14-01 - Efficacy and crop safety of foliar applications FUSHA, GEOXE and SAKALIA against *Botrytis* rot of grapes in South Africa, DACO: 10.2.3.3,IIIA 6.1.2
- 2570558 2013, LEA13-01 - Evaluate 974 for *Sclerotinia* control in lettuce, DACO: 10.2.3.3,IIIA 6.1.2
- 2570559 2013, LEA13-02 - Evaluate 974 for *Sclerotinia* control in lettuce, DACO: 10.2.3.3,IIIA 6.1.2
- 2570560 2014, LEA14-02 - A19649B - 200SC, Efficacy and crop safety registration trials against *Botrytis* in lettuce (Field), DACO: 10.2.3.3,IIIA 6.1.2

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- 2571325 2015, A21461 - Adepidyn (SYN545974), Azoxystrobin and Propiconazole, 300 g/L - Document M-III, Section 7 - Efficacy Data and Information - Canada, DACO: 1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6,12.7,5.2,Document M,IIIA 3.1,IIIA 3.2,IIIA 3.3.1,IIIA 3.3.2,IIIA 3.4,IIIA 3.5,IIIA 3.6,IIIA 3.7.1,IIIA 3.8.1,IIIA 3.8.2,IIIA 6.1.1,IIIA 6.1.2,IIIA 6.1.3,IIIA 6.1.4.1,IIIA 6.1.4.2,IIIA 6.1.4.3,IIIA 6.2.1,IIIA 6.2.2,IIIA 6.2.3,IIIA 6.2.4,IIIA 6.2.5,IIIA 6.2.6,IIIA 6.2.7,IIIA 6.2.8,IIIA 6.3,IIIA 6.4.1,IIIA 6.4.2,IIIA 6.4.3,IIIA 6.5,IIIA 6.6,IIIA 6.7
- 2571414 2013, COR13-07 - SYN545974: Evaluate Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571415 2013, COR13-05 - SYN545974: Evaluate Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571417 2013, COR13-11 - Stage 3: FUSHA - Efficacy and crop safety of A19649B against foliar diseases of corn in CN 2013, DACO: 10.2.3.3,IIIA 6.1.2
- 2571418 2013, COR13-10 - Stage 3: FUSHA - Efficacy and crop safety of A19649B against foliar diseases of corn in CN 2013, DACO: 10.2.3.3,IIIA 6.1.2
- 2571422 2013, COR13-09 - SYN545974: Evaluate Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2

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- 2571423 2013, COR13-12 - Stage 3: FUSHA - Efficacy and crop safety of A19649B against foliar diseases of corn in CN 2013, DACO: 10.2.3.3,IIIA 6.1.2
- 2571432 2014, COR14-03 - Development Fungicide: Evaluate Foliar Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571433 2014, COR14-04 - Development Fungicide: Evaluate Foliar Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571434 2014, SOY14-05 - Evaluate Development Fungicide for Foliar Diseases of Soybean (*Cercospora* sp.), DACO: 10.2.3.3,IIIA 6.1.2
- 2571435 2014, PEA14-02 - Evaluate Fusha LER for the control of mycoshaerella in peas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571436 2014, CHI14-03 - Evaluate Fusha LER for the control of ascochyta in chickpeas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571437 2014, SOY14-07 - Evaluate Development Fungicide for Foliar Diseases of Soybean (*Cercospora* sp.), DACO: 10.2.3.3,IIIA 6.1.2
- 2571440 2014, COR14-01 - Evaluate SYN545974 control of leaf diseases in corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571441 2014, COR14-05 - Development Fungicide: Evaluate Foliar Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571442 2014, SOY14-06 - Evaluate Development Fungicide for Foliar Diseases of Soybean (*Cercospora* sp.), DACO: 10.2.3.3,IIIA 6.1.2
- 2571443 2014, SOY14-04 - Evaluate Development Fungicide for Foliar Diseases of Soybean (*Cercospora* sp.), DACO: 10.2.3.3,IIIA 6.1.2
- 2571447 2014, BAR14-03 - Evaluate FUSHA LER for the control of leaf diseases in cereals, DACO: 10.2.3.3,IIIA 6.1.2
- 2571448 2014, CHI14-01 - Evaluate Fusha LER for the control of ascochyta in chickpeas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571449 2014, LEN14-03 - Evaluate Fusha LER for the control of anthracnose in lentils, DACO: 10.2.3.3,IIIA 6.1.2
- 2571450 2014, PEA13-01 - Evaluate Fusha LER for the control of mycoshaerella in peas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571454 2014, CHI14-02 - Evaluate Fusha LER for the control of ascochyta in chickpeas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571455 2014, LEN14-01 - Evaluate Fusha LER for the control of anthracnose in lentils, DACO: 10.2.3.3,IIIA 6.1.2
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- 2571456 2014, LEN14-02 - Evaluate Fusha LER for the control of anthracnose in lentils, DACO: 10.2.3.3,IIIA 6.1.2
- 2571457 2014, PEA14-01 - Evaluate Fusha LER for the control of mycoshaerella in peas, DACO: 10.2.3.3,IIIA 6.1.2
- 2571458 2014, SOY14-08 - Evaluate Development Fungicide for Foliar Diseases of Soybean (*Cercospora* sp.), DACO: 10.2.3.3,IIIA 6.1.2
- 2571459 2014, COR14-06 - Development Fungicide: Evaluate Foliar Disease Efficacy in Corn, DACO: 10.2.3.3,IIIA 6.1.2
- 2571460 2014, SOY15-02 - 2015 FUSHA+DFZ Soya Powdery mildew, DACO: 10.2.3.3,IIIA 6.1.2
- 2571461 2014, SOY15-03 - 2015 FUSHA+DFZ Soya Powdery mildew, DACO: 10.2.3.3,IIIA 6.1.2
- 2571462 2014, SOY15-05 - 2015 FUSHA+DFZ Soya Powdery mildew, DACO: 10.2.3.3,IIIA 6.1.2
- 2571463 2014, SOY15-04 - 2015 FUSHA+DFZ Soya Powdery mildew, DACO: 10.2.3.3,IIIA 6.1.2
- 2571467 2015, Supplemental Data to Support A21461 - Adepidyn (SYN545974), Azoxystrobin and Propiconazole, 300 g/L - Document M-III, Section 7 - Efficacy Data and Information - Canada, DACO: 1.1,10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.2.3.3,10.3.3,5.2,IIIA 3.1,IIIA 3.2,IIIA 3.3.1,IIIA 3.3.2,IIIA 3.3.3,IIIA 3.4,IIIA 3.5,IIIA 3.6,IIIA 3.7.1,IIIA 3.8.1,IIIA 3.8.2,IIIA 6.1.2
- 2696147 2013, COR13-03 - SYN545974: Evaluate Fusarium Stalk Rot Control in Corn, DACO: 10.2.3.3
- 2772863 2015, Evaluate SYN545974 control of Fusarium ear rot in corn, DACO: 10.2.3.3
- 2772864 2015, Evaluate SYN545974 control of Fusarium ear rot in corn, DACO: 10.2.3.3
- 2772866 2015, Evaluate SYN545974 control of Fusarium ear rot in corn, DACO: 10.2.3.3

B. Additional Information Considered

i) Published Information

1.0 Chemistry

2.0 Human and Animal Health

3.0 Environment

- 1573006 Atkins E.L., Kellum D., and Atkins K.W. 1981. Reducing Pesticide Hazards to Honey Bees: Mortality prediction techniques and integrated management strategies. Univ. Calif., Div. Agric. Sci. Leaflet 2883.

- 1918520 Cohen, S.Z., Creeger, S.M., Carsel, R.F., Enfield, C.G. 1984. Potential for pesticide contamination of groundwater resulting from agricultural uses. In: Krueger, R. F. And J.N. Seiber (eds.), Treatment and Disposal of Pesticide Wastes. Am. Chem. Soc., Washington, DC. ACS Symp. Ser. 259. pp. 297-325.
- 2439880 Crailsheim, K., Schneider, L.H.W, Hrassnigg, N., Bühlmann, G., Brosch, U.; Gmeinbauer, R., and B. Schöffmann. 1992. Pollen consumption and utilization in worker honeybees (*Apis mellifera carnica*): dependence on individual age and function. J. Insect Physiol., 38 (6): 409-419.
- 2439881 Crailsheim, K.; Hrassnigg, N.; Gmeinbauer, R.; Szolderits, M.J.; Schneider, L.H.W. and U. Brosch. 1993. Pollen utilization in non-breeding honeybees in winter. J. Insect Physiol. 39 (5): 369-373.
- 1918522 Fletcher JS; Nellessen JE; Pfleeger TG. 1994. Literature review and evaluation of the EPA food chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Toxicol. Chem. 13:1383 - 1391.
- 2037242 Goring, C.A.I., D.A. Laskowski, J.W. Hamaker and R.W. Meikle 1975. Principle of pesticide degradation in soil. In (Haque, R. and V.H. Freed, eds.) Environmental dynamics of pesticides. Plenum Press, New York, pp. 135–172.
- 1918524 Gustafson, D.I. 1989. Groundwater ubiquity score: a simple method for assessing pesticide leachability. Environmental Toxicology and Chemistry, 8: 339–357.
- 1918526 Hoerger, F. and Kenaga, E.E. 1972. Pesticide residues on plants: correlation of representative data as a basis for estimation of their magnitude in the environment. In (F. Coulston and F. Korte, eds.) Environmental quality and safety: chemistry, toxicology and technology. Vol. I. Global aspects of chemistry, toxicology and technology as applied to the environment. Georg Thieme Publishers, Stuttgart, and Academic Press, New York. pp. 9–28.
- 1918527 Kenaga, E.E. 1973. Factors to be considered in the evaluation of the toxicity of pesticides to birds in their environment. In (F. Coulston and F. Korte, eds.) Environmental quality and safety: global aspects of chemistry, toxicology and technology as applied to the environment. Vol. II. Georg Thieme Publishers, Stuttgart, and Academic Press, New York. pp. 166–181.
- 2439884 Koch H. and Weisser P. 1997. Exposure of honey bees during pesticide application under field conditions. Apidologie, 28: 439-447.
- 2024011 McCall PJ, Laskowski DA, Swann RL, Dishburger HJ. 1981. Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. In Test Protocols for Environmental Fate and Movement of Toxicants. Proceedings of AOAC Symposium, AOAC, Washington D.C.

McEwen F.L. and G.R. Stephenson, 1979. The use and significance of pesticides in the environment. John Wiley and Sons Inc. Toronto. 282 pp.

1918529 Nagy, KA, 1978. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monograph. Vol.57, No.2, pp.111-128.

2439883 Rortais A., Arnold G., Halm M.P., and Touffet-Briens F. 2005. Modes of exposure of honeybees to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36: 71-83.

US EPA, 1985a. Hazard Evaluation Division, Standard Evaluation Procedure, Acute Toxicity Test for Freshwater Invertebrates. EPA 540/9-85-005. June, 1985. U.S. EPA, Washington, D.C.

US EPA, 1985b. Hazard Evaluation Division, Standard Evaluation Procedure, Acute Toxicity Test for Freshwater Fish. EPA 540/9-85-006. June, 1985. U.S. EPA, Washington, D.C.

US EPA, 1985c. Hazard Evaluation Division, Standard Evaluation Procedure, Avian Single-dose Oral LD50. EPA 540/9-85-001. June, 1985. U.S. EPA, Washington, D.C.

US EPA, 1985d. Hazard Evaluation Division, Standard Evaluation Procedure, Avian Dietary LC50 Test. EPA 540/9-85-008. June, 1985. U.S. EPA, Washington, D.C.

4.0 Value

- 2722445 Boland, G. J. and Hall, R., 1994, Index of plant hosts of *Sclerotinia sclerotiorum*, Canadian Journal of Plant Pathology, 16:2, 93 - 108, DACO: 10.2.2
- 2722446 Purdy, L. H., 1979, *Sclerotinia sclerotiorum*: History, Diseases and Symptomatology, Host Range, Geographic Distribution, and Impact, Phytopathology, 69:8, 875 - 880, DACO: 10.2.2