Proposed Registration Decision PRD2013-09

Cyantraniliprole

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Overview

Proposed Registration Decision for Cyantraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dupont Cyazypyr Technical Insecticide and Cyantraniliprole Technical and the end-use products Dupont Verimark Insecticide, Dupont Benevia Insecticide, Dupont Lumiderm Insecticide Treatment, Dupont Exirel Insecticide, A17960A 600FS, and A17960B 600FS, containing the technical grade active ingredient cyantraniliprole. A16901B 40WG Insecticide and Mainspring Insecticide, containing both cyantraniliprole and thiamethoxam, are proposed for conditional registration based on the conditional registration of thiamethoxam. The end-use products are proposed to control a variety of insect pests on fruits and vegetables, oilseeds, greenhouse ornamentals and outdoor ornamentals.

Subsequent to the completion of the risk assessment for cyantraniliprole the following product name changes were made; the brand name for A16901B 40WG Insecticide is now Minecto Duo 40WG, the brand name for A17960A 600FS is now Fortenza and the name for A17960B 600FS is Fortenza Colourless.

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

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Dupont Cyazypyr Technical Insecticide and Cyantraniliprole Technical and the end-use products listed above.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on cyantraniliprole, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on cyantraniliprole, 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 section of this consultation document.

What Is Cyantraniliprole?

Cyantraniliprole is a diamide insecticide, Mode of Action (MoA) Group 28. Diamides affect ryanodine receptors in insect muscle, causing paralysis. Formulated as DuPont Verimark Insecticide, DuPont Benevia Insecticide, DuPont Lumiderm Insecticide Seed Treatment, DuPont Exirel Insecticide, A17960A 600FS, A17960B 600FS, A16901B 40WG Insecticide and Mainspring Insecticide and applied as a seed treatment, as a foliar spray or as a soil drench, it controls, suppresses or reduces damage caused by listed insect pests of field, tree fruit, tree nut and bushberry crops, and greenhouse and outdoor ornamentals. A16901B 40WG and Mainspring Insecticides are formulated with the neonicotinoid insecticide thiamethoxam.

Health Considerations

Can Approved Uses of Cyantraniliprole Affect Human Health?

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

Potential exposure to cyantraniliprole (also known as cyazypyr) may occur through the diet (food and water) or when handling and applying the 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

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient cyantraniliprole was of low acute toxicity via the oral, dermal and inhalation routes. It was non-irritating to the skin, non- to minimally irritating to the eye and did not cause an allergic skin reaction.

Results of testing in laboratory animals with the various end-use products containing cyantraniliprole revealed the following:

DuPont Verimark Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to the skin and eyes and did not cause an allergic skin reaction.

DuPont Benevia Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was slightly irritating to skin and minimally irritating to eyes. It demonstrated the potential to cause an allergic skin reaction and, consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the label.

DuPont Lumiderm Insecticide Seed Treatment was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin and minimally irritating to eyes and did not cause an allergic skin reaction.

DuPont Exirel Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. Moderate irritation to the skin was identified and, consequently, the hazard statement "WARNING-SKIN IRRITANT' is required on the label. It was minimally irritating to the eyes. The potential for an allergic skin reaction was identified and, therefore, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the label.

A17960A 600FS was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin and minimally irritating to eyes. It did not cause an allergic skin reaction.

A17960B 600FS was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin. Mild irritation to eyes was identified and, consequently, the hazard statement "CAUTION-EYE IRRITANT" is required on the label. It did not cause an allergic skin reaction.

A16901B 40WG Insecticide and Mainspring Insecticide were of low acute toxicity via the oral, dermal, and inhalation routes of exposure. They were not irritating to the skin and were minimally irritating to the eyes. They did not cause an allergic skin reaction.

Cyantraniliprole did not cause cancer in animals and did not damage genetic material. There was no indication that cyantraniliprole caused damage to the nervous system or immune system. Cyantraniliprole did not cause birth defects in animals and there were no effects on the ability to reproduce. Health effects in animals given repeated doses of cyantraniliprole included effects on the liver, thyroid and adrenal glands. The evidence indicated that the thyroid effects were caused by alteration of liver enzymes and that cyantraniliprole is not directly toxic to the thyroid gland. Effects were noted in the adrenal glands but were not considered to be adverse in nature.

When cyantraniliprole was given to pregnant animals, reduced fetal body weight was observed at doses that were clearly toxic to the mother as demonstrated by reduced body weight, mortality, increased incidence of early deliveries and abortion. In reproductive toxicity testing in animals, reductions in offspring body weight were observed at doses that were toxic to the mother as reflected by effects in the thyroid gland. These results indicate that the young do not appear to be more sensitive to cyantraniliprole than the adult animal.

The risk assessment protects against the effects of cyantraniliprole by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and children, the subpopulation which would ingest the most cyantraniliprole relative to body weight, are expected to be exposed to less than 43% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from cyantraniliprole is not of concern for all population sub-groups.

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 cyantraniliprole on a range of representative commodities were deemed acceptable. Residue trials conducted throughout the United States using cyantraniliprole in/on citrus fruits, cotton, and in the European Union on grapes and olives were also acceptable for these imported commodities.

The MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Risks in Residential and Other Non-Occupational Environments

Bystander exposure should be negligible since the potential for drift is expected to be minimal.

Applications are limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity, such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Occupational Risks From Handling Cyantraniliprole Products

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

Farmers and custom applicators who mix, load or apply cyantraniliprole as well as field workers re-entering freshly treated fields, nurseries and greenhouses, and workers in commercial and on-farm seed treatment facilities can come in direct contact with cyantraniliprole residues on the skin or through inhalation. Therefore, the labels recommend a variety of personal protective equipment (PPE) depending on the use scenario/end use product, as well as various mitigation measures such as closed seed treatment systems and closed cab planting.

The labels also require that workers do not enter treated areas for 12 hours after application. Taking into consideration these label statements, the precautionary measures, the number of applications and the expectation of the exposure period for handlers and workers, it was determined that the risk to these individuals is not a concern for most uses/end-use products.

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 Cyantraniliprole Is Introduced Into the Environment?

Cyantraniliprole may pose a risk to beneficial arthropods, bees and aquatic organisms.

Cyantraniliprole can enter the environment when it is used as an insecticide for control of a large number of pests in a variety of crops. Cyantraniliprole can be applied as a seed treatment, by foliar spray application, and also soil application. Cyantraniliprole is systemic and, therefore, can also reach pollen and nectar through the movement of cyantraniliprole inside the plant. In both soil and water cyantraniliprole transforms quickly. There are a total of eight major transformation products formed in soil and/or water. The degradation of the major transformation products ranges from not persistent to persistent. Cyantraniliprole and its transformation products have the potential to leach through the soil profile to enter ground water.

The two end-use products, A16901B 40WG Insecticide and Mainspring Insecticide, contain both cyantraniliprole and thiamethoxam. The fate and ecotoxicity information pertaining to thiamethoxam can be found under Evaluation Report ERC2007-01, *Thiamethoxam*.

Overall, cyantraniliprole and its major transformation products present a negligible risk to soil dwelling organisms, aquatic plants, algae, (freshwater and marine), fish (freshwater and marine), some species of aquatic invertebrates, and amphibians. However, cyantraniliprole may affect some species of aquatic invertebrates from soil and foliar applications. Cyantranilprole may also affect beneficial arthropods, and bees from foliar applications.

In order to mitigate the potential effects of cyantraniliprole to aquatic organisms, buffer zones and reduction of run-off are required on the label. In order to mitigate the potential effects of cyantraniliprole to terrestrial organisms (beneficial arthropods and bees), foliar applications are limited while bees are actively foraging, and reduction of drift are required on the label.

Value Considerations

What Is the Value of DuPont Verimark Insecticide?

DuPont Verimark Insecticide controls or reduces early season damage by certain insect pests of potato and brassica vegetables.

Applied to seed pieces or in furrow at planting of potatoes, DuPont Verimark Insecticide provides control of Colorado potato beetle and spring adults of potato flea beetle. Applied in furrow, in transplant water or as a banded surface application at transplanting, DuPont Verimark Insecticide provides control of imported cabbageworm, diamondback moth and cabbage looper and reduces early season damage by flea beetles and swede midge on brassica vegetables.

Seed piece treatment and soil application are new methods of application for active ingredients from MoA Group 28.

What Is the Value of DuPont Benevia Insecticide?

DuPont Benevia Insecticide provides control or suppression of a variety of insect pests of potato and oilseed crops.

Applied to foliage of potatoes by ground or aerial application, DuPont Benevia Insecticide provides control or suppression of Colorado potato beetle, European corn borer, variegated cutworm and aphids. Applied to foliage of oilseed crops by ground application, DuPont Benevia Insecticide provides control or suppression of diamondback moth, bertha armyworm, cabbage looper, cabbage seedpod weevil, cutworms, imported cabbageworm, sunflower head moth and swede midge. Cyantraniliprole is a new MoA for use against the pests on oilseeds. There are no alternative active ingredients registered against sunflower head moth and swede midge on oilseed crops.

This product can contribute to resistance management because use on oilseed crops is new for active ingredients from MoA Group 28.

What Is the Value of DuPont Lumiderm Insecticide Seed Treatment?

DuPont Lumiderm Insecticide Seed Treatment provides protection from early season damage by certain insect pests of canola, rapeseed and oilseed mustard.

Applied to seed of canola, rapeseed and oilseed mustard, DuPont Lumiderm Insecticide Seed Treatment provides protection from early season feeding damage by flea beetles and cutworms. Cyantraniliprole is a new MoA for use against the pests on these crops.

This product can contribute to resistance management because use on oilseed crops is new for active ingredients in MoA Group 28. Seed treatment is a new application method for this group.

What Is the Value of DuPont Exirel Insecticide?

DuPont Exirel Insecticides provides control or suppression of a wide variety of insect pests of field vegetables, berries, tree fruits and nuts.

Applied to the foliage of tuberous and corm, leafy, brassica, fruiting and cucurbit vegetables by ground or aerial application, DuPont Exirel Insecticide provides control or suppression of Colorado potato beetle, cabbage looper, imported cabbageworm, diamondback moth, corn earworm/tomato fruitworm, cutworms, armyworms, hornworms, swede midge, dipteran leafminers and aphids. Applied to the foliage of bulb vegetables by ground or aerial application, it provides suppression of thrips. Applied to the foliage of bushberries by ground or aerial application, DuPont Exirel Insecticide provides control or suppression of blueberry aphid, blueberry gall midge, blueberry maggot, cranberry fruitworm, plum curculio, Japanese beetle and leafrollers. Applied to the foliage of pome fruit, stone fruit, and nut trees by ground application, it provides control of leafrollers, codling moth, European fruit moth, apple maggot, peach twig borer, plum curculio, European apply sawfly, Japanese beetle, tentiform leafminers, leafhoppers and aphids. There are no alternative active ingredients registered against eyespotted budmoth and peach twig borer on tree nuts.

Cyantraniliprole is a new MoA for use against aphids on tuberous and corm vegetables, thrips on bulb vegetables, aphids and dipteran leafminers on leafy and fruiting vegetables, aphids and dipteran leafminers on brassica vegetables, aphids, corn earworm and dipteran leafminers on cucurbit vegetables, apple maggot, European apple sawfly, eyespotted budmoth, tufted apple budmoth, green peach aphid, rosy apple aphid, Japanese beetle, plum curculio and white apple leafhopper on pome fruit, cherry fruit flies, eyespotted budmoth, green peach aphid, plum aphid, Japanese beetle and plum curculio on stone fruit, blueberry aphid, blueberry gall midge (cranberry tipworm), blueberry maggot, eyespotted budmoth, Japanese beetle, leafrollers and plum curculio on bushberries, and eyespotted budmoth, oriental fruit moth and peach twig borer on tree nuts.

This product can contribute to resistance management because use on bulb vegetables is new for active ingredients from MoA Group 28.

This product is a replacement for uses of older chemistries, such as azinphos-methyl and endosulfan which are being phased out, in pome fruits, stone fruits, blueberry and bulb vegetables.

What Is the Value of A17960A 600FS and A17960B 600FS?

A17901A 600FS and A17901B 600FS provide early season control of Colorado potato beetle.

Applied to potato seed pieces, A17890A 600FS and A17960B 600FS provide early season control of Colorado potato beetle, a key pest of potato.

Seed piece treatment is a new method of application for active ingredients from MoA Group 28.

What Is the Value of A16901B 40WG Insecticide?

A16901B 40WG Insecticide provides control or suppression of a variety of insect pests of field vegetable crops.

Applied to the soil at planting or transplanting, A16901B 40WG Insecticide provides control or suppression of Colorado potato beetle, flea beetles, dipteran leafminers, armyworms, cabbage loopers, corn earworm, diamondback moth, imported cabbageworm, cucumber beetles, aphids and leafhoppers on potato and leafy, brassica, fruiting and cucurbit vegetables.

Cyantraniliprole is a new MoA for use against potato leafhopper on potatoes, aphids, dipteran leafminers, flea beetles and leafhoppers on leafy vegetables, aphids, dipteran leafminers, flea beetles and thrips on brassica vegetables, aphids, dipteran leafminers, flea beetles, leafhoppers, potato psyllids, thrips and tomato fruitworm on fruiting vegetables, and aphids, cucumber beetles dipteran leafminer, flea beetles and thrips on cucurbit vegetables.

A16901B 40WG Insecticide contains the new active ingredient cyantraniliprole combined with the active ingredient thiamethoxam. Thiamethoxam alone is registered for soil application to all the supported crops. For soil application, more pests are supported for the premix than for either active ingredient alone.

What Is the Value of Mainspring Insecticide?

Mainspring Insecticide provides control or suppression of a variety of insect pests of greenhouse and outdoor ornamentals.

Applied to the foliage of greenhouse and outdoor ornamentals, Mainspring Insecticide provides control or suppression of aphids, lace bugs, leafhoppers, mealy bugs, psyllids, soft scales, black vine weevil, dipteran leafminers and thrips. Applied as a soil drench to greenhouse ornamentals, Mainspring Insecticide provides control or suppression of aphids, mealybugs, whiteflies, dipteran leafminers, thrips and fungus gnats. Cyantraniliprole is a new MoA for use against the pests on ornamentals.

Mainspring Insecticide contains two active ingredients, cyantraniliprole and thiamethoxam. Cyantraniliprole alone is not proposed for registration for use on ornamentals, and thiamethoxam alone is not registered for use on greenhouse ornamentals. More pests and crops are supported for the premix than for either active ingredient alone.

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 labels of the proposed end-use products to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health
Because there is a concern with workers coming into direct contact with cyantraniliprole on the skin or through inhalation, additional PPE and mitigation measures are recommended (e.g., closed seed treatment systems and closed cab planting).

Environment

- *Terrestrial*: DuPont Exirel Insecticide and DuPont Benevia Insecticide cannot be sprayed within a maximum of 15 metres of susceptible non-target terrestrial plant species. Mainspring Insecticide cannot be sprayed within 1 metre of susceptible non-target terrestrial plant species.
- *Aquatic*: DuPont Exirel Insecticide and DuPont Benevia Insecticide cannot be sprayed within a maximum of 5 metres from freshwater aquatic habitats. Mainspring Insecticide cannot be sprayed within a maximum of 1 metre from freshwater aquatic habitats.

- Hazard and risk based label statements for toxicity will be required for predators and parasites, bees and aquatic organisms on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide, DuPont Verimark Insecticide, and A16901B 40WG labels, and for plants on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide labels.
- Run-off reduction statements will be required on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide, DuPont Verimark Insecticide, and A16901B 40WG labels.
- Drift reduction statements will be required on the DuPont Exirel Insecticide, DuPont Benevia Insecticide and Mainspring Insecticide labels.

Next Steps

Before making a final registration decision on cyantraniliprole, the PMRA will consider all 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

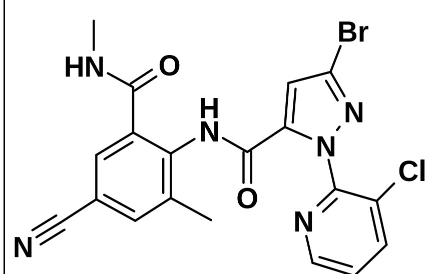
When the PMRA makes its registration decision, it will publish a Registration Decision on cyantraniliprole (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application,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

Science Evaluation

Cyantraniliprole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	**Cyantraniliprole**
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide
2. Chemical Abstracts Service (CAS)	3-bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide
CAS number	736994-63-1
Molecular formula	$C_{19}H_{14}BrClN_6O_2$
Molecular weight	473.7 g/mol
Structural formula	
Purity of the active ingredient	96.7 % nominal

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

Technical Product—CyantraniliproleTechnical (DuPont Cyazypyr Technical Insecticide)

Property	Result
Colour and physical state	Off-white fine powder
Odour	No characteristic odour
Melting range	217 – 219 °C
Boiling point or range	Decomposes at 350 °C prior to boiling
Density	1.38 g/cm^{-3}
Vapour pressure at 20°C	5×10^{-12} mPa (estimated)
Henry's law constant at 20°C	1.7×10^{-18} atmosphere•m^3/mole

Property	Result
Ultraviolet (UV)-visible spectrum	Neutral methanol: λmax = 205nm , 267nm; ε = 7801 L/(mol cm) at 290 nm Acidic methanol: λmax = 204nm , 264nm; ε = 7267 L/(mol cm) at 290 nm Basic methanol: λmax = 222nm , 272nm, 312 nm; ε = 12249 L/(mol cm) at 290 nm
Solubility in water at 20°C	pH — solubility Purified water — 14.2 mg/L pH 4 buffer — 17.4 mg/L pH 7 buffer — 12.3 mg/L pH 9 buffer — 5.9 mg/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — Solubility Acetone — 0.654 Dichloromethane — 0.505 Methanol — 0.473 Acetonitrile — 0.245 Ethyl Acetate — 0.196 n-Octanol — 0.079 o-Xylene — 0.029 n-Hexane — 6.7×10^{-6}
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} distilled water — 1.97 pH 4 buffer — 1.97 pH 7 buffer — 2.02 pH 9 buffer — 1.74
Dissociation constant (pK_a)	pKa = 8.80
Stability (temperature, metal)	Stable at elevated temperatures, and at elevated temperatures in contact with iron and aluminum metal and their acetate salts.

End-Use Product—DuPont Verimark Insecticide

Property	Result
Colour	Off-white
Odour	No odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	200 g/L
Container material and description	High Density Polyethylene (HDPE) plastic bottles, jugs, drums, totes, tanks
Density	1.068 g/mL
pH of 1% dispersion in water	7.3
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage at 54 °C for fourteen days and at ambient temperatures for two years.
Corrosion characteristics	Non-corrosive to HDPE

Explodability	Not explosive

End-Use Product—DuPont Benevia Insecticide

Property	Result
Colour	Off-white
Odour	Mild oily characteristic odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	100 g/L
Container material and description	HDPE plastic bottles, jugs, drums, totes, tanks
Density	0.978 g/mL
pH of 1% dispersion in water	5.1
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage at 54 °C for fourteen days and at ambient temperatures for two years.
Corrosion characteristics	Non-corrosive to HDPE
Explodability	Not explosive

End-Use Product— DuPont Lumiderm Insecticide Seed Treatment

Property	Result
Colour	Off-white
Odour	Paint like
Physical state	Liquid
Formulation type	Suspension
Guarantee	625 g/L
Container material and description	Metal or plastic bottles, jugs, drums, totes, tanks
Density	1.24 g/mL
pH of 1% dispersion in water	6.97
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage at ambient temperature for one year.
Corrosion characteristics	Non-corrosive to HDPE
Explodability	Not explosive

End-Use Product—DuPont Exirel Insecticide

Property	Result
Colour	Off-white
Odour	Mild phenyl compound odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	100 g/L

Property	Result
Container material and description	HDPE plastic bottles, jugs, drums, totes, tanks
Density	0.982 g/mL
pH of 1% dispersion in water	5.6
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage at 54 °C for fourteen days and at ambient temperatures for two years.
Corrosion characteristics	Non-corrosive to HDPE
Explodability	Not explosive

End-Use Product—A17960A 600FS

Property	Result
Colour	Pink
Odour	Chalky
Physical state	Liquid
Formulation type	Suspension
Guarantee	600 g/L
Container material and description	HDPE plastic jugs or totes
Density	1.255 g/cm^3
pH of 1% dispersion in water	4.7
Oxidizing or reducing action	Compatible with oxidizing and reducing agents
Storage stability	Stable on storage in HDPE containers at 54 °C for fourteen days and at 20°C for one year.
Corrosion characteristics	Not corrosive to HDPE containers or stainless steel
Explodability	Not explosive

End-Use Product— A17960B 600FS

Property	Result
Colour	Cream coloured
Odour	Chalky
Physical state	Liquid
Formulation type	Suspension
Guarantee	600 g/L
Container material and description	HDPE plastic jugs or totes
Density	1.253 g/cm^3
pH of 1% dispersion in water	5.7
Oxidizing or reducing action	Compatible with oxidizing and reducing agents
Storage stability	Stable on storage in HDPE containers at 54 °C for fourteen days and at 20°C for one year.
Corrosion characteristics	Not corrosive to HDPE containers or stainless steel
Explodability	Not explosive

End-Use Product—A16901B

Property	Result
Colour	Beige brown
Odour	Weak loamy
Physical state	Solid
Formulation type	Wettable Granules
Guarantee	20 % Cyantraniliprole 20 % Thiamethoxam
Container material and description	HDPE plastic jug or tote, paper bags
Density	0.557 g/mL (bulk density)
pH of 1% dispersion in water	9.5
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage in HDPE or PE containers, and laminated paper/plastic bags at 54°C for fourteen days; and in HDPE at 20°C for one year.
Corrosion characteristics	Not corrosive to HDPE containers, stainless steel, sheet steel, galvanized sheet metal or tin plate
Explodability	Not explosive

End-Use Product—Mainspring Insecticide

Property	Result
Colour	Beige brown
Odour	Weak loamy
Physical state	Solid
Formulation type	Wettable Granules
Guarantee	20 % Cyantraniliprole 20 % Thiamethoxam
Container material and description	HDPE plastic jug or tote, paper bags
Density	0.557 g/mL (bulk density)
pH of 1% dispersion in water	9.5
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage in HDPE or PE containers, and laminated paper/plastic bags at 54°C for fourteen days; and in HDPE at 20°C for one year.
Corrosion characteristics	Not corrosive to HDPE containers, stainless steel, sheet steel, galvanized sheet metal or tin plate
Explodability	Not explosive

1.3 Directions for Use

DuPont Verimark Insecticide
Apply in furrow at 6.75–9.00 mL product/100 m of row (750–1000 mL product/ha based on 90-cm row spacing) to control Colorado potato beetle and spring adults of potato flea beetle on potato.

Apply to potato seed pieces at 45 mL product/100 kg of seed pieces (1000 mL product/ha based on 2200 kg/ha planting rate) to control Colorado potato beetle and spring adults of potato flea beetle on potato.

Apply to brassica vegetable transplants as an in-furrow spray, in the transplant water, or as a banded surface application at the time of transplanting at 750–1000 mL product/ha for control of imported cabbageworm, diamondback moth, and cabbage looper and reduction of early season damage by flea beetles and swede midge on brassica vegetables.

DuPont Benevia Insecticide
Apply as a foliar spray using ground or aerial application on potatoes and oil seed crops.

Apply at 500–1500 g product/ha on potatoes for control of aphids, Colorado potato beetle, European corn borer and variegated cutworm.

Apply at 250–1000 g product/ha on oilseed crops for control of cutworms, diamondback moth, bertha armyworm, cabbage looper, imported cabbageworm, sunflower head moth and cabbage seedpod weevil and suppression of swede midge.

DuPont Lumiderm Insecticide Seed Treatment
Apply at 480–960 mL product/100 kg seed for early season protection from cutworm feeding damage to canola, rapeseed and oilseed mustard.

Apply at 960–1600 mL product/100 kg seed for early season protection from flea beetle feeding damage to canola, rapeseed and oilseed mustard.

DuPont Exirel Insecticide
Apply as a foliar spray using ground application on all listed crops. Aerial application may be used on bushberries and on bulb, leafy, brassica, fruiting, cucurbit and tuberous and corm vegetables.

Apply at 250–1500 mL product/ha, depending on the target pest, on tuberous and corm vegetables, leafy vegetables, brassica vegetables, fruiting vegetables and cucurbit vegetables for control or suppression of aphids, listed lepidopteran larvae, Colorado potato beetles, swede midges and dipteran leafminers.

Apply at 1000–1500 mL product/ha on bulb vegetables for suppression of thrips.

Apply at 500–1500 mL product/ha, depending on the target pest, on bushberries for control of blueberry aphid, blueberry gall midge, cranberry fruitworm, eyespotted bud moth, leafrollers, plum curculio and Japanese beetle and suppression of blueberry maggot.

Apply at 500–1500 mL product/ha, depending on the target pest, on pome fruits, stone fruits, and tree nuts for control of aphids, leafrollers, codling moth, oriental fruit moth, tufted apple bud moth, peach twig borer, apple maggot, plum curculio, European apple sawfly, Japanese beetle, white apple leafhopper and tentiform leafminers.

Refer to the product label for complete details of the directions for use of DuPont Exirel Insecticide.

A17960A 600FS and A17960B 600FS
Apply A17960A 600FS or A17960B 600FS at a 10.0–22.5 mL product/100 kg seed for early season control of Colorado potato beetle.

A16901B 40WG Insecticide
Apply as an in-furrow spray at seeding or transplant or a narrow surface band above the seedline during planting. For surface-banded applications, incorporate to the seeding depth with sufficient irrigation within 24 hours.

Apply at 750 g product/ha on leafy vegetables to control aphids, dipteran leafminer and leafhoppers; early season control of cabbage looper; early season suppression of flea beetles and reduce damage caused by beet armyworm, cabbage looper, corn earworm and fall armyworm.

Apply at 750 g product/ha on brassica vegetables to control aphids, flea beetles and dipteran leafminer, reduce damage caused by beet armyworm, corn earworm, fall armyworm and yellowstriped armyworm, and for early season control of cabbage looper, diamondback moth and imported cabbageworm and early season suppression of thrips and flea beetles.

Apply at 750 g product/ha on cucurbit vegetables for control of aphids, dipteran leafminer and leafhoppers and early season suppression of cucumber beetles, flea beetles and thrips.

Apply at 440–750 g product/ha on fruiting vegetables to control aphids, Colorado potato beetle, leafhoppers and dipteran leafminer, reduce damage caused by beet armyworm, potato psyllid, fall armyworm, tomato fruitworm and yellowstriped armyworm, and for early season control of cabbage looper and for early season suppression of thrips and flea beetles.

Apply at 440–700 g product/ha on potatoes to control aphids, Colorado potato beetle, flea beetles and potato leafhopper.

Mainspring Insecticide
Apply 37.5–75.0 g product/100 L of water as a foliar treatment for outdoor and greenhouse ornamentals. For outdoor ornamentals apply a maximum of one application at 75 g product/100 L or apply a maximum of two applications at 37.5 g product/100 L with a minimum of 14 days between applications. For greenhouse ornamentals apply a maximum of two applications at

either 37.5 or 75.0 g product/100 L with a minimum of 14 days between applications. Foliar applications to outdoor ornamentals control aphids, black vine weevil, dipteran leafminer, lace bugs, leafhoppers, mealybugs, psyllids and soft scales, and suppress thrips. Foliar applications to greenhouse ornamentals control aphids, dipteran leafminer, mealybugs and soft scales, and suppress thrips and whiteflies.

Apply 50–75 g product/100 L of water as a drench treatment for greenhouse ornamentals. Apply a maximum of one application. Drench applications to greenhouse ornamentals control aphids, dipteran leafminer, fungus gnats, mealybugs, soft scales, root aphids and whiteflies and suppress thrips.

1.4 Mode of Action

Cyantraniliprole is in MoA Group 28, active ingredients that affect ryanodine receptors in insect muscle. Insects exposed to cyantraniliprole become paralysed, stop feeding and die. Cyantraniliprole is active through both ingestion and contact routes; however, it is more potent via ingestion. It is mobile in the xylem of plants, showing systemic activity via root uptake but only limited systemic activity via foliar application.

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 the impurities in cyantraniliprole technical 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 ingredient 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 spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

Enforcement Method, DuPont-1187, a high pressure liquid chromatography with tandem mass spectrometry (HPLC-MS/MS), for the analysis of cyantraniliprole and its metabolites (IN-N7B69, IN-JCZ38, IN-K7H19, IN-MYX98, IN-MLA84 and IN-J9Z38) in plants and processed commodities, was validated using grapes, apples, peaches, tomatoes, almonds (nutmeat), lettuce, wheat grain, wheat straw, potatoes, lemons, rape seed, tomato paste and sun-dried tomato. The limit of quantitation (LOQ) is 0.01 ppm for each of the analytes. Samples were extracted with a 9:1 acetonitrile:water solution. When matrix effects were observed, the quantification was performed using matrix matched bracketing standard response. Acceptable recoveries (70–120%) of cyantraniliprole and analytes were obtained in plant and processed commodities at spiking levels that bracket the expected residues. The proposed enforcement method was successfully validated by an independent laboratory using almonds, onions, tomato paste and sun-dried tomatoes. Adequate extraction efficiencies were demonstrated in plant matrices using radiolabelled samples from metabolism studies and confined rotational crop study such as wheat (grain, hay), beet (foliage), and lettuce.

The HPLC-MS/MS method, DuPont-1552, for the determination of cyantraniliprole, IN-HGW87, IN-N7B69, IN-K7H19, IN-JCZ38, IN-MYX98, IN-J9Z38 and IN-MLA84 in livestock tissues, milk and eggs, involved extraction of the residues with acetonitrile (*ca.* 5:1 by volume) and then partitioning against hexane. The LOQ is 0.01 ppm for all analytes in all matrices. The method fulfills the requirements with regards to specificity, accuracy and precision. Acceptable recoveries (70–120%) of cyantraniliprole and analytes were obtained in animal matrices, including eggs, and milk, at spiking levels that bracket the expected residues. The method was successfully validated by independent laboratory using kidney, muscle, and milk. The extraction efficiency was successfully demonstrated with samples of liver, muscle, milk, egg white, and egg yolk from livestock metabolism studies that were subjected to the extraction procedures of the proposed enforcement analytical method.

Cyantraniliprole was subjected to the United States Food and Drug Administration multi-residue methodologies (MRM) protocols A through F. The results indicate that cyantraniliprole residues cannot be analyzed using the United States Food and Drug Administration MRM; however, the European MRM, DFG-19, is adequate.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Cyantraniliprole belongs to the anthranilic diamide class of pesticides, which control insects through unregulated activation of ryanodine receptor channels leading to internal calcium store depletion that impairs regulation of muscle contraction. Insects exposed to the anthranilic diamide class of pesticides exhibit general lethargy and muscle paralysis followed ultimately by death. Mammalian ryanodine receptors are substantially less sensitive to the effects of anthranilic diamides than the insect ryanodine receptors.

A detailed review of the toxicological database for cyantraniliprole was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to cyantraniliprole.

Following oral dosing in rats with radiolabelled cyantraniliprole, absorption was rapid and high (63–80 % of the administered dose (AD)) following a single low dose, and slightly lower (31–40% of the AD) following a single high dose administration in both sexes. Excretion following a single low dose occurred primarily via the urine. When animals were exposed to a single high dose, the primary route of excretion was feces. Regardless of dosing regimen, a significant amount of radiolabel was excreted via the bile (10–37%). Excretion did not occur via respired air.

Following single dose administration, radioactivity was quickly and widely distributed with the highest concentrations of radioactivity in the liver, gastro-intestinal tract, thyroid, lungs, pituitary and adrenal glands. At 168 hours, concentrations in most tissues dropped markedly, but remained highest in plasma, thyroid and adrenal glands and, in females only, fat. Absorption was slightly higher in males than females, but male plasma half-lives were shorter. However, in females, tissue levels were higher, and half-lives were longer than in males, suggesting a higher internal dose in females. This was also observed following repeat dosing, where plasma and fat levels in females were four-times and twenty-times higher, respectively, than levels in males.

Following repeat dosing, plasma levels were six times the levels reached in the single dose study. In females, the highest levels were present in plasma, fat, whole blood and liver. Following cessation of dosing, tissue half-lives ranged from 2.6 days in fat to 5.6/5.7 days in plasma/whole blood. Based on this half-life value and the fact that tissue levels were still rising steadily at day 14, it is likely that peak tissue concentration would be reached after approximately 30 days of dosing.

Cyantraniliprole was extensively metabolized mainly via methylyphenyl and N-methyl carbon hydroxylation. Further metabolism of the hydroxylated metabolites included N-demethylation, nitrogen-to carbon cyclization with loss of a water molecule, oxidation of alcohol to carboxylic acid, amide bridge cleavage, amine hydrolysis, and o-glucuronidation.

Following a single dose, ten metabolites were identified in urine and 13 metabolites were identified in feces. The primary metabolites identified were IN-N7B69 (urine only), Bis-OH-HGW86, IN-DBC80 (feces only), and IN-MYX98. In bile, numerous metabolites were identified, the primary being glucuronides of IN-MLA84, IN-N7B69, IN-NBC94 and unresolved metabolite m/z 647-2. In urine, the parent compound comprised a small portion of the AD (0.3–5%); however, it was more prevalent in feces: 5–15% at low dose and 55–66% at the high dose. No parent was found in bile. Following repeat dosing, metabolites in urine and feces were similar to those identified following single dose administration, although levels of IN-MLA84 increased with time.

Additional plasma assessments were conducted in the 90-day and 1-year oral toxicity studies in rats, mice and dogs. In rodents, the metabolite IN-MLA84 was detected at levels that were orders of magnitude greater than the parent compound, plateauing in plasmas at doses of 300–400 ppm in diet and reaching levels equivalent to 100–400 µg/mL in plasma. In dogs, the parent compound was the dominant component found in plasma and IN-MLA84 was only a minor component.

When tested in the rat, technical cyantraniliprole was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to the skin and was non-irritating to minimally irritating to the eyes of rabbits. It was not considered a potential skin sensitizer when tested on guinea pigs (Buehler, Maximization methods) and mice (LLNA).

DuPont Verimark Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was not irritating to the skin or the eyes of rabbits. It was not considered to be a potential skin sensitizer when tested on guinea pigs (Buehler, Maximization methods) and mice (LLNA).

DuPont Benevia Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was slightly irritating to the skin and minimally irritating to the eyes of rabbits. It was considered to be a potential skin sensitizer when tested on guinea pigs (Buehler, Maximization methods) and mice (LLNA).

DuPont Lumiderm Insecticide Seed Treatment was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was not irritating to the skin and was minimally irritating to the eyes of rabbits. It was not considered to be a potential skin sensitizer when tested on guinea pigs (Buehler, Maximization methods) and mice (LLNA).

DuPont Exirel Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was moderately irritating to the skin and minimally irritating to the eyes of rabbits. It was considered to be a potential skin sensitizer when tested on guinea pigs (Maximization method).

A17960A 600FS (also known as A17960A ST Insecticide) was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was not irritating to the skin and minimally irritating to the eyes of rabbits. It was not considered to be a potential skin sensitizer when tested on guinea pigs (Buehler method).

A17960B 600FS (also known as A17960B ST Insecticide) was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was not irritating to the skin and mildly irritating to the eyes of rabbits. It was not considered to be a potential skin sensitizer when tested on guinea pigs (Buehler method).

A16901B 40WG Insecticide and Mainspring Insecticide were of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. They were not irritating to the skin and were minimally irritating to the eyes of rabbits. They were not considered to be potential skin sensitizers when tested on guinea pigs (Buehler method).

Repeat-dose dietary toxicity studies with cyantraniliprole produced changes in the liver, thyroid gland, and adrenal gland. Some of these changes were adverse while some were adaptive. Consistent findings of mild to moderate increases in liver weights across multiple species (rats, mice, dogs) were observed. Dogs were more sensitive to liver effects than rats, which in turn were more sensitive than mice. The increases in liver weights were accompanied by hepatocellular hypertrophy and increases in metabolic liver enzymes (cytochrome P450) and UDP-glucuronyltransferase activity.

In rats, the liver effects were more pronounced in females than in males; this was consistent with toxicokinetic data which demonstrated a greater internal dose in females than males. Increases in liver weights and hepatocellular hypertrophy were observed in rats following shorter-term repeated dosing and were considered to be adaptive effects. As the duration and/or the dose increased, adverse effects on the rat liver were noted such as foci of cellular alteration and focal vacuolation. In dogs, consistent findings in 28-day, 90-day, and 1-year dietary studies were changes in clinical chemistry parameters including increases in alkaline phosphatase, alanine aminotransferase and gamma glutamyltransferase and decreases in total protein, albumin, and cholesterol. Significant increases in absolute and relative liver weights, when considered in combination with altered enzyme levels, were indicative of adverse liver effects. Microscopic observations in the liver included hepatocellular degeneration, and inflammation of the portal regions with increased fibrous connective tissues and pigment deposition, and/or bile duct hyperplasia. The liver effects in the dog also showed progressive severity with increased duration of exposure. For example, in all three dog studies mentioned above, clinical chemistry parameters indicative of liver toxicity were observed; however, in the 1-year dog study, these findings were accompanied by histopathological changes in the liver.

The available data also showed that thyroid hormone homeostasis was altered in rats following dietary exposure to cyantraniliprole for 28 or 90 days. The findings included decreases in T4 and, in some cases, T3, as well as increases in TSH. Thyroid follicular cell hypertrophy (graded as minimal in severity) was evident in both the 28-day and 90-day studies with rats, but did not persist with longer term dosing since it was not present at the 1-year interim sacrifice or following 2 years of exposure in the chronic toxicity/carcinogenicity dietary study in rats. In F_1 and F_2 adult parental animals of a reproduction study, a dose-related increase in the incidence of thyroid follicular epithelial cell hypertrophy/hyperplasia and an increase in thyroid gland weight were also found. High variability in the thyroid hormone data from the 28-day study in dogs precluded definitive interpretation of possible treatment-related findings.

The available data in rats indicate that the thyroid findings may have resulted from increased liver enzyme activity. Specifically, increases in hepatic cytochrome P450 content and UDP-glucuronyltransferase activity can lead to decreases in plasma T4 thyroid hormone level and alteration of thyroid hormone homeostasis, resulting in compensatory increases in TSH levels. Increases in TSH would stimulate the thyroid gland, resulting in thyroid follicular epithelial cell hypertrophy/hyperplasia. An in vitro mechanistic study showed that cyantraniliprole did not inhibit thyroid peroxidase activity; this lends support to the conclusion that cyantraniliprole was not directly toxic to the thyroid.

In the 90-day rat and mouse repeated dose toxicology studies as well as the 2-generation reproductive toxicity study, there was an increase in the incidence of microvesiculation of the zona fasciculata of the adrenal cortex. This finding was observed in male rats and mice but not dogs. The microvesiculation in affected groups was predominately graded as minimal in severity with a few incidences graded as mild, and was not associated with changes in gross appearance, adrenal cortical cytotoxicity, hypertrophy or atrophy. No effect on cortical cell function was associated with the microvesiculation as demonstrated by studies evaluating corticosterone concentrations in serum and urine with ACTH stimulation. In addition, no treatment-related neoplastic changes were observed in the adrenal cortex of rats following chronic dietary administration of cyrantraniliprole. Microvesiculation of the adrenal cortex is a normal finding resulting from the storage of lipid to be used as a precursor for steroid hormone synthesis. Rats exposed to cyantraniliprole showed a slight increase in lipid storage in the adrenal cortex. Although clearly treatment-related, the slight microvesiculation of the adrenal cortex noted following exposure to cyantraniliprole was not considered to be toxicologically significant.

An effect that was observed only in dogs, and at higher doses in all three dog studies, was an increase in the incidence of vascular arteritis. The vessels affected (including heart and coronary artery) were suggestive of Spontaneous Canine Juvenile Polyarteritis, which may have been exacerbated by exposure to cyantraniliprole; therefore, the increase in vascular arteritis was considered to be treatment-related and adverse. Other effects observed in the dog, at higher doses included reductions in body weight and body weight gain, food consumption, and food efficiency.

During development of cyantraniliprole, a modification was made to the manufacturing process to eliminate the presence of an impurity that was associated with genotoxicity as well as liver toxicity following chronic dosing. Consequently, chronic toxicity/carcinogenicity studies were conducted with batches of cyantraniliprole that are considered to be representative of the commercial production process. The results of these studies did not identify carcinogenic or genotoxic potential. Many of the other repeat-dose toxicity studies were conducted with the pre-production batch containing the impurity.

There was no evidence of increased sensitivity of the young following in utero or early life exposure to cyantraniliprole. In the rat developmental toxicity study, there was no maternal or fetal toxicity up to the limit dose of testing. In rabbits, reduced fetal weights were noted at doses which elicited late gestation abortions or early deliveries in dams. At these doses, dams exhibited clear signs of toxicity (diarrhea, mortality, and reduced food consumption, body weight and body weight gain). In a 2-generation reproductive toxicity study, cyantraniliprole did not adversely affect any reproductive parameter. Parental toxicity was evident as increased thyroid weights in both generations with a corresponding increase in the incidence of thyroid follicular epithelial cell hypertrophy/hyperplasia. In addition to the increase in adrenal cortical vacuolation in males mentioned previously, effects on the liver included increased weight and hepatocellular hypertrophy observed at high doses. Reduced body weights as well as lower thymus weight and thymus atrophy were additional observations in females at the higher doses. A reduction in offspring body weight and, at higher doses, organ weights (thymus and spleen) as well as clinical signs such as dehydration were noted at dietary concentrations where there was clear evidence of maternal toxicity. These findings demonstrate that the young animal was not more sensitive than the adult animal to cyantraniliprole toxicity.

There was no evidence of neurotoxicity in acute and subchronic oral neurotoxicity studies conducted in rats, nor was there any indication of neurotoxic potential for cyantraniliprole in the rest of the database.

Cyantraniliprole did not adversely impact the immune system in rats and mice, and the decreases in thymus and spleen weights recorded in the 2-generation reproductive toxicity study were not observed in either the rat or mouse immunotoxicity study.

The results of a 28-day dermal toxicity study conducted in rats up to the limit dose of testing did not demonstrate irritation or systemic toxicity. In a 28-day inhalation toxicity study in rats, laryngeal mucosal metaplasia was observed in treated males at the highest dose tested; in all but one animal, the effect was reversible after 14 days of recovery. The finding was considered to be treatment-related, but not adverse, and the results suggest that animals could have tolerated higher dose levels. With longer duration of exposure or higher test concentrations, the effect seen in the larynx could potentially progress, resulting in an adverse finding.

The toxicity of some metabolites and degradation products of cyantraniliprole were investigated. Studies showed that they had low acute toxicity and were not genotoxic. A 28-day study in rats with the soil metabolite IN-JSE76 did not indicate any toxicity, although a limited capacity to alter thyroid homeostasis in males was noted.

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

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found in the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. Incidents from Canada and the United States were searched and reviewed for cyantraniliprole. As of 16 January 2012, no incidents following exposure to cyantraniliprole were reported within Canada or the United States.

3.1.1 PCPA Hazard Characterization

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

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for cyantraniliprole. The database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the developmental toxicity studies or the 2-generation reproductive toxicity study. No adverse effects were noted in the rat developmental toxicity study. In rabbits, reduced fetal weight occurred at doses producing pronounced maternal toxicity as evidenced by late gestation abortions or early deliveries, diarrhea/reduced feces, decreased food consumption and body weight, and early sacrifices. In the 2-generation reproductive toxicity study, effects on pup body weight, organ weight, and the adrenal and thyroid occurred in the presence of maternal toxicity.

Overall, the database is adequate for determining the sensitivity of the young. There is a low level of concern for sensitivity of the young, and effects on the young are well-characterized. The toxicity observed in rabbit fetuses and rat offspring occurred at maternally toxic doses. On the basis of this information, the PCPA factor was reduced to 1-fold.

3.2 Acute Reference Dose (ARfD)

General Population

An ARfD was not established as no effect attributable to a single exposure to cyantraniliprole was identified in the toxicology database.

3.3 Acceptable Daily Intake (ADI)

To estimate the risk of repeat dietary exposure, the 1-year dog dietary study with a NOAEL of 1 mg/kg bw/day was selected for risk assessment. At the LOAEL of 6 mg/kg bw/day, increased liver weights and liver enzymes as well as reduced albumin levels were observed in males. This study provides the lowest NOAEL in the database. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold. The composite assessment factor (CAF) is, therefore, 100.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{1 \text{ mg/kg bw/day}}{100} = 0.01 \text{ mg/kg bw/day of cyantraniliprole}$$

Cancer Assessment

Cyantraniliprole was not genotoxic and there was no evidence of carcinogenicity in the database. Therefore, a cancer risk assessment was not necessary.

3.4 Occupational Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to cyantraniliprole is characterized as short- to long-term exposure and is predominantly by the dermal route.

Short-term Dermal

For the short-term dermal risk assessment, the selection of an endpoint was not required as no systemic toxicity was seen in the 28-day dermal study in rats after repeated dermal exposure at the limit dose of testing. This lack of systemic toxicity suggests low dermal penetration. Further, in the oral studies, there was no developmental toxicity observed following in utero exposure, no reproductive toxicity noted above the limit dose, and no neurotoxicity observed in either the acute or sub-chronic neurotoxicity studies.

Intermediate-term Dermal

For the intermediate-term dermal risk assessment, the selection of an endpoint was not required for the reasons outlined above for the short-term dermal endpoint. This was supported by the fact that there did not appear to be a significant increase in toxicity observed in the database over the short- to intermediate-term duration.

Long-term Dermal

For long-term exposure via the dermal route, the NOAEL of 1 mg/kg bw/day from the 1-year dog dietary study was selected for risk assessment. This endpoint was selected as there was no route-specific (dermal) study of the appropriate duration, and there was indication in the database of increased toxicity from intermediate- to long-term duration. In this study, a NOAEL of 1 mg/kg bw/day was determined, based on increased liver weights and liver enzymes as well as reduced albumin levels in males at the LOAEL of 6 mg/kg bw/day. 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.

Short-term Inhalation

For the short-term inhalation risk assessment, the 28-day inhalation study in rats was selected. In this study the NOAEC was determined to be 0.1 mg/L air, the highest dose tested, which is equivalent to a NOAEL of 26.1 mg/kg bw/day.

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.

Intermediate-term Inhalation

For intermediate-term exposure via the inhalation route, the 28-day inhalation study in rats was selected. In this study the NOAEC was determined to be 0.1 mg/L air, the highest dose tested, which is equivalent to a NOAEL of 26.1 mg/kg bw/day.

The target MOE is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. In view of the fact that the route-specific adaptive effects (laryngeal mucosal metaplasia) observed in the 28-day inhalation study have the potential of becoming adverse with increased duration of dosing, an additional 3-fold uncertainty factor was applied. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and unborn children.

Long-term Inhalation

For long-term exposure via the inhalation route, the NOAEL of 1 mg/kg bw/day from the 1-year dog dietary study was selected for risk assessment. This endpoint was selected as there was no route-specific (inhalation) study of the appropriate duration. At the LOAEL of 6 mg/kg bw/day, increased liver weights and liver enzymes as well as reduced albumin levels were observed in males. A NOAEL of 1 mg/kg bw/day was established. This study provides the lowest NOAEL in the database.

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.

Acute Aggregate

Acute aggregate exposure to cyantraniliprole may be comprised of food, drinking water and oral and dermal exposure from harvesting activity at pick-your-own farm operations. It was determined that the selection of an endpoint was not required as no effect attributable to a single exposure to cyantraniliprole was identified in the toxicology database.

3.4.1.1 Dermal Absorption

In support of the cyantraniliprole applications, an in vivo dermal absorption study in rats and an in vitro dermal absorption study in rat and human skin were submitted. The submitted dermal penetration studies for cyantraniliprole were of good quality and the 'triple pack' approach was considered for setting a dermal absorption value. However, the post-exposure durations for data collection were 0 and 498 hours for the in vivo rat study, and 0 and 18 hours for the in vitro rat study. Therefore, in light of the discrepancy in the post-exposure observation periods the percent of dermally absorbed dose in the rat in vitro and rat in vivo studies could not be directly compared for the triple pack approach. Hence, only the rat in vivo study was used to determine a dermal absorption value to be used in the risk assessment of cyantraniliprole.

The rat in vivo study used concentrations (2000 µg/cm² and 10 µg/cm² for the 200 g/L undiluted concentrate and the 1 g/L aqueous dilution) designed to mimic potential field-use exposures. The applied formulations remained in contact with the skin for 6 hours. At 6 hours, the skin surface of all rats was washed with a dilute soap solution and one group of 4 rats per dose concentration was sacrificed to determine the distribution of the applied dose at the end of the exposure phase (0-hours post-exposure). The remaining 4 rats at each dose level were maintained until 504 hours post-dose (498 hours post-exposure; 21 days). Given the variability in actual deposition under field conditions, it is considered appropriate to derive an estimate of dermal absorption based on the low dose group, as percent dermal absorption was greatest at the low dose level. In addition, since a longer post-exposure period provides more information about the fate of absorbable and absorbed dose over time, the dermal absorption was derived based on groups sacrificed at 498 hours. The dermal absorption estimate of 2% from the low dose group at 498 hours sacrifice was considered most appropriate to adopt for use in the post-application dermal risk assessment for workers re-entering greenhouses (ornamentals).

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Exposure to workers mixing, loading and applying cyantraniliprole is expected to be short- to intermediate-term in duration and to occur primarily by the dermal route. However, since, no dermal endpoint was selected for short- to intermediate-term exposure; the occupational risk assessments are limited to inhalation exposure for every scenario except greenhouse post-application exposure.

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 a 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (no observed adverse effects levels) to obtain the margin of exposure (MOE); the target MOE is 300.

Foliar/in-furrow soil application
Field/orchard crops and outdoor/greenhouse ornamentals

Workers have potential for inhalation exposure to cyantraniliprole during mixing, loading and application. Inhalation exposure estimates, derived for mixers/loaders/applicators applying cyantraniliprole to a variety of crops using aircraft, airblast, open cab groundbooms, backpacks and hand held (mechanically and manually pressurized) sprayers, were generated from PHED v3.1.

All exposure estimates were based on workers using equipment and wearing PPE that are in keeping with label instructions.

Inhalation risks to workers, mixing, loading and applying cyantraniliprole were not of concern (MOEs were above the target MOE; Appendix I, Table 7), however, a risk of concern was identified for custom applicators who mix/load and apply thiamethoxam (which is co-formulated with cyantraniliprole) to the soil of potato crops using an open cab groundboom. Therefore, a requirement for closed cab applications will be added to the product label containing both cyantraniliprole and thiamethoxam for potato soil treatments.

Seed treatment
A dust-off study was submitted to bridge the exposure studies conducted on cereal and maize to the treatment and planting of potato seed pieces, canola, rapeseed and mustard seeds for Lumiderm, Verimark and A17960A/B 600FS. The dust-off data were generated using the

Heubach dust measurement apparatus. The applicant tested cyantraniliprole 625 g/L FS alone on canola, Gaucho CS FL (imidacloprid) on corn and Jockey (fluquinconazole and prochloraz) on wheat and sampled the average dust level in g/100kg. 'Seed coating and Analysis' was conducted in one laboratory while 'Dust-Off and Analysis' was conducted in a separate laboratory.

This non-guideline study was conducted to support Cyantraniliprole 625 g/L FS for seed treatment of canola in Canada. The corn and wheat treatments reflect treatments studied in two exposure studies that have been used as surrogate exposure studies to support registration of Cyantraniliprole 625 g/L FS for seed treatment of canola. This study demonstrated that canola is the least dusty of the tested seeds. Therefore, it is unlikely that applying unit exposure data from the selected studies would underestimate exposure for workers handling cyantraniliprole-treated canola and mustard seeds.

For potato seed pieces, the study authors neglected to compare the impact of seed type, varying formulations and a.i. application rate on dust-off and then link it to the submitted exposure studies.

However, given the lack of a short- to intermediate-term dermal endpoint and the nature of the treatment (i.e., closed system), dust-off exposure is not of concern.

Canola/Rapeseed/Mustard seed

Inhalation exposure estimates, summarized in Appendix 1, Table 8, were derived from a closed mixing and loading exposure study using wheat seeds treated with Jockey fungicide. Using the inhalation unit exposure values from this study, risks to workers mixing, loading, treating, bagging and cleaning were not of concern (MOEs were above the target MOE of 300).

Potato seed piece

Inhalation exposure estimates for potato seed piece treaters and cutters/sorters in on-farm and commercial facilities, summarized in Appendix I, Table 9, were derived from an exposure study that measured exposure to workers treating potato seed pieces with Admire 240F. Using the inhalation unit exposure values from this study, risks to workers treating and cutting/sorting were not of concern (MOEs were above the target MOE of 300).

A rationale based on a weight of evidence approach, was also submitted, which involves adding mitigation measures to the product label. The rationale was deemed acceptable for this use.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Foliar/In-furrow application

There is potential for exposure to workers re-entering areas treated with cyantraniliprole to perform a variety of tasks, both indoors (greenhouses) and outdoors. Post-application exposure assessments were only conducted for foliar treatments as exposure was deemed negligible following soil treatments. The duration of exposure is considered to be long-term for greenhouse post-application tasks. Inhalation risks to post-application workers were deemed negligible considering the vapour pressure of cyantraniliprole and the 12 hour restricted entry interval (REI). Therefore, the primary route of exposure for workers re-entering treated areas would be through dermal exposure.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients and a chemical-specific dermal absorption factor. As such, the current default assumptions used in the exposure assessment are 0% daily dissipation and a default deposition value of 25% of the application rate.

Exposure estimates were compared to the toxicological endpoint to obtain the margin of exposure (MOE); the target MOE is 100.

Dermal risks to workers re-entering greenhouses to perform post-application activities were not of concern (see Appendix I, Table 10).

Seed Treatment

Canola/Rapeseed/Mustard seed

Workers have potential for exposure to seed treatment products containing cyantraniliprole while planting treated seed. Chemical specific data for assessing human exposure during planting were not submitted. As such, generic exposure data have been used to estimate inhalation risk to workers planting treated seed.

Using the inhalation unit exposure values from this study, risks to workers planting treated oilseeds, using a closed cab planter, were not of concern (MOEs were above the target MOE of 300; Appendix I, Table 11).

Potato seed piece

No adequate data exists to assess exposure for workers involved with potato seed piece planting. In the absence of a potato seed piece planting exposure study, a planter inhalation risk assessment was conducted based on a weight of evidence approach using an exposure study conducted with maize. Using the inhalation unit exposure values from this study, risks to workers planting, using a closed cab planter, were not of concern (MOEs were above the target MOE of 300; Appendix I, Table 12).

3.4.2.3 Bystander Exposure and Risk

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

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

According to the nature of the residue studies (plant, high-temperature hydrolysis, confined crop rotation, and livestock), parent cyantraniliprole was the major residue in the foods for human consumption (i.e., lettuce leaves, cereal grain, eggs, milk, etc.). Based on this, cyantraniliprole per se is considered an appropriate marker for primary crops, processed commodities, rotational crops and livestock commodities and is recommended as the residue definition for enforcement purposes. In the high temperature hydrolysis study, degradation of cyantraniliprole occurred resulting in the formation of IN-J9Z38 and two other degradates (IN-FL699 and IN-N5M09). While the 2 degradates did not contribute significantly to the estimate of processing factors, IN-J9Z38 was quantified in higher amounts than the parent. Therefore, it is recommended that both cyantraniliprole and IN-J9Z38 be included in the residue definition for risk assessment purposes. According to the livestock feeding studies, the parent cyantraniliprole and several metabolites (IN-N7B69, IN-MLA84, IN-MYX98, and IN-J9Z38) were present in measurable amounts in some commodities. These metabolites are assumed to have similar toxicity to the parent cyantraniliprole. Therefore, the residue definition for risk assessment for animal commodities will include the parent and specific metabolites, on a matrix-specific basis. The proposed residue definitions for enforcement and risk assessment are consistent with those of the United States Environmental Protection Agency.

HPLC-MS/MS methods were developed for data gathering and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the LOQ (0.01 ppm for each analyte) in plant and livestock matrices. The demonstrated storage stability intervals cover the actual intervals of frozen storage for plant and livestock commodity samples (–20°C) from crop field trials, processing, and livestock feeding studies. Therefore, no corrections for loss of residues during storage are required. An adequate number of residue trials (including bridging trials) with acceptable geographical distribution were submitted on a range of representative commodities of various crop groups (CG), namely CG1C, CG3-07, CG4, CG5, CG8-09, CG9, CG11-09, CG12-09, CG13-07B, CG14-11, and CG20, to allow the establishment of MRLs. Sufficient residue trials were conducted in/on imported commodities (citrus fruits, cotton, olives, and grapes) according to the critical good agricultural practices (GAPs) and relevant guideline requirements, providing data appropriate for setting import MRLs. Based on processing studies, a separate MRL is only necessary for citrus oil as the anticipated residue of cyantraniliprole (2.4 ppm) exceeds the proposed MRL (0.7 ppm) for the crop group.

Feedstuff items associated with proposed domestic uses are almonds, apples, potatoes, and oilseeds (canola, sunflower). The more balanced diet calculation to estimate the anticipated residues in meat, milk, and eggs also took into account feed items derived from rotational crops (cereals, grasses, and legumes) at a 30-day plantback interval. Anticipated residues in animal matrices are all below the LOQ. All of the proposed MRLs are aligned with the US Tolerances.

3.5.2 Dietary Risk Assessment

A refined chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.16), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

A refined chronic risk assessment was conducted using the following assumptions: median residue values from crop field trials; experimental processing factors (where applicable); and residue values at the limit of quantification for animal matrices. The refined chronic dietary exposure from all supported cyantraniliprole food uses (alone) for the total population is 22% of the acceptable daily intake (ADI), with the highest contribution from children 1–2 years old at 40% of the ADI. Aggregate exposure from food and water is considered acceptable. The chronic dietary exposure to cyantraniliprole from food and water is 24% of the ADI for the total population. The highest exposure and risk estimate is for children 1–2 years old at 43% of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified. Therefore, no acute dietary exposure assessment was conducted.

3.5.3 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Leafy *Brassica* vegetables (CG5B)	**30**
Leafy vegetables (CG4)	**20**
Green onions (CG3-07B)	**8**
Cherries (CG12-09A)	**6**
Bushberries (CG13-07B)	**4**
Head and Stem *Brassica* vegetables (CG5A)	**3**
Citrus oil	**2.4**
Fruiting vegetables (CG8-09)	**2**
Pome fruits (CG11-09)	**1.5**
Peaches (CG12-09B)	**1.5**
Oilseeds (CG20)	**1.5**
Grapes	**1.5**
Olives	**1.5**
Citrus (CG10)	**0.7**
Plums (CG12-09C)	**0.5**
Cucurbit vegetables (CG9)	**0.4**

Commodity	Recommended MRL (ppm)
Tuberous and corm vegetables (CG1C)	**0.15**
Bulb onions (CG3-07A)	**0.04**
Tree nuts (CG14-11)	**0.04**
Leaves of root and tuber vegetables (CG2)	**0.04**
Root vegetables (CG1A)	**0.02**
Fat, meat and meat by products of cattle, sheep, goats, hogs, horses, poultry	**0.01**
Milk	**0.01**
Eggs	**0.01**

For additional information on 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 methodology, field trial data, and the chronic dietary risk estimates are summarized in Appendix I, Tables 1, 4 and 5.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Data on the fate and behaviour of cyantraniliprole and its major transformation products are summarized in Appendix I, Tables 13 and 14.

Cyantraniliprole enters the environment when it is used as an insecticide for the control of a large number of pests in a variety of crops such as vegetables (including fruiting vegetables), cucurbits, orchards, oilseed crops, tree nuts, potatoes and ornamental crops. Cyantraniliprole can be used as a seed treatment and can be sprayed on foliage or applied directly to soil. Because of the systemic nature of cyantraniliprole, this compound can be taken up by plants when it is applied on foliage, on the seed, or by plants roots. Once in the plant, cyantraniliprole can move to various plant parts including pollen and nectar.

Cyantraniliprole will primarily come in contact with soil from in-furrow soil and foliar applications. Abiotic processes may contribute to the dissipation of cyantraniliprole under certain conditions. For example, cyantraniliprole has been shown to hydrolyse quickly to IN-J9Z38 under basic conditions. Conversely, hydrolysis is decreased under neutral conditions and is minimal under acidic conditions. Following in-furrow application, phototransformation may also contribute to the degradation of cyantraniliprole when the soil is moist (and there is limited plant growth which could impede light penetration). Major phototransformation products formed on moist soil are IN-J9Z38, IN-QKV54 and IN-RNU1. Phototransformation was shown to be minimal on dry soil. Another route of transformation for cyantraniliprole is biotransformation, under both aerobic and anaerobic conditions. Major transformation products formed in aerobic soils are IN-JCZ38, IN-JSE76, IN-PLT97, IN-K5A78 and IN-J9Z38. The persistence of the major transformation products ranged. Depending on soil type, IN-JSE76, IN-K5A78, and IN-J9Z38 ranged from moderately persistent to persistent; IN-PLT97 was classified as persistent;

and IN-JCZ38 ranged from non-persistent to slightly persistent. Under anaerobic conditions (flooded soil), cyantraniliprole transforms to IN-J9Z38, IN-K5A78, IN-K5A77.

Cyantraniliprole is expected to be mobile in most soils based on low adsorption coefficients. The mobility of major soil transformation products vary from immobile (for IN-J9Z38) to highly mobile (for IN-JCZ38). Other than mobility, parameters such as solubility in water, volatility and persistence in soil are considered when determining the potential for a compound to leach through the soil profile and enter groundwater. Cyantraniliprole is soluble in water and exhibits a low potential for volatilization from moist soils, both of which can increase the leaching potential. The leaching potential also increases with increased persistence. For cyantraniliprole, the persistence is variable depending on soil conditions. When considering the most conservative persistence and mobility parameters, the groundwater ubiquity score (GUS) for cyantraniliprole indicates that this compound is a probable leacher. Under field conditions, cyantraniliprole was generally found in the uppermost soil layer although small amounts of cyantraniliprole moved to a depth of 15 cm below soil surface. Most of the transformation products were found in the uppermost soil layer, and dissipation of the two major transformation products formed in the pathway (IN-J9Z38 and IN-JCZ38) formed and declined by study termination. Based on water modelling, cyantraniliprole and its transformation products have the potential to leach through the soil profile to enter groundwater.

In all field studies, the major transformation products IN-J9Z38 (hydrolysis, phototransformation, biotransformation) and IN-JCZ38 (biotransformation) were formed early on, thereby indicating that many transformation processes occur simultaneously under field conditions. It was noted that sites receiving the most moisture tended to show the lowest formation of phototransformation products, which may have been due to transport of cyantraniliprole out of the upper soil layer where the photolysis reactions take place. Given this observation and given that phototransformation is not expected to occur on dry soil, it is thought that the overall contribution of phototransformation in the dissipation of cyantraniliprole is low under field conditions. Biotransformation is thought to be the most important route of transformation of cyantraniliprole under field conditions.

Cyantraniliprole could reach surface water from spray drift or runoff. Once in water, cyantraniliprole is not expected to partition to sediment in large amounts. Hydrolysis is expected in basic water conditions only. Phototransformation and biotransformation are thought to be important routes of transformation in aquatic systems as both transformation processes are fairly rapid. Major phototransformation products observed in a sterile buffer solution were IN-NXX69, IN-NXX70 and IN-QKV54. In water/sediment systems, IN-J9Z38 was identified as a major transformation product from the aerobic aquatic biotransformation of cyantraniliprole. IN-J9Z38 and IN-K5A78 were identified as major transformation products under anaerobic aquatic conditions. Outdoor studies investigating the contribution of phototransformation to the overall dissipation of cyantraniliprole in water/sediment systems showed that the dissipation rate was faster in systems exposed to sunlight compared to corresponding systems that were shielded from sunlight.

Cyantraniliprole is not expected to bioconcentrate in fish. The steady-state and kinetic bioconcentration factors for cyantraniliprole were less than 1 at both test concentrations in the fillet, carcass, and whole fish. This was expected based on the low log K_{ow} for cyantraniliprole. Similarly, major transformation products are not expected to bioconcentrate given that their log K_{ow} was less than 3.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications (Appendix I, Tables 15–21). Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level)(Appendix I, Tables 2533).

Taxonomic group	Exposure	Endpoint	Species Uncertainty Factor
Earthworm	Acute	LC_{50}	0.5
	Chronic	NOEC	1
Other non-target arthropods	Acute	LR_{50}	LOC of 2 (screening level)
Birds	Acute oral	LD_{50}	0.1
	Dietary	LD_{50}	0.1
	Reproduction	NOEL	1
Mammals	Acute oral	LD_{50}	0.1
	Reproduction	NOEL	1
Non-target terrestrial plants	Acute	EC_{25}, or HR_5 of SSD of ER_{50}*	1
Aquatic invertebrates	Acute	LC_{50} or EC_{50}	0.5
	Chronic	NOEC	1
Fish	Acute	LC_{50}	0.1
	Chronic	NOEC	1
Amphibians	Acute	Fish LC_{50}	0.1
	Chronic	Fish NOEC	1
Algae	Acute	EC_{50}	0.5
Aquatic vascular plants	Acute	EC_{50}	0.5

* 5^{th} percentile hazard rate of the species sensitivity distribution of ER_{50} values
The LOC for bees is set to 0.4.

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 by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1, except for *T. pyri* and *Aphidius* screening level studies which have an LOC=2, and bees which have an LOC=0.4, as described in Appendix I, Table 30)). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

Risk of cyantraniliprole (including end-use product (Cyantraniliprole 100 g/L OD (representing DuPont Benevia Insecticide), Cyantraniliprole 100 g/L SE (representing DuPont Exirel Insecticide), and Cyantraniliprole 200 g/L SC (representing DuPont Verimark Insecticide), and cyantraniliprole/Thiamethoxam (representing Mainspring Insecticide)) and transformation products) to terrestrial organisms (see Appendix I, Tables 25–31) was based upon evaluation of toxicity data for the following:

- 2 mammal and 3 bird species representing vertebrates (acute gavage, short- and long term reproduction, dietary exposure)
- 2 bee species, 8 other arthropods and 1 earthworm species representing invertebrates (acute, short term and long term exposure with technical grade active ingredient, end-use product, and major soil transformation products), including higher tier studies for bees and predators and parasites.
- 10 crop species representing non-target plants

Terrestrial vertebrates

Birds and Mammals (Appendix I, Tables 25 and 26): For terrestrial vertebrates cyantraniliprole did not cause mortality or sublethal effects in Northern bobwhite quail, mallard duck, or zebra finch upon acute exposure (LC_{50}>1357 to >2250 mg/kg bw/day). Nor did it adversely affect reproductive endpoints in Northern bobwhite quail (NOEC: 93 mg/kg bw/day).

Following acute exposure of rats to cyantraniliprole, no mortality was observed (LD_{50}>5000 mg/kg bw). Therefore, the acute toxicity of cyantraniliprole is low. In short-term and chronic studies on laboratory animals, the primary targets were the liver, the thyroid gland, and the adrenal gland. Evidence indicated that effects on thyroid were secondary to liver enzyme activation by cyantraniliprole. In reproduction studies, there was no oberservation of maternal toxicity, and therefore, no evidence of increased susceptibility of the young.

Birds and mammals may be exposed to cyantraniliprole following the ingestion of plant material and insects sprayed with cyantraniliprole during foliar application of Exirel and/or Benevia insecticides, and also to thiamethoxam from application of Mainspring insecticide, which contains both cyantraniliprole and thiamethoxam. In addition, birds and mammals may be exposed to cyantraniliprole from the ingestion of treated seed from application of Lumiderm and/or A17960A 600FS insecticides. Thus these two types of exposure scenarios were considered in the risk assessment.

Following the screening level risk assessment for foliar applications, it was determined that there was negligible risk for acute, dietary or reproductive effects to birds and mammals from in-field exposure (Appendix I, Table 25). For seed treatment applications, results indicated that the risk quotient exceeded the level of concern for acute and reproductive effects (RQ values ranging from <2.6 to <27.2) and for mammals (RQ values ranging from 1.1 to 2.9) (Appendix I, Table 26). It should be noted, however, that no effects (mortality or sublethal effects) were observed up to the highest test concentration in acute oral and dietary studies, indicating that cyantraniliprole is practically non-toxic to birds and mammals on an acute basis. Similarly, no reproductive effects were noted in laboratory studies up to the highest concentration tested. In addition, birds would have to consume between 93 and 11250 seeds per day (depending on the size of bird and endpoint considered) to reach a level of cyantraniliprole that would compare to levels represented by the toxicity endpoints, and mammals would require even more. Furthermore, seed drilling practices would also reduce the amount of seeds available to the birds and mammals thereby reducing the exposure to cyantraniliprole. Only 0.5% to 3.3% of the seeds would be available following precision drilling or standard drilling practices, respectively (de Snoo and Luttik, 2004). Using standard drilling practices, birds and mammals would have to consume all treated seeds found in an area ranging between 15 and 1805 m^2 in order to be exposed to enough cyantraniliprole to reach the same level as the highest levels tested in laboratory studies. That area would increase to between 99 and 11912 m^2 if precision drilling was used, which is unlikely to occur. Therefore, the overall risk to birds and mammals exposed to cyantraniliprole contaminated food items or treated seeds was considered negligible, and thus not a concern (Appendix I, Table 26).

Terrestrial invertebrates

Soil dwelling arthropods (Earthworms, *Hypoaspsis aculeifer*, and collembola) (Appendix I, Tables 27 and 28): For soil dwelling terrestrial arthropods, acute and chronic effects of cyantraniliprole, its end-use products (Cyantraniliprole 200 g/L SC, Cyantraniliprole 100 g/L OD with and without codacide oil, Cyantraniliprole/Thiamethoxam), and transformation products (IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-K5A79, IN-PLT97, IN-QKV54 and IN-RNU71) were studied with earthworms (*Eisenia fetida*), *Hypoaspis aculeifer* (a soil mite), and collembola. No effects were observed for earthworms or the soils mites when exposed ip to the highest concentration tested following a 14 day acute exposure and a 56 day chronic exposure. In contrast, mortality and sublethal effects were observed for collembola exposed for a period of 28 days to the technical grade active ingredient (NOEC of 0.08 mg/kg soil), and also for some of the soil transformation products, including IN-JCZ38 (NOEC of 12 mg/kg soil), IN-K5A77 (NOEC of <62.5 mg/kg soil), IN-JSE76 (NOEC of 250 mg/kg soil), IN-K5A79 (NOEC of 125 mg/kg soil), and IN-RNU71 (NOEC of 12.5 mg/kg soil).

Soil dwelling arthropods can be exposed to cyantraniliprole from both foliar and soil applied end-use products. Thus, risk assessments were conducted for both types of formulations. Following the screening level risk assessment, it was determined that there was negligible risk for acute and chronic effects for both earthworms and *Hypoaspis aculeifer,* from exposure to the technical grade active ingredient, the end-use products, or transformation products. However, there was an initial screening risk identified for collembola (RQ value between 1.4 and 2.4). Therefore, in order to further examine the potential risk, more "realistic" exposure estimates were used in the risk calculation. These estimates included the incorporation of soil deposition fractions from foliar application (e.g. the amount of residue which may land on soil, and that intercepted by foliage depending on growth stage of the plant), and also the use of half-lives derived from terrestrial field studies (as opposed to laboratory studies) for the estimation of the cumulative exposure from multiple applications. The off-field risk was also considered for foliar applications. Off-field exposure incorporates the amount of drift which is expected to occur based on the type of application method (11, 26, 59 or 74%) (Appendix I, Table 21). Based on these additional considerations, there was still a slight risk identified for Cyantraniliprole 100 g/L SE which has higher drift based on application methods, and also for soil application of Cyantraniliprole 200 g/L SC. In addition to the refinement of exposure estimates, a higher tier field study (with exposure to three end-use product formulations, Cyantraniliprole 100 g/L OD, Cyantraniliprole 100 g/L SE and Cyantraniliprole 200 g/L SC) with collembola was also assessed. The higher tier field study is intended to represent the potential risk under realistic use conditions. The results of this study indicated that there was some short term reduction in abundance of some taxa groups (compared to controls), however, collembola densities and species richness observed after 159 days (4th sampling period) and 368 days (5th sampling period) of the exposure period were not affected by exposure to cyantraniliprole. Therefore, overall, negligible risk was expected for collembola when exposed to cyantraniliprole under field conditions.

Predators and parasites

Foliage dwelling beneficial arthropods (*Aphidius rhopalosiphi, Typhlodromus pyri*, *Coccinella septemunctata* and *Chrysoperla carnea*): Predators and parasites (Appendix I, Tables 27 and 28)

<u>Tier I studies</u>: Initially, Tier I studies were conducted with the indicator species, *Aphidius rhopalosiphi,* and *Typhlodromus pyri*, whereby insects were exposed to residues of cyantraniliprole on glass plates. After 7 to 14 days of exposure to the end-use product formulations (Cyantraniliprole 100 g/L OD, Cyantraniliprole 100 g/L SE, and Cyantraniliprole 200 g/L SC) on glass plates, there were no mortalities observed for the predatory mite, *Typhlodromus pyri,* at the highest concentrations tested (LR_{50} values ranging from >230 to >300 g ai/ha). In contrast, following 48 hours of exposure of the parasitoid wasp, *Aphidius rhopalosiphi*, to the same end-use products on glass plates, up to 100% mortality was observed at the highest concentration tested (LR_{50} values ranging from 0.095 to 0.36 g a.i./ha), with higher sensitivity observed from exposure to Cyantraniliprole 100 g/L SE.

Non-target foliage dwelling arthropods could be exposed to residues of cyantraniliprole as a result of direct application (on leaves, or soil depending on species), contact with treated material or ingestion of a contaminated food source. The in-field exposure equals the application rate (applied at the maximum cumulative application rate with consideration of degradation using a foliage dissipation half-life). The off-field exposure considers the amount of drift that may occur from foliar applications (Cyantraniliprole 100 g/L OD and Cyantraniliprole 100 g/LSE) (11, 26, 59 and 74% drift). For spray applications, the level of concern for the screening level assessment is 2 based on an empirical comparison of risk quotients and known effects from field and semi-field studies for these two species. Following the screening level risk assessment, it was determined that there was negligible risk for *Typhlodromus pyri* from either in-field or off-field exposure to the end-use products. In contrast, the screening level assessment for the parasitoid, *Aphidius rhopalosiphi* resulted in risk (RQ values ranging from 284 to 2763) from both in-field and off-field exposure to all of the end-use products. In order to further characterize the potential risk for *Aphidius rhopalosiphi*, more “realistic” exposure estimates were used in the risk calculation for screening level studies. These estimates included the incorporation of foliar and soil deposition fractions from foliar application (e.g. the amount of residue which may land on soil, and that intercepted by foliage depending on growth stage of the plant). Following these additional considerations, there was still a risk identified for *Aphidius rhopalosiphi* (RQ values ranging from 28 to 2316) (Appendix I, Tables 27 and 28). Therefore, higher tiered laboratory studies with residues on foliage (Tier II) and field studies (Tier III) were conducted in order to further characterize the risk under more “realistic” conditions. The results of these studies are discussed below.

Tier II studies: Since the screening level risk quotients exceeded the level of concern, additional Tier II studies were assessed. These Tier II studies exposed insects (those which were identified in the Tier I study as well as additional species) to residues of cyantraniliprole on foliage under extended laboratory conditions.

Following the Tier II risk assessment for *Aphidius rhopalosiphi*, it was concluded that there was still potential for acute in-field and off-field risk following exposure to newly dried residues of either Cyantraniliprole 100 g/L OD or Cyantraniliprole 100 g/L SE formulations. However, when *Aphidius rhopalosiphi* were exposed to residues of cyantraniliprole for 7 days (of fresh and dried residues), there were negligible effects expected, particularly from off-field drift exposure. Negligible risk was identified from off-field exposure for mummies. Overall, comparison of the off-field risk for various end-use products indicates that less risk is expected from the Cyantraniliprole 100 g/L OD formulation for ground application since the method of application includes ground spray equipment (with 11% drift off the target field) compared to Cyantraniliprole 100 g/L SE formulation since the method of application includes airblast spray equipment for orchard crops (with up to 74% drift off the target field/orchard). Of course, the aerial application of either end-use product (with 26% drift) results in the same risk quotient. In addition, the drying or dissipation of residues from the leaf surface is expected to result in reduction of risk for foliage dwelling beneficial insects.

Following 12 to 19 days of exposure of *Coccinella septemunctata* (ladybird beetle) or *Chrysoperla carnea* (green lacewing) to either Cyantraniliprole 100 g/L OD or SE formulations on leaves, up to 87.5% mortality was observed at the highest concentrations tested (LR_{50} values of 43.3 and 61.5 g a.i./ha for ladybird beetle, and 212.6 and 260.9 g a.i./ha for the green lacewing), indicating a higher sensitivity for the ladybird beetle. An additional study which exposed the green lacewing to dried residues of Cyantraniliprole 100 g/L SE on apple leaves for 28 days resulted in no effects on mortality or reproduction. These results may indicate a higher toxicity resulting from fresh residues, compared to dried residues which may be expected to dissipate from the leaf surface. The risk for *Coccinella septemunctata* (ladybird beetle) or *Chrysoperla carnea* (green lacewing) was assessed for both in-field and off-field exposure with consideration of foliar and soil deposition fractions, as previously discussed. There was negligible Tier II risk from off-field exposure resulting from drift for either *Coccinella septemunctata* or *Chrysoperla carnea.* There was also negligible risk identified for in-field exposure for *Chrysoperla carnea.* However, there was still a potential risk to *Coccinella septemunctata* from in-field exposure to either Cyantraniliprole 100 g/L OD or Cyantraniliprole 100 g/L SE (RQ value of 3.8)(Appendix I, Table 28).

Soil dwelling arthropods: Additional studies were also conducted which assessed the potential risk from exposure of soil dwelling beneficial insects to dried residues on soil under extended laboratory (Tier II) conditions. These included exposure of *Aleochara bilineata* or *Pardosa* to applications of Cyantraniliprole 200 g/L SC, which is being proposed for in-furrow use. There was no mortality observed for *Aleohcara bilineata* or *Pardosa* spiders following exposure up to 400 g a.i./ha. Following exposure of *Aleohcara bilineata* to dried residues of Cyantraniliprole 200 g/L (aged for 2, 30 and 86 days on soil) following two applications up to 1400 g a.i./ha, reproductive effects (100% reduction compared to control) were observed at the 1^{st} observation (2 days after application). However, no significant effects were observed on the 30^{th} day and 86^{th} day after initial application, thereby indicating that the effects were transient. Taking into consideration the lack of effects observed in the first laboratory study, and the transient effects observed in the second (dried residue) laboratory study conducted at extremely high rates in comparison to the proposed use pattern in Canada, it was concluded that there was negligible risk expected (Appendix I, Tables 27 and 28).

Tier III studies: Following the Tier I and Tier II risk assessment, it was determined that there was still a potential risk for some species of predators and parasites. Therefore, in order to further examine the potential effects of cyantraniliprole to beneficial insects, particularly *Aphidius rhopalosiphi*, additional field (Tier III) studies were conducted with both foliar formulations of cyantraniliprole (Cyantraniliprole 100 g/L OD and Cyantraniliprole 100 g/L SE). The Tier III field study is intended to evaluate the potential risk following exposure under more "realistic" conditions in the natural environment, and also incorporate reproductive observations.

The three semi-field studies which were submitted for *Aphidius rhopalosphi* were conducted with either 1) outdoor barley plants sprayed with 2.2 g a.i./ha of Cyantraniliprole 100 g/L OD with codacide oil (referred to as Benevia insecticide); 2) outdoor barley plants sprayed with 6, 12 or 18 g a.i./ha of either the Cyantraniliprole 100 g/L OD formulation without codacide oil, or Cyantraniliprole 100 g/L OD formulation with codacide oil; and 3) outdoor barley plants treated with 3, 6, 9, 12 and 18 g a.i./ha Cyantraniliprole 100 g/L SE with codacide oil (referred to as

Exirel insecticide). The IOBC hazard classification was used to determine if effects were observed in the study. The IOBC categories are as follows: 1. harmless (E<25%); 2. slightly harmful (25%<E<50%); 3. moderately harmful (50%<E<75%); and 4. harmful (E>75%). Less than 25% effect is expected to allow for the population to recover for the following season.

In the first study, only reproduction was assessed, and the results (22.4% reduction after 11 days of exposure) indicated no overall effects. However, the application rates in the study (2.2 g a.i./ha) was very low compared to proposed Canadian rates, and thus, higher effects may be expected from application at 150 g a.i./ha. In the second study reduced reproduction was observed at all treatment levels, and magnitude of effects increased with increasing application rate (up to 99.5% reduction) at 18 g a.i./ha exposure level. In addition, there was no apparent difference between effects when codacide was included in the treatment. In the third study, the rate of parasitism was reduced by 90 to 100% at all treatment levels. It should be noted that the application rates used in the latter two studies (up to 18 g a.i./ha) were much lower than proposed maximum Canadian application rates (3 × 150 g a.i./ha) (Appendix I, Table 28).

Two additional field studies were submitted for predatory mites with either 1) apple trees sprayed with two applications of 150 g a.i./ha Cyantraniliprole 100 g/L SE with codacide oil (referred to as Exirel insecticide), and 2) grape vines sprayed with two applications of 150 g a.i./ha Cyantraniliprole 100 g/L SE with codacide oil (referred to as Exirel insecticide). In both studies, there was no significant reduction in predatory mite populations (19 and 20.6% reduction compared to control plots) (Appendix I, Table 28).

Taking into consideration the results of the lower Tier risk assessments in addition to the refined risk assessment, it was concluded that there was negligible risk for *Typhlodromus pyri* from exposure to cyantraniliprole. However, there were potential effects to *Aphidius rhopalosphi* from use of either Cyantraniliprole 100 g/L SE or Cyantraniliprole 100 g/L OD insecticides, and thus, label statements are required on the label for both in-field and off-field exposure.

Honey bees:

<u>Tier I studies (Appendix I, Table 29–31)</u>: Initially, screening level (Tier I) laboratory studies were conducted to assess both the acute oral and contact toxicity of cyantraniliprole, its end-use products and transformation products formed in plants and soil (IN-HGW87, IN-J9Z38 and IN-K5A78) to honey bees. After acute oral exposure to cyantraniliprole, less than 2% of the exposed bees died and less than 12% were apathetic (LD_{50} >0.1055 μg cyantraniliprole/bee). Following acute contact exposure, 34% mortality was observed in the highest dose (LD_{50} >0.0934μg cyantraniliprole/bee). Acute oral exposure to the end-use products with only cyantraniliprole (100 g/L OD, 100 g/L SE and 200 g/L SC) resulted in between 77.6 to 92% mortality in the highest tested doses, resulting in LD_{50} values ranging from 0.39 to 0.92 μg cyantraniliprole/bee. In comparison, oral exposure to the cyantranliliprole/thiamethoxam end-use product resulted in up to 93% mortality at the highest dose tested resulting in an LD_{50} value of 0.00639 μg/bee, which indicates higher toxicity from the additional exposure to thiamethoxam in the formulation. Following acute contact exposure to the end-use products Cyantraniliprole 100 g/L OD and Cyantraniliprole 100 g/L SE formulations (which represent a relevant route of contact exposure following foliar application), between 77.5 and 94% mortality was observed at the highest test dose (LD_{50} values between 0.65 and 2.78 μg cyantraniliprole/bee). Similar to the acute oral trend observed for thiamethoxam, up to 100% mortality was observed for bees exposed to the highest test dose of Cyantraniliprole/Thiamethoxam (LD_{50} value of 0.0597 μg/bee), indicating higher toxicity from the addition of thiamethoxam.

Following foliar spray, bees can be exposed to residues of cyantraniliprole (and thiamethoxam) through 1) contact (to either the spray droplets during flight, and/or, by residues which may be on the leaves following application), and 2) oral exposure (i.e. consumption of contaminated pollen or nectar). Contact exposure is mainly relevant for adult forager bees, while oral exposure is relevant for both adult bees (inside and outside the hive) as well as brood. As cyantraniliprole (and thiamethoxam) are systemic, translocation from leaves and soil to pollen and nectar may also occur. The highest contact exposure is expected from foliar or aerial spray applications (from spray droplets) onto bees while adult bees are foraging in the field and via contact with spray droplets remaining on vegetation post-application. Following soil or seed applications, bees can be exposed to residues of cyantraniliprole (and thiamethoxam for soil application) through the diet via translocation of residues (including parent and transformation products) from the soil, and/or seed into the pollen/nectar of the plant.

Potential risk following contact exposure: Following the screening level risk assessment from contact exposure, comparison of the toxicity endpoints derived from the technical grade active ingredient study with exposure estimates, resulted in indeterminable risk since less than 50% mortality was observed in the toxicity study. Additional consideration of end-use product data concluded there was potential risk when foraging bees come in direct contact with cyantraniliprole spray droplets following application of Cyantraniliprole 100 g/L OD, or from thiamethoxam (and cyantraniliprole) spray droplets following application of Mainspring Insecticide (RQ values ranging from 0.55 to 6.0). However, no acute contact risk was identified for Cyantraniliprole 100 g/L SE (Appendix I, Table 30).

Foraging bees may also be exposed to dried spray droplets on plants following foliar application. Therefore, the results of the extended residual toxicity test (i.e., pesticides with residues which remain toxic to >25% of the organisms tested for periods >24 hours) was also considered in the risk assessment. Considering this route of contact exposure**,** a negligible risk was expected when foraging bees come in contact with cyantraniliprole residues on foliage (only 4% mortality after 3 hours of exposure).

Potential risk following oral exposure: The risk assessment for oral exposure incorporated the results of field residue trials. These studies were designed to collect pollen and nectar from a number of different plants following different potential application scenarios. Generally, application rates for the residue studies were close or identical to the proposed rates in Canada for the crop group in question. Maximum residue values were selected for the Tier I oral risk assessment without consideration of the application rate, use pattern or date of sampling after treatment at which they were observed. In addition, the castes associated with the most conservative pollen and nectar consumption rates for adults were used in the risk assessment (Appendix I, Tables 23 and 24). Following the screening level risk assessment from oral exposure, comparison of the toxicity endpoints derived from the technical grade active ingredient study with exposure estimates, resulted in indeterminable risk since less than 50% mortality was observed in the toxicity study. Additional consideration of end-use product data concluded there was potential risk when foraging and nurse bees consume cyantraniliprole on pollen and nectar following application of Cyantraniliprole 100 g/L OD, or from thiamethoxam (and cyantraniliprole) spray droplets following application of Mainspring Insecticide. However, no acute oral risk was identified for Cyantraniliprole 100 g/L SE (Appendix I, Table 31). The risk to brood could not be assessed using laboratory data, however, higher tier studies evaluated potential effects to brood/larvae, and are discussed below.

Tier II studies: Ten semi-field studies were conducted in order to investigate the potential effects of cyantraniliprole (from three different formulations) to honey bee adults and brood. In these studies, small colonies were introduced inside tunnels placed on treated crops thereby restricting the foraging activity of the bees to the treated crop. Depending on the study, applications of cyantraniliprole were made during the pre-bloom period, during bloom when bees were actively foraging, or during bloom after bee flight. The three formulations included Cyantraniliprole 100 g/L OD (relevant for Benevia insecticide, foliar applied end-use product), Cyantraniliprole 100 g/L SE (relevant for Exirel insecticide, foliar applied end-use product) and Cyantraniliprole 200 g/L SC (relevant for Verimark, soil applied end-use product). Overall, the semi-field studies conducted with the two foliar end-use products indicated that there were negligible effects (on mortality or brood) resulting from pre-bloom application for any end-use product. When applications were made during bloom while bees were foraging, transient mortality (up to 3 days) and short term effects on foraging and flight behaviour were observed at most rates of application (90, 100, and 450 g a.i./ha). There were also transient effects on mortality, foraging and flight behaviour from application during bloom *after* bees were foraging (following applications at 90, 100 and 150 g a.i./ha). The magnitude of effects observed in bees when they were exposed after foraging, appeared less in comparison to effects during foraging. This is expected since exposure to direct foliar spray would result in both direct contact and oral ingestion of cyantraniliprole. In comparison, exposure after flight would include oral ingestion and also the potential for contact exposure from residues on the plant surface, although dried residues in a laboratory study resulted in limited effects. No short term brood or colony effects were observed in these semi-field studies. The semi-field studies conducted with the soil formulation (Cyantraniliprole 200 g/L SC) concluded negligible effects on mortality following 1) three applications via drip irrigation at 100 g a.i./ha to melons, and 2) two applications via drip irrigation at 100 g a.i./ha to melons, applied at the beginning of flowering and also during flowering, after bee flight. In another study conducted with sugar to simulate honeydew in wheat, effects on mortality, brood and behaviour were observed at both 10 g a.i./ha and also 100 g a.i./ha, when bees were exposed during bee flight. Therefore, additional exposure to honey bees may occur from the ingestion of contaminated honeydew in the field, although it is currently unclear whether the exposure in the semi-field study mimics the expected exposure in the field.

An additional study which exposed bumblebees to two formulations of cyantraniliprole under greenhouse conditions, resulted in short term effects on mortality, as well as some effects on brood and queen mortality.

Tier III studies: Five relevant field studies were conducted with the OD formulation at either 150 g a.i./ha or 90 g a.i./ha pre-bloom followed by a second application at the same rate either *during* bee foraging or *after* bee foraging. Applications were made to *Brassica napus*, which represents a bee attractive crop. The field studies examined effects at the colony level over a longer period of time, compared to the semi-field studies. Results of the field studies indicated negligible effects from pre-bloom application. Following a second application at either 90 or 150 g a.i./ha, a transient increase in mortality (generally up to 3 days) and a transient decrease in behavioural activity (including foraging and flight) was observed, when bees were exposed to Cyantraniliprole 100 g/L OD applied *during foraging* (during bloom). Although results of the field studies (conducted at 150 g a.i./ha) indicated a transient increase in mortality and a transient decrease in behavioural activity when bees were exposed to Cyantraniliprole 100 g/L OD applied *after foraging* (during bloom), there were no significant effects on mortality or behaviour observed at 90 g a.i./ha applied *after foraging* (during bloom). In addition, the magnitude of effects appeared less when the product was applied after foraging compared to when it was applied during foraging. Development of the hive, and colony strength were similar between treatment and control groups in many of the studies, with similar overwintering survival among the two groups. Factors included in the interpretation of effects included varroa mite and/or wax moth infestations, nutrition, weather, and data variability, which inevitably occur in the field, and are thus, were reflected in these field studies. Overall, from the large amount of comprehensive data submitted for this chemical, there is no clear indication of long term effects.

Overall summary: Based on consideration of all of the available data (including acute laboratory studies, Tier I semi-field and Tier II field studies), and a weight of evidence approach, it was concluded that following pre-bloom exposure, there were negligible effects observed for adult mortality, adult behavior, and brood (short term). For bees, following exposure during foraging, there were negligible short term effects for brood. There was a temporary increase in adult mortality (up to 3 days following application) and temporary behavioural effects (reduced foraging and flight activity) observed at various application rates. Following exposure after foraging, there were negligible short term effects for brood. There was a temporary increase in adult mortality (up to 3 days following application) and temporary behavioural effects (reduced foraging and flight activity), however, these effects were less in magnitude compared to exposure during foraging, and not observed at lower application rates. In all cases, bees only exhibited adults effects (mortality and behavioural) for a short time period, with no lasting effects on the colony. Regarding longer term effects, field studies indicated similar colony development, hive effects, and disease between control and treatment groups. Overall, the data indicates that long term risk for the health of the colony is low. Therefore, hazard and risk based labeling will be required to reduce the potential exposure to bees during active foraging. Negligible effects are expected from pre-bloom applications, and also from either seed or soil treatment applications.

Although no semi-field or field studies were conducted with cyantraniliprole and thiamethoxam, additional field studies are currently underway for thiamethoxam, which may aid in refinements for the co-formulated products containing cyantraniliprole. The current risk assessment was conducted using previous submitted data for thiamethoxam, as well as data for the co-formulated product.

Non-target terrestrial plants (Appendix I, Table 27): Effects on vegetative vigour and seedling emergence of ten non-target terrestrial plants have been studied with the end-use product Cyantraniliprole 100 g/L OD (with and without codacide oil) up to 150 g a.i./ha. In the seedling emergence study, shoot dry weight of tomato plants was affected following exposure to Cyantraniliprole 100 g/L OD with codacide oil (ER_{25} value of 123 g a.i./ha). In comparison, exposure to Cyantraniliprole 100 g/L OD without codacide oil resulted in no effects at the highest concentration tested. In the vegetative vigour studies conducted with and without codacide oil, there were less than 25% effects observed at the highest concentration tested, however, there were two species, onion and ryegrass, which exhibited 22 and 20% shoot dry weight inhibition, respectively, following exposure to Cyantraniliprole 100 g/L OD. Since effects were approaching 25% at the single maximum application rate (150 g a.i./ha), potential toxicity at cumulative rates are possible.

The risk assessment for seedling emergence is based on soil exposure of cyantraniliprole and thus the EEC considers a soil half-life (the aerobic soil 80^{th} percentile, 130 days) in the calculation of the cumulative application rate. The risk assessment for vegetative vigour is based on foliar exposure of cyantraniliprole and thus the EEC considers a foliage phase dissipation half-life (5 days) in the calculation of the cumulative application rate. Since studies were only conducted with the Cyantraniliprole 100 g/L OD formulation (with and without codacide oil), the results of these studies were used to assess the potential risk from exposure to the Cyantraniliprole 100 g/L SE formulation. Following the screening level risk assessment, it was determined that there was a potential risk for seedling emergence (Appendix I, Table 27). Thus, in order to mitigate for the potential adverse effects of cyantraniliprole on non-target plants, a buffer zone and hazard statements will be required on the label.

4.2.2 Risks to Aquatic Organisms

Risk of cyantraniliprole (including end-use product (Cyantraniliprole 100 g/L OD (representing DuPont Benevia Insecticide), Cyantraniliprole 100 g/L SE (representing DuPont Exirel Insecticide), and Cyantraniliprole 200 g/L SC (representing DuPont Verimark Insecticide), and cyantraniliprole/thiamethoxam (representing Mainspring Insecticide) and transformation products) to aquatic organisms (Appendix I, see Tables 32 and 33) was based upon evaluation of toxicity data for the following:

- 11 acute invertebrate studies with technical grade active ingredient (daphnia, mayfly, caddisfly, stonefly, *Gammarus, Hyalella*, *ceriodaphnia*, crayfish, chironomid, midge, and *lumbriculus variegatus)*;
- Chronic and acute studies with daphnid with soil and aquatic transformation products;
- Acute and chronic studies with daphnid with end-use products;
- 3 freshwater fish species (bluegill sunfish, rainbow trout and channel catfish (acute and long term exposure)) with technical grade active ingredient
- amphibian species using fish as a surrogate
- 1 algae species, diatom and 1 vascular plant (duckweed) with end-use products

Risk of cyantraniliprole to marine aquatic organisms was based upon evaluation of toxicity data for the following:

- 3 invertebrates; mysid shrimp (acute and chronic) and eastern oyster (acute exposure), diatom
- 1 fish species, sheepshead minnow (acute exposure)

Aquatic organisms can be exposed to cyantraniliprole and its transformation products through spray drift and/or from run-off. To assess the potential for adverse effects, screening level EECs in the aquatic environment based on a direct application to water were used as the exposure estimates. This assessment identifies the taxonomic groups at potential risk. Screening level EEC values for cyantraniliprole and its transformation products in water were calculated assuming a conservative scenario of direct application to water bodies of two different depths (80 cm and 15 cm) (Appendix I, Table 16). The 80 cm water body is chosen to represent a permanent body of water and 15 cm depth is chosen to represent a seasonal body of water. The permanent body of water was used to assess the risk to organisms that depend on it year-round (i.e., fish); whereas the seasonal body of water was used to assess the risk to organisms that use shallower, potentially ephemeral bodies of water (i.e., amphibians). The pesticide is assumed to be instantaneously and completely mixed within the water body. In addition, acute toxicity values are divided by an uncertainty factor of 2 for aquatic plants and invertebrates and 10 for fish species. The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level to withstand, or recover from, a stressor at the level of the population. No uncertainty factor is applied to chronic endpoints.

Freshwater invertebrates: Cyantraniliprole was acutely toxic to freshwater invertebrates and mortality was seen over the range of concentrations tested for all species tested. Since daphnia exhibited the highest sensitivity to cyantraniliprole in comparison to other aquatic invertebrates, additional acute toxicity studies were conducted which exposed daphnids to different end-use product formulations, as well as major transformation products formed in soil and water. Overall, mortality was observed for all end-use product formulations. Results indicate that the OD formulation was the most toxic overall. Following acute exposure to the transformation products, there were limited effects observed for IN-RNU71, IN-K5A77, IN-K5A78, IN-K5A79, IN-NXX70 and IN-QKV54, resulting in LC_{50} values which are all above the highest concentrations tested. However, acute exposure to IN-JCZ38, IN-JSE76 and IN-PLT97 resulted in mortality but was much less toxic than the parent (LC_{50} range between 0.40 mg/L and 22.46 mg/L). Two additional studies with the transformation products were conducted for 21 days, which evaluated growth, mortality and reproduction. Following chronic exposure to IN-J9Z38, there were no effects observed at the highest concentration tested (NOEC of 0.24 mg/L). Although no effects were observed following acute exposure to IN-K5A77, the long term effects included reduction of body length (NOEC of 0.117 mg/L).

Following the screening assessment it was determined that there was also a potential risk to other invertebrates including Mayfly, Caddisfly, and *Ceriodaphnia dubia*, following exposure to cyantraniliprole (RQ values ranging from 1.7 to 11.7)(Appendix I, Table 32).

Although cyantraniliprole is soluble in water and was primarily detected in the water column in aquatic/sediment studies, there is still some potential for cyantraniliprole to be found in water around the sediment layer of aquatic environments. Therefore, in order to consider aquatic species that reside in close proximity to sediement, the potential risk of chironomid and *Lumbriculus variegatus* to cyantraniliprole was also considered. There was no acute risk identified for either species of sediment dwelling organism. Although a potential chronic risk was identified for chironomid (RQ) value of <5.5), there were no effects noted at the highest concentration tested. Although there were some minor effects noted for emergence, the effects were only observed in one of three replicates, and the three replicates were otherwise comparable to the control. Therefore, it was concluded that the effects were not likely treatment related (Appendix I, Table 33).

A number of considerations were made during the refined risk assessment for aquatic invertebrates. The first refinement was to assess spray drift off the treated site and the percent deposition of spray for ground boom (11%), aerial crop use (26%) and orchard airblast (74% early use, 59% late use) into an adjacent water body 1 m downwind from the site of application. As an additional refinement, the amount of cyantraniliprole resulting from run-off was also considered. This represents a more "realistic" exposure scenario for the amount of active ingredient which may run-off from the soil surface following either foliar or soil application . This type of exposure scenario also takes into account the physical/chemical and fate properties of the chemical (Appendix I, Tables 17–20).

Since multiple acute toxicity endpoints were available for freshwater invertebrates (Appendix I, Tables 32 and 33), a species sensitivity distribution (SSD) was calculated for freshwater invertebrates based on normally distributed toxicity data. Acute toxicity endpoints for the end-use products were converted to technical grade active ingredient equivalents and also used to calculate the SSD, and where multiple toxicity values were available for one species (such as for daphnia), the geometric mean was calculated and used in the SSD. The hazardous concentration to 5% of the species (HC_5) was then determined for freshwater invertebrates from the SSD and used to calculate the risk quotients instead of the most sensitive species tested. This provided a more scientific endpoint, which uses all of the data, and is intended to protect 95% of the aquatic invertebrate population.

Based on the HC_5, a potential risk was identified from exposure to spray drift when the end-use product is applied aerially or by airblast applications (RQ values up to 3.3) (Appendix I, Table 33). Therefore, mitigative drift reduction statements and buffer zones will be required on the label. A potential risk was also identified for run-off from both the foliar and soil applied end-use product formulations (RQ values up to 1.4), therefore, mitigative statements for run-off reduction will be required on the label.

Fish and amphibians: For freshwater vertebrates, cyantraniliprole did not cause acute mortality up to the highest concentrations tested for rainbow trout, bluegill sunfish and channel catfish (LC_{50} value of >13 mg/L). Chronic exposure of rainbow trout to cyantraniliprole resulted in effects to growth (NOEC value of 1.01 mg/L based on length); no other endpoints, such as mortality or reproduction were affected up to the highest concentration tested (10.7 mg/L).

Using the most sensitive fish species as a surrogate for amphibians, there were no acute or chronic effects. The screening level risk quotients did not exceed the trigger value of one for freshwater fish or amphibian (Appendix I, Table 33).

Algae: For algae (*Pseudokirchneriella subcapitata)*, exposure to the four end-use products (Cyantraniliprole 100 g/L SE, Cyantraniliprole 100 g/L OD and Cyantraniliprole 200 g/L SC, and Cyantraniliprole/thiamethoxam) resulted in some effects to cell density and growth (E_bC_{50} for cell density ranging from 0.825 mg/L to 9.8 mg/L, with the highest toxicity from the Cyantraniliprole 100 g/L SE formulation). Following exposure of vascular plants (*Lemna gibba* and *Navicula pelliculosa*) to the technical grade active ingredient, cyantraniliprole, there were no effects on density or growth rate up to the highest concentrations tested. Despite the inhibition of cell density and biomass observed in the algal and diatom studies, cyantraniliprole did not exceed the screening level risk trigger value of one for algae and the diatom (Appendix I, Table 33).

Estuarine / marine species: Acute toxicity studies with cyantraniliprole were conducted with the marine invertebrate, *Americamysis bahia*, Eastern oyster, the saltwater diatom (*Skeletonema costatum)* and sheepshead minnow. Cyantraniliprole was acutely toxic to the mysid shrimp (96 hour LC_{50}: 1.2 mg/L) and the eastern oyster (96 hour EC_{50} of 0.45 mg/L). Some effects to cell density were also observed for the marine diatom (*Skeletonema costatum*) (E_bC_{50} value of 3.2 mg/L). There were no acute effects observed in the sheepshead minnow highest concentration tested. Following long term exposure in an early life stage test, there were no effects for hatching success or survival of minnow larvae, however, there was a slight effect on length (NOEC value of 2.9 mg/L). Despite some observations of toxicity from the laboratory studies, there was negligible risk identified from the screening level risk assessment (Appendix I, Table 33).

4.3 Incident reports / additional considerations

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

Cyantraniliprole is a new technical grade active ingredient being proposed for registration in a number of countries. Chlorantraniliprole, which has a similar mode of action and is currently registered in the US and Canada, does not have any incident reports. There are two end-use products which contain both cyantraniliprole and thiamethoxam. Thiamethoxam is conditionally registered in Canada and is currently undergoing re-evaluation.

As of 13 January 2013, there have been bee mortality incidents reported from over 40 beekeepers to the PMRA, most of which coincided with the planting of corn seed treated with thiamethoxam and/or clothianidin. An analysis is currently being undertaken at the PMRA in order to further understand these bee incidents. It should be noted that the current proposed use pattern for the product being considered in this document does not include seed treatment. The PMRA has released a document on Best Management Practices for protecting pollinators (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_fact-fiche/bees-incidents-abeilles-2012/index-eng.php).

In addition, the United States Environmental Protection Agency's Ecological Incident Information System reports one incident related to thiamethoxam in 2010 involving the death of young larvae in 4 apiaries. No further details were provided in the summary.

5.0 Value

5.1 Effectiveness Against Pests

DuPont Verimark Insecticide
Sixteen field trials against Colorado potato beetle and four field trials against potato flea beetle on potato supported control of these pests on potato by seed-piece treatment at 45 mL product/100 kg seed pieces or by in-furrow application at 750–1000 mL product/ha.

Two field trials against imported cabbageworm and diamondback moth and four field trials against cabbage looper on cabbage and broccoli supported control of imported cabbageworm, diamondback moth and cabbage looper on brassica vegetables by soil application (in-furrow, transplant water, banded surface application) at 750–1000 mL product/ha.

Two field trials against flea beetles on cabbage and broccoli and one field trial against swede midge on broccoli supported early season damage reduction by these pests on brassica vegetables by soil application (in furrow, transplant water, banded surface application) at 750–1000 mL product/ha.

DuPont Benevia Insecticide
Six field trials each against cabbage looper and imported cabbageworm and ten field trials against diamondback moth on cabbage, broccoli and rapeseed supported control of these pests on oilseed crops at 250–500 mL product/ha.

One field trial against redbacked cutworm in canola supported early season control of cutworms on oilseed crops at 500–750 mL product/ha and control of variegated cutworm on potato at 750–1000 mL product/ha.

Five field trials against beet armyworm on broccoli, tomato and cabbage and one laboratory trial against bertha armyworm on canola plants supported control of bertha armyworm on oilseed crops at 500 mL product/ha.

Five field trials against European corn borer on potato and pepper supported control of this pest on potatoes at 500–750 mL product/ha.

Three field trials against sunflower head moth on sunflowers supported control of this pest on sunflower at 250–500 mL product/ha.

Nine field trials against Colorado potato beetle on potato and tomato supported control of this pest on potato at 750–1000 mL product/ha.

Four trials against potato aphid on potato and tomato as well as various other aphid species on other crops supported control of aphids on potato at 500–1500 mL product/ha.

Three field trails against cabbage seedpod weevil on canola supported control of this pest on oilseed crops at 500–1000 mL product/ha.

Three field trials against swede midge on cabbage supported control of this pest on oilseed crops at 500–750 mL product/ha.

DuPont Lumiderm Insecticide Seed Treatment
Twenty-two field trials against flea beetles on rapeseed supported early season protection from flea beetle feeding damage to canola, rapeseed and oilseed mustard at 960–1600 mL product/100 kg seed.

Two greenhouse trials against black cutworm on rapeseed supported early season protection from cutworm feeding damage to canola, rapeseed and oilseed mustard at 480–960 mL product/100 kg seed.

DuPont Exirel Insecticide
Six field trials against cabbage looper on cabbage, broccoli and rapeseed and extrapolation to other field vegetables supported control of this pest on tuberous and corm vegetables, leafy, brassica, fruiting and cucurbit vegetables at 250–500 mL product/ha.

Six field trials against imported cabbageworm and ten field trials against diamondback moth on cabbage, broccoli, and rapeseed supported control of these pests on brassica vegetables at 250–500 mL product/ha.

One field trial against redbacked cutworm on canola and extrapolation from data for various other Lepidoptera larvae supported control of cutworms on leafy, brassica, fruiting and cucurbit vegetables and variegated cutworm on tuberous and corm and fruiting vegetables at 500–750 mL product/ha.

Five field trials against beet armyworm on broccoli, tomato and cabbage and one laboratory trial against bertha armyworm on canola plants supported control of armyworms (armyworm, beet armyworm and/or fall armyworm) on tuberous and corm, leafy, brassica, fruiting and cucurbit vegetables at 500 mL product/ha.

Two field trials against tobacco hornworm on tobacco and one field trial against tomato hornworm on tomato supported suppression of these pests on tuberous and corm and fruiting vegetables at 750 mL product/ha.

Five field trials against European corn borer on potato and pepper supported control of this pest on tuberous and corm and fruiting vegetables at 500–750 mL product/ha.

Four field trials against corn earworm (tomato fruitworm) on sweet corn and lettuce and extrapolation to other field vegetables supported control of this pest on tuberous and corm, leafy brassica, fruiting and cucurbit vegetables at 750 mL product/ha.

Nine field trials against Colorado potato beetle on potato and tomato supported control of this pest on tuberous and corm and fruiting vegetables at 750–1000 mL product/ha.

Five field trials against green peach aphid on broccoli, pumpkin and bell pepper, four field trials against potato aphid on potato and tomato, three field trials against melon aphid on pumpkin, and three field trials against cabbage aphid cabbage and broccoli supported control of aphids on tuberous and corm, leafy, brassica, fruiting and cucurbit vegetables at 500–1500 mL product/ha.

Three field trials against thrips on onions supported suppression of thrips on bulb vegetables at 500–1500 mL product/ha.

Three field trials against dipteran leafminers (*Liriomyza* spp.) on lettuce supported control of dipteran leafminer larvae on leafy and brassica vegetables at 1000–1500 mL product/ha and on cucurbit vegetables at 750–1000 mL product/ha.

Three field trials against swede midge on cabbage supported control of this pest on brassica vegetables at 500–750 mL product/ha.

Three field trials against cranberry fruitworm on blueberry and cranberry supported control of this pest on bushberries at 500–1000 mL product/ha.

Four field trials against blueberry gall midge (cranberry tipworm) on blueberry and cranberry supported control of this pest on bushberries at 750–1000 mL product/ha.

Three field trials against blueberry maggot on lowbush and highbush blueberry supported suppression of this pest on bushberries at 1000–1500 mL product/ha.

Two field trials against blueberry aphid on highbush blueberry as well as data for other aphid species on pome fruits and stone fruits supported control of blueberry aphid on bushberries at 750–1500 mL product/ha.

Five field trials against obliquebanded leafroller on apple and cherry supported control of obliquebanded leafroller, threelined leafroller, fruittree leafroller, European leafroller and eyespotted bud moth on bushberries, pome fruits, stone fruits and tree nuts at 500–1000 mL product/ha.

Nine field trials against codling moth on apple, pear and walnut supported control of this pest on pome fruits and tree nuts at 500–750 mL product/ha.

Six field trials against oriental fruit moth on apple and peach supported control of this pest on pome fruits, stone fruits and tree nuts at 500–750 mL product/ha.

Extrapolation from data for other lepidopteran pests of pome fruits supported control of tufted apple bud moth on pome fruits at 500–1000 mL product/ha.

Four field trials against apple maggot on apple supported control of this pest on pome fruits at 1000–1500 mL product/ha.

Five field trials against European apple sawfly on apple supported control of this pest on pome fruits at 500–1000 mL product/ha.

Two field trials against spotted tentiform leafminer on apple supported control of spotted and western tentiform leafminers on pome fruits at 500–750 mL product/ha.

Seven field trials against white apple leafhopper on apple supported control of this pest on pome fruits at 750–1500 mL product/ha.

Four field trials against rosy apple aphid on apple supported control of this pest on pome fruits at 750–1500 mL product/ha.

Three field trials against plum aphid on plum as well as the data for rosy apple aphid on apple supported control of this pest on stone fruits at 750–1500 mL product/ha.

Efficacy against green peach aphid on field crops and application rates for other aphid species on fruit trees supported control of green peach aphid on pome fruits and stone fruits at 750–1500 mL product/ha.

Six field trials against peach twig borer on peach and almond supported control of this pest on stone fruits and tree nuts at 750–1000 mL product/ha.

Five field trials against plum curculio on apple, peach and cherry and four trials against Japanese beetle on apple, grape and soybean supported control of these pests on pome fruits, stone fruits and bushberries at 1000–1500 mL product/ha.

A17960A 600FS and A17960B 600FS
Six field trials against Colorado potato beetle on potato supported early season control of this pest on potatoes at 10–22.55 mL product/100 kg seed.

A16901B 40WG Insecticide
Two field trials against lettuce aphid and green peach aphid on lettuce and cabbage, respectively, and extrapolation from thiamethoxam's registered uses supported control of aphids by soil applications to leafy, brassica and cucurbit vegetables at 750 g product/ha, fruiting vegetables at 440–750 g product/ha and potato at 440–700 g product/ha.

Four field trials against corn earworm (tomato fruitworm) and armyworm on tomato, one trial against beet armyworm on lettuce and extrapolation from other lepidopteran pests of brassica vegetables supported a claim of reduces damage caused by beet armyworm, corn earworm (tomato fruitworm) and fall armyworm by soil application on leafy vegetable at 750 g product/ha, and reduces damage caused by these same pests and yellowstriped armyworm on brassica and fruiting vegetables at 750 g product/ha.

Three field trials against diamond back moth on cabbage, three field trials against diamondback moth, cabbage looper and imported cabbageworm on cabbage, broccoli and cauliflower, one field trial against imported cabbageworm on broccoli, one field trial against cabbage looper on cabbage supported early season control of cabbage looper by soil application on leafy and brassica vegetables at 750 g product/ha and on fruiting vegetables at 440–750 g product/ha, and early season control of diamond back moth and imported cabbageworm by soil application on brassica vegetables at 750 g product/ha. Claims for cabbage looper on leafy and fruiting vegetables were supported based on extrapolation from other lepidopteran pests on these vegetables.

Four field trials against cabbage flea beetle on cabbage and broccoli, and extrapolation from thiamethoxam's registered uses supported the early season suppression of flea beetles by soil application on leafy, brassica and cucurbit vegetables at 750 g product/ha, on fruiting vegetables at 440–750 g product/ha and on potato at 440–700 g product/ha.

Extrapolation from registered uses of thiamethoxam on these crops and pests supported control of leafhoppers by soil application on leafy and cucurbit vegetables at 750 g product/ha and on fruiting vegetables at 440–750 g product/ha.

One trial against a dipteran leafminer on tomato and two greenhouse trials against a dipteran leafminer on gerbera and petunia supported control of dipteran leafminers by soil application on leafy, brassica and cucurbit vegetables at 750 g product/ha and on fruiting vegetables at 440–750 g product/ha.

Two field trials against thrips on eggplant and cucumber supported early season suppression of thrips by soil application on brassica and cucurbit vegetables at 750 g product/ha and on fruiting vegetables at 440–750 g product/ha.

Six field trials against Colorado potato beetle on tomato and potato supported control of Colorado potato beetle by soil application on fruiting vegetables at 440–750 g product/ha and on potato at 440–700 g product/ha.

Two field trials against spotted cucumber beetle and striped cucumber beetle on cucumber and zucchini supported early season suppression of cucumber beetles by soil application on cucurbit vegetables at 750 g product/ha.

Extrapolation from registered uses of thiamethoxam supported control of potato leafhopper and aphids on potato by soil application at 440–700 g product/ha.

Mainspring Insecticide

Use history for registered uses for thiamethoxam alone on ornamentals in the US supported control of aphids, mealybugs and soft scales by foliar application to greenhouse ornamentals at 37.5–75 g product/100 L of water.

One greenhouse trial against a dipteran leafminer on petunia supported control of dipteran leafminers by foliar application to greenhouse ornamentals at 37.5–75 g product/100 L.

Five greenhouse trials against silverleaf whitefly on gerbera, gentian and hibiscus supported suppression of whiteflies by foliar application to greenhouse ornamentals at 37.5–75 g product/100 L.

One greenhouse trial against western flower thrips on chrysanthemum supported suppression of thrips by foliar application to greenhouse ornamentals at 37.5–75 g product/100 L.

Three greenhouse trials against three aphid species on hibiscus, marigold and zinnia supported control of aphids by soil drench application to greenhouse ornamentals at 50–75 g product/100 L.

Two greenhouse trials against a dipteran leafminer on gerbera and petunia supported control of dipteran leafminer leafminers by soil drench application to greenhouse ornamentals at 50–75 g product/100 L.

Use history for registered uses for thiamethoxam alone on ornamentals in the US supported control of root aphids, mealybugs and soft scales by soil drench application to greenhouse ornamentals at 50–75 g product/100 L.

One greenhouse trial against a fungus gnat on petunia supported control of fungus gnats on greenhouse ornamentals by soil drench application at 50–75 g product/100 L.

Three greenhouse trials against silverleaf whitefly on gerbera, hibiscus and poinsettia supported control of whiteflies on greenhouse ornamentals by soil drench application at 50–75 g product/100 L.

Three trials against thrips on greenhouse marigold and field vegetables supported the suppression of thrips on greenhouse ornamental by soil drench application at 50–75 g product/100 L.

Rationales and use history for registered uses for thiamethoxam alone on ornamentals in the US supported control of aphids, lace bugs, leafhoppers, mealybugs, psyllids and soft scales by foliar application to outdoor ornamentals at 37.5–75 g product/100 L.

Extrapolation from the uses of thiamethoxam alone to control black vine weevil on bushberries and pepper weevil on greenhouse peppers supported the control of black vine weevil on outdoor greenhouse ornamentals by foliar application at 37.5–75 g product/100 L.

One greenhouse trial against a dipteran leafminer on petunia and accepted rationales supported control of dipteran leafminers by foliar application to outdoor ornamentals at 37.5–75 g product/100 L.

One greenhouse trial against western flower thrips on chrysanthemum and accepted rationales supported suppression of thrips by foliar application to outdoor ornamentals at 37.5–75 g product/100 L.

5.1.1 Acceptable Efficacy Claims

The six end-use products containing cyantraniliprole alone provide control or suppression of various pests on bushberries, oilseed crops, potatoes, tree fruits, tree nuts, tuberous and corm, bulb, leafy, brassica, fruiting and cucurbit vegetables. The two end-use products containing cyantraniliprole and thiamethoxam provide control, suppression or reduction in damaged caused by various pests on potatoes, leafy, brassica, fruiting and cucurbit vegetables and outdoor and greenhouse ornamentals.

5.2 Phytotoxicity to Host Plants

Efficacy trials were conducted on a wide variety of field, tree fruit, tree nut, bushberry, ornamental crops, with no reports of adverse effects on host plants.

5.3 Sustainability

5.3.1 Survey of Alternatives

Most of the crop/pest combinations have active ingredients registered as alternatives from at least four MoA groups, although at least one of these four MoA groups is an older chemistry (i.e., MoA groups 1A (carbamates), 1B (organophosphates) or 3A (pyrethroids)). Other alternatives are newer chemistries (e.g., MoA groups 4A (neonicotinoids) or 5 (spinosyns)), or unclassified active ingredients such as pheromones or insecticidal soap.

- **No registered alternative active ingredients for these crops / pests:**
    - Tree nuts: eyespotted budmoth, peach twig borer;
    - Oilseeds: sunflower head moth, swede midge.

- **Cyantraniliprole (MoA group 28) is a new mode of action for:**
    - Potato: potato leafhoppers;
    - Tuberous and corm vegetables: aphids, flea beetles;
    - Bulb vegetables: thrips;
    - Leafy vegetables: aphids, dipteran leafminers, flea beetles, leafhoppers;
    - Brassica vegetables: aphids, dipteran leafminers, flea beetles, thrips;
    - Fruiting vegetables: aphids, dipteran leafminers, flea beetles, leafhoppers, potato psyllid, thrips, tomato fruitworm (corn earworm);
    - Cucurbit vegetables: aphids, cucumber beetles, corn earworm, dipteran leafminers, flea beetles, leafhoppers, thrips;
    - Pome fruit: apple maggot, European apple sawfly, eyespotted budmoth, tufted apple budmoth, green peach aphid, rosy apple aphid, Japanese beetle, plum curculio, white apple leafhopper;

- Stone fruit: cherry fruit fly, western cherry fruit fly, eyespotted budmoth, green peach aphid, plum aphid, Japanese beetle, plum curculio;
- Bushberries: blueberry aphid, blueberry gall midge (cranberry tipworm). blueberry maggot, eyespotted budmoth, Japanese beetle, leafrollers, plum curculio;
- Tree nuts: eyespotted budmoth, oriental fruit moth, peach twig borer;
- Oilseeds: bertha armyworm, cabbage looper, cabbage seedpod weevil, cutworms, diamondback moth, flea beetles, imported cabbage worm, sunflower head moth, swede midge;
- Outdoor ornamentals: aphids, black vine weevil, dipteran leafminers, lace bugs, leafhoppers, mealybugs, psyllids, soft scales, thrips;
- Greenhouse ornamentals: aphids, dipteran leafminers, fungus gnats, mealybugs, root aphids, soft scales, thrips, whiteflies.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

The eight end-use products are generally compatible with most current management practices for the supported crops and pests.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Reports of resistance to chlorantraniliprole, another active ingredient in MoA Group 28, are recorded in the Michigan State University Arthropod Pesticide Resistance Database. Resistance was noted for beet armyworm and diamondback moth. Therefore, resistance to cyantraniliprole could develop and careful stewardship to minimize the potential for the development of resistance should be followed.

5.3.4 Contribution to Risk Reduction and Sustainability

Canadian Grower Priority Database: The supported use pattern for cyantraniliprole addresses high priorities in brassica vegetable, pome fruit, stone fruit, bushberry, and oilseed crops, and in greenhouse and outdoor ornamentals. Uses on all of these crops were supported.

Transition Strategies: Under its re-evaluation program, PMRA examines the continued acceptability of older pesticides. In instances where critical uses are being phased out, the PMRA can work with Canadian stakeholders toward reasonable transitions to alternative management strategies. These are known as transition strategies at PMRA. Cyantraniliprole is identified by Canadian stakeholders as a potential replacement product under transition strategies for azinphos-methyl in pome fruits (apple maggot, European apple sawfly, oriental fruit moth and plum curculio) and cherry (cherry fruit fly), endosulfan in stone fruits (green peach aphid and plum aphid), and diazinon in bulb vegetables (thrips). It is also identified as a potential replacement product for the organophosphate replacement strategy for blueberries (blueberry maggot, Japanese beetle and leafrollers).

Resistance management: Cyantraniliprole alone: These end-use products contribute to resistance management because they will be a new mode of action for use on oilseeds and bulb vegetables. Chlorantraniliprole, which is also in MoA Group 28, is registered for use on the other labelled crops.

5.4 Increased numbers of crops and pests for formulations with cyantraniliprole and thiamethoxam

For the end-use product containing cyantraniliprole and thiamethoxam for soil application to vegetable crops, the pest spectrum is increased compared to what is registered for either active ingredient alone. For the end-use product containing these two active ingredients for use on greenhouse and outdoor ornaments, more crops and pests are supported compared to what is registered for either active ingredient alone. Greenhouse ornamentals are a new use for thiamethoxam. Cyantraniliprole alone is not registered for use on ornamentals.

5.5 New application methods

Soil and seed piece application methods are new to active ingredients from MoA Group 28. For example, cyantraniliprole is the only active ingredient of this group proposed for registration as a seed piece and in-furrow treatment on potatoes, for use as an in-furrow or at transplant application to brassica and as a seed treatment on canola, rapeseed and oilseed mustard.

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, i.e., 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 of cyantraniliprole and its related end-use products, DuPont Verimark Insecticide, DuPont Benevia Insecticide, DuPont Lumiderm Insecticide Seed Treatment, DuPont Exirel Insecticide, A17960A 600FS, A16901B 40WG Insecticide and Mainspring Insecticide, PMRA has taken into account the federal Toxic Substances Management Policy and has followed its Regulatory Directive DIR99-03. It has been determined that this product does not meet TSMP Track-1 criteria because:

- Cyantraniliprole does not meet the criteria for persistence in soil or sediment. Its values for half-life in soil (maximum soil half-life of 138 days (lab), 32 days (field), maximum) and sediment (maximum half-life is 67 days) are below the TSMP Track-1 cut-off criteria for both soil and sediment (water/sediment) (≥ 182 days; sediment (>365 days).

- Cyantraniliprole is not bioaccumulative. The octanol-water partition coefficient (log K_{ow}) is (1.94), which is below the TSMP Track-1 cut-off criterion of ≥5.0, and the BCF is less than one (1).

- Cyantraniliprole does not meet the criteria for toxicity (see Sections 3.6, 4.7 and 6.4).

- Cyantraniliprole does not form any major transformation products that meet the TSMP Track-1 criteria.

- Cyantraniliprole (technical grade) does not contain any by-products or microcontaminants that meet the TSMP Track-1 criteria. Impurities of toxicological concern are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[5]. The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[7] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

> Technical grade cyantraniliprole (and thiamethoxam) and the associated end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*
>
> The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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

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

7 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for cyantraniliprole is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of carcinogenicity in laboratory animals after longer-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Cyantraniliprole was not neurotoxic or immunotoxic. In short-term and chronic studies on laboratory animals, the primary targets were the liver, the thyroid gland, and the adrenal gland. Evidence indicated that effects on the thyroid were secondary to liver enzyme activation by cyantraniliprole. 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.

The nature of the residue in four diverse crops (lettuce, rice, cotton, and tomato) and animals (goat and hen) is adequately understood. The residue definition in livestock, plants, and rotational crops, for enforcement purposes, is cyantraniliprole. The residue definition for the purpose of dietary exposure assessment is cyantraniliprole and IN-J9Z38 expressed as parent equivalents in processed commodities. Cyantraniliprole, IN-N7B69, IN-MLA84, IN-MYX98, and IN-J9Z38 are considered on a livestock matrix-specific basis in terms of parent equivalents for the purpose of dietary exposure.

The proposed use of cyantraniliprole in/on CG1C, CG3-07, CG4, CG5, CG8-09, CG9, CG11-09, CG12-09, CG13-07B, CG14-11, and CG20, including imported commodities (citrus fruits and cotton (US), grapes and olives (EU)) does not constitute an unacceptable chronic dietary risk (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 maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limits be specified for residues of cyantraniliprole:

- 30 ppm in and on leafy *Brassica* vegetables (CG5B)
- 20 ppm in and on leafy vegetables (CG4)
- 8 ppm in and on green onions (CG3-07B)
- 6 ppm in and on cherries (CG12-09A)
- 4 ppm in and on bushberries (CG13-07B)
- 3 ppm in and on head and stem *Brassica* vegetables (CG5A)
- 2.4 ppm in and on citrus oil
- 2.0 ppm in and on fruiting vegetables (CG8-09)
- 1.5 ppm in and on pome fruits (CG11-09)
- 1.5 ppm in and on peaches (CG12-09B)
- 1.5 ppm in or on oilseeds (CG20)
- 1.5 ppm in and on grapes
- 1.5 ppm in and on olives
- 0.7 ppm in and on citrus fruits (CG10)

- 0.5 ppm in and on plums (CG12-09C)
- 0.4 ppm in and on cucurbit vegetables (CG9)
- 0.15 ppm in and on tuberous and corm vegetables (CG1C)
- 0.04 ppm in and on bulb onions (CG3-07A)
- 0.04 ppm in and on tree nuts (CG14-11)
- 0.04 ppm in and on leaves of root and tuber vegetables (CG2)
- 0.02 ppm in and on root vegetables (CG1A)
- 0.01 ppm in and on fat, meat and meat by products of cattle, sheep, goats, hogs, horses, and poultry
- 0.01 ppm in and on milk
- 0.01 ppm in and on eggs

Mixers, loaders, applicators handling cyantraniliprole and workers re-entering treated areas are not expected to be exposed to levels of cyantraniliprole that will result in an unacceptable risk when products are used according to label directions and the proposed mitigation measures.

The personal protective equipment on the product labels and the additional mitigation measures are adequate to protect workers.

Residential and bystander exposure is not of concern.

7.2 Environmental Risk

Cyantraniliprole and its major transformation products present a negligible risk to soil dwelling organisms, aquatic plants, algae, (freshwater and marine), fish (freshwater and marine), some species of aquatic invertebrates, and amphibians. However, cyantraniliprole may affect some species of aquatic invertebrates from soil and foliar applications. Cyantranilprole may also affect beneficial arthropods, and bees from foliar applications.

In order to mitigate the potential effects of cyantraniliprole to aquatic organisms, buffer zones and reduction of run-off are required on the label. In order to mitigate the potential effects of cyantraniliprole to terrestrial organisms (beneficial arthropods, and bees), foliar applications are limited while bees are actively foraging, and reduction of drift are required on the label.

7.3 Value

The eight end-use products have value for the control, suppression or reduction in damaged caused by the listed insect pests on field, fruit tree, tree nut, outdoor ornamental and greenhouse ornamental crops. Cyantraniliprole contributes to resistance management because its MoA is new for use on oilseeds and bulb vegetables.

Soil and seed treatment application methods of end-use products containing cyantraniliprole are new to MoA Group 28. For example, it is the only MoA Group 28 active ingredient registered as a seed piece and in-furrow treatment on potatoes, for use as an in-furrow or at transplant application to brassicas and as a seed treatment on canola, rapeseed and oilseed mustard.

The value of the two end-use products containing cyantraniliprole and thiamethoxam is increased pest spectrum and increased number of crops on the label compared to what is currently registered for either active ingredient alone.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dupont Cyazypyr Technical Insecticide and Cyantraniliprole Technical and the end-use products Dupont Verimark Insecticide, Dupont Benevia Insecticide, DuPont Lumiderm Insecticide Seed Treatment, Dupont Exirel Insecticide, A17960A 600FS, and A17960B 600FS, containing the technical grade active ingredient cyantraniliprole. The end-use products A16901B 40WG Insecticide and Mainspring Insecticide are also proposed, these contain both cyantraniliprole and thiamethoxam. The end-use products are proposed to control a variety of insect pests on fruits and vegetables, oilseeds, greenhouse ornamentals and outdoor ornamentals.

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

List of Abbreviations

µCi	microCurie
µg	micrograms
A	applicator
a.i.	active ingredient
a.s.	active substance
ACN	actonitrile
ACTH	adenocorticotropic hormone
AD	administered dose
ADI	acceptable daily intake
ALP	alkaline phosphatase
ALT	alanine transaminase
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
ATPD	area treated per day
BBCH	Biologische Bundesanstalt, Bundessortenamt and Chemical industry
BCF	bioconcentration factor
bw	body weight
BW	generic body weight
bwg	body weight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CEC	cation-exchange capacity
CG	crop group
cm	centimetres
CN	cyano group
CYT	cyantraniliprole
d	day
DAA	Sampled × Days after Application A
DAB	Sampled × Days after Application B
DAT	day after treatment
DF	dry flowable
DFOP	double first order in parallel
DFR	dislodgeable foliar residue
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
dw	dry weight
E_bC_{50}	effective concentration on 50% of the population, based on algal biomass
E_rC_{50}	effective concentration on 50% of the population, based on growth rate
EC_3	concentration required to induce a threshold positive sensitization response (SI=3)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	estimated dietary exposure

EEC	estimated environmental concentration
ELISA	enzyme-linked immunosorbent assay
EP	end-use product
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
ESCORT	European Standard Characteristics of Beneficial Regulatory Testing
EU	European Union
F_1	first generation
F_2	second generation
fc	food consumption
fe	food efficiency
FIFRA	United States *Federal Insecticide, Fungicide, and Rodenticide Act*
FIR	food ingestion rate
FS	flowable suspension formulation
g	gram
GAP	good agricultural practice
GR	granular formulation
GUS	groundwater ubiquity score
h	hour
ha	hectare
HAFT	highest average field trial
HC_5	hazardous concentration to 5% of the species
HDPE	high density polyethylene
HDT	highest dose tested
HPLC	high performance liquid chromatography
IgM	immunoglobulin M
IOBC	International Organisation for Biological Control
IORE	indeterminate order rate equation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_{des}	soil-water desorption coefficient
K_{desoc}	soil-water desorption coefficient adjusted according to organic carbon content
K_{doc}	soil-water partition coefficient adjusted according to organic carbon content
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration 50%
LD_{50}	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
LR_{50}	lethal rate 50%
LSC	liquid scintillation counting
M/L	mixer/loader

m	metre
MAS	maximum average score for 24, 48 and 72 hours
MBD	more balanced diet
mg	milligram
MIS	maximum irritation score
mL	millilitre
MoA	mode of action
MOE	margin of exposure
m.p.	mechanically-pressurized
mPa	milliPascals
MRL	maximum residue limit
MRM	multi-residue methodologies
MS/MS	tandem mass spectrometry
m/z	mass-to-charge ratio for an ion
N/A	not applicable
na	not analysed
NAFTA	North American Free Trade Agreement
nc	not collected
NC	not conducted
ng	nanogram
nm	nanometre
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
OC	organic carbon content
OCSPP	Office of Chemical Safety and Pollution Prevention
OD	oil dispersant formulation
p.	manually-pressurized
Pa	Pascals
PBI	plantback interval
PC	pyrazole ring
PCPA	*Pest Control Product Act*
PE	polyethylene
P*f*	processing factor
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal day
ppb	parts per billion
ppm	parts per million
RAC	raw agricultural commodity
RD	residue definition
REI	restricted entry interval
RQ	risk quotient
rT3	reverse T3

SC	soluble concentrate
SDEV	standard deviation
SI	stimulation index
SE	suspo-emulsion formulation
SFO	single first order
SRBC	sheep red blood cells
SSD	species sensitivity distribution
T3	tri-iodothyronine
T4	thyroxine
TGAI	technical grade active ingredient
tmt	treatment
TP	transformation products
TRR	total radioactive residue
TSH	thyroid stimulating hormone
TSMP	Toxic Substances Management Policy
UDP-GT	UDP glucuronyltransferase
UF	uncertainty factor
US	United States of America
UV	ultraviolet
WBC	white blood cells
WG	wettable granule formulation
wt	weight

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ (ppm)	Reference (PMRA No.)
Tomato paste; Sun-dried tomato	DuPont-1187	CYT; IN-J9Z38; IN-JCZ38; IN-K7H19; IN-MLA84; IN-MYX98; IN-N5M09; IN-N7B69; IN-F6L99	Processed fractions HPLC-MS/MS in electrospray interface or atmospheric pressure chemical ionization in positive ion mode	0.01	2070308
Grapes; Apples Peaches; Tomatoes; Almonds; Lettuce; Wheat grain; Wheat straw; Potatoes Lemons; Rapeseed	DuPont-1187	CYT; IN-J9Z38; IN-JCZ38; IN-K7H19 IN-MLA84; IN-MYX98 IN-N7B69	HPLC-MS/MS Data gathering/Enforcement Method Validation	0.01	2070311
Almonds; Onions; Tomato paste; Sun-dried tomatoes	DuPont-1187	CYT; IN-J9Z38; IN-JCZ38; IN-K7H19 IN-MLA84; IN-MYX98 IN-N5M09; IN-N7B69 IN-F6L99	HPLC-MS/MS Independent Laboratory Validation	0.01	2070338 2070451
Wheat grain; Wheat hay; Beet foliage; Lettuce	DuPont-1187	CYT; IN-J9Z38; IN-JCZ38; IN-K7H19 IN-MLA84; IN-MYX98 IN-N7B69	HPLC-MS/MS Extraction Efficiency	0.01	2070315
Muscle; Fat; Kidney; Liver; Heavy cream; Skim milk; Whole milk; Eggs	D Pont-1552	CYT; IN-HGW87; IN-JCZ38; IN-MYX98 IN-MLA84; IN-J9Z38 IN-N7B69; IN-K7H19 IN-K5A79	HPLC-MS/MS using turbo ion spray ionisation in positive mode Data gathering and enforcement	0.01	2070320
Muscle; Liver; Kidney; Fat; Milk; Eggs	DuPont-1552	CYT; IN-HGW87; IN-JCZ38; IN-MYX98 IN-MLA84; IN-J9Z38 IN-N7B69; IN-K7H19	HPLC-MS/MS using turbo ion spray ionisation in positive mode	0.01	2070317
Muscle; Liver Milk; Eggs	DuPont-1552 Version 1	CYT; IN-HGW87; IN-JCZ38; IN-MYX98; IN-MLA84; IN-J9Z38	HPLC-MS/MS Extraction Efficiency	0.01	2070313
Milk; Muscle; Kidney	DuPont-1552	CYT; IN-HGW87; IN-JCZ38; IN-MYX98; IN-MLA84; IN-J9Z38	HPLC-MS/MS Independent Laboratory Validation	0.01	2070333
Soil	DuPont 15540	cyantraniliprole	HPLC-MS/MS 475 to 286 *m/z*	1.0 ppb	2070346
		IN-K7H19	HPLC-MS/MS 479 to 286 *m/z*		
		IN-JCZ38	HPLC-MS/MS 493 to 286 *m/z*		
		IN-K5A77	HPLC-MS/MS 475 to 188 *m/z*		
		IN-J9Z38	HPLC-MS/MS 457 to 188 *m/z*		
		IN-K5A79	HPLC-MS/MS 480 to 286 *m/z*		

Matrix	Method ID	Analyte	Method Type	LOQ (ppm)	Reference (PMRA No.)
		IN-JSE76	HPLC-MS/MS 494 to 286 *m/z*		
		IN-PLT97	HPLC-MS/MS 462 to 317 *m/z*		
		IN-K5A78	HPLC-MS/MS 476 to 188 *m/z*		
Sediment	DuPont 18848	cyantraniliprole	HPLC-MS/MS 475 to 286 *m/z*	1.0 ppb	2070357
		IN-J9Z38	HPLC-MS/MS 457 to 188 *m/z*		
		IN-JCZ38	HPLC-MS/MS 493 to 286 *m/z*		
		IN-JSE76	HPLC-MS/MS 494 to 286 *m/z*		
		IN-K5A77	HPLC-MS/MS 475 to 188 *m/z*		
		IN-K5A78	HPLC-MS/MS 474 to 188 *m/z*		
		IN-K5A79	HPLC-MS/MS 480 to 286 *m/z*		
		IN-NXX70	HPLC-MS/MS 437 to 344 *m/z*		
		IN-PLT97	HPLC-MS/MS 462 to 317 *m/z*		
		IN-QKV54	HPLC-MS/MS 344 to 236 *m/z*		
		IN-RNU71	HPLC-MS/MS 437 to 300 *m/z*		
		IN-K7H19	HPLC-MS/MS 479 to 286 *m/z*		
Water	DuPont 18850	cyantraniliprole	HPLC-MS/MS 475 to 286 *m/z*	0.10 ppb	2070342
		IN-J9Z38	HPLC-MS/MS 457 to 188 *m/z*		
		IN-JCZ38	HPLC-MS/MS 493 to 286 *m/z*		
		IN-JSE76	HPLC-MS/MS 494 to 463*m/z*		
		IN-K5A77	HPLC-MS/MS 475 to 299 *m/z*		
		IN-K5A78	HPLC-MS/MS 474 to 186 *m/z*		
		IN-K5A79	HPLC-MS/MS 480 to 463 *m/z*		
		IN-PLT97	HPLC-MS/MS 462 to 317 *m/z*		

Table 2 Toxicity Profile of End-use Products Containing Cyantraniliprole

(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
DUPONT VERIMARK INSECTICIDE	
Oral Toxicity (Up and Down) Sprague-Dawley Rats PMRA # 2070341	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Oral Toxicity (Up and Down) CD-1 Mice PMRA # 2070340	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Sprague-Dawley Rats PMRA # 2070343	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Sprague-Dawley Rats PMRA # 2070345	LC_{50} > 3.7 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2070349	MIS= 0.67 (1 hour) MAS = 0 Non-irritating
Dermal Irritation NZW Rabbits PMRA # 2070347	MAS= 0 MIS=0 Non-irritating
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA # 2070351	Not a skin sensitizer
Skin Sensitization (Buehler) Hartley Guinea pigs PMRA # 2070353	Not a skin sensitizer
DUPONT BENEVIA INSECTICIDE	
Oral Toxicity (Up and Down) Sprague-Dawley Rats PMRA # 2070545	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Sprague-Dawley Rats PMRA # 2070546	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Sprague-Dawley Rats PMRA # 2070547	LC_{50} > 3.3 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2070549	MIS= 6 (1 hour) MAS=1.11 Minimally irritating
Dermal Irritation NZW Rabbits PMRA # 2070548	MIS= 3 MAS=1.11 Slightly irritating
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA # 2070550	Positive at all treated concentration, EC_3 < 5% Potential skin sensitizer

Study Type/Animal/PMRA #	Study Results
Skin Sensitization (Buehler) Hartley Guinea pigs PMRA # 2070552	Potential skin sensitizer
DUPONT LUMIDERM INSECTICIDE SEED TREATMENT	
Oral Toxicity (Up and Down) Sprague Dawley Rats PMRA # 2071023	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Sprague Dawley Rats PMRA # 2071024	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Sprague Dawley Rats PMRA # 2071025	LC_{50} > 2.2 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2071027	MIS= 6.67 (1 hour) MAS = 0.22 Minimally Irritating
Dermal Irritation NZW Rabbits PMRA # 2071026	MIS= 0 MAS=0 Non Irritating
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA # 2071028	Not a skin sensitizer
Skin Sensitization (Buehler) Hartley Guinea Pigs PMRA # 2071029	Not a skin sensitizer
DUPONT EXIREL INSECTICIDE	
Oral Toxicity (Up and Down) Sprague-Dawley Rats PMRA # 2070877	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Oral Toxicity (Up-Down) Mice (strain erroneously reported as SD) PMRA # 2070878	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Sprague-Dawley Rats PMRA # 2070879	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Sprague-Dawley Rats PMRA # 2070880	LC_{50} > 2.2 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2070882	MIS= 8.67 MAS = 2.67 Minimally Irritating
Dermal Irritation NZW Rabbits PMRA # 2070881	MIS= 3.33 MAS=3.11 Moderately Irritating
Skin Sensitization (Buehler) Hartley Guinea Pigs PMRA # 2070883	Potential skin sensitizer

Study Type/Animal/PMRA #	Study Results
A17960A 600FS	
Oral Toxicity (Up and Down) Wistar Rats PMRA # 2071264	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Wistar Rats PMRA # 2071266	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Wistar Rats PMRA # 2071267	LC_{50} > 5.14 mg/L Low Acute Toxicity
Eye irritation NZW Rabbits PMRA # 2071269	MIS= 5.67 (1hour) MAS = 1.11 Minimally Irritating
Dermal irritation NZW Rabbits PMRA # 2071268	MIS= 0 MAS= 0 Non Irritating
Skin Sensitization (Buehler) LAL/HA/BR Guinea pigs PMRA # 2071270	Not a skin sensitizer
A17960B 600FS	
Oral Toxicity (Up and Down) Wistar Rats PMRA # 2071355	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Wistar Rats PMRA # 2071357	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Wistar Rats PMRA # 2071358	LC_{50} > 5.16 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2071362	MIS= 6 (1hour) MAS = 2.67 Mildly Irritating
Dermal Irritation NZW Rabbits PMRA # 2071360	MIS= 0 MAS= 0 Non Irritating
Skin Sensitization (Buehler) LAL/HA/BR Guinea Pigs PMRA # 2071364	Not a skin sensitizer
A16901B 40WG Insecticide and Mainspring Insecticide	
Oral Toxicity (Up and Down) Wistar Rats PMRA # 2071414	LD_{50} > 5000 mg/kg bw, 1/5 mortality Low Acute Toxicity
Dermal Toxicity Wistar Rats PMRA # 2071415	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Wistar Rats PMRA # 2071416	LC_{50} > 5.04 mg/L Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA # 2071418	MIS= 8.67 (1hour) MAS = 1.56 Minimally Irritating

Study Type/Animal/PMRA #	Study Results
Dermal Irritation NZW Rabbits PMRA # 2071417	MIS= 0.33 (1 hour) MAS= 0 Non Irritating
Skin Sensitization (Buehler) LAL/HA/BR Guinea Pigs PMRA # 2071419	Not a sensitizer

Table 3 Toxicity Profile of Technical Cyantraniliprole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Toxicokinetics	
Metabolism Sprague Dawley rats PMRA # 2070366 PMRA # 2070368	**Absorption** Absorption was rapid (within 48 hours) with maximum plasma concentration at 2 hours. Absorption from the gastrointestinal tract was approximately 63–80% at the low dose and 31–40% at the high dose. Area-under-the curve was higher in females by a factor of 2.5 indicating that females received a slightly higher dose than males. Plasma levels continued to increase throughout repeated dosing period. **Distribution** Cyantraniliprole was distributed in all tissues with maximum tissue concentration at approximately 2 hours. The highest concentrations were in the gastrointestinal tract, thyroid, lungs, pituitary gland, and adrenal glands. Females had higher levels, especially in fat, with longer retention in the tissue than males. Following repeat dosing, radioactivity half-lives in females were of 5.6 days in plasma and 2.6 days in fat. **Excretion** Following a single low dose, urinary excretion was the primary route of elimination (33–42%). Following a single high dose or repeated dose, fecal excretion tended to be greater route of elimination. Biliary excretion accounted for 10–37% at the low dose and 10–16% at the high dose. Excretion via respiration was negligible. **Metabolism** Unmetabolized cyantraniliprole was present in minor amounts in urine (0.3–5.0%) and in more significant amounts in feces (5% in females and 15–17% in males) at the low dose, and at 55–66% at the high dose, both sexes. Parent cyantraniliprole was not detected in bile. Ten metabolites were identified in urine and 13 metabolites were identified in feces. The primary metabolites were IN-N7B69 (urine only), Bis-OH-HGW86, IN-DBC80 (feces only) and IN-MYX98. In bile, numerous metabolites were identified, the primary being glucuronides of IN-MLA84, IN-N7B69 IN-NBC94 and IN-MYX98. Following 90 day dosing, in rodents plasma, the metabolite IN-MLA84 was detected at levels that were orders of magnitude greater than the parent compound, plateauing at doses of 300–400 ppm in diet and reaching levels equivalent to 100–400 µg/mL. In dogs, following 57 day dosing, the parent compound was the dominant component found in plasma and IN-MLA84 was only a minor component. The proposed metabolic pathway for cyantraniliprole involves hydroxylation and/or

Study Type/Animal/PMRA #	Study Results
	ring closure, followed by further hydroxylation, formation of carboxylic acids, and or glucuronidation.
Acute Toxicity Studies – Cyantraniliprole Technical	
Oral Toxicity (Up and Down) CD1 Mice PMRA# 2010374	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Oral Toxicity (Up and Down) Sprague Dawley Rats PMRA# 2070375, 2070376, 2070377, 2070378 (multiple studies)	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Dermal Toxicity Sprague Dawley Rats PMRA# 2070379	LD_{50} > 5000 mg/kg bw Low Acute Toxicity
Inhalation Toxicity (nose-only) Sprague Dawley Rats PMRA# 2070380	LC_{50} > 5.2 mg/L air Low Acute Toxicity
Eye Irritation NZW Rabbits PMRA#2070385	MIS= 9 (1 hour) MAS = 1.11 Minimally Irritating
Eye Irritation NZW Rabbits PMRA#2070386	MIS= 11 (1 hour) MAS = 0.22 Minimally Irritating
Eye Irritation NZW Rabbits PMRA# 2070387	MIS= 11(1 hour) MAS = 0.22 Minimally Irritating
Eye Irritation NZW Rabbits PMRA# 2070388	MIS= 4.7 (1 hour) MAS = 0 Non-irritating
Dermal Irritation NZW Rabbits PMRA# 2070381	MAS= 0 MIS=0 Non-irritating
Dermal Irritation NZW Rabbits PMRA# 2070382	MAS= 0 MIS=0 Non-irritating
Dermal Irritation NZW Rabbits PMRA# 2070383	MAS= 0 MIS=0 Non-irritating
Dermal Irritation NZW Rabbits PMRA #2070384	MAS= 0 MIS=0 Non-irritating
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA# 2070389	Not a skin sensitizer

Study Type/Animal/PMRA #	Study Results
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA# 2070390	Not a skin sensitizer
Skin Sensitization (LLNA) CBA/JHsd Mice PMRA# 2070391	Not a skin sensitizer
Skin Sensitization (Buehler) Hartley Guinea Pigs PMRA# 2070392	Not a skin sensitizer
Skin Sensitization (Maximization) Hartley Guinea Pigs PMRA# 2070394	Not a skin sensitizer
Short-Term Toxicity Studies	
28-Day Oral Toxicity (diet) CD-1 Mice PMRA # 2070396	NOAEL = 528/664 mg/kg bw/day LOAEL = 1261/1476 mg/kg bw/day, based on ↑ minimal focal liver necrosis, slight ↓ WBC (♂)
90-Day Oral Toxicity (diet) CD-1 Mice PMRA # 2070402 and 2070400 (supplement)	NOAEL = 150/204 mg/kg bw/day LOAEL = 1092/1344 mg/kg bw/day based on ↑ liver wt, ↓ WBC, ↑ minimal focal liver necrosis, ↑ absolute epididymal wt (♂); ↑ ovary wt (♀)
28-Day Oral Toxicity (diet) Sprague-Dawley Rats PMRA 2070395	NOAEL (♂) = not established NOAEL (♀) = 62 mg/kg bw/day LOAEL (♂)= 53 mg/kg bw/day, based on ↑ thyroid wt, thyroid follicular cell hypertrophy LOAEL (♀) = 188 mg/kg bw/day, based on thyroid follicular cell hypertrophy
90-Day Oral Toxicity (diet) Sprague-Dawley Rats PMRA# 2070399	NOAEL = 6/7 mg/kg bw/day LOAEL = 22/27 mg/kg bw/day, based on ↓T_4, ↓T_3, ↑TSH(♂),↑ liver wt, ↑ absolute thyroid wt (♀), ↑ thyroid follicular cell hypertrophy (♀)
28-Day Oral Palatability (diet) Beagle Dogs PMRA# 2070398	NOAEL not established ≥ 35 mg/kg bw/day: ↓ bw/bwg, fc/fe, albumin, ↑ ALP, ↑ P450 content Supplemental
90-Day Oral Toxicity (diet) Beagle dogs PMRA# 2070403/2070404	NOAEL = 3 mg/kg bw/day LOAEL = 32/34 mg/kg bw/day, based on ↓ total protein, albumin, cholesterol, ↑ ALP, ↑ liver wt

Study Type/Animal/PMRA #	Study Results
1-Year Oral Toxicity (diet) Beagle Dogs PMRA# 2070406/2070407	NOAEL = 1 mg/kg bw/day [♂] NOAEL = 6 mg/kg bw/day [♀] LOAEL = 6 mg/kg bw/day [♂] , based on ↑ ALP, ↓ albumin , ↑ liver wt NOAEL = 27 mg/kg bw/day [♀], based on ↑ ALT, ↑ ALP, ↓ total protein, ↓ albumin,↑ liver wt, hepatocellular degeneration; arteritis
28-day Dermal Toxicity Sprague-Dawley Rats PMRA# 2070408	NOAEL > 1000 mg/kg bw/day (HDT)
28-Day Inhalation Toxicity (nose-only) Sprague-Dawley Rats PMRA # 2139907/2220108	NOAEC = 0.1 mg/L [♂/♀] HDT Equivalent to 26.1 mg/kg bw/day
Chronic Toxicity/Oncogenicity Studies	
18-Month Oncogenicity study (diet) CD-1 Mice PMRA# 2070420	NOAEL = 104/131 mg/kg bw/day NOAEL = 769/904 mg/kg bw/day, based on slight ↓ bw, ↓ fc, ↓ fe, ↑ liver wt
2-Year Combined Chronic Toxicity /Oncogenicity (diet) Sprague-Dawley rats PMRA# 2070419	NOAEL = 8.3/10.5 mg/kg bw/day [♂/♀] LOAEL = 85/107 mg/kg bw/day based on ↓ fe (♀),↑ liver wt and liver hypertrophy, ↑ liver foci of cellular alteration (clear, eosinophilic) and vacuolation (♂)
Developmental/Reproductive Toxicity Studies	
Developmental Toxicity (gavage) Sprague-Dawley rats PMRA#2070422	**Maternal** NOAEL = 1000 mg/kg bw/day No adverse effects noted. **Developmental** NOAEL = 1000 mg/kg bw/day No adverse effects noted. No evidence of teratogenicity or sensitivity of the young
Developmental Toxicity (gavage) NZW rabbits PMRA# 2070423	**Maternal** NOAEL = 25 mg/kg bw/day LOAEL = 100 mg/kg bw/day, based on ↑incidence of diarrhea, ↓bwg, ↓fc, ↑early sacrifice **Developmental** NOAEL = 100 mg/kg bw/day LOAEL = 250 mg/kg bw/day based on ↓ mean fetal wt (↓6%); ↑abortion/early delivery following prolonged periods of ↓ fc and bw in the dam. No evidence of teratogenicity or sensitivity of the young

Study Type/Animal/PMRA #	Study Results
2-generation Reproductive Toxicity (diet) Sprague-Dawley rats PMRA# 2070042	**Parental Toxicity** NOAEL = 1.2/1.4 mg/kg bw/day LOAEL = 11.4/13.9 mg/kg bw/day, based on↑ thyroid follicular cell hypertrophy/hyperplasia (F_1) [♂/♀] ; ↑ adrenal cortical vacuolation (F_1) (♂), ↑ adrenal wt (F_1), ↑ thyroid wt (♀) **Reproductive Toxicity** NOAEL = 1166/1344 mg/kg bw/day [♂/♀] No adverse reproductive toxicity (including sperm count, motility and morphology as well as oestrous cycling) **Offspring Toxicity** NOAEL = 1.2/1.4 mg/kg bw/day [♂/♀] LOAEL = 11.4/13.9 mg/kg bw/day based on ↓ bw F_2 (birth – PND 22) No evidence of sensitivity of the young
Genotoxicity Studies	
Bacterial Reverse Gene Mutation PMRA# 2070409	Negative
Bacterial Reverse Gene Mutation PMRA# 2070410	Negative
Bacterial Reverse Gene Mutation PMRA# 2070411	Negative
Chromosome Aberrations (in vitro) Chinese Hamster Ovary Cells PMRA# 2070416	Negative
Chromosome Aberration (in vitro) Human peripheral blood lymphocytes PMRA# 2070414	Negative
Chromosome Aberrations (in vitro) Chinese Hamster Ovary Cells PMRA# 2070417	Negative
Chromosome Aberration (in vitro) Human peripheral blood lymphocytes PMRA# 2070413	Negative
Micronucleus Assay (in vivo) CD-1 mice PMRA# 2070418	Negative
Neurotoxicity Studies	
Acute Neurotoxicity (gavage) Sprague-Dawley rats PMRA# 2070424	NOAEL= 2000 mg/kg bw No evidence of neurotoxicity

Study Type/Animal/PMRA #	Study Results
90-day Neurotoxicity (diet) Sprague-Dawley rats PMRA# 2070425	NOAEL=1195/1404 mg/kg/bw/day No evidence of neurotoxicity
Immunotoxicity	
28-day immunotoxicity study (diet) (SRBC-specific IgM ELISA) Sprague-Dawley rats PMRA# 2070369	NOAEL = 1699 mg/kg bw/day (HDT) No evidence of an immunosuppressant effect
28-day immunotoxicity study (diet) (SRBC-specific IgM ELISA) CD-1 mice PMRA# 2070370	NOAEL = 1065 mg/kg bw/day (HDT) No evidence of an immunosuppressant effect
Special Studies (non-guideline)	
In vitro thyroid peroxidase inhibition (mechanistic study) PMRA# 2070371	No evidence of inhibition of thyroid peroxidase activity
Adrenal and thyroid mechanistic study Sprague-Dawley rats PMRA# 2070372	1903 mg/kg bw/day: ↓ bw, ↑ fe, ↑ liver, adrenal and thyroid wt (♀) Thyroid function (♀):↑ TSH (67%), ↓ T4 (30%), ↑ UDP-GT activity (77%) ↓ 5'-deiodinase activity (23%) ↑ thyroid follicular cell hypertrophy (5/15 vs. 0 in control) T3/rT3 levels were unaffected Adrenal function (♂): No difference in urine levels of corticosterone, ratio of corticosterone/creatinine, or in serum corticosterone levels in ♂ rats challenged with ACTH ↑ incidence of adrenal gland microvesiculation (4/10 vs. 0 in controls). Electron microscopic examination: minimal to mild increase in adrenal cytoplasm lipid vacuoles but no effects on cellular organelles or evidence of cytotoxicity or degeneration. Supplemental
Studies on Metabolites/degradation products	
Oral Toxicity (Up and Down) CD-1 Mice IN-PLT97 (soil metabolite) PMRA# 2070436	LD_{50} > 5000 mg/kg bw **Low Acute Toxicity**
Oral Toxicity (Up and Down) CD-1 Mice IN-N5M09 (degradation product) PMRA# 2070437	LD_{50} > 5000 mg/kg bw **Low Acute Toxicity**
Oral Toxicity (Up and Down) CD-1 Mice	LD_{50} > 2000 mg/kg bw

Study Type/Animal/PMRA #	Study Results
IN-F6L99 (degradation product) PMRA# 1365510	**Low Acute Toxicity**
Oral Toxicity (Up and Down) Sprague- Dawley Rats IN-JSE76 (soil metabolite) PMRA# 2070439	LD_{50} > 5000 mg/kg bw **Low Acute Toxicity**
28-day oral toxicity study IN-JSE76 (soil metabolite) Sprague-Dawley rats PMRA#2070435/2070438 (supplement)	NOAEL = 1445/1474 mg/kg bw/day
Bacterial Reverse Gene Mutation IN-JSE76 (soil metabolite) PMRA# 2070431	Negative
Bacterial Reverse Gene Mutation IN-PLT97 (soil metabolite) PMRA# 2070430	Negative
Chromosome Aberration (in vitro) Human peripheral blood lymphocytes IN-PLT97 (soil metabolite) PMRA# 2070429	Negative
Gene Mutation (in vitro) Chinese Hamster Ovary (CHO) cells IN-PLT97 (soil metabolite) PMRA# 2070427	Negative
Bacterial Reverse Gene Mutation IN-N5M09 (degradation product) PMRA# 2070432	Negative
Bacterial Reverse Gene Mutation IN-F6L99 (degradation product) PMRA# 20704	Negative

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Cyantraniliprole

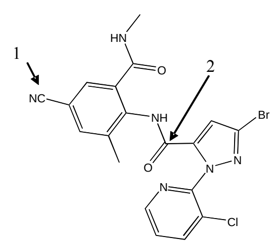
Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
ARfD	Not required as no endpoint of concern attributable to a single exposure was identified.		
Repeated dietary	1-year dietary toxicity study in the dog	NOAEL = 1 mg/kg bw/day Increased liver weight and liver enzymes, decreased albumin	100
	ADI = 0.01 mg/kg bw/day		
Short and intermediate-term dermal	Not required No systemic toxicity after repeated dermal exposure, no developmental or reproductive toxicity, no neurotoxicity		
Short-term inhalation	28-day inhalation toxicity study in the rat	NOAEC = 0.1 mg/L (HDT) (equivalent to NOAEL = 26.1 mg/kg bw/day) No adverse effects	100

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Intermediate-term inhalation	28-day inhalation toxicity study in the rat	NOAEC = 0.1 mg/L (HDT) (equivalent to NOAEL of 26.1 mg/kg bw/day) No adverse effects An additional 3-fold UF was employed to the standard 100-fold UF to account for durational toxicity	300
Long-term dermal and inhalation[2,3]	1-year dietary toxicity study in the dog	NOAEL = 1 mg/kg bw/day Increased liver weight and liver enzymes, decreased albumin	100
Acute Aggregate	Not required as no endpoint of concern attributable to a single exposure was identified.		
Cancer	Not required as no treatment-related increase in tumour incidence.		

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

Table 5 Integrated Food Residue Chemistry Summary

Nature of the Residues Studies



1. [CN-^{14}C]-cyantraniliprole
2. [PC-^{14}C]-cyantraniliprole

<table>
<tr><th colspan="6">Study Design for Nature of the Residue in Laying Hens.</th><th colspan="2">PMRA No. 2070446</th></tr>
<tr><th rowspan="2">Group</th><th rowspan="2">Species</th><th rowspan="2">Radiolabel position</th><th rowspan="2">No. of animal</th><th colspan="2">Application details</th><th colspan="2">Sampling details</th></tr>
<tr><th>Dose/day</th><th>Duration (days)</th><th>Commodity</th><th>Collection Time</th></tr>
<tr><td rowspan="3">Laying hens</td><td rowspan="3">Hens (ISA Warren)</td><td>[CN-^{14}C]-CYT: 99.8% purity 16.95 µCi/mg</td><td rowspan="3">5/radiolabel and 2 control</td><td rowspan="3">11.2 ppm in diet</td><td rowspan="3">14</td><td>Eggs</td><td>Twice daily</td></tr>
<tr><td rowspan="2">[PC-^{14}C]-CYT: 99.7% purity 15.33 µCi/mg</td><td>Excreta</td><td>Once daily</td></tr>
<tr><td>Tissues</td><td>23 hours after sacrifice</td></tr>
</table>

Overall Radioactive Residues in Laying Hen Matrices.				
Matrix	[CN-^{14}C]-CYT		[PC-^{14}C]-CYT	
	(ppm)	% of dose	(ppm)	% of dose
Egg whites (Day 1–14)	0.26	0.54	0.20	0.40
Egg yolks (Day 1–14)	0.09	0.07	0.09	0.07
Fat	<0.01	<0.01	<0.01	0.01
Liver	0.14	0.03	0.17	0.04
Muscle	<0.01	<0.01	<0.01	0.01
Skin with fat	<0.01	0.01	<0.01	0.01
Excreta	na	96.95	na	99.72
Cage washings	na	3.83	na	2.52
Total recovery	na	101.4	na	102.7

Predominant Residues (> 10% of the TRR) Identified in Laying Hen Matrices.				
Matrix	Radiolabel Position		TRR	
	[CN-^{14}C]-CYT	[PC-^{14}C]-CYT	(%)	(ppm)
Egg White (1–14 day composite)	CYT	CYT	32.5–41.7	0.08–0.09
	IN-J9Z38	IN-J9Z38	17.1–29.2	0.03–0.08
	IN-MLA84	IN-MLA84	18.2–18.7	0.04–0.05
Egg Yolk (1–14 day composite)	CYT	--	10.3	<0.01
	IN-HGW87	--	12.0	0.01
	IN-MLA84	IN-MLA84	13.1	0.01
	--	IN-J9Z38	11.6–16.8	0.01–0.02

Study Design for the Nature of the Residues in Lactating Goat.							PMRA No. 2070447	
Group	Species	Radiolabel position	No. of animal	Application details		Sampling details	
				Dose/day	Duration (days)	Commodity	Collection Time
Lactating goat	Goat (*British Saanen*)	[CN-^{14}C]-CYT: 99.8%; 16.95µCi/mg	1/ radiolabel	10 ppm in diet; (0.44 mg/kg bw/d)	7	Milk	Twice daily
		[PC-^{14}C]-CYT : 99.7%; 15.33 µCi/mg				Urine and faeces	Once daily
						Tissues	23 hours after sacrifice

Overall Radioactive Residues in Lactating Goat Matrices.				
Matrix	[CN-^{14}C]-CYT		[PC -^{14}C]-CYT	
	TRR (ppm)	% Dose	TRR (ppm)	% Dose
Faeces	na	87.5	na	84.3
Urine	na	6.7	na	6.9
Cage wash	NA	1.4	na	2.3
Bile	1.57	<0.01	2.42	0.02
Milk	0.08	1.0	0.15	1.8
Liver	0.46	0.3	0.50	0.3
Kidney	0.12	0.01	0.18	0.01
Muscle	0.02	na	0.04	na
Omental fat	0.05	na	0.11	na
Renal fat	0.05	na	0.11	na
Subcutaneous fat	0.05	na	0.11	na
Total recovery	na	96.8	na	95.6

Predominant Residues (> 10% of the TRR) Identified in Lactating Goat Matrices.				
Matrix	Radiolabel Position		TRR	
	[CN-^{14}C]-CYT	[PC-^{14}C]-CYT	(%)	(ppm)
Milk (1–7 day composite)	CYT	CYT	39.5–49.6	0.03–0.07
	IN-N7B69		11.8	<0.01
	IN-MYX98	IN-MYX98	15.1–18.3	0.01–0.03
Kidney	CYT	CYT	12.7–18.9	0.02–0.04
Muscle	CYT	CYT	15.3–30.3	<0.01
	–	IN-MYX98	32.8	0.01
Liver	CYT	CYT	17.1–27.3	0.07–0.14
Fat (omental, renal, subcutaneous)	CYT	CYT	30.8–45.4	0.02–0.05
	IN-J9Z38	IN-J9Z38	24.4–26.9	0.01–0.03

Nature of the Residue in Rice				**PMRA No. 2070442**			
Crop	Radiolabel position	Formulated Product	Type of treatment	Application details			
				Growth stage at application	Rate (g a.i./ha)	#	Sampling
Rice(*Oryza sativa subsp. japonica* cv. Gleva)	[Cyano-^{14}C]-CYT: [Pyrazole carbonyl-^{14}C]-CYT (1:1) >97.9%; 17.06 µCi/mg	10% SC	Foliar/ Greenhouse under flooded conditions until 2–3 days before final harvest	1. BBCH 13 2. BBCH 14 3. BBCH 14	150	3	Foliage: 0, 7-DAT$_1$ 7-DAT$_2$ 7, 14-DAT$_3$ Roots: 7-DAT$_1$/DAT$_2$/DAT$_3$ Straw, roots, grain (with bran): 140-DAT$_3$
	[Cyano-^{14}C]-CYT 99.0%; 16.95 µCi/mg	0.4% GR	Granular soil application/ Greenhouse under flooded conditions maintained until 2–3 days before final harvest	1. BBCH 13	300	1	Foliage: 3, 7, 14, 56-DAT Roots: 7, 56-DAT 56-DAT Straw, roots, grain (with bran): 175-DAT
	[Pyrazole carbonyl-^{14}C]-CYT 98.1%; 17.18 µCi/mg						

Overall Radioactive Residues in Rice Matrices Following Foliar Treatment.											
Treatment	Total radioactive residues (ppm)										
	Foliage					Straw	Grain	Roots			
	0 DAT$_1$	7 DAT$_1$	7 DAT$_2$	7 DAT$_3$	140 DAT$_3$	140 DAT$_3$	140 DAT$_3$	7 DAT$_1$	7 DAT$_2$	7 DAT$_3$	140 DAT$_3$
Foliar application [CN/PC-^{14}C]-CYT	2.13	0.38	1.00	1.56	1.21	0.45	0.02	0.24	0.30	0.68	0.45
Overall TRRs were determined in roots, however, root samples were not extracted or profiled.											

Predominant Residues (> 10% of the TRR) in Rice Matrices Following Foliar Treatment (140DAT$_3$).			
Matrix	Radiolabel position	TRR	
	[CN-^{14}C]/[PC-^{14}C]	(%)	(ppm)
Rice grain	CYT	20.9	<0.01
Rice foliage	CYT	81.1	0.98
	IN-J9Z38	10.9	0.13
Rice straw	CYT	24.4	0.11

Overall Radioactive Residues in Rice Matrices Following Granular Soil Treatment.									
Treatment	Total radioactive residues (ppm)								
	Rice Foliage				Rice Straw	Rice Grain	Rice Roots		
	3-DAT	7-DAT	14-DAT	56-DAT	175-DAT	175-DAT	7-DAT	56-DAT	175-DAT
[CN-^{14}C]-CYT	NC	0.08	0.15	0.40	0.28	0.01	<0.02	0.25	0.28
[PC-^{14}C]-CYT	0.15	0.07	0.15	0.42	0.30	0.03	<0.04	0.30	0.37

Predominant Residues (>10% of the TRR) in Rice Matrices Following Granular Soil Drench Treatment				
Matrix	Radiolabel position		TRR	
	[CN-^{14}C]-CYT	[PC-^{14}C]-CYT	(%)	(ppm)
Rice grain (140-DAT$_3$)	CYT	CYT	46.2–62.7	<0.01–0.01
Rice foliage (56- DAT$_3$)	CYT	CYT	48.7–57.4	0.21–0.23
	IN-J9Z38	IN-J9Z38	16.2–22.1	0.07–0.09
Rice straw (175-DAT$_3$)	CYT	CYT	42.1–44.9	0.13
	IN-J9Z38	IN-J9Z38	14.3–18.4	0.04–0.05

Nature of the Residue in Cotton				PMRA No. 2070443			
Crop	Radiolabel position	Formulated Product	Type of treatment	Application details			
				Growth stage at application	Rate (g a.i./ha)	#	Sampling
Cotton (*Gossypium hirsutum* cv. Crema 111)	[Cyano-^{14}C]-CYT and [Pyrazole carbonyl-^{14}C]-CYT, mixed in one formulation Purity: >98.7% 15.83 µCi/mg	10% SC	Foliar/Outdoor Field	1. BBCH 16 2. BBCH 18 3. BBCH 19	150	3	Foliage: 0, 7-DAT$_1$ 0, 7-DAT$_2$ 0, 7, 13-DAT$_3$ Leaves and bolls: 124DAT$_3$
	[Cyano-^{14}C]-CYT Purity: 99.0% 16.95 µCi/mg	10% SC	Soil drench/Outdoor Field	1. BBCH 19 (BBCH 51) 2. BBCH 19 (BBCH 51) 3. BBCH 19 (BBCH 51)	150	3	Foliage: 7-DAT$_1$ 7-DAT$_2$ 8, 14-DAT$_3$ Leaves and bolls: 125-DAT$_3$
	[Pyrazole carbonyl-^{14}C]-CYT Purity: 99.0% 15.33 µCi/mg						

Overall Radioactive Residues in Cotton Matrices.										
Treatment	Total Radioactive Residues (ppm)									
	Leaves							Gin by-products	Lint	Seed
	0 DAT$_1$	7 DAT$_1$	0 DAT$_2$	7 DAT$_2$	0 DAT$_3$	7–8 DAT$_3$	13–14 DAT$_3$	124–125 DAT$_3$		
Soil drench [CN-^{14}C]	NC	<0.01	NC	<0.01	NC	<0.01	<0.01	0.10	<0.01	<0.01
Soil drench [PC-^{14}C]	NC	<0.01	NC	<0.01	NC	<0.01	<0.01	0.02	<0.01	<0.01
Foliar [CN/ PC-^{14}C]	2.71	5.41	14.53	2.65	7.93	0.51	0.43	0.13	<0.01	<0.01

Predominant Residues (>10% of the TRR) in Cotton Matrices Following Foliar Treatments.			
Matrix	Radiolabel position	TRR	
	[CN-^{14}C]/[PC-^{14}C]	(%T)	(ppm)
Cotton gin byproducts (124–125DAT$_3$)	CYT	34.4	0.04

Cotton leaves (13–14DAT$_3$)	CYT	27.1	0.12

Predominant Residues (>10% of the TRR) in Cotton Matrices Following Soil Drench Treatments.

Matrix	Radiolabel position		TRR	
	[CN-^{14}C]-CYT	[PC -^{14}C]-CYT	(%)	(ppm)
Cotton gin byproducts (124-125DAT$_3$)	CYT	CYT	25.6–46.8	0.01–0.03

Nature of the Residue in Tomatoes. **PMRA No. 2070444**

Crop	Radiolabel position	Formulated Product	Type of treatment	Application details			
				Growth stage at application	Rate (g a.i./ha)	#	Sampling
Tomato (*Solanum lycopersicum, cv.* Montserrat)	[Cyano-^{14}C]-CYT and [Pyrazole carbonyl-^{14}C]-CYT (1:1); >95.0%; 15.83 µCi/mg	10% SC	Foliar/Outdoor Field in growing medium	1. BBCH 14–15 2. BBCH 16 3. BBCH 53, 61	150	3	Foliage: 0, 7-DAT$_1$ 0, 7-DAT$_2$ 0, 7, 14-DAT$_3$ Leaves and fruits: 125DAT$_3$
	[Cyano-^{14}C]-CYT; 99.0%; 16.95 µCi/mg [Pyrazole carbonyl-^{14}C]-CYT; 99.0%; 15.33 µCi/mg	10% SC	Soil drench/Field In growing medium	1. BBCH 19, 51 2. BBCH 51 3. BBCH 55, 61	150	3	0, 7-DAT$_1$ 0, 7-DAT$_2$ 0, 7, 14-DAT$_3$ Foliage: Leaves and fruits: 125DAT$_3$

Overall Residues in Tomato Matrices.

Treatment	Sample point								
	0 DAT$_1$	7 DAT$_1$	0 DAT$_2$	7 DAT$_2$	0 DAT$_3$	7 DAT$_3$	14 DAT$_3$	125 DAT$_3$	
	Leaves							Leaves	Fruit
	Total Radioactive Residues (ppm)								
Soil Drench [CN-^{14}C]-CYT	NC	<0.01	NC	0.02	NC	0.030	0.03	<0.01	<0.01
Soil Drench [PC-^{14}C]-CYT	NC	<0.01	NC	0.01	NC	<0.01	<0.01	<0.01	<0.01
Foliar [CN/PC-^{14}C]-CYT	2.55	1.85	8.50	4.81	7.62	2.22	1.30	<0.01	<0.01

Predominant Residues (>10% of the TRR) in Tomato Matrices Following Foliar Treatments.

Matrix	Radiolabel position	TRR	
	[CN-^{14}C]/[PC-^{14}C]	(%)	(ppm)
Tomatoes leaves (14-DAT$_3$)	CYT	43.4	0.56

Predominant Residues (>10% of the TRR) in Tomato Matrices Following Soil Treatment.

Matrix	Radiolabel position		TRR	
	[CN-^{14}C]-CYT	[PC -^{14}C]-CYT	(%)	(ppm)
Tomato leaves (14-DAT$_3$)	CYT	NC	26.1	<0.01

Nature of the Residue in Lettuce.				PMRA No. 2070445			
Crop	Radiolabel position	Formulated Product	Type of treatment	Application details			
				Growth stage at application	Rate (g a.i./ha)	#	Sampling
Lettuce (*Lactuca sativa*, *cv*. Green Salad Bowl, which is a non-hearting cultivar)	[Cyano-^{14}C]-CYT/ [Pyrazole carbonyl-^{14}C]-CYT (1:1); >97.0%; 15.95 µCi/mg	10% SC	Foliar/Outdoor Field	1. BBCH 14/15 (BBCH 33) 2. BBCH 16 (BBCH 35) 3. BBCH 18 (BBCH 36)	150	3	0,7-DAT_1 0,7-DAT_2 0, 7, 14, 32-DAT_3
	[Cyano-^{14}C]-CYT 99.0%; 16.95 µCi/mg	10% SC		1. BBCH 18/19 (BBCH 36) 2. BBCH 19 (BBCH 37/38) 3. BBCH 19 (BBCH 37/38)	150	3	0,7-DAT_1 0,7-DAT_2 0, 7, 14, 32-DAT_3
	[Pyrazole carbonyl-^{14}C]-CYT 99.0%; 15.33 µCi/mg						

Overall Radioactive Residues in Lettuce.								
Treatment	0 DAT_1	7 DAT_1	0 DAT_2	7 DAT_2	0 DAT_3	7 DAT_3	14 DAT_3	$32DAT_3$ Maturity
	Total radioactive residues (ppm)							
Soil Drench [CN-^{14}C]-CYT	NC	0.14	NC	0.05	NC	0.05	0.04	0.01
Soil Drench [PC-^{14}C]-CYT	NC	0.02	NC	0.04	NC	<0.01	<0.01	0.06
Foliar [CN/PC-^{14}C]-CYT	10.84	1.67	9.62	2.80	7.79	1.99	0.98	0.03

Predominant Residues (>10% of the TRR) in Lettuce Following Foliar Treatments.			
Matrix	Radiolabel position	TRR	
	[CN-^{14}C]/[PC-^{14}C]	(%)	(ppm)
Lettuce leaves	CYT	50.3	0.02
	IN-J9Z38	23.3	0.01

Predominant Residues (>10% of the TRR) in Lettuce Following Soil Drench Treatment.				
Matrix	Radiolabel position		TRR	
	[CN-^{14}C]-CYT	[PC -^{14}C]-CYT	(%)	(ppm)
Lettuce leaves ($32DAT_3$)	CYT	CYT	37.1–69.0	<0.01–0.04

Nature of the Residues in Confined Rotational Crop Study.		PMRA No. 2070536
Crops	Label position	Application details
		Rate (g a.i./ha)
Spring wheat (*Triticum aestivum* cv Pragon)	[CN-^{14}C]- CYT: 99.0% purity; 16.95µCi/mg [PC-^{14}C]-CYT: 99.7% purity; 15.33 µCi/mg	450 applied to bare soil in a temperature-controlled glasshouse
Lettuce (*Lactuca sativa* cv Green Salad Bowl		
Red beets (*Beta vulgaris* cv Detroit Crimson Globe 2109)		
Study Soil Characteristics: sandy loam; pH (6.2); OC (1.4%); sand (70%); silt (15%); clay (15%); moisture holding capacity (35.7%); CEC (9.3 mg/L). Samples of forage, hay, straw, and grain of spring wheat; foliage and roots of red beets; and whole lettuce were harvested from plants sown after plant back intervals (PBI) of 30, 120, and 365 days. Soil cores were taken at the times of sowing and separated into 0 to 15 cm and 15 to 30 cm portions.		

Total Radioactive Residues in Food Items.						
Matrix	[CN-^{14}C]-CYT TRR (ppm)			[PC -^{14}C]-CYT TRR (ppm)		
PBI	Wheat grain	Lettuce	Red beet roots	Wheat grain	Lettuce	Red beet roots
30	0.06	0.11	0.02	0.05	0.08	0.03
120	<0.01	0.04	<0.01	<0.01	0.02	<0.01
365	0.01	NC	NC	0.02	NC	NC

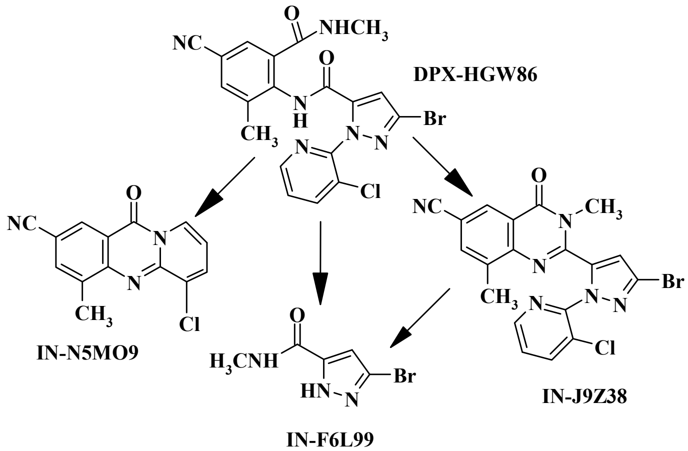
Major Metabolites in Food Items of Rotational Crops (CN and PC-^{14}C-CYT).							
Matrix	Analytes	30 PBI (%TRR)	120 PBI (%TRR)	365 PBI (%TRR)	30 PBI (ppm)	120 PBI (ppm)	365 PBI (ppm)
Wheat grain	CYT	20.0–36.3	NC	13.6–33.0	0.01–0.02	NC	<0.01
Lettuce	CYT	60.0–68.1	39.6–69.1	NC	0.05–0.08	<0.01–0.03	NC
	IN-MYX98	--	16.4	NC	--	<0.01	NC
Red beet roots	CYT	21.0–23.8	NC	NC	<0.01	NC	NC

Total Radioactive Residues in Feed Items of Rotational Crops.								
Matrix	[CN-^{14}C]-CYT TRR (ppm)				[PC -^{14}C]-CYT TRR (ppm)			
PBI	Wheat forage	Wheat hay	Wheat straw	Red beet foliage	Wheat forage	Wheat hay	Wheat straw	Red beet foliage
30	0.31	1.46	0.97	0.06	0.29	1.63	0.97	0.15
120	0.13	0.31	0.35	0.01	0.10	0.45	0.27	0.05
365	0.13	0.56	0.43	NC	0.09	0.56	0.48	NC

Major Metabolites in Feed Items of Rotational Crops (CN and PC-^{14}C-CYT).							
Matrix	Analytes	30 PBI (%TRR)	120 PBI (%TRR)	365 PBI (%TRR)	30 PBI (ppm)	120 PBI (ppm)	365 PBI (ppm)
Wheat forage	CYT	71.0–72.7	34.6–70.5	25.2	0.21–0.23	0.04–0.09	0.03
	IN-J9Z38	--	11.0–11.5	--	--	0.01–0.02	--
Wheat hay	CYT	52.2–53.4	35.8–50.0	--	0.78–0.85	0.15–0.16	--
	IN-J9Z38	10.9–12.3	--	12.9	0.18	--	0.06
	IN-K7H19	--	--	10.9	--	--	0.06
Wheat straw	CYT	41.3–44.8	22.9–38.4	33.0–35.1	0.40–0.44	0.06–0.13	0.14–0.15
	IN-J9Z38	9.5–10.9	--	--	0.09–0.11	--	--
	IN-K7H19	--	--	10.9	--	--	0.04

Study Design for High-Temperature Hydrolysis of [^{14}C]-CYT	**PMRA No. 2070528**
Hydrolysis of radiolabelled cyantraniliprole at 1.0 mg a.i./L was studied at 90, 100, and 120°C at pH 4, 5, and 6, respectively, using aqueous citrate buffer. The test solutions were placed in 12-mL glass vessels and the headspace was minimized. Acetonitrile (1%) was used as a co-solvent. Samples were analyzed at zero time, after 20 minutes (pH 4 and 6) and 1 hour (pH 5) by LSC and HPLC-MS/MS.	
Radiochemical purity and specific activity	[CN-^{14}C]-CYT: 99%; 44.86 µCi/mg; [PC-^{14}C]-CYT: 99%; 49.23 µCi/mg
During conditions representative of baking, brewing, or boiling degradation of cyantraniliprole led to the formation of degradates IN-J9Z38, IN-F6L99, and IN-N5M09 at 90˚C (pH4), 100˚C (pH5), and 120˚C (pH6). The range of cyantraniliprole, from both radiolabels (CN and PC-^{14}C-CYT), under the various hydrolytic conditions was 74.5–93.6% of the applied radioactivity. Similarly, IN-J9Z38 (3.7–13.6%), IN-N5M09 (<0.01–8.4%), and IN-F6L99 (0.12–5.3%) were also formed.	

Proposed Degradation Pathway for Cyantraniliprole at High-Temperature Hydrolysis Conditions.



Overall Assessment for the Nature of the Residue Studies.

The nature of cyantraniliprole residues in commodities of animal origin was investigated in lactating goats and laying hens using (cyano) CN-^{14}C and (carbonyl next to pyrazole ring) PC-^{14}C labelled cyantraniliprole. Following the repeated oral administration of radiolabelled cyantraniliprole to goats and laying hens (7 and 14 consecutive daily oral administrations, respectively, at a nominal dose of 10 ppm in the feed), a high proportion of the dose was eliminated in the excreta. There was no evidence of any significant accumulation of radioactivity in milk, eggs or edible tissues. The nature of the residue in livestock is adequately understood.

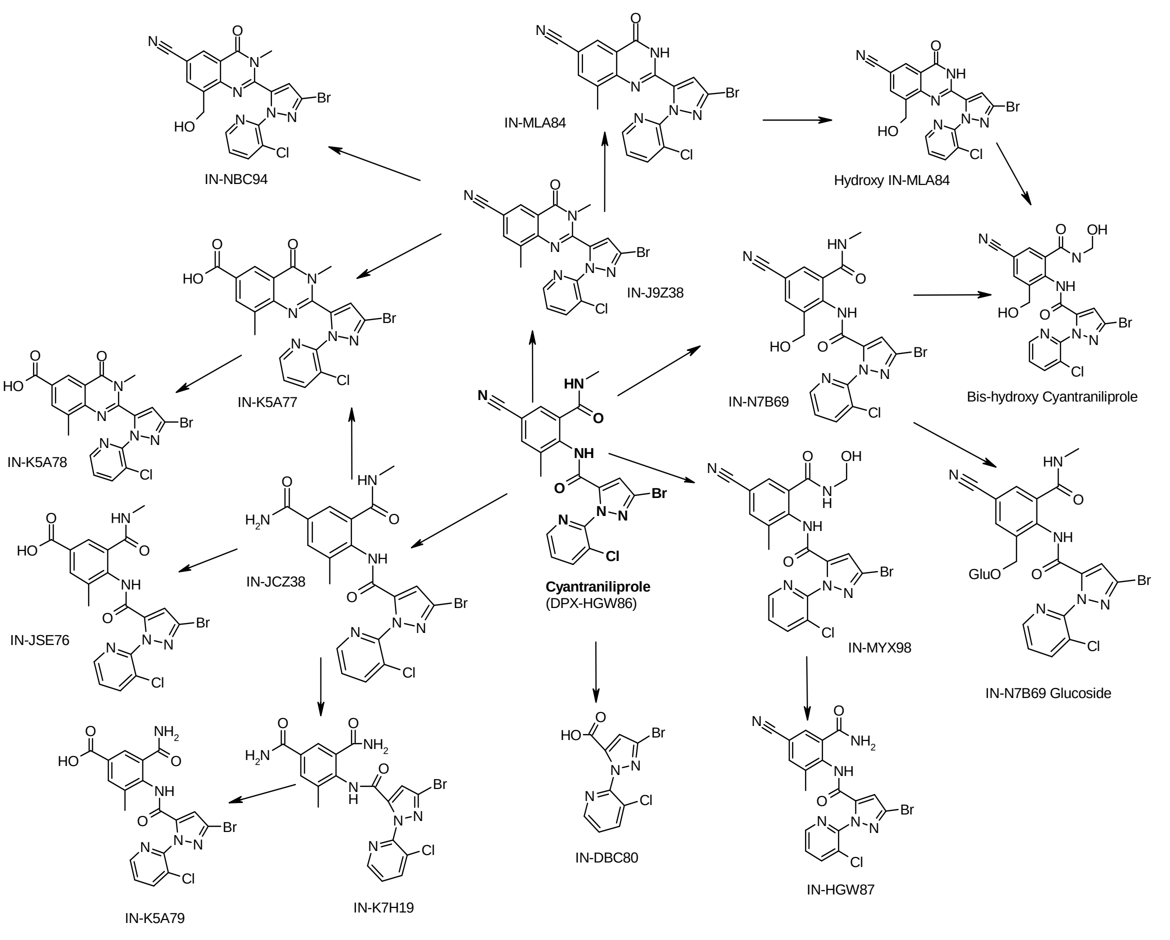
Two different radiolabels were used in the nature of the residues in plant studies, either in the cyano group [CN] or in the carbonyl next to the pyrazole ring [PC]. Studies were also conducted using a mixture of the two radiolabels. The metabolic fate of [^{14}C]-CYT was investigated in cotton (oilseeds), lettuce (leafy), tomato (fruiting vegetable), and rice (cereals) following soil applications (CN and PC-^{14}C-CYT) and foliar applications (1:1 CN/PC-^{14}C-cyantraniliprole). The application rate was 450 g a.i./ha/season for foliar applications and soil drench, which represent 1-fold GAP (foliar) and 2.3-fold GAP (soil drench). The only exception was for rice plants, which received one soil drench application at 300 g a.i./ha (1.5-fold GAP).

Cyantraniliprole was the predominant residue in most crop fractions at various sampling points up to crop maturity. The metabolites identified in foliar treated samples were also detected in samples following soil drench application, indicating that cyantraniliprole metabolism was independent of the application method. Overall, total radioactive residues were greater following foliar treatment than following soil application. A similar profile was observed in four dissimilar crops: oilseed, leafy vegetable, fruiting vegetable, cereal using foliar treatment, and soil drench application. Information gathered with these two types of applications, in addition to supervised crop field trials, indicates that the proposed pathway in plants can be extended to seed treatment for canola, and mustard; and potato seed piece treatment.

Rotational crops (leafy vegetables; cereals; root vegetables) were grown in soil treated at 450 g a.i./ha with CN and PC-^{14}C-CYT and aged for various intervals (30, 120, or 365 days) prior to planting. TRRs in commodities for human consumption (wheat grain, lettuce, and red beet roots) ranged from <0.01 ppm to 0.11 ppm, at all PBIs. Cyantraniliprole was the predominant residue at the 30-day PBI. TRRs in animal feed items were higher than observed in the commodities for human consumption, ranging from 0.013 to 1.62 ppm, at all PBI's. Cyantraniliprole was also the predominant residue at the 30-day PBI. Under hydrolytic conditions representative of baking, brewing, or boiling at 100°C for 60 min in pH 5 solutions, degradation of cyantraniliprole occurred resulting in the formation of IN-J9Z38, and two other degradates (IN-F6L99, and IN-N5M09).

There were only a few differences noted between plant and animal metabolic pathways. More extensive metabolism was observed in rotational crops based on the additional minor polar metabolites formed such as hydroxy-IN-MLA84, bis-hydroxy cyantraniliprole, and IN-N7B69 glucoside.

Proposed Metabolic Profile in Plant and Animal Matrices.
In primary plants, rotational crops, and livestock, the biotransformation and/or degradation pathways were similar. Five main routes were identified leading to the formation of a number of metabolites. 1. Hydrolysis of the amide methyl moiety of cyantraniliprole leading to metabolites such as IN-MYX98. 2. Hydroxylation of the aryl methyl moiety of cyantraniliprole leading to metabolites such as IN-N7B69. 3. Condensation of the cyantraniliprole molecule to quinazolinone derivatives leading to metabolites such as IN-JCZ38. 4. Hydrolysis of the nitrile moiety of cyantraniliprole to an amide leading to metabolites such as IN-J9Z38. 5. Cleavage of the carboxamide linkage between the pyrazole and phenyl rings of the cyantraniliprole molecule leading to IN-DBC80.



Residue Definition (RD) for Enforcement and Risk Assessment Purposes.
Cyantraniliprole was the main residue in the metabolism studies, crop field trials and livestock feeding studies. Based on this, it is considered an appropriate marker for primary crops, rotational crops and livestock commodities and is recommended as the residue definition for enforcement purposes. *Primary Crops:* Metabolism studies showed parent cyantraniliprole as a major residue in rice, lettuce, cotton and tomato, and IN-J9Z38 as a major residue in rice foliage and lettuce. The crop field trials showed the presence of several metabolites at levels below the limit of quantitation or at significantly lower amounts than parent cyantraniliprole. When taking into account the residues of IN-J9Z38 from the crop field trials as parent equivalents, the change is insignificant. Therefore, it is proposed that parent be the only component in the residue definition for dietary risk assessment. *Rotational Crops:* Parent cyantraniliprole was the main residue in all commodities for human consumption. Residue

levels of other metabolites (IN-J9Z38, IN-JCZ38, IN-MLA84) were similar or at higher levels than parent cyantraniliprole in feedstuff commodities only. Inclusion of these metabolites as parent equivalents in the calculation of the dietary burden indicated that they were not major contributors to the overall estimate of anticipated residues in animal matrices. Therefore, it is proposed that parent be the only component in the residue definition for dietary risk assessment. *Processed Commodities:* Although degradates IN-J9Z38, IN-N5M09 and IN-F6L99 were formed under conditions of heat and/or hydrolysis, in general, only IN-J9Z38 was observed in significant concentrations. IN-N5M09 and IN-F6L99 were only quantifiable in a few processed commodities (e.g. cooked spinach, apple sauce). The levels of IN-N5M09 and IN-F6L99 in apple sauce and cooked spinach are much lower than the parent and IN-J9Z38. Inclusion of IN-N5M09 and IN-F6L99 as parent equivalents does not affect the concentration factor significantly. Therefore, it is proposed that parent and IN-J9Z38 be the components in the residue definition for dietary risk assessment. *Livestock:* Feeding studies showed that parent cyantraniliprole, IN-N7B69, IN-MLA84, IN-MYX98, and/or IN-J9Z38 are likely to be present in measurable amounts in some animal matrices. Therefore, it is recommended that they be included in the residue definition on a matrix-specific basis for the purpose of dietary risk assessment.		
Matrices	**Residue Definition for Dietary Risk Assessment in Livestock Matrices**	
Liver- Poultry Cattle	Parent + IN-MLA84 + IN-N7B69 + IN-MYX98 Parent + IN-MLA84	
Kidney	Parent + IN-N7B69	
Muscle	Parent	
Fat	Parent + IN-J9Z38	
Milk	Parent + IN-N7B69	
Skin with fat	Parent	
Eggs	Parent + IN-MLA84 + IN-J9Z38 + IN-MYX98	
Storage Stability in Plants and Plant Products.		**PMRA No. 2070440**
The storage stability of cyantraniliprole and its metabolites (IN-F6L99, IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N5M09, and IN-N7B69) was investigated in five representative commodities: apples (high-water content), grapes (high-acid content), potatoes (high-starch content), dried beans (high-protein content), and peanuts (high-oil content). Control representative crop sample replicates were each individually spiked at 0.20 ppm with cyantraniliprole and its metabolites. Samples were stored at –20ºC and were analyzed concurrently under the same conditions and for the same length of time as the spiked stored stability samples using procedures based on DuPont-1187 using LC-MS/MS. Residues of cyantraniliprole and metabolites were extracted from various crops with 90:10 ACN:water. Samples were removed from storage and analyzed after 0, 1, 3, 6, 12, 18, and 24 months, with an additional contingency time point analyzed for peanuts at 63 days. Since the residue definition in primary, rotational crops and processed commodities for the purpose of enforcement is cyantraniliprole, the storage stability data presented for cyantraniliprole only.		

Summary of Cyantraniliprole Stability in Various Matrix Types During Freezer Storage at –20°C.			
Matrix Type	**Representative Commodity**	**Analyte**	**Demonstrated Storage Interval (months)**
High-water	Apples	CYT	24
High-starch	Potatoes	CYT	24
High-acid	Grapes	CYT	24
High-protein	Dried beans	CYT	24
High-oil	Peanuts	CYT	24
Cyantraniliprole was stable for 24 months in high-water content (apple) plant matrices, high-starch content (potatoes) matrices, high-acid content (grapes) matrices, high-protein content (dried beans) matrices, and high-oil content (peanut) matrices. The intervals of demonstrated storage stability cover the storage intervals of samples from the primary crop field trials, processing studies, and rotational crop field trials.			
Storage Stability in Animal Matrices.			
Milk and egg samples from the poultry and cattle feeding studies were stored at *ca.* –80°C for a maximum of 97 days which is within the demonstrated storage interval of 99 days for cyantraniliprole and its 7 metabolites (IN-HGW87, IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, and IN-N7B69). All other tissues were			

extracted and analyzed within 30 days; therefore, no further freezer storage information is necessary.
Crop Field Trials
The applicant submitted crop field trial data from field trials conducted in North America with a variety of crops, end-use products, and different application types. For the North American field trials, the applicant collected residue data for cyantraniliprole and several metabolites; however cyantraniliprole was the major component of the residues in raw agricultural crop commodities (RACs). It should be noted that bridging trials (confirmatory data) were provided by Syngenta in support of their end-use products under the co-development project for cyantraniliprole. The Canada/US field trial results were generated using an adequate data collection method. Adequate storage stability data are available on diverse crop types. The number and geographic distribution of trials are generally in accordance with OCSPP harmonized test guideline 860.1500 and Health Canada's DIR2010-05.

Study Design for Potato Tubers Trials.				**PMRA No. 2070453/2071525**
Application Types	3 foliar late season of 100 g/L OD 3 foliar late season of 100 g/L SE 1 seed treatment 625 g/L FS + 1 late season foliar 100 g/L OD 1 in-furrow 200 g/L SC at planting + 1 late season foliar of 100 g/L OD 1 in-furrow A16901B 40WG 1 in-furrow of 200 g/L SC			
Crop	Potato tubers	Potato tubers	Potato tubers	Potato tubers
EP	625 g/L FS + 100 g/L OD	100 g/L OD	100 g/L SE	200 g/L SC + 100 g/L OD
No. of Applications	1 seed at planting + 1 Foliar	3 Foliar	3 Foliar	1 In-furrow + 1 Foliar
Total Rate (g a.i./ha)	372–465	428–462	447–455	466
PHI (days)	6–8	6–8	6–7	7
Statistic	CYT	CYT	CYT	CYT
n	36	38	12	2
Min	0.01	0.01	0.01	0.01
Max	0.11	0.03	0.04	0.01
HAFT	0.11	0.03	0.03	--
Median	0.01	0.01	0.01	--
Mean	0.03	0.01	0.02	0.01
SDEV	0.03	0.01	0.01	--

Crop	Potatoes	Potatoes
EP	40 WG A16901B	200 SC
No. of Applications	1	1
Total Rate (g a.i./ha)	140	140
PHI (days)	90–105	90–105
Statistic	CYT	CYT
n	6	6
Min	<0.01	<0.01
Max	0.04	0.04
HAFT	0.03	0.04
Median	0.01	0.01
Mean	0.02	0.02
SDEV	0.01	0.01

The proposed use pattern for potato tubers includes Verimark 200 g/L SC (seed piece), Benevia 100 g/L OD (foliar), Exirel 100 g/L SE (foliar), Syngenta 600 FS (seed treatment), and Syngenta 40 WG (in-furrow). Bridging studies indicated similar residue levels from foliar applications with the OD and SE formulations. The potato seed treatment portion of the trials was conducted at 13.5 g a.i./100 kg seed, which is consistent with the proposed label. Also, trials were conducted in support of the in-furrow treatment with either the 40 WG or 200 SC formulated products, which demonstrated similarity in the residue levels of cyantraniliprole. Overall, the data support the registration of the DuPont formulated products (Benevia, Verimark, Exirel), and Syngenta formulations (A17690A/B 600 FS, and A16901B 40WG) on tuberous and corm vegetable crop subgroup 1C, that reflect the different use patterns.

Study Design for Dry Bulb Onion, and Green Onions Trials.			PMRA No. 2070454
Application Types	3 late season foliar applications of 100 g/L OD 2 drip line soil applications of 200 g/L SC (comparative trial for green onions only)		
Crop	Dry bulb onions	Green Onions	Green Onions
EP	100 g/L OD	100 g/L OD	200 g/L SC
No. of Applications	3 Foliar	3 Foliar	2 Drip Line Soil
Total Rate (g a.i./ha)	443–474	452–465	454
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	18	10	2
Min	0.01	0.35	0.03
Max	0.03	4.10	0.04
HAFT	0.03	4.10	--
Median	0.02	1.35	--
Mean	0.02	1.61	0.04
SDEV	0.01	1.39	--
The trials were conducted in accordance with the proposed DuPont GAP for foliar application using the 100 g/L OD formulation. Residues of cyantraniliprole were lower in green onions following 2 drip-line soil applications of 200 g/L SC. Although, there is no side-by-side trial with bulb onions or green onions, comparing the OD versus the SE formulated product, it is expected that residues will be encompassed by the trials conducted with the OD formulation based on the trend of similarity observed in other crops tested (leafy, *Brassica*, potatoes, almonds). Therefore, the trials support the registration of Exirel 100 g/LSE on the bulb onion crop subgroup (3-07A) and the green onion crop subgroup (3-07B).			

Study Design for Head Lettuce, Leaf Lettuce, Celery, and Spinach Trials.					**PMRA No. 2070369/2070458/ 2071476/2071521**
Application Types	3 late season foliar application of 100 g/L OD 3 late season foliar application of 100 g/L SE (head/leaf lettuce) 1 soil shank or in-furrow of 200 g/L SC + 2 late season foliar of 100 g/L OD 2 drip irrigation of 200 g/L SC + 1 late season foliar of 100 g/L OD A16971B 40WG: 1 soil application (drench and/or shank); 1 soil application (drench and/or shank) followed by 2 foliar applications; 3 foliar applications 3 foliar Syngenta 40WG versus DuPont 100 g/L OD (leaf lettuce, head lettuce)				
Crop	**Head Lettuce (without wrapper leaf)**	**Head Lettuce**	**Head Lettuce**	**Head Lettuce**	**Head Lettuce**
EP	100 g/L OD	100 g/L OD	200 g/L SC 100 g/L OD	100 g/L SE	200 g/L SC 100 g/L OD
No. of Applications	3 Foliar	3 Foliar	1 Soil + 2 Foliar	3 Foliar	2 Soil + 1 Foliar
Total Rate (g a.i./ha)	440–464	440–464	453–457	446–466	451–453
PHI (days)	1	1	1	1	1
Statistic	CYT	CYT	CYT	CYT	CYT
n	6	24	2	12	2
Min	0.01	0.02	0.02	0.12	0.81
Max	0.60	2.90	0.02	2.20	1.00
HAFT	0.60	2.75	--	2.10	--
Median	0.01	0.73	--	0.68	--
Mean	0.20	0.96	0.02	0.88	0.91
SDEV	0.31	0.86	--	0.77	--
Crop	Head Lettuce	Head Lettuce	Leaf Lettuce		Leaf Lettuce
EP	40 WG A16971B	100 OD A15929B	40 WG A16971B		100 OD A15929B
No. of Applications	3 Foliar	3 Foliar	3 Foliar		3 Foliar
Total Rate (g a.i./ha)	450	450	448–453		448–464
PHI (days)	1	1	1		1
Statistic	CYT	CYT	CYT		CYT
N	9	9	9		9
Min	0.31	0.62	1.20		1.10

Max	1.96	1.55	4.60	4.50
HAFT	1.49	1.35	4.10	4.30
Median	1.19	1.09	2.60	3.10
Mean	1.09	1.07	2.70	3.00
SDEV	0.59	0.35	1.20	1.30
Crop	**Leaf Lettuce**	**Leaf Lettuce**	**Leaf Lettuce**	**Leaf Lettuce**
EP	100 g/L SE	100 g/L OD	200 g/L SC 100 g/L OD	200 g/L SC 100 g/L OD
No. of Applications	3 Foliar	3 Foliar	1 Soil + 2 Foliar	2 Soil + 1 Foliar
Total Rate (g a.i./ha)	446–466	440–464	453–457	451–453
PHI (days)	1	1	1	1
Statistic	CYT	CYT	CYT	CYT
n	12	24	2	2
Min	2.30	0.92	1.00	0.01
Max	7.70	7.40	1.10	0.01
HAFT	6.80	6.85	--	--
Median	4.05	2.65	--	--
Mean	4.44	3.11	1.10	0.01
SDEV	2.02	1.68	--	--
Crop	**Celery (without tops)**	**Celery with tops**	**Celery with tops**	**Celery with tops**
EP	100 g/L OD	100 g/L OD	200 g/L SC 100 g/L OD	200 g/L SC 100 g/L OD
No. of Applications	3 Foliar	3 Foliar	1 Soil + 2 Foliar	2 Soil + 1 Foliar
Total Rate (g a.i./ha)	440–464	440–464	453–457	451–453
PHI (days)	1	1	1	1
Statistic	CYT	CYT	CYT	CYT
n	6	22	2	2
Min	0.01	0.24	3.00	0.01
Max	0.01	9.50	4.10	0.01
HAFT	0.01	9.10	--	--
Median	0.01	2.00	--	--
Mean	--	2.79	3.50	0.01
SDEV	--	2.65	--	--

Crop	**Spinach**	**Spinach**	**Spinach**
EP	100 g/L OD	200 g/L SC 100 g/L OD	200 g/L SC 100 g/L OD
No. of Applications	3 Foliar	1 Soil + 2 Foliar	2 Soil + 1 Foliar
Total Rate (g a.i./ha)	440–464	453–457	451–453
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	14	2	2
Min	3.60	6.70	6.70
Max	13.00	6.80	6.80
HAFT	13.00	--	--
Median	4.60	--	--
Mean	6.24	6.70	6.80
SDEV	3.22	--	--
Crop	**Spinach**	**Spinach**	**Spinach**
EP	A16971B (40 WG)	A16971B (40 WG)	A16971B (40 WG)
Application method	Soil	Soil and foliar	Foliar
No. of Applications	1	1 soil + 2 foliar	3 foliar
Total Rate (g a.i./ha)	199–200	444–449	445–452
PHI (days)	30	1	1
Statistic	CYT	CYT	CYT
n	6	6	6
Min	<0.01	3.9	4.6
Max	0.02	6.8	9.0

HAFT	0.01	6.6	9.0
Median	0.01	5.8	6.7
Mean	0.01	5.5	6.8
SDEV	0.003	1.2	1.9

The requested end-use products in Canada for use in/on leafy vegetables (except *Brassica)* crop group 4 include foliar applications with DuPont Exirel (100 g/L SE); and a single in-furrow application with Syngenta A16901B 40WG.

Side-by-side trials with foliar-treated representative commodities of CG4 (head lettuce and leaf lettuce) indicate that residues of cyantraniliprole are similar between the OD and SE formulated products, which can be extended to the other commodities within CG4. Although no trials were conducted for in-furrow applications using Syngenta's 40WG formulated product, average residues of cyantraniliprole in all representative commodities of CG4, from trials conducted with 1 in-furrow treatment using 200 g/L SC followed by 2 foliar applications of 100 g/L OD, were lower than with 3 foliar applications. In addition, Syngenta presented data for spinach comparing the same regimes as those for DuPont, but using Syngenta 16901B 40WG. Based on those results, it is expected that residues of cyantraniliprole will be lower in leafy vegetables when Syngenta 40 WG is applied as a single in-furrow soil treatment. Consistent with those results, residues were highest to lowest in spinach following 3 foliar applications, 1 soil followed by 2 foliar applications, and 1 soil application. Overall, the data support the registration of Exirel 100 g/L SE and Syngenta 40WG on leafy vegetables crop group 4 (except *Brassica* vegetables).

Study Design for Broccoli/Cauliflower, Cabbage, and Mustard Greens Trials.			**PMRA No. 2070499/2071462/2071516**
Application Types	3 late season foliar applications of 100 g/L OD 3 late season foliar applications of 100 g/L SE (broccoli/cauliflower) 1 soil shank application of 200 g/L SC followed by 2 late season foliar application of 100 g/L OD A16971B 40WG: 1 soil application (drench and/or shank); 1 soil application (drench and/or shank) followed by 2 foliar applications; 3 foliar applications (cabbage, mustard greens) 1 in-furrow A16901B 40WG (mustard greens)		
Crop	**Broccoli/cauliflower**	**Broccoli/cauliflower**	**Broccoli/cauliflower**
EP	100 g/L OD	200 g/L SC + 100 g/L OD	100 g/L SE
No. of Applications	3 Foliar	1 Soil + 2 Foliar	3 Foliar
Total Rate (g a.i./ha)	445–465	451–454	442–451
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	20	2	8
Min	0.01	0.47	0.43
Max	1.10	0.49	1.10
HAFT	1.10	--	1.10
Median	0.49	--	0.70
Mean	0.48	0.48	0.74
SDEV	0.33	--	0.25
Crop	**Cabbage**	**Cabbage**	**Cabbage (without wrapper leaf)**
EP	100 g/L OD	200 g/L SC + 100 g/L OD	100 g/L OD
No. of Applications	3 Foliar	1 Soil + 2 Foliar	3 Foliar
Total Rate (g a.i./ha)	445–465	451–454	445–465
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	22	2	6
Min	0.27	0.40	0.01
Max	0.98	0.59	0.10
HAFT	0.95	--	0.07
Median	0.53	--	0.02
Mean	0.56	0.49	0.03
SDEV	0.22	--	0.03

Crop	Cabbage	Cabbage	Cabbage
EP	A16971B (40 WG)	A16971B (40 WG)	A16971B (40 WG)
Application method	Soil	Soil and foliar	Foliar
No. of Applications	1	1 soil + 2 foliar	3 foliar
Total Rate (g a.i./ha)	198–200	444–449	447–449
PHI (days)	30	1	1
Statistic	CYT	CYT	CYT
n	6	10	10
Min	<0.01	0.09	0.13
Max	<0.01	3.00	1.50
HAFT	<0.01	1.30	1.50
Median	<0.01	0.26	0.34
Mean	<0.01	0.69	0.52
SDEV	--	0.93	0.51

Crop	Mustard Greens	Mustard Greens	Mustard Greens	Mustard Greens
EP	100 g/L OD	200 g/L SC + 100 g/L OD	40 WG A16901B	200 SC
No. of Applications	3 Foliar	1 Soil + 2 Foliar	1	1
Total Rate (g a.i./ha)	445–465	451–454	150	150
PHI (days)	1	1	28–46	28–46
Statistic	CYT	CYT	CYT	CYT
n	22	2	6	6
Min	2.20	3.00	<0.01	0.01
Max	20.00	3.30	0.04	0.07
HAFT	18.50	--	0.04	0.07
Median	5.90	--	0.03	0.04
Mean	7.38	3.10	0.03	0.04
SDEV	4.74	--	0.01	0.02

Crop	Mustard Greens	Mustard Greens	Mustard Greens
EP	A16971B (40 WG)	A16971B (40 WG)	A16971B (40 WG)
Application method	Soil	Soil and foliar	Foliar
No. of Applications	1	1 soil + 2 foliar	3 foliar
Total Rate (g a.i./ha)	199–200	444–449	445–452
PHI (days)	30	1	1
Statistic	CYT	CYT	CYT
n	6	6	6
Min	<0.01	3.2	5.4
Max	0.02	8.9	10.6
HAFT	0.01	8.4	10.4
Median	0.01	7.4	9.5
Mean	0.01	6.3	8.7
SDEV	0.003	2.5	2.1

The requested end-use products in Canada for use in/on *Brassica* leafy vegetables include foliar applications with DuPont Exirel (100 g/L SE); in-furrow soil application with DuPont Verimark (200 g/L SC); and a single in-furrow application with Syngenta 40WG.

The maximum residues of cyantraniliprole following 3 foliar applications (100 g/L SE) in/on broccoli/cauliflower, as a representative commodity of CG5, demonstrating similarity between the OD and SE formulated product, which can be extended to the other commodities within CG5. Although no trials were conducted for in-furrow applications using Syngenta's 40WG formulated product, average residues of cyantraniliprole in all representative commodities of CG5, from trials conducted with 1 in-furrow treatment using 200 g/L SC followed by 2 foliar applications of 100 g/L OD, were lower than with 3 foliar applications.

In addition, Syngenta presented data for cabbage, and mustard greens comparing the application methods with Syngenta A16901B 40WG. Residues were highest to lowest in cabbage, and mustard greens following 3 foliar applications, 1 soil followed by 2 foliar applications, and 1 soil application. Syngenta also conducted comparative trials with a single in-furrow drench soil application (150 g a.i./ha; PHI of 28–46 days) using Syngenta 40WG

A16901B and DuPont Cyantraniliprole 200 SC in/on mustard greens, which on average showed similar residues of cyantraniliprole.

Overall, the data support the registration of Exirel 100 g/L SE, Verimark 200 g/L SC, and Syngenta's A16901B 40WG on *Brassica* vegetables crop subgroups *Brassica* head and stem (5A) and *Brassic*a leafy greens (5B).

Study Design for Bell Peppers, Non-Bell Peppers, and Tomatoes Trials.	**PMRA No. 2070494/2071519/2071531/2200372/2200373**
Application Types	3 late season foliar applications of 100 g/L OD 1 soil drip application of 200 g/L SC followed by 2 late season foliar application of 100 g/L OD A16971B 40WG: 1 soil application (drench and/or shank);1 soil application (drench and/or shank) followed by 2 foliar applications; 3 foliar applications (hot peppers) 1 in-furrow A16901B 40WG (tomatoes) 3 foliar Syngenta 40WG versus DuPont 100 g/L OD (bell peppers, tomatoes)

Crop	**Bell-Peppers**	**Bell-Peppers**	**Non-Bell Peppers**
EP	100 g/L OD	200 g/L SC + 100 g/L OD	100 g/L OD
No. of Applications	3 Foliar	1 Drip Irrigation + 2 Foliar	3 Foliar
Total Rate (g a.i./ha)	443–470	448–452	443–470
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	22	2	18
Min	0.03	0.09	0.07
Max	0.28	0.09	0.47
HAFT	0.28	--	0.43
Median	0.08	--	0.10
Mean	0.12	0.09	0.18
SDEV	0.09	--	0.13
Crop	**Non-Bell Peppers**	**Tomatoes**	**Tomatoes**
EP	200 g/L SC + 100 g/L OD	100 g/L OD	200 g/L SC + 100 g/L OD
No. of Applications	1 Drip Irrigation + 2 Foliar	3 Foliar	1 Drip Irrigation + 2 Foliar
Total Rate (g a.i./ha)	448–452	443–470	448–452
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	2	40	2
Min	0.15	0.04	0.04
Max	0.21	0.28	0.05
HAFT	--	0.27	--
Median	--	0.08	--
Mean	0.18	0.10	0.05
SDEV	--	0.06	--

Crop	**Tomatoes**	**Tomatoes**	**Bell Peppers**	**Bell Peppers**
EP	40 WG A16901B	100 OD A15929B	40 WG A16901B	100 OD A15929B
No. of Applications	3 Foliar	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	450	450	450	450
PHI (days)	1	1	1	1
Statistic	CYT	CYT	CYT	CYT
n	9	9	9	9
Min	0.06	0.06	0.06	0.09
Max	0.27	0.21	0.43	0.44
HAFT	0.23	0.18	0.37	0.37
Median	0.12	0.11	0.27	0.31
Mean	0.14	0.13	0.25	0.26
SDEV	0.08	0.05	0.11	0.12
Crop	**Hot Peppers**	**Hot Peppers**	**Hot Peppers**	**Tomatoes**
EP	A16971B (40 WG)	A16971B (40 WG)	A16971B (40 WG)	40 WG A16901B
No. of Applications	1 Soil	1 Soil and 2 foliar	3 Foliar	1 In-furrow

Total Rate (g a.i./ha)	198–203	447–450	446–458	76–88
PHI (days)	30	1	1	
Statistic	CYT	CYT	CYT	CYT
n	6	6	14	6
Min	<0.01	0.053	0.13	<0.01
Max	<0.01	0.32	0.80	<0.01
HAFT	<0.01	0.30	0.77	<0.01
Median	<0.01	0.22	0.34	<0.01
Mean	<0.01	0.19	0.41	<0.01
SDEV	--	0.11	0.22	--

The requested end-use products in Canada for use in fruiting vegetables CG8-09 include 3 foliar applications with DuPont Exirel (100 g/L SE); and a single in-furrow application with Syngenta 40WG. Although no trials were conducted for in-furrow applications using A16901B 40WG formulated product, average residues of cyantraniliprole in all representative commodities of CG8-09, from trials conducted with 1 in-furrow treatment using 200 g/L SC followed by 2 foliar applications of 100 g/L OD, were lower than with 3 foliar applications.

In addition, Syngenta presented data for hot peppers comparing the application regimes using Syngenta 16901B 40WG. Residues were highest to lowest in hot peppers following 3 foliar applications, 1 soil followed by 2 foliar applications, and 1 soil application. Application of Syngenta A16901B 40WG formulation was conducted to assess the residues of cyantraniliprole and its metabolites in/on tomatoes following a single in-furrow spray drench application (150 g a.i./ha; PHI of 76–88 days). Residues of cyantraniliprole and each metabolite were <0.01 ppm in tomatoes.

Overall, the data support the registration of Exirel 100 g/L SE, and A16901B 40WG, on fruiting vegetables crop group 8-09.

Summary of residue data from EU greenhouse trials.	**PMRA No. 2070470/2070472**

Greenhouse trials were conducted on tomatoes, cherry tomatoes, and non-bell peppers with cyantraniliprole applied as foliar treatment with an OD formulation at an application rate of 4 × 120 g a.i./ha for a total seasonal rate of 480 g a.i./ha. Comparative trials were also conducted with cyantraniliprole applied via drip irrigation with an SC formulation at an application rate of 4 × 100 g a.i./ha for a total of 400 g a.i./ha. Mature samples of tomatoes and non-bell peppers were analyzed for cyantraniliprole, IN-N7B69, IN-JCZ38, IN-MYX98, IN-K7H19, IN-MLA84 and IN-J9Z38 using the EU validated method 1187A with an LOQ of 0.01 ppm.

Region	Commodity	Application rate (g a.i./ha)	Type of application and formulation	PHI (days)	n	CYT (ppm)		
						Min	Max	Median
Indoor	Tomatoes	4 x120	Foliar, OD	1	9	0.043	0.22	0.14
		4 x100	Drip, SC	1	5	<0.01	0.01	0.01
	Cherry Tomatoes	4 x120	Foliar, OD	1	5	0.14	0.62	0.42
		4 x100	Drip, SC	1	3	<0.01	<0.01	<0.01
Indoor	Non-Bell Peppers	4 x120	Foliar, OD	1	5	0.01	1.00	0.135
		4 x100	Drip, SC	1	5	<0.01	0.01	0.01

The European greenhouse results were generated using an adequate data collection method. Adequate storage stability data are available on diverse crop types. The greenhouse uses are not approved on the Exirel 100 g/L label, however, since residues were higher under greenhouse conditions than field trials, the EU data will be considered for import MRLs.

Study Design for Cucumbers, Summer Squash, and Whole Melon Supervised Residue Trials.	PMRA No. 2070497/2071464/2071500/2071524/2200370
Application Types	3 late season foliar applications of 100 g/L OD 2 soil drip application of 200 g/L SC followed by 1 late season foliar application of 100 g/L OD A16971B 40WG: 1 soil application (drench and/or shank);1 soil application (drench and/or shank) followed by 2 foliar applications; 3 foliar applications 1 in-furrow A16901B 40WG (cucumbers) 3 foliar Syngenta 40WG versus DuPont 100 g/L OD (summer squash, cucumber, cantaloupe)

Crop	**Cucumbers**	**Cucumbers**	**Cantaloupes**
EP	100 g/L OD	200 g/L SC + 100 g/L OD	100 OD A15929B
No. of Applications	3 Foliar	2 Soil + 1 Foliar	3 Foliar
Total Rate (g a.i./ha)	430–463	452–453	446–462
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
N	20	2	35*
Min	0.02	0.06	0.01
Max	0.20	0.12	0.35
HAFT	0.16	--	0.31
Median	0.04	--	0.10
Mean	0.06	0.09	0.12
SDEV	0.05	--	0.10

Crop	**Cantaloupes**	**Cantaloupes**		**Cantaloupes**	
EP	40 WG A16971B	100 g/L OD		200 g/L SC + 100 g/L OD	
No. of Applications	3 Foliar	3 Foliar		2 Soil + 1 Foliar	
Total Rate (g a.i./ha)	446–456	430–463		452–453	
PHI (days)	1	1		1	
Statistic	CYT	CYT		CYT	
n	37*	18		2	
		Whole	Rind	Whole	Rind
Min	0.02	0.05	0.02	0.02	0.04
Max	0.46	0.20	0.54	0.02	0.05
HAFT	0.30	0.19	0.49	0.02	0.04
Median	0.13	0.11	0.18	--	--
Mean	0.17	0.12	0.18	0.02	0.04
SDEV	0.10	0.04	0.13	--	--

Crop	**Summer Squash**	**Summer Squash**	**Summer Squash**	**Summer Squash**
EP	100 g/L OD	200 g/L SC + 100 g/L OD	40 WG A16971B	100 OD A15929B
No. of Applications	3 Foliar	2 Soil + 1 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	430–463	452–453	450	450
PHI (days)	1	1	1	1
Statistic	CYT	CYT	CYT	CYT
n	18	2	10*	11*
Min	0.01	0.03	0.03	0.02
Max	0.12	0.03	0.16	0.11
HAFT	0.11	--	0.13	0.09
Median	0.06	--	0.05	0.04
Mean	0.06	0.03	0.07	0.06
SDEV	0.03	--	0.04	0.03

*Sample size is greater since replicates were done to confirm the presence of the parent compound at each trial site.

Crop	**Cucumbers**	**Cucumbers**	**Cucumbers**
EP	40 WG A16971B	100 OD A15929B	40 WG A16901B
No. of Applications	3 Foliar	3 Foliar	1 In-furrow
Total Rate (g a.i./ha)	450	450	150
PHI (days)	1	1	54–60

Statistic	DPX-HGW86	DPX-HGW86	CYT
n	13*	11*	6
Min	0.03	0.02	<0.01
Max	0.09	0.09	<0.01
HAFT	0.07	0.08	<0.01
Median	0.06	0.07	<0.01
Mean	0.06	0.06	<0.01
SDEV	0.02	0.03	--
Crop	**Cucumbers**	**Cucumbers**	**Cucumbers**
EP	A16971B (40 WG)	A16971B (40 WG)	A16971B (40 WG)
Application method	Soil	Soil and foliar	Foliar
No. of Applications	1	1 soil + 2 foliar	3 foliar
Total Rate (g a.i./ha)	199–201	446–449	450–455
PHI (days)	30	1	1
Statistic	CYT	CYT	CYT
n	6	6	6
Min	<0.01	0.05	0.06
Max	<0.01	0.09	0.11
HAFT	<0.01	0.08	0.10
Median	<0.01	0.06	0.07
Mean	<0.01	0.07	0.08
SDEV	--	0.01	0.02

The requested use pattern is for foliar applications of Exirel 100 g/L SE in/on cucurbit vegetables; and a single in-furrow soil application using Syngenta A16901B 40WG. Although the trials were conducted with the 100 g/L OD formulated product instead of the proposed SE formulation, DuPont bridging residue data conducted in/on various crops (PMRA No. 2070450; leafy, *Brassica*, almonds, potatoes) indicated a trend that the two formulated products yielded comparable residues.

One trial for each of the representative commodities of CG9 was conducted using 2 soil drip application of 200 g/L SC followed by 1 late season foliar application of 100 g/L OD. However, the proposed use pattern in Canada includes a single in-furrow soil application with A16901B 40WG end-use product. Syngenta conducted bridging trials to compare different application methods using A16901B 40WG formulated product, which indicated that residues of cyantraniliprole were highest to lowest in cucumbers following 3 foliar applications, 1 soil followed by 2 foliar applications, and 1 soil application. Syngenta also conducted trials using a single in-furrow spray drench application (150 g a.i./ha; PHI of 54–60 days) of the water dispersible granule (WG) formulation A16901B 40WG, which showed that residues of cyantraniliprole were <0.01 ppm in cucumbers.

In addition, Syngenta conducted side-by-side trials to compare DuPont oil dispersion (100 OD- A15929B) with Syngenta's water dispersible granules (40WG –A16971B) formulated products in cucumbers, summer squash, and cantaloupes. On average, residues of cyantraniliprole were similar in cucumbers, and summer squash. In the case of cantaloupes, residues of cyantraniliprole reached a maximum of 0.46 ppm (40WG) in one sample out of 37, which is in excess of the proposed MRL of 0.4 ppm for cucurbits. However, on average, residues of cyantraniliprole were comparable between formulations [0.17 ppm (n=37; 40WG), and 0.12 ppm (n=35; 100OD)].

Overall, the data support the registration of Exirel 100 g/L SE (foliar treatment), and A16901B 40 WG (in-furrow treatment) on cucurbit vegetables crop group 9.

Study Design for Oranges, Lemons, and Grapefruits Trials.			**PMRA No. 2070505**
Application Types	3 early season foliar applications with 100 g/L SE 1 single soil band application with 200 g/L SC (lemon only)		
Crop	**Whole Orange**	**Orange Peel**	**Orange Pulp**
EP	100 g/L SE	100 g/L SE	100 g/L SE
No. of Applications	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	429–463	429–463	429–463
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
N	26	26	26

Min	0.09	0.14	0.01
Max	0.40	0.91	0.09
HAFT	0.39	0.89	0.09
Median	0.20	0.42	0.04
Mean	0.21	0.46	0.05
SDEV	0.10	0.21	0.02
Crop	**Whole Lemon**	**Lemon Peel**	**Lemon Pulp**
EP	100 g/L SE	100 g/L SE	100 g/L SE
No. of Applications	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	452–462	452–462	452–462
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
N	12	12	12
Min	0.11	0.24	0.02
Max	0.30	0.63	0.11
HAFT	0.30	0.63	0.11
Median	0.20	0.41	0.07
Mean	0.20	0.41	0.06
SDEV	0.06	0.12	0.03
Crop	**Whole Grapefruit**	**Grapefruit Peel**	**Grapefruit Pulp**
EP	100 g/L SE	100 g/L SE	100 g/L SE
No. of Applications	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	446–461	446–461	446–461
PHI (days)	1	1	1
Statistic	CYT	CYT	CYT
n	14	14	14
Min	0.07	0.18	0.01
Max	0.33	0.77	0.06
HAFT	0.31	0.72	0.05
Median	0.13	0.34	0.03
Mean	0.16	0.39	0.03
SDEV	0.08	0.16	0.01
The proposed US end-use products for citrus fruits include Exirel 100 g/L SE (foliar), and Verimark 200 g/L SC (1 soil drench). Although only limited trials were conducted using a single soil drench application (lemons only), the results show that 3 foliar applications yield higher residues of cyantraniliprole. Therefore, the data support an import MRL for the citrus crop group 10 that reflects the different use patterns proposed.			

Study Design for Pears and Apples Trials.			**PMRA No. 2070502**	
Application Types	3 late season foliar applications of 100 g/L SE 3 foliar Syngenta 40WG versus DuPont 100 g/L OD (apples)			
Crop	**Pears**	**Apples**	**Apples**	**Apples**
EP	100 g/L SE	100 g/L SE	40 WG A16971B	100 OD A15929B
No. of Applications	3 Foliar	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	446–460	446–460	446–454	446–452
PHI (days)	3	3	3	3
Statistic	CYT	CYT	CYT	CYT
n	20	32	9	9
Min	0.07	0.05	0.22	0.08
Max	0.65	0.31	0.60	0.41
HAFT	0.54	0.31	0.41	0.35
Median	0.19	0.16	0.30	0.31
Mean	0.28	0.17	0.32	0.29
SDEV	0.20	0.08	0.04	0.09
The requested use pattern is for foliar applications of Exirel 100 g/L SE formulated product in/on pome fruits and a PHI of 3 days. Overall, the data support the registration of Exirel 100 g/L SE on pome fruits (crop group 11-09).				

Study Design for Peaches, Plums, and Cherries Trials.		PMRA No. 2070512	
Application Types	3 late season foliar applications of 100 g/L SE with samples harvested at 3 days following the last application.		
Crop	Peaches	Plums	Cherries
EP	100 g/L SE	100 g/L SE	100 g/L SE
No. of Applications	3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	446–463	445–463	434–465
PHI (days)	3	3	3
Statistic	CYT	CYT	CYT
n	24	16	14
Min	0.16	0.03	0.29
Max	1.40	0.30	3.90
HAFT	0.94	0.28	3.75
Median	0.32	0.06	0.93
Mean	0.40	0.09	1.17
SDEV	0.26	0.08	1.13
The requested use pattern is for foliar applications of Exirel 100 g/L SE formulated product in/on stone fruits. Overall, the data support the registration of Exirel 100 g/L SE on stone fruits subgroups (crop group 12-09) and a PHI of 3 days.			

Study Design for Blueberries Trials.	PMRA No. 2070461/ 2070462
Application Types	3 late season foliar applications of 100 g/L SE
Crop	Blueberries
EP	100 g/L SE
No. of Applications	3 Foliar
Total Rate (g a.i./ha)	445–458
PHI (days)	2–4
Statistic	CYT
n	20
Min	0.37
Max	2.00
HAFT	1.95
Median	0.65
Mean	0.91
SDEV	0.53
The requested use pattern is for foliar applications of Exirel 100 g/L SE formulated product in/on bushberries (CSG 13-07B) at a PHI of 3 days. Overall, the data support the registration of Exirel 100 g/L SE on crop subgroup 13-07B.	

Study Design for Almond and Pecan Trials.			PMRA No. 2070460	
Application Types	3 foliar applications of 100 g/L OD 3 foliar applications of 100 g/L SE 1 post-bloom shank or subsurface side-dress of 200 g/L SC			
Crop	**Almond nutmeat**	**Almond nutmeat**	**Pecan nutmeat**	**Pecan nutmeat**
EP	100 g/L OD	100 g/L SE	100 g/L OD	200 g/L SC
No. of Applications	3 Foliar	3 Foliar	3 Foliar	1 Soil
Total Rate (g a.i./ha)	437–459	453–458	445–465	462
PHI (days)	5	5	4–5	4–5
Statistic	CYT	CYT	CYT	CYT
n	12	4	12	2
Min	0.01	0.01	0.01	0.01
Max	0.02	0.02	0.01	0.01
HAFT	0.02	0.02	0.01	--
Median	0.01	0.01	0.01	--
Mean	0.01	0.01	--	0.01
SDEV	0.005	0.004	--	--

The requested use pattern is for foliar applications of Exirel 100 g/L SE formulated product in/on tree nuts and a PHI of 5 days. Side-by-side trials with 100 g/L OD and 100 g/L SE indicate that the average residues of cyantraniliprole are similar. Overall, the data support the registration of Exirel 100 g/L SE in/on tree nuts (crop group 14-11).

Study Design for Cotton Trials.			**PMRA No. 2070510**
Application Types	3 late season foliar applications of 100 g/L OD Side-by-side plots comparing 3 late season foliar applications of 100 g/L OD with 1 in-furrow soil followed by 2 late season foliar applications		
Crop	Cottonseed	Cottonseed	Cottonseed
EP	200 g/L SC + 100 g/L OD	100 g/L OD	100 g/L OD
No. of Applications	1 In-furrow Soil + 2 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	446	446	446–466
PHI (days)	8	8	6–9
Statistic	CYT	CYT	CYT
n	2	2	22
Min	0.14	0.27	0.01
Max	0.16	0.32	1.20
HAFT	--	--	1.02
Median	--	--	0.16
Mean	0.15	0.30	0.21
SDEV	--	--	0.26
A trial confirmed that residues of cyantraniliprole are generally higher in cottonseed following 3 foliar applications (100 g/L OD) in comparison to a single in-furrow soil application (200 g/L SC) followed by 2 foliar applications of 100 g/L OD at a PHI of 6–8 days. The data supports the requested registration of Benevia 100 g/L OD in/on cottonseed. Overall, the data support an import MRL for cottonseed that reflects the different use patterns proposed.			

Study Design for Canola and Sunflower Trials.				**PMRA No. 2070459**
Application Types	3 late season foliar applications with 100 g/L OD 1 seed treatment of 625 g/L FS followed by 3 late season foliar applications of 100 g/L OD			
Crop	Canola Seeds	Canola Seeds	Canola Seeds	Sunflower Seeds
EP	100 g/L OD	625 g/L FS + 100 g/L OD	100 g/L OD	100 g/L OD
No. of Applications	3 Foliar	1 Seed + 3 Foliar	3 Foliar	3 Foliar
Total Rate (g a.i./ha)	448–455	452–454	444–458	441–456
PHI (days)	6–7	6–7	7	5–7
Statistic	CYT	CYT	CYT	CYT
n	10	10	34	18
Min	0.02	0.02	0.02	0.03
Max	0.34	0.22	0.61	0.32
HAFT	0.32	0.20	0.61	0.32
Median	0.04	0.04	0.08	0.07
Mean	0.10	0.08	0.15	0.10
SDEV	0.13	0.09	0.15	0.09
The requested use pattern is for foliar applications of Benevia 100 g/L OD formulated product; and seed treatment with Lumiderm (625 g/L FS). While the trials are representative of the requested use as foliar applications of Benevia 100 g/L OD, the trials required to support seed treatment use involved seed treatment followed by 3 foliar applications (625 g/L FS + 3 foliar of 100 g/L OD). This represents a worse-case scenario as residues of cyantraniliprole are expected to be lower following 1 seed treatment using Lumiderm. The MRL for crop group 20 will be driven by the foliar uses with 100 g/L OD formulated product in/on canola, sunflower seeds, and cottonseeds.				

Residue Decline Studies for NAFTA Trials and Estimates of Half-Lives.				
Crop Group	**Crop**	**EP**	**Sampling Times (Days)**	**Half-Life (Days)**
Tuberous and corm vegetables	Potato Tubers	625 g/L FS + 100 g/L OD	0, 1, 5, 7	No quantifiable residues
Bulb Vegetables	Dry bulb onions	100 g/L OD	1, 4, 10, 15	No quantifiable residues
	Green onions	100 g/L OD	1, 3, 7, 13	2.8
Leafy Vegetables	Leaf lettuce	100 g/L OD	0, 1, 3, 5	2.4
Brassica (Cole) Leafy Vegetables	Broccoli	100 g/L OD	0, 1, 3, 5	3.8
Fruiting Vegetables	Field tomatoes	100 g/L OD	0, 1, 3, 5	No trend could be determined
Cucurbit Vegetables	Cucumbers	100 g/L OD	0, 1, 3, 5, 7	6.7
Citrus Fruits	Lemons	200 g/L SC	1, 7, 14	No quantifiable residues
Pome Fruits	Apples	100 g/L SE	0, 1, 3, 6	17.1
Stone Fruits	Peaches	100 g/L SE	0, 1, 3, 7	11.8
Small Fruit and Berries	Blueberries	100 g/L SE	0, 4, 7, 10	4.2
Oilseeds	Cottonseed	100 g/L OD	0, 1, 5, 7	4.5

Study Design for Grape Trials from EU.	**PMRA No. 2092907**
Application Types	2 foliar treatment with 100 g/L SE at 120 g a.i./ha with re-treatment interval of 14 days; PHI of 10 days. 2 foliar treatment with 100 g/L SE at 150 g a.i./ha with re-treatment interval of 14 days; PHI of 10 days.
Environment	Field
No. of Trials	9 trials in Southern Europe; 10 trials in Northern Europe
EU Regions	France, Italy, Spain, Germany, UK
Adjuvants Used	None.

Study Design for Olive Trials from EU.	**PMRA No. 2092906**
Trt. Types	2 foliar treatment with 100 g/L SE at 150 g a.i./ha with re-treatment interval of 10 days; PHI of 14 days.
Environment	Field
# of Trials	9 trials in Southern Europe
EU Regions	France, Italy, Spain, Greece
Adjuvants Used	Yes

Crop	**Grapes**	**Grapes**	**Olives**
EP	100 g/L SE	100 g/L SE	100 g/L SE
No. of Applications	2 Foliar	2 Foliar	2 Foliar
Total Rate (g a.i./ha)	240	300	300
PHI (days)	10	10	14
Statistic	CYT	CYT	CYT
n	10	9	9
Min	0.07	0.07	0.21
Max	0.80	0.56	1.10
HAFT	--	--	0.74
Median	0.17	0.30	0.27
Mean	0.28	0.29	0.39
SDEV	0.23	0.15	0.28

Sufficient residue trials were conducted in/on grapes and olives according to the critical EU GAPs and relevant guideline requirements. The studies are reported in sufficient details and with acceptable analytical information, providing data appropriate for setting import MRLs.

Field Accumulation Crop Studies.	PMRA No. 2070541/2070544/2070551/2070557/2070562

Different studies were conducted in Canada and the US in order to determine the residue levels in rotational crops following treatment with cyantraniliprole. In three of the five studies, bare soil was treated with 3 applications of 100 g/L OD, and four rotational crops were subsequently planted (lettuce/spinach, oat, radishes, soybean) at PBI of 14, 30, 120, and 365 days. In the fourth study, bare soil was treated with 3 applications of 100 g/L SE, and seventeen rotational crops were subsequently planted (turnip, sugar beet, garden beet, carrot, bean, pea, soybean, field corn, sweet corn, sorghum, rice, wheat, Bermuda grass, alfalfa, bromegrass, clover, and bluegrass) with PBI of 30 days. In the fifth study, bare soil was treated with 3 applications of 100 g/L SE, and ten rotational crops were subsequently planted (turnip, sugar beet, radish, carrot, pea, soybean, alfalfa, clover, peanut, and strawberries) with PBIs of 30 days. In all studies, the seasonal rate was 450 g a.i./ha.

Highest Residues of Cyantraniliprole in Crops Sown as Rotational Crops Across NAFTA Regions at a 30-Day PBI.

Commodities used for human consumption		
RAC	Part	CYT (ppm)
Lowgrowing berry subgroup 13-07G (strawberry)	Strawberry	<0.01
Leafy vegetables CG4 (lettuce; spinach)	Immature leaves	0.03
	Mature leaves	0.02
Root vegetables, subgroup (carrot; radish; sugar beet; garden beet) CG1A	Roots	0.02
Leaves of Root and Tuber Vegetables (Human food or Animal Feed) CG2	Tops	0.04
Cereals grains (corn, oats, rice, sorghum, wheat) CG15	Grain	0.01
Legume vegetables (succulent or dried) CG6	Seed	<0.01
Peanuts	Nutmeat	<0.01
Commodities used for feedstuff		
Forage, fodder and straw of cereal grains (corn; wheat; and any other cereal grain) CG16	Hay	0.21
	Straw	0.08
	Forage	0.11
	Stover	0.01
Grass forage, fodder, and hay group (Bermuda grass; bluegrass; bromegrass) CG17	Hay	0.23
	Forage	0.09
Foliage of legume vegetables (any cultivar of bean, field pea, and soybean) CG7	Hay	0.63
	Forage	0.14
Nongrass Animal Feeds (forage; fodder; straw; and hay – alfalfa; clover) CG18	Forage	0.05
	Hay	0.14
Peanuts	Hay	<0.01
Leaves of Root and Tuber Vegetables (Human food or Animal Feed) CG2	Tops	0.04

Overall, residues of cyantraniliprole (residue definition for enforcement purposes) are less than LOQ by the 365-day PBI. However, based on a PBI of 30 days, as requested by the applicants, MRLs will be required for inadvertent residues of cyantraniliprole in commodities for human consumption for crop groups 1A, and 2, as residues are not covered by primary crops.

Processed Food and Feed

Following field treatment of potatoes, spinach, tomatoes, oranges, apples, plums, and cottonseed in NAFTA regions, residues of cyantraniliprole and eight metabolites were determined in the raw agricultural commodity and the processed fractions. Processing studies were also reviewed from European trials in/on grapes and olives. The varieties were typical of the regions where tests were conducted. Samples were processed using simulated industrial or domestic practices as closely as possible. The mean and median values were considered as the processing factors (P*f*) for MRL setting, when two or three independent field trial sites were used to conduct the processing trials, respectively.

Potatoes (RAC): 1 seed treatment (625 g/L FS) + 2 foliar (100 g/L OD); 412–448 g a.i./ha/season; PHI = 7 d	**PMRA No. 2070453**
Fraction	Processing Factor (Pf)
Flakes	0.71
Potato waste	0.71
Peeled potatoes	0.71
Chips	0.71
Wet peel	0.71
Culls	1.00
Fries	0.71
Cooking water	0.71
Unpeeled boiled	0.71
Unpeeled microwaved	0.71
Spinach Leaves (RAC): 3 foliar (100 g/L OD); 447–455 g a.i./ha/season; PHI = 1 d	PMRA No. 2070458
Spinach leaves cooked	0.16
Spinach cooking water	0.02
Tomatoes (RAC): 3 foliar (100 g/L OD); 902–904 g a.i./ha/season; PHI = 1 d	PMRA No. 2070531
Washed tomatoes	0.18
Peeled tomatoes	0.08
Sun-dried tomatoes	3.46
Canned tomatoes	0.08
Tomato juice	0.09
Wet tomato pomace	0.65
Dried tomato pomace	1.77
Tomato paste	0.60
Tomato purée	0.19
Oranges (RAC): 3 foliar (100 g/L SE); 452–460 g a.i./ha/season; PHI = 1 d	PMRA No. 2070505
Orange Juice	0.08
Orange Wet Pulp	0.21
Orange Dry Pulp	0.38
Orange Meal	0.39
Orange Molasses	0.08
Orange Marmalade	0.08
Orange Oil	6.23
Orange Canned	0.08
Plum (RAC): 3 foliar (100 g/L SE); 449–451 g a.i./ha/season; PHI = 3 d	PMRA No. 2070512
Dried Prunes	1.54
Whole Olives (RAC): 2 foliar (100 g/L SE); 299–306 g a.i./ha/season; PHI =14d	PMRA No. 2092906
Whole Processed Olives	0.21
Raw Oil	0.55
Refined Oil	0.19
Apples (RAC): 3 foliar (100 g/L SE); 424–454 g a.i./ha/season; PHI = 3 d	PMRA No. 2070502
Washed Apples	0.57

Potatoes (RAC): 1 seed treatment (625 g/L FS) + 2 foliar (100 g/L OD); 412–448 g a.i./ha/season; PHI = 7 d	PMRA No. 2070453
Apple Purée	1.12
Canned Apples	0.12
Frozen Apples	0.95
Apple Juice	0.32
Apple Wet Pomace	1.03
Apple Dry Pomace	2.59
Apple Sauce	1.39
Cottonseed (RAC): 3 foliar (100 g/L OD); 2194–2259 g a.i./ha/season; PHI = 7 d	PMRA No. 2070510
Cottonseed raw oil	0.03
Cottonseed refined oil	0.01
Cottonseed meal	0.04
Cottonseed hull	0.34
Cottonseed raw oil (cold press)	0.26
Cottonseed refined oil (cold press)	0.01
Cottonseed Meal (cold press)	0.06
Mature grapes (RAC): 3 foliar (100 g/L SE); 296–302 g a.i./ha/season; PHI = 9–11 d	PMRA No. 2092907
Stem	4.00
Must	2.67
Wet pomace	4.81
Lees	2.59
Dry pomace	6.08
Bottled wine	1.69
Juice	0.83
Raisins	1.36
Final Assessment for the Processing Studies	
The data indicates that concentration of residues of cyantraniliprole was observed in the following human food commodities: sun-dried tomatoes, orange oil, apple sauce, apple purée, dried plums, raisins, and bottled wine. Based on median processing factors and the highest average field trial values, only citrus oil needs a separate MRL from the RAC for enforcement purposes.	

Anticipated Residues in Processed Commodities				
Matrix	HAFT (ppm)	Median P*f*	Anticipated Residue (ppm)	RAC MRL (ppm)
Apple sauce	0.31	1.39	0.43	1.5
Apple purée	0.31	1.12	0.35	1.5
Dried plums	0.28	1.54	0.43	0.5
Raisins	0.80	1.36	1.09	1.5
Bottled wine	0.80	1.69	1.35	1.5
Orange oil	0.39	6.23	2.41	0.7
Sun-dried tomatoes	0.27	3.46	0.97	2.0

Poultry Feeding Study Design.				PMRA No. 2070516			
Species	Age/Weight At Dosing	Average Food Consumption	# Animal	Application details		Sampling details	
				Rate (ppm feed)	Duration (days)	Commodity	Collection Time
Chicken (*ISA Warren*)	ca. 23 weeks old; 1.3–1.9 kg	0.128–0.143 kg/bird/day within groups	10/group split into 3 sub-groups of 3 or 4 animals	Group 1: 0 Group 2: 3 Group 3: 10 Group 4: 30 Group 5: 30	[7 days acclimation] Dosing occurs for 28 d.	Eggs	Twice daily; pooled on a daily basis
						Liver, muscle (equal quantities of leg and breast), skin with fat	After sacrifice (< 6 hours)

Summary of Cyantraniliprole Residue Levels in Poultry Matrices After 28 Days of Dosing.							
Matrix	Dose level (ppm)	Residue Levels of Cyantraniliprole (ppm)					
		n	Min	Max	Median	Mean	SDEV
Whole eggs	0	3	<0.01	<0.01	<0.01	<0.01	<0.01
	3	3	0.04	0.11	0.10	0.08	0.04
	10	3	0.10	0.25	0.17	0.17	0.08
	30	3	0.30	0.53	0.48	0.44	0.12
Muscle	0	3	<0.01	<0.01	<0.01	<0.01	<0.01
	3	3	<0.01	<0.01	<0.01	<0.01	<0.01
	10	3	<0.01	0.02	<0.01	0.01	0.00
	30	3	<0.01	0.05	0.02	0.03	0.02
Liver	0	3	<0.01	<0.01	<0.01	<0.01	<0.01
	3	3	0.01	0.03	0.01	0.02	0.01
	10	3	0.02	0.06	0.03	0.04	0.02
	30	3	0.04	0.24	0.10	0.13	0.10
Skin with fat	0	3	<0.01	<0.01	<0.01	<0.01	<0.01
	3	3	<0.01	0.01	<0.01	0.01	0.00
	10	3	0.02	0.06	0.02	0.03	0.02
	30	3	0.03	0.16	0.06	0.08	0.07

Overall Assessment of Laying Hen Feeding Study.

When laying hens were fed 3 ppm, 30 ppm, and 30 ppm for 28 days, residues were dose-dependent. Residues of cyantraniliprole in whole eggs reached a maximum at day 3. Following cessation of dosing, residues rapidly declined. The highest residues were found in eggs, followed by liver, skin with fat, and muscle.

Poultry Matrices	Quantifiable Residues at All Feeding Levels
Muscle	Parent
Liver	Parent + IN-MLA84 + IN-N7B69 +IN-MYX98
Skin with Fat	Parent
Whole Eggs	Parent + IN-MLA84 + IN-MYX98 + IN-J9Z38

Lactating Cow Feeding Study.				PMRA No. 2070520			
Species	Age/ Weight At Dosing	Average Food Consumption	# Animal	Application details		Sampling details	
				Rate (ppm feed)	Duration (days)	Commodity	Time
Dairy cow (Holstein/ Friesian)	2–7 yrs old; 437–680 kg	8 kg concentrate/ day	3/group and 2 controls	Group 1: 0 Group 2: 3 Group 3: 10 Group 4: 30 Group 5: 100	[26 d acclimation] Dosing occurs in the mornings for 28 d.	Milk	Twice daily pooled on daily basis
						Liver, kidney, muscle (loin and flank, or round leg), fat (omental, perirenal, sub-cutaneous)	After sacrifice (<24 hours)

Summary of Cyantraniliprole Residue Levels in Cattle Matrices After 28 Days of Dosing.							
Matrix	Dose (ppm)	CYT Residue Levels (ppm)					
		n	Min	Max	Median	Mean	SDEV
Whole milk	3	15	0.01	0.03	0.02	0.02	0.01
	10	15	0.04	0.16	0.06	0.07	0.04
	30	15	0.07	0.40	0.18	0.21	0.12
	100	15	0.48	0.82	0.63	0.65	0.10
Fat	3	3	0.01	0.02	0.01	0.01	0.00
	10	3	0.03	0.07	0.03	0.04	0.02
	30	3	0.09	0.15	0.13	0.12	0.03
	100	3	0.46	0.58	0.48	0.51	0.07
Muscle	3	3	<0.01	0.01	<0.01	<0.01	--
	10	3	0.02	0.04	0.02	0.03	0.01
	30	3	0.05	0.09	0.07	0.07	0.02
	100	3	0.26	0.33	0.26	0.28	0.04
Liver	3	3	0.05	0.07	0.05	0.05	0.01
	10	3	0.13	0.16	0.15	0.15	0.02
	30	3	0.29	0.60	0.50	0.46	0.16
	100	3	1.50	2.10	1.60	1.70	0.30
Kidney	3	3	0.01	0.03	0.02	0.02	0.01
	10	3	0.05	0.14	0.06	0.08	0.05
	30	3	0.13	0.25	0.21	0.20	0.06
	100	3	0.63	0.89	0.68	0.73	0.14

Overall Assessment of Lactating Cow Feeding Study.

When lactating cows were fed 3 ppm, 10 ppm, 30 ppm, and 100 ppm for 28 days, residues were dose-dependent. Residues of cyantraniliprole in whole milk reached a maximum at day 14. The highest residues were found in liver, followed by kidney, fat, and muscle. Following cessation of dosing, residues rapidly declined.

Cow Matrices	Quantifiable Residues at All Feeding Levels
Muscle	Parent
Liver	Parent + IN-MLA84
Kidney	Parent + IN-N7B69
Fat	Parent + IN-J9Z38
Whole Milk	Parent + IN-N7B69

More Balanced Diet (MBD) and Anticipated Residues in Meat, Milk, Poultry, and Eggs

The livestock feedstuff items associated with proposed uses are potatoes, almonds, apples, oilseeds (canola, sunflower). Imported commodities were not included (citrus, cotton). Highest values or median values for residues of cyantraniliprole, as prescribed, from feed items derived from rotational crops at 30-day PBI such as cereals, grasses, and legumes were also included. The anticipated residues of cyantraniliprole and relevant metabolites (expressed as parent equivalent) in animal matrices are all below the LOQ.

Matrix Type	MBD (ppm)
Beef Cattle	0.21
Dairy Cattle	0.40
Poultry	0.01
Swine	0.01

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

<table>
<tr><th colspan="4">PLANT STUDIES</th></tr>
<tr><td colspan="4">RESIDUE DEFINITION FOR ENFORCEMENT</td></tr>
<tr><td colspan="2">Primary crops (Cotton, Lettuce, Rice, Tomato)</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">Rotational crops (Wheat, Red beet, Lettuce)</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">Processed Commodities</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">RESIDUE DEFINITION FOR DIETARY EXPOSURE ASSESSMENT</td><td colspan="2"></td></tr>
<tr><td colspan="2">Primary crops</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">Rotational crops</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">Processed Commodities</td><td colspan="2">Cyantraniliprole and IN-J9Z38, expressed as parent equivalent</td></tr>
<tr><td colspan="2">METABOLIC PROFILE IN DIVERSE CROPS</td><td colspan="2">The profile in diverse crops was similar.</td></tr>
<tr><th colspan="4">ANIMAL STUDIES</th></tr>
<tr><td colspan="2">ANIMALS</td><td colspan="2">Ruminant</td></tr>
<tr><td colspan="2">RESIDUE DEFINITION FOR ENFORCEMENT</td><td colspan="2">Cyantraniliprole</td></tr>
<tr><td colspan="2">RESIDUE DEFINITION FOR DIETARY EXPOSURE ASSESSMENT</td><td colspan="2">Cyantraniliprole, IN-J9Z38, IN-N7B69, IN-MLA84, IN-MYX98, expressed as parent equivalent on a matrix-specific basis</td></tr>
<tr><td colspan="2">METABOLIC PROFILE IN ANIMALS
(goat, hen, rat)</td><td colspan="2">The profile is similar in all investigated animals.</td></tr>
<tr><td colspan="2">FAT SOLUBLE RESIDUE</td><td colspan="2">No</td></tr>
<tr><td colspan="4">DIETARY RISK FROM FOOD AND WATER</td></tr>
<tr><td rowspan="11">Refined chronic non-cancer dietary risk

ADI = 0.01 mg/kg bw

Estimated chronic drinking water concentration = 0.011 ppm</td><td rowspan="2">POPULATION</td><td colspan="2">ESTIMATED RISK
% of ACCEPTABLE DAILY INTAKE (ADI)</td></tr>
<tr><td>Food Only</td><td>Food and Water</td></tr>
<tr><td>All infants < 1 year</td><td>26.8</td><td>34.5</td></tr>
<tr><td>Children 1–2 years</td><td>39.7</td><td>43.2</td></tr>
<tr><td>Children 3 to 5 years</td><td>34.1</td><td>37.3</td></tr>
<tr><td>Children 6–12 years</td><td>23.2</td><td>25.4</td></tr>
<tr><td>Youth 13–19 years</td><td>17.7</td><td>19.4</td></tr>
<tr><td>Adults 20–49 years</td><td>20.5</td><td>22.7</td></tr>
<tr><td>Adults 50+ years</td><td>21.2</td><td>23.5</td></tr>
<tr><td>Females 13–49 years</td><td>21.1</td><td>23.3</td></tr>
<tr><td>Total population</td><td>22.0</td><td>24.3</td></tr>
</table>

Table 7 Mixer/Loader/Applicator Risk Assessment for Foliar/In-furrow uses [a]

Crop	Application Equipment	Application Rates [b] (kg a.i./ha)	Area treated per day [c] (ha)	Inhalation Exposure [d] (µg/kg bw/day)	Inhalation MOE [e]
Foliar					
potatoes	groundboom	0.15	360	1.53	17000
	aerial (M/L)		400	0.87	30000
	aerial (A)			0.06	435000
bushberries, pome and stone fruit trees	airblast	0.15	20	0.32	82000
tree nuts	airblast	0.10	20	0.21	123000
bushberries, tuberous and corm, leafy, brassica, bulb, fruiting, and cucurbit vegetables	groundboom	0.15	360	1.97	13000
	aerial (M/L)		400	1.37	19000
	aerial (A)			0.06	435000
oilseed group	groundboom	0.10	360	1.32	20000
	aerial (M/L)		400	0.91	29000
	aerial (A)			0.04	653000
outdoor ornamentals	backpack	1.50E-04 kg a.i./L	150 L	0.02	1286000
greenhouse ornamentals	m.p. handheld sprayer		3800 L	1.24	21000
	p. handheld sprayer		150 L	0.46	5700
Soil					
leafy, Brassica, fruiting & cucurbit vegetables	groundboom	0.15	26	0.11	237000
potato	groundboom	0.14	360	1.43	18000
potato, brassica	groundboom	0.20	360	2.63	10000
greenhouse ornamentals	backpack	1.50E-04 kg a.i./L	150 L	0.02	1286000
	m.p. handheld sprayer		3800 L	1.24	21000
	p. handheld sprayer		150 L	0.46	57000

MOE = Margin of Exposure; M/L = Mixer/Loader; A = Applicator; m.p. mechanically pressurized; p. = manually-pressurized.
[a] Mixer/Loader/Applicators: open mixing, open cab groundboom, a single layer + chemical-resistant gloves. Pilot PPE: Single layer, no gloves.
[b] Maximum label rate.
[c] Maximum Area Treated per day based on PMRA HED ATPD Table July 2010.
[d] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw
[e] Based on an intermediate-term inhalation NOAEC of 26.1 mg/kg bw/day and a target inhalation MOE of 300.

Table 8 Oilseed Seed Treatment Risk Assessment

Application Equipment	Application Rates [a] (kg a.i./kg seed)	Activity [b]	Inhalation Unit Exposure [c]	Amount treated per day [d] (kg)	Inhalation Exposure [e] (µg /kg bw/day)	Inhalation MOE [f]
Closed system	1.00E-02	mixer/loader/applicator [g]	0.02	70000	0.16	163000
		bagger [h]	0.89		8.90	3000
		cleaner [i]	N/A		1.02	26000

[a] Maximum label rate.
[b] Mixer/Loader/Applicator activities as described in the studies.
[c] Inhalation Unit Exposure values were derived from the most appropriate available study. Mixer/loader/applicators, baggers and cleaners were assessed using inhalation unit exposure values from the Wilson 2009 study 'Fluquinconazole and Prochloraz: Determination of operator exposure during cereal seed treatment with Jockey fungicide in Germany, United Kingdom and France'.
[d] Amount Treated per day based on PMRA HED Seed Treatment & Seed Planted Table 2010, agricultural practices, registrant recommendations and PMRA precedent.
[e] Where inhalation exposure µg/kg/day = (unit exposure × amount treated × rate)/70 kg bw.
[f] Based on an inhalation NOAEC of 26.1 mg/kg bw/day and a target inhalation MOE of 300.
[g] Inhalation unit exposure values were derived from the PMRA review of the study of a closed mixing and loading operator exposure study using wheat. Mixer/Loader/Applicators: closed mixing, a single layer + nitrile gloves.
[h] Inhalation unit exposure values were derived from the PMRA review of the study of a closed mixing and loading operator exposure study using wheat. Baggers: a single layer with or without nitrile gloves.
[i] Inhalation unit exposure values were derived from the PMRA review of the study of a closed mixing and loading operator exposure study using wheat. Cleaner: a single layer, Tyvek coveralls and nitrile gloves. Daily inhalation unit exposure values were normalized by application rate to provide an estimate of daily exposure.

Table 9 Potato Seed Piece Treatment Risk Assessment

Application Equipment	Application Rates [a] (kg a.i./kg seed)	Activity [b]	Inhalation Unit Exposure [c] (µg/kg a.i.)	Amount treated per day [d] (kg)	Inhalation Exposure [e] (µg /kg bw/day)	Inhalation MOE [f]
Open system	1.35E-04	treaters [g]	11.50	90000	2.00	13000
		cutters & sorters [h]	18.00		3.12	8000

[a] Maximum label rate.
[b] Mixer/Loader/Applicator activities as described in the studies.
[c] Inhalation Unit Exposure values were derived from the most appropriate available study. Treaters, cutters and sorters were assessed using inhalation unit exposure values from the study 'ADMIRE 240F – Determination of Dermal and Inhalation Exposure of Workers during On-Farm Seed Piece Treatment of Potatoes'.
[d] Amount Treated per day based on PMRA HED Seed Treatment & Seed Planted Table 2010, agricultural practices, registrant recommendations and PMRA precedent.
[e] Where inhalation exposure µg/kg/day = (unit exposure × amount treated × rate)/70 kg bw.
[f] Based on an inhalation NOAEC of 26.1 mg/kg bw/day and a target inhalation MOE of 300.
[g] Inhalation unit exposure values were derived from the PMRA review of the open system potato seed piece treatment study. Treaters: open mixing, a single layer + chemical-resistant gloves. Some workers wore dust masks.
[h] Inhalation unit exposure values were derived from the PMRA review of the open system potato seed piece treatment study. Cutters and sorters: a single layer. Some workers wore dust masks.

Table 10 Post-application Risk Assessment – Greenhouse Ornamentals

Application Rates [a] (kg a.i./ha)	Activities	Transfer Coefficient (cm^2/hr)	DFR On Day 0 of final application	Dermal Exposure [b] (µg /kg bw/day)	Dermal MOE [c]
0.15	irrigation	1750	0.75	3.00	333
	all other activities	230	0.75	0.20	2536

[a] Maximum label rate assuming 1000L/ha; 15g a.i./100 L = 0.15 kg a.i./ha. Two applications 14 days apart were assumed.
[b] Where dermal exposure (µg/kg/day) = DFR × TC × 8 hr / 70 kg. A 2% dermal absorption factor was applied.
[c] Based on a long-term dermal NOAEL of 1.0 mg/kg bw/day and a target dermal MOE of 100.

Table 11 Planter Risk Assessment [a] – Oilseeds

Equipment	Application Rate [b] (kg a.i./kg seed)	Inhalation Unit Exposure [c]	Amount treated per day [d] (kg)	Inhalation Exposure [e] (µg/kg bw/day)	Inhalation MOE [f]
Closed cab planter	1.00E-02	82.83	600	7.10	3700

[a] Post-Application activities as described in the studies. Planter: closed cab, a single layer.
[b] Maximum label rate.
[c] Inhalation Unit Exposure values were derived from the most appropriate available study. No appropriate data was available for assessing closed cab potato seed piece planting. Instead, as part of a weight of evidence approach, exposure to planters was assessed using inhalation unit exposure values from the study 'Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy'.
[d] Amount Treated per day based on PMRA HED Seed Treatment & Seed Planted Table 2010, agricultural practices, registrant recommendations and PMRA precedent.
[e] Where inhalation exposure µg/kg/day = (unit exposure × amount treated × rate)/70 kg bw.
[f] Based on an inhalation NOAEC of 26.1 mg/kg bw/day and a target inhalation MOE of 300.

Table 12 Planter Risk Assessment [a] – Potato seed pieces

Equipment	Application Rates [a] (kg a.i./kg seed)	Inhalation Unit Exposure [c] (µg/kg a.i.)	Amount treated per day [d] (kg)	Inhalation Exposure [e] (µg/kg bw/day)	Inhalation MOE [f]
Closed cab planter	1.35E-04	82.83	30000	4.79	5000

[a] Post-Application activities as described in the studies. Planter: closed cab, a single layer.
[b] Maximum label rate.
[c] No appropriate data was available for assessing closed cab potato seed piece planting. Instead, as part of a weight of evidence approach, planters were assessed using inhalation unit exposure values from the study 'Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy'.
[d] Amount Treated per day based on PMRA HED Seed Treatment & Seed Planted Table 2010 (on-farm for potato seed piece planting), agricultural practices, registrant recommendations and PMRA precedent.
[e] Where inhalation exposure µg/kg/day = (unit exposure × amount treated × rate)/70 kg bw.
[f] Based on an inhalation NOAEC of 26.1 mg/kg bw/day and a target inhalation MOE of 300.

Table 13 Fate and behaviour in the terrestrial environment

Property	**Test substance**	**Value**	**Comments**	**Major TPs formed (maximum percent formed) Note: major is defined as ≥10%**	**Reference (PMRA #)**
Abiotic transformation					
Hydrolysis pH 4, pH 7, and pH 9 for 30 days	Cyantraniliprole	<u>DT_{50} values (25ºC)(SFO)</u> pH 4: 212 days (stable) pH 7: 30.3 days (stable) pH 9: 0.85 days <u>DT_{50} values (15ºC)(SFO)</u> pH 4: 362 days (stable) pH 7: 126 days (stable) pH 9: 3.10 days <u>DT_{50} values (35ºC)(SFO)</u> pH 4: 55.2 days (stable) pH 7: 7.5 days pH 9: 0.576 days <u>DT_{50} values (extrapolated to 20 ºC)</u> pH 4: 260 days (stable) pH 7: 60.7 days (stable) pH 9: 1.8 days	Stable at pH 4 and pH 7 Not persistent at pH 9.	IN-J9Z38 (pH 7 at 35°C), maximum concentration of 88.59% AR at study end	2070289
Phototransformation on dry soil (corrected for dark control)	Cyantraniliprole	DT_{50} : 142 days (20°C) DT_{90} : 471 days (20°C)	Based on irradiated continuous lighting	No major TPs	2070584

Property	Test substance	Value	Comments	Major TPs formed (maximum percent formed) Note: major is defined as ≥10%	Reference (PMRA #)
Phototransformation on moist soil (corrected for dark control)	Cyantraniliprole	DT_{50} : 12.2 days (20°C) DT_{90} : 40.5 days (20°C)	Based on irradiated continuous lighting	IN-J9Z38 (max 48.69% AR at Day 10) IN-RNU71 (max of 13.14% AR by study end) IN-QKV54 (max of 13.99% AR at Day 10)	2070582
Phototransformation in air	No data required		Not volatile under field conditions		
Biotransformation [a]					
Biotransformation in aerobic soil (22 ± 3°C in the dark for 358 days; loam and silty clay loam)	Cyantraniliprole	PMRA DT_{50} (model): Nambsheim (loam): 9.2 days (IORE) Tama (silty clay loam): 37.9 days (DFOP)	Non-persistent to slightly persistent	IN-J9Z38 (16% day 16) IN-JCZ38 (16% day 7) IN-JSE76 (43% day 358) IN-K5A78 (29% day 358) IN-PLT97 (26% day 358)	2070577
Biotransformation in aerobic soil (20°C and one soil at 10°C for 120 days; silt loam, sandy loam, silty clay loam)	Cyantraniliprole	PMRA DT_{50} (model) Gross-Umstadt (silt loam) 20ºC: 43.2 days (DFOP) Gross-Umstadt (silt loam) 10ºC: 135 days (DFOP) Sassafras (sandy loam): 89.4 days (DFOP) Lleida (silty clay loam): 16.2 days (IORE)	Slightly to moderately persistent	IN-J9Z38 (18% day 60) IN-JSE76: 33.28 (day 120) IN-JCZ38: 39.60 (day 120) IN-K5A78: 10.53 (day 120)	2070585
Additional information [b]		80th percentile of linear DT_{50} values for cyantraniliprole (using 19.1, 142, 81.6, 158 (divided by 2 and averaged with other Gross Umstadt soil), 127, and 48.5 days = 130 days			
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; silt loam, 2 × sandy loams, and 2 × silty clay loam)	IN-J9Z38 Major aerobic soil and phototransformation on moist soil transformation product	PMRA DT_{50} (days)(model) Gross-Umstadt (silt loam): 118 days (IORE) Nambsheim (sandy loam): 82 days (IORE) Sassafras (sandy loam): 205 days (DFOP) Lleida (silty clay loam): 104 days (SFO) Tama (silty clay loam): 179 days (SFO) 80th percentile (303, 48.4, 347, 104 and 179 days = 311.8 days used for soil EEC calculation.	Moderately persistent to persistent	IN-K5A77 (32.39% AR at Day 120) IN-K5A78 (36.71% AR at Day 120)	2070586
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; silt loam, sandy loam, loam, and 2 × silty clay loam)	IN-JCZ38 Major aerobic soil transformation product	PMRA DT_{50} (days)(model) Tama (silty clay loam): 8.7 days (IORE) Sassafras (loam): 10.1 days (IORE) Lleida (silty clay loam): 4.8 days (IORE) Nambsheim (sandy loam): 3.48 days (IORE) Gross-Umstadt (silt loam): 11.5 days (IORE) 80th percentile (30.3, 24.7, 9.4, 6.05, and 19.5 days = 25.82 days) used for soil EEC calculation.	Non-persistent	IN-K5A79 (25% day 120) IN-JSE76 (69% day 60) IN-PLT97 (40.47% day 120) IN-K5A78 (15.41% day 120)	2070591

Property	**Test substance**	**Value**	**Comments**	**Major TPs formed (maximum percent formed) Note: major is defined as ≥10%**	**Reference (PMRA #)**
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; silt loam, sandy loam, loam, and 2 × silty clay loam)	IN-JSE76 Major aerobic soil transformation product	PMRA DT_{50} (days)(model) Gross-Umstadt (silt loam): 358 days (IORE) Nambsheim (sandy loam): 80.1 days (DFOP) Sassafras (loam): 342 days (DFOP) Lleida (silty clay loam): 157 days (SFO) Tama (silty clay loam): 844 days (DFOP) 80th percentile (6010, 97.3, 419, 157, 1320 days = approx 2258 days) used for soil EEC calculation.	Moderately persistent to persistent	IN-PLT97 (19.8% day 120) IN-K5A78 (18.68% day 90)	2070587
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; silt loam, 2 × sandy loams, and 2 × silty clay loam)	IN-K5A78 Major aerobic soil transformation product	PMRA DT_{50} (days)(model) Tama (silty clay loam): 233 days (SFO) Sassafras (loam): 89.5 days (IORE) Lleida (silty clay loam): 483 days (SFO) Nambsheim (sandy loam): 958 days (SFO) Gross-Umstadt (silt loam): 308 days (SFO) 80th percentile (233, 488, 483, 958, and 308 days = 582 days) used for soil EEC calculation.	Moderately persistent to persistent	IN-K5A77 (37.21% AR at Day 120)	207089
Biotransformation in aerobic soil (20 ± 2°C for up to 121 days; silty clay, sandy loam, 2 × loam, and silty clay loam)	IN-PLT97 Major aerobic soil transformation product	PMRA DT_{50} (days)(model) Gross-Umstadt (loam): 1627 days (SFO) Lleida (silty clay): 439 days (SFO) Nambsheim (sandy loam): 710 days (SFO) Sassafras (loam): 1830 days (SFO) Tama (silty clay loam): 429 days (SFO) 80th percentile (1627, 439, 710, 1830 and 429 days = 1667.9 days) used for soil EEC calculation.	Persistent	No major TPs	2070596
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; loam, sandy loam, loamy sand, clay, and silty clay loam)	IN-QKV54 Minor transformation product in soil and a major from phototransformation on soil	PMRA DT_{50} (days)(model) Gross-Umstadt (loam): 2142 days (DFOP) Nambsheim (sandy loam): 146 days (DFOP) Sassafras (loamy sand): 455 days (IORE) Lleida (clay): 61.8 days (IORE) Tama (silty clay loam): 206 days (DFOP) 80th percentile (4540, 227, 2820000, 403 and 339 days = 267632 days) used for soil EEC calculation.	Persistent	No major TPs	2070592

Property	Test substance	Value	Comments	Major TPs formed (maximum percent formed) Note: major is defined as ≥10%	Reference (PMRA #)
Biotransformation in aerobic soil (20 ± 2°C for up to 120 days; loam, sandy loam, loamy sand, clay, and silty clay loam)	IN-RNU71 Minor transformation product in soil and a major from phototransformation on soil	PMRA DT_{50} (days)(model) Gross-Umstadt (loam): 104 days (DFOP) Nambsheim (sandy loam): 36.5 days (IORE) Sassafras (loamy sand): 401 days (DFOP) Lleida (clay): 38.6 days (IORE) Tama (silty clay loam): 27.8 days (DFOP) 80th percentile (126, 53.1, 888, 51.7, and 119 days = 278.4 days) used for soil EEC calculation.	Slightly persistent to persistent	A: (32% AR at Day 120) B: (35% AR at Day 120) C: <10% Note: Metabolites A, B and C were not identified further within this study. However it should be noted that IN-RNU71 reached a mean maximum level of 13.14% during the moist soil photolysis study. Individual components, they would not be expected to reach levels greater than 5% of applied parent	2070588
Anaerobic (flooded soil) Aerobic conditions in the dark for 10 days at 20°C and then under anaerobic conditions in the dark for 120 days at 20°C following flooding of the test systems with deaerated water	Cyantraniliprole	PMRA DT_{50} (days)(model) Using anaerobic as time 0 5.65 days (DFOP) for PC label 4.36 days (IORE) for CN label Using aerobic and anaerobic (aerobic as time 0) 8.3 days (SFO)	Non-persistent	IN-J9Z38 (71.9% AR at Day 120) IN-K5A78 (16.2% AR at Day 120) IN-K5A77 (9.9% AR at Day 120)	2070580
Flooded aerobic soil Viable and sterile incubations were maintained for up to 180 days under aerobic conditions in the dark at 25°C.	Cyantraniliprole	PMRA DT_{50} (days)(model) Flooded soil 19 days (DFOP) Sterile flooded soil 63.4 days (DFOP)	Slightly to moderately persistent	IN-J9Z38 (41% AR at Day 180)	2070627

<table>
<tr><th>Property</th><th>Test substance</th><th>Value</th><th>Comments</th><th>Major TPs formed (maximum percent formed)
Note: major is defined as ≥10%</th><th>Reference (PMRA #)</th></tr>
<tr><td colspan="4">Mobility[c]</td><td></td><td></td></tr>
<tr><td rowspan="4">Adsorption / desorption in soil</td><td>Cyantraniliprole</td><td>
<table>
<tr><th colspan="5">PMRA adsorption and desorption coefficients for cyantraniliprole</th></tr>
<tr><th>Soil</th><th>Kd</th><th>Kdoc</th><th>Kdes</th><th>Kdesoc</th></tr>
<tr><td>Tama</td><td>5.66</td><td>297.9</td><td>3.849</td><td>202.58</td></tr>
<tr><td>Sassafras</td><td>2.88</td><td>205.5</td><td>2.158</td><td>154.11</td></tr>
<tr><td>Lleida</td><td>2.49</td><td>155.9</td><td>1.713</td><td>107.07</td></tr>
<tr><td>Nambsheim</td><td>2.13</td><td>133.3</td><td>1.603</td><td>100.19</td></tr>
<tr><td>Gross-Umstadt</td><td>2.44</td><td>221.8</td><td>1.906</td><td>173.23</td></tr>
<tr><td>Arithmetic mean</td><td>3.12</td><td>202.9</td><td>2.246</td><td>147.44</td></tr>
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</td><td>Moderate to high mobility</td><td></td><td>2070615</td></tr>
<tr><td>IN-J9Z38</td><td>
<table>
<tr><th colspan="5">PMRA adsorption and desorption coefficients for IN-J9Z38</th></tr>
<tr><th>Soil</th><th>Kd</th><th>Kdoc</th><th>Kdes</th><th>Kdesoc</th></tr>
<tr><td>Tama</td><td>349.4</td><td>18390</td><td>60.00</td><td>3158</td></tr>
<tr><td>Sassafras</td><td>91.86</td><td>6562</td><td>42.82</td><td>3058</td></tr>
<tr><td>Lleida</td><td>80.20</td><td>5013</td><td>35.85</td><td>2241</td></tr>
<tr><td>Nambsheim</td><td>64.13</td><td>4008</td><td>36.51</td><td>2282</td></tr>
<tr><td>Gross-Umstadt</td><td>80.09</td><td>7281</td><td>40.16</td><td>3651</td></tr>
<tr><td>Arithmetic mean</td><td>121.30</td><td>8251</td><td>43.07</td><td>2878</td></tr>
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</td><td>Slightly mobile to immobile</td><td></td><td>2070619</td></tr>
<tr><td>IN-JCZ38</td><td>
<table>
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<tr><th>Soil</th><th>Kd</th><th>Kdoc</th><th>Kdes</th><th>Kdesoc</th></tr>
<tr><td>Tama</td><td>7.14</td><td>375.65</td><td>4.53</td><td>238.59</td></tr>
<tr><td>Sassafras</td><td>2.38</td><td>169.94</td><td>1.71</td><td>122.03</td></tr>
<tr><td>Lleida</td><td>2.10</td><td>131.54</td><td>1.45</td><td>90.70</td></tr>
<tr><td>Nambsheim</td><td>1.56</td><td>97.51</td><td>1.14</td><td>71.14</td></tr>
<tr><td>Gross-Umstadt</td><td>1.85</td><td>168.02</td><td>1.36</td><td>123.21</td></tr>
<tr><td>Arithmetic mean</td><td>3.01</td><td>188.53</td><td>2.04</td><td>129.13</td></tr>
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</td><td>High to moderate mobility</td><td></td><td>2070617</td></tr>
<tr><td>IN-JSE76</td><td>
<table>
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<tr><th>Soil</th><th>Kd</th><th>Kdoc</th><th>Kdes</th><th>Kdesoc</th></tr>
<tr><td>Tama</td><td>1.05</td><td>55.30</td><td>0.75</td><td>39.53</td></tr>
<tr><td>Sassafras</td><td>0.39</td><td>27.52</td><td>0.23</td><td>16.71</td></tr>
<tr><td>Lleida</td><td>0.25</td><td>15.78</td><td>0.12</td><td>7.65</td></tr>
<tr><td>Nambsheim</td><td>0.21</td><td>13.02</td><td>0.11</td><td>6.61</td></tr>
<tr><td>Gross-Umstadt</td><td>0.27</td><td>24.26</td><td>0.15</td><td>13.61</td></tr>
<tr><td>Arithmetic mean</td><td>0.43</td><td>27.18</td><td>0.27</td><td>16.82</td></tr>
</table>
</td><td>High to very high mobility</td><td></td><td>2070622</td></tr>
</table>

Property	Test substance	Value					Comments	Major TPs formed (maximum percent formed) Note: major is defined as ≥10%	Reference (PMRA #)
	IN-K5A77 Minor TP, but in the pathway of degradation	PMRA adsorption and desorption coefficients for IN-K5A77					Slight mobile to immobile		2070616
		Soil	Kd	Kdoc	Kdes	Kdesoc			
		Tama	431.92	22733	99.52	5238			
		Sassafras	76.31	5451	40.47	2891			
		Lleida	78.01	4876	41.36	2585			
		Nambsheim	50.23	3140	31.18	1949			
		Gross-Umstadt	63.22	5747	34.55	3141			
		Arithmetic mean	139.94	8389	49.42	3161			
	IN-K5A78	PMRA adsorption and desorption coefficients for IN-K5A78					Moderate to low mobility		2070616
		Soil	Kd	Kdoc	Kdes	Kdesoc			
		Tama	30.41	1600.40	13.67	719.28			
		Sassafras	8.83	630.37	5.83	416.34			
		Lleida	5.86	366.09	3.21	200.42			
		Nambsheim	4.77	298.20	3.02	188.68			
		Gross-Umstadt	6.92	629.10	3.79	344.47			
		Arithmetic mean	11.36	704.83	5.90	373.84			
	IN-K5A79 Minor TP, but in the pathway of degradation	PMRA adsorption and desorption coefficients for IN-K5A79					Very highly mobile		2070624
		Soil	Kd	Kdoc	Kdes	Kdesoc			
		Tama	1.19	44.24	0.76	27.99			
		Sassafras	0.85	70.60	0.62	51.80			
		Lleida	0.42	21.22	0.20	9.82			
		Nambsheim	0.35	21.57	0.22	13.93			
		Gross-Umstadt	0.43	38.74	0.24	22.19			
		Arithmetic mean	0.65	39.28	0.41	25.15			
	IN-PLT97	PMRA adsorption and desorption coefficients for IN-PLT97					Moderate to slight mobility		2070618
		Soil	Kd	Kdoc	Kdes	Kdesoc			
		Tama	64.98	3419.90	16.05	844.60			
		Sassafras	16.50	1178.71	10.52	751.19			
		Lleida	10.16	635.08	6.52	407.71			
		Nambsheim	7.63	477.18	5.53	345.74			
		Gross-Umstadt	12.90	1172.84	7.48	679.64			
		Arithmetic mean	22.24	1376.74	9.22	605.78			
	IN-QKV54	PMRA adsorption and desorption coefficients for IN-QKV54					Immobile		2070623
		Soil	Kd	Kdoc	Kdes	Kdesoc			
		Tama	1009.3	30584	65.3	1979			
		Sassafras	62.3	7789	28.4	3548			
		Lleida	174.3	24907	44.1	6299			
		Nambsheim	170.1	8507	49.7	2484			
		Gross-Umstadt	139.4	9956	44.6	3185			
		Arithmetic mean	311.1	16348	46.4	3499			

<table>
<tr><th>Property</th><th>Test substance</th><th>Value</th><th>Comments</th><th>Major TPs formed (maximum percent formed)
Note: major is defined as ≥10%</th><th>Reference (PMRA #)</th></tr>
<tr><td></td><td>IN-RNU71</td><td><table>
<tr><th colspan="5">PMRA adsorption and desorption coefficients for IN-RNU71</th></tr>
<tr><td>Soil</td><td>Kd</td><td>Kdoc</td><td>Kdes</td><td>Kdesoc</td></tr>
<tr><td>Tama</td><td>4.98</td><td>150.85</td><td>2.72</td><td>82.47</td></tr>
<tr><td>Sassafras</td><td>1.54</td><td>191.92</td><td>0.71</td><td>88.62</td></tr>
<tr><td>Lleida</td><td>1.78</td><td>254.42</td><td>0.82</td><td>116.94</td></tr>
<tr><td>Nambsheim</td><td>2.25</td><td>112.65</td><td>1.15</td><td>57.68</td></tr>
<tr><td>Gross-Umstadt</td><td>2.06</td><td>146.88</td><td>1.06</td><td>75.78</td></tr>
<tr><td>Arithmetic mean</td><td>2.52</td><td>171.34</td><td>1.29</td><td>84.30</td></tr>
</table></td><td>High to moderate mobility</td><td></td><td>2070621</td></tr>
<tr><td>Bioconcentration</td><td colspan="3">The steady-state and kinetic BCF values for cyantraniliprole were less than 1 at both test concentrations (9.41 and 93.8 µg/L) in the fillet, carcass, and whole fish.</td><td></td><td>2070666</td></tr>
<tr><td colspan="6">Field studies</td></tr>
<tr><td>Field dissipation</td><td colspan="2"><u>DT_{50} values (days)</u>
Grant County, Washington, USA: 8.87 days
Manitoba, Canada: 13 days
North Rose, New York, USA: 21.6 days</td><td>N/A</td><td></td><td>2070601
2070605
2070604</td></tr>
</table>

a For aerobic soil studies, the persistence classification is based on criteria from Goring et al. 1975; and for the aquatic studies (including flooded soil), the persistence classification is based on criteria from McEwan and Stephenson 1979.

b 80th percentile for aerobic soil biotransformation used in EEC calculations and water modelling.

c. Mobility classification is based on McCall et al 1981.

Table 14 Fate and behaviour in the aquatic environment

Property	Test material	Value	Comments	Major TPs formed	References (PMRA #)
Abiotic transformation					
Hydrolysis pH 4, pH 7, and pH 9 for 30 days	Cyantraniliprole	DT_{50} values (25ºC)(SFO) pH 4: 212 days (stable) pH 7: 30.3 days (stable) pH 9: 0.85 days DT_{50} values (15ºC)(SFO) pH 4: 362 days (stable) pH 7: 126 days (stable) pH 9: 3.10 days DT_{50} values (35ºC)(SFO) pH 4: 55.2 days (stable) pH 7: 7.5 days pH 9: 0.576 days DT_{50} values (extrapolated to 20ºC) pH 4: 260 days (stable) pH 7: 60.7 days (stable) pH 9: 1.8 days	Stable at pH 4 and pH 7 Not persistent at pH 9.	IN-J9Z38 (pH 7 at 35°C), maximum concentration of 88.59% AR at study end	2070289
Phototransformation in water 15 days (corrected for dark control)	Cyantraniliprole	Buffer DT_{50} : 0.17 days	Based on irradiated continuous lighting	IN-NXX69 (max of 100% AR at Day 2)	2070291
		Natural water DT_{50}: 0.22 days	The quantum yield for the test substance (φ) was estimated by comparison with an actinometer with known quantum yield; this results in a quantam yield of ‘$\Phi = 1.195\times10^{-4}$ molecules degraded/photon’; this value can subsequently be used to calculate the light intensity equivalence at any latitude.	IN-NXX70 (max of 53.13% AR at 8 hours). IN-QKV54 (max of 84.71% AR at Day 5)	

Property	Test material	Value	Comments	Major TPs formed	References (PMRA #)
Biotransformation[a]					
Biotransformation in aerobic water/sediment systems 100 days under aerobic conditions in the dark at 20 ± 2°C with two aquatic sediment systems	Cyantraniliprole	PMRA DT_{50} (Days)(model) Sand: 25 days (SFO) Silt: 3.86 days (SFO)	Non-persistent to slightly persistent	IN-J9Z38 (89% day 28)	2070628
Biotransformation in anaerobic water/sediment systems 353 days under anaerobic conditions in the dark at 20 ± 2°C	Cyantraniliprole	PMRA DT_{50} (Days)(model) Whole system: 2.1days (IORE)	Non-persistent	IN-J9Z38 (77% day 28) IN-K5A78 (10% day 353)	2070631
Biotransformation in anaerobic water/sediment systems 100 days under anaerobic conditions in the dark at 20 ± 2°C	Cyantraniliprole	PMRA DT_{50} (Days)(model) Whole system: 9.94 days (IORE)	Non-persistent	IN-J9Z38 (82% day 75)	2070630
Higher tier aerobic water/sediment study 14 days under natural sunlight at 23 ± 2°C (outdoor)	Cyantraniliprole	Silt loam DT_{50}: 3.5 days; DT_{90}: 11.6 days Sandy soil DT_{50}: 4.4 days; DT_{90}: 14.8 days	Non-persistent	IN-J9Z38 (55% day 10) IN-RNU71 (15% day 14)	2070633

a For the aquatic studies the persistence classification is based on criteria from McEwan and Stephenson 1979.

Table 15 EEC calculation for parent and transformation products in soil from various end-use products (and application types).

Chemical*	Cyantraniliprole	Cyantraniliprole	Thiamethoxam +	IN-J9Z38	IN-JCZ38	IN-JSE76	IN-K5A78	IN-PLT97	IN-QKV54	IN-RNU71	IN-K5A77	IN-K5A79
EEC for Exirel, Benevia and Mainspring insecticides* (mg a.i./kg soil)*	0.195	0.067 0.073	0.067 0.073	0.19	0.18	0.24	0.198	0.194	0.145	0.18	0.20	0.20
EEC for Verimark (mg a.i./kg soil)*	0.13	0.067		0.13	0.14	0.14	0.13	0.13	0.097	0.12		

*The application rate for the transformation products were calculated using: 150 g a.i./ha × (molecular weight of parent/molecular weight of TP) × 3 (using the relevant 80th percentile half-lives) for Benevia and Exirel. For Verimark the application is 1 × 300 g a.i./ha. Mainspring the application rate is 1 × 150 g a.i./ha.
Note: 80th percentile of aerobic soils was used for EEC calculation, as reported in Table 5.1.
+ fate information for thiamethoxam are from ERC2007-01 (PMRA # 143701)
Note: minimum number of days between applications on the label is 5 days.

Table 16 EEC calculation for parent and transformation products in water from various end-use products (and application types).

Chemical*	Cyantraniliprole	Cyantraniliprole	Thiamethoxam+	IN-J9Z38	IN-JCZ38	IN-JSE76	IN-PLT97	IN-QKV54	IN-RNU71	IN-NXX70	IN-K5A78
EEC (15 cm)(mg/L) for Exirel, Benevia and Mainspring insecticides*	0.29	0.1 0.11	0.1 0.11	0.28	0.31	0.31	0.29	0.22	0.28	0.095	0.30
EEC (80 cm)(mg/L) for Exirel, Benevia and Mainspring insecticides*	0.055	0.019 0.021	0.019 0.021	0.053	0.058	0.058	0.055	0.04	0.052	0.018	0.056
EEC (15 cm)(mg/L) for Verimark insecticide*	0.2	0.1		0.19	0.21	0.207	0.19	0.15	0.18	0.18	0.20
EEC (80 cm)(mg/L)	0.034	0.019		0.04	0.04	0.04	0.036	0.027	0.035	0.035	0.04

*The application rate for the transformation products were calculated using: 150 g a.i./ha × (molecular weight of parent/molecular weight of TP) × 3 (using the relevant 80th percentile half-lives) for Benevia and Exirel. For Verimark the application is 1 × 300 g a.i./ha. Mainspring the application rate is 1 × 150 g a.i./ha.
+ fate information for thiamethoxam are from Evaluation Report ERC2007-01, *Thiamethoxam*
Note: All major soil transformation products and major aquatic products were considered relevant for aquatic exposure since soil TP are available for runoff and aquatic TP are available in the aquatic environment. The half-life would be zero and it is assumed that the TP was formed and immediately entered the water body.
Note: minimum number of days between applications on the label is 5 days.

Table 17 Refined Tier I aquatic EECs for Cyantraniliprole based on spray drift input only, assuming a 1 m distance between sprayer and aquatic habitat, resulting from 3 × 150 g a.i./ha application rate.

Sprayer Type	% Drift at 1 m (based on ASAE Medium spray quality)	EEC (mg a.i./L)	
		Non-permanent/ shallow water bodies (15 cm deep)	Permanent water bodies (80 cm deep)
Field and airblast sprayers	0	0.29	0.055
Field sprayer (fine) (ground boom)	11	0.032	0.0061
Airblast sprayer (late season)	59	0.17	0.032
Airblast sprayer (early season)	74	0.22	0.041
Aerial application (fine spray)	26	0.075	0.014

Table 18 Major groundwater and surface water model inputs for Level 1 and 2 assessment of cyantraniliprole

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Tuberous corm vegetables, leafy, brassica, fruiting and cucurbit vegetables, canola, rapeseed, mustard, potatoes, bushberries, bulb vegetables, orchard crops including pomme and stone fruits and greenhouse vegetables
	Maximum allowable application rate per year (g a.i./ha)	450 (foliar), 300 (soil)
	Maximum rate each application (g a.i./ha)	150 (foliar), 300 (foliar)
	Maximum number of applications per year	3, 1
	Minimum interval between applications (days)	5
	Method of application	Aerial, ground
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	30.3 for parent for Level 1 modelling only 611 for the combined residues Level 1 modelling only
	Photolysis half-life in water (days)	0.44 for Level 1 modelling
	Adsorption K_{OC} (mL/g)	151.4 for parent (20th percentile of 5 K_{OC} values for "cyantraniliprole") for eco and Level 1 surface water modelling 15.23 (20th percentile of 5 K_{OC} values for "IN-JSE76")for Level 1combined residues groundwater modelling 151.4 for parent (20th percentile of 5 K_{OC} values for "cyantraniliprole") for Level 2 groundwater modelling 124.74 for IN-JCZ38 (20th percentile of 5 K_{OC} values for "IN-JCZ38") for Level 2 groundwater modelling 4811.7 for IN-J9Z38 (20th percentile of 5 K_{OC} values for "IN-J9Z38") for Level 2 groundwater modelling
	Aerobic soil biotransformation half-life (days)	130 for parent (80th percentile of 5 half-life values) for Level 1 modelling 4071 for the combined residues (80th percentile of 5 half-life values) for Level 1 modelling 130 for parent (80th percentile of 5 half-life values) for Level 2 modelling 25.8 for IN-JCZ38 (80th percentile of 5 half-life values) for Level 2 modelling 312 for IN-J9Z38 (80th percentile of 5 half-life values) for Level 2 modelling
	Aerobic aquatic biotransformation half-life (days)	90 for parent (80th percentile of 3 half-life values) for Level 1 modelling 574 for the combined residues (80th percentile of 3 half-life values) for Level 1 modelling
	Anaerobic aquatic biotransformation half-life (days)	11.01 for parent (80th percentile of 3 half-life values) for Level 1 modelling 3240 for the combined residues (80th percentile of 3 half-life values) for Level 1 modelling

Table 19 Level 1 aquatic ecoscenario modelling water column EECs (µg a.i./L) for cyantraniliprole in a water body 80 cm deep, excluding spray drift (note: only the highest EECs are reported).

Region	EEC (µg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Use 1, 3 × 0.15 kg a.i./ha, at 5-day intervals						
Atlantic	17	15	9.4	5.1	3.9	1.0
Use 2, 1 × 0.3 kg a.i./ha						
Atlantic	14	13	7.8	3.7	2.5	0.63

1 90[th] percentile of daily average concentrations
2 90[th] percentile of yearly average concentrations
3 90[th] percentile of yearly peak concentrations
4 90[th] percentile of yearly average concentrations

Table 20 Level 1 aquatic ecoscenario modelling pore water EECs (µg a.i./L) for cyantraniliprole in a water body 80 cm deep, excluding spray drift (note: only the highest EECs are reported).

Region	EEC (µg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Use 1, 3 × 0.15 kg a.i./ha, at 5-day intervals						
Atlantic	4.1	4.1	3.9	2.9	2.3	0.64
Use 2, 1 × 0.3 kg a.i./ha						
Atlantic	2.9	2.9	2.8	1.9	1.4	0.35

1 90[th] percentile of daily average concentrations
2 90[th] percentile of yearly average concentrations
3 90[th] percentile of yearly peak concentrations
4 90[th] percentile of yearly average concentrations

Table 21 Exposure for predators and parasites and terrestrial plants (in terms of application rate, g a.i./ha) for both foliar and soil application methods.

End-use product	In-field+	Off-field (11%)*	Off-field (59%)**	Off-field (74%)***	Off-field (26%)****
Foliar Surfaces					
Benevia 100 g/L OD Insecticide Foliar application at 3 × 150 g a.i./ha – oilseed group, 5 day interval	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	28.9	Not applicable	Not applicable	68
Exirel 100 g/L SE Insecticide Foliar application at 3 × 150 g a.i./ha, including orchard, 5 day interval	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	Not applicable	155	194	68
Mainspring (20% cyantraniliprole and 20% thiamethoxam) Foliar outdoor 1 × 150 g a.i./ha	150 g a.i./ha	16.5 g a.i./ha	Not applicable	Not applicable	Not applicable
Soil Surfaces					
Soil applied end-use products					
Verimark 200 g/L SC Insecticide In furrow, 1 × 300 g a.i./ha (therefore relevant soil exposure)	300 g a.i./ha	Not applicable	Not applicable	Not applicable	Not applicable

Foliar applied end-use products++					
Benevia 100 g/L OD Insecticide Foliar application at 3 × 150 g a.i./ha – oilseed group, 5 day interval	In-field 3 × 150 g a.i./ha using 130 day half life = 438.3 g a.i./ha	48.2 g a.i./ha	Not applicable	Not applicable	114
Exirel 100 g/L SE Insecticide Foliar application at 3 × 150 g a.i./ha, including orchard, 5 day interval	In-field 3 × 150 g a.i./ha using 130 day half life = 438.3 g a.i./ha	Not applicable	259	324	114
Mainspring (20% cyantraniliprole and 20% thiamethoxam) Foliar outdoor 1 × 150 g a.i./ha	150 g a.i./ha	16.5 g a.i./ha	Not applicable	Not applicable	Not applicable
Off-field EECs based on application with a field sprayer with an ASAE fine spray quality for aerial application (26%)**** for both labels, orchard spray with early season airblast with a ASAE fine (74%***), late season airblast with an ASAE fine (59%**) and fine sprayer on field crops with a ASAE fine (11%*). + Soil EEC used 130 days (80th percentile of aerobic soil study); Foliar dissipation phase half-life consideration: A dissipation phase half-life of 5 days was used as it was most conservative. ++ assumption of wash off from treated foliage.					

Table 22 Estimated food consumption rates for various castes of bees, as used in the risk assesment.

Life Stage	Caste (task in hive)	Average age (days)	Daily consumption rate (mg/bee/day)		
			Brood food / royal jelly	Nectar	Pollen
	Worker (brood and queen tending, nurse bees)	6–17	none	**140**	**8.85**
	Worker (foraging for pollen)	>18	none	43.5	0.041
	Worker (foraging for nectar)	>18	none	**292**	**0.041**
Bolded values are used in the risk assessment. *Modifcation of content presented in the White Paper in Support of the Proposed Risk Assessment Process for Bees Submitted to the FIFRA Scientific Advisory Panel for Review and Comment 11–14 September 2012.					

Table 23 Residue data provided for refined Tier 1 screening in the risk assessment

Study Type	Crop Group	Crop	Proposed Application Method and rate	Study Application Rate (g a.i./ha)	Study Application timing	Sampling	Pollen residues (mg/kg)	Nectar residues (mg/kg)	IN-HGW87 pollen (mg/kg)	PMRA #
Field	CG 20	**Rapeseed** 100 OD	Foliar; 4 applications of 100 g a.i./ha; 7 day intervals	120	Trial 1: 14 days prior to flowering	17 DAT	0.739	0.018	0.011	2070733
						20 DAT	0.124	0.005	0.005	2070733
					Trial 2: during flowering	13 DAT	1.933	0.038	0.028	2070733
						19 DAT	0.453	0.009	0.005	2070733
		Canola (Sask.) 100 FS	Seed 79 g a.i./ha	79	prior to sowing	45 DAT	<LOQ	<LOQ	<LOQ	2070715
		Canola (Sask.) 100 FS				57 DAT	<LOQ	<LOQ	<LOQ	2070715
		Canola (Alta.) 100 FS				49 DAT	<LOQ	<LOQ	<LOQ	2070715
		Canola (Alta.) 100 FS				58 DAT	<LOQ	<LOQ	<LOQ	2070715
	CG 8	**Tomato** 100 OD	Foliar 150 g/ha; 4 apps; 1 day PHI; max seasonal 450 g/ha	90 2 apps. (A & B)	Trial 2: Shortly before flowering	1 DAB	0.103	<LOQ	<LOQ	2070724
						3 DAB	0.016	<LOQ	<LOQ	2070724
					Trial 2: flowering; 2 apps, 7 days apart	3 DAB	0.212	<LOQ	<LOQ	2070728
						7 DAB	0.016	<LOQ	<LOQ	2070728
	CG 9	**Melon** 100 OD	Foliar 150 g/ha; 4 apps; 1 day PHI; max seasonal 450 g/ha	90 2 apps. (A & B)	Trial 1: early growth	35 DAB	<LOQ	<LOQ	<LOQ	2070726
						38 DAB	0	0.005	<LOQ	2070726
					Trial 2: shortly before flowering	7 DAB	0.078	0.005	<LOQ	2070726
						10 DAB	0.005	<LOQ	<LOQ	2070726
				120 1 app.	Trial 1: pre-bloom	14 DAT	0.014	0.01	<LOQ	2070722
						18 DAT	0.005	0.005	<LOQ	2070722
					Trial 2: during bloom	14 DAT	0.031	0.03	<LOQ	2070722
						20 DAT	0.018	0.02	<LOQ	2070722
	CG 11	**Apple** 100 SE	Foliar 150 g/ha; 4 apps; 3 day PHI; max seasonal 450 g/ha	150 1 app.	preflowering	13 DAT	1.45	0.01	0.01	2070748
						16 DAT	0.75	0.005	0.01	2070748
						17 DAT	0.21	<LOQ	<LOQ	2070748
						21 DAT	0.08	<LOQ	<LOQ	2070748
						9 DAT	1.59	0.11	0.005	2070737
						11 DAT (10 DAT for nectar)	1.04	0.04	0.005	2070737

Study Type	Crop Group	Crop	Proposed Application Method and rate	Study Application Rate (g a.i./ha)	Study Application timing	Sampling	Pollen residues (mg/kg)	Nectar residues (mg/kg)	IN-HGW87 pollen (mg/kg)	PMRA #
						11 DAT	1.28	0.02	<LOQ	2070737
						14 DAT	0.39	0.04	0.01	2070737
	CG 12	**Nectarine** 100 SE	Foliar 150 g/ha; 4 apps; 3 day PHI; max seasonal 450 g/ha	100	12 days prior to flowering	12 DAT	2.915	0.077	<LOQ	2070721
						15 DAT	0.022	0.146	<LOQ	2070721
						7 DAT	2.445	0.047	0.012	2070731
						10 DAT	3.45	0.026	0.017	2070731
	no CG	**Grapes** 100 OD	Foliar	112.5	pre-flowering	20 DAT	0.77	0.01	<LOQ	2070741
						23 DAT	0.15	0.01	<LOQ	2070741
						20 DAT	0.49	0.11	<LOQ	2070743
						22 DAT		0.14	<LOQ	2070743
						24 DAT		0.05	<LOQ	2070743
						26 DAT	0.15	<LOQ	<LOQ	2070743
	N/A	**Citrus** 100 SE	foliar	2 × 150	16 days prior to flowering, 7 days apart,	21 DAT	1.21	0.041	0.005	2070732
			soil	1 × 150	Pre-flowering	14 DAT (pollen) 16 DAT (nectar)	2.51	**0.837**	0.005	2070736
		Olives 100 SE	foliar	2 × 50	during bloom	7 DAT	1.607	nc	0.012	2070725
						9 DAT	0.155	nc	<LOQ	2070725
						7 DAT	0.19	nc	<LOQ	2070727
						9 DAT	0.107	nc	<LOQ	2070727
	CG 1	**Potatoes** 100 OD	Foliar 150 g a.i./ha; 4 apps, 7 day PHI, max. seasonal 450 g a.i./ha	2 × 12.5	early growth	11 DAT	0.005	nc	<LOQ	2070739
					pre-flowering	4 DAT	0.005	nc	<LOQ	2070739
					pre-flowering	14 DAT	0.005	nc	<LOQ	2070739
					during flowering	7 DAT	0.005	nc	<LOQ	2070739
					1 app. prior to flowering,	2 DAT	0.005	nc	<LOQ	2070740
					2nd app at early flowering	5 DAT	0.005	nc	<LOQ	2070740
					1 app. prior to flowering,	3 DAT	0.005	nc	<LOQ	2070740
					2nd app at early flowering	6 DAT	0.005	nc	<LOQ	2070740
Radiola belled	CG 20	**Canola** SC formulation	Foliar	3 × 150	3–4 weeks before flowering, 7–10 days apart	throughout flowering	0.198	<LOQ	<LOQ	2070718
			Soil	450	1 app prior to sowing		0.15	<LOQ	<LOQ	2070718
		Sunflower SC formulation	Foliar	3 × 150	3–4 weeks before flowering, 7–10 days apart		**4.354**	<LOQ	0.028	2070718
			Soil	450	1 app, prior to sowing		0.199	<LOQ	0.018	2070718

Study Type	Crop Group	Crop	Proposed Application Method and rate	Study Application Rate (g a.i./ha)	Study Application timing	Sampling	Pollen residues (mg/kg)	Nectar residues (mg/kg)	IN-HGW87 pollen (mg/kg)	PMRA #
	CG 8	**Tomato** SC formulation	Foliar	3 × 150	3–4 weeks before flowering, 7–10 days apart		1.695	<LOQ	0.028	2070718
			Soil	450	3–4 weeks before flowering		0.076	<LOQ	<LOQ	2070718
	CG 9	**Zucchini** SC formulation	Foliar	3 × 150	3–4 weeks before flowering, 7–10 days apart		0.005	<LOQ	0.074	2070718
			Soil	450	3–4 weeks before flowering		<LOQ	<LOQ	<LOQ	2070718
	N/A	**Phacelia** SC formulation	Foliar	3 × 150	4 weeks prior to flowering, 7 days between each application		0.003	nc	na	2070717
			Soil	450	prior to sowing		0.022	nc	na	2070717

nc = not collected
na = not analysed
Shaded cells indicate no proposed uses in Canada or crop not grown in Canada, but could still be used in risk assessment.
LOQ = 5.0 µg/kg
If more than one application, sampling dates are designated as DAA = Sampled × Days After Application A i.e. first application and DAB = Sampled × Days After Application B i.e. second application
If only one application, sampling dates are listed as DAT i.e. days after treatment

Results for cyantraniliprole and transformation product IN HGW87 only are shown since IN HGW87 was the most toxic transformation product from the acute oral toxicity studies:
Technical grade active ingredient: 48 h acute oral LD_{50}>0.1055 µg ai/bee
IN HGW87: 72 h acute oral LD_{50} = 0.298 µg ai/bee
IN J9Z38: 48 h oral LD_{50}> 8.34 µg ai/bee
IN K5A78: 48 h oral LD_{50}> 45.61 µg ai/bee
Cyantraniliprole/thiamethoxam WG (A16901B): 48 h acute oral LD_{50}=0.031 µg product A16901B /bee
200 g/L SC formulation: 96 h acute oral LD_{50}=0.404 µg ai/bee

Proposed application rates for crop groups with no residues data:

- Bushberries e.g. blueberries have same application rates as proposed for pome and stone fruits i.e. 150 g a.i./ha; 4 apps; 3 day PHI; max seasonal 450 g a.i./ha
- Tree nuts have same application rates as proposed for pome and stone fruits i.e.150 g a.i./ha; 4 apps; max seasonal 450 g a.i./ha with the exception of a 5 day PHI

1600 mL EP/100 kg seed × 625 g a.i./1000 mL EP = 10 g a.i./kg seed
Canola seeding rate (max.; all varieties) = 7.9 kg seed/ha
Application rate for active ingredient = 7.9 kg seed/ha × 10 g a.i./kg seed = 79 g a.i./ha

Table 24 A summary of honey bee field trials to evaluate maximum residues (µg/kg) detected in nectar and pollen from experimental crops

Test substance	Crop	Rate g ai/ha	Use type	Matrix	Cyantraniliprole	IN-J9Z38	IN-JCZ38	IN-HGW87	IN-MLA84	IN-MYX98	IN-N7969	Reference
Cyantraniliprole 100 g/L OD	Potato	2 × 12.5	Pre-flowering sprays	Nectar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	DuPont-30546
Cyantraniliprole 100 g/L OD	Potato	2 × 12.5	Pre-flowering sprays	Pollen	*	*	*	*	*	*	*	DuPont-30546
Cyantraniliprole 100 g/L OD	Potato	2 × 12.5	Pre-flowering sprays	Nectar	*	*	*	*	*	*	*	DuPont-30547
Cyantraniliprole 100 g/L OD	Potato	2 × 12.5	Pre-flowering sprays	Pollen	*	*	*	*	*	*	*	DuPont-30547
Cyantraniliprole 100 g/L OD	Grapevine	1 × 112.5	Pre-flowering spray	Nectar	9.8	*	*	*	*	*	*	DuPont-30549
Cyantraniliprole 100 g/L OD	Grapevine	1 × 112.5	Pre-flowering spray	Pollen	769.7			5.2		7.3		DuPont-30549
Cyantraniliprole 100 g/L OD	Melon	2 × 90	Pre-flowering sprays	Nectar	*	*	*	*	*	*	*	DuPont-30553
Cyantraniliprole 100 g/L OD	Melon	2 × 90	Pre-flowering sprays	Pollen	78.32	*	*	*	*	*	*	DuPont-30553
Cyantraniliprole 100 g/L OD	Melon	2 × 90	Pre- and flowering spray	Nectar	13.4	*	*	*	*	*	*	DuPont-30543
Cyantraniliprole 100 g/L OD	Melon	2 × 90	Pre- and flowering spray	Pollen	97	*	*	*	*	*	*	DuPont-30543
Cyantraniliprole 100 g/L OD + codacide oil	Melon	1 × 120	Pre- and Flowering spray	Nectar	31.3	*	*	*	*	*	*	DuPont-27846, Revision No. 2
Cyantranilipr	Melon	1 × 120	Pre- and	Pollen	86.8	6.3	*	*	*	*	*	DuPont-

Test substance	Crop	Rate g ai/ha	Use type	Matrix	Cyantraniliprole	IN-J9Z38	IN-JCZ38	IN-HGW87	IN-MLA84	IN-MYX98	IN-N7969	Reference
ole 100 g/L OD + codacide oil			Flowering spray									27846, Revision No. 2
Cyantraniliprole 100 g/L OD + codacide oil	Oilseed rape	1 × 120	Pre- and flowering spray	Nectar	38.5	*	*	*	*	*	*	DuPont-27845, Revision No. 2
Cyantraniliprole 100 g/L OD + codacide oil	Oilseed rape	1 × 120	Pre- and flowering spray	Pollen	1933	25.3	*	28.3	*	15.5	*	DuPont-27845, Revision No. 2
Cyantraniliprole 100 g/L OD + codacide oil	Tomato	2 × 90	Pre- and flowering spray	Nectar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	DuPont-30544
Cyantraniliprole 100 g/L OD + codacide oil	Tomato	2 × 90	Pre- and flowering spray	Pollen	211.5	*	*	*	15.7	*	*	DuPont-30544
Cyantraniliprole 100 g/L OD + codacide oil	Tomato	2 × 90	Early growth stage spray	Nectar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	DuPont-30545
Cyantraniliprole 100 g/L OD + codacide oil	Tomato	2 × 90	Pre-flowering spray	Pollen	103.1	*	*	*	*	*	*	DuPont-30545
Cyantraniliprole 100 g/L SE	Olives	1 × 50	Pre-flowering spray	Nectar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	DuPont-30030
Cyantraniliprole 100 g/L SE	Olives	1 × 50	Pre-flowering spray	Pollen	1607	10	*	12.2	*	12.6	*	DuPont-30030
Cyantraniliprole 100 g/L SE	Olives	1 × 50	Pre-flowering spray	Nectar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	DuPont-30031
Cyantraniliprole 100 g/L	Olives	1 × 50	Pre-flowering	Pollen	189.7	*	*	*	*	*	*	DuPont-30031

Test substance	Crop	Rate g ai/ha	Use type	Matrix	Cyantraniliprole	IN-J9Z38	IN-JCZ38	IN-HGW87	IN-MLA84	IN-MYX98	IN-N7969	Reference
SE			spray									
Cyantraniliprole 100 g/L SE	Grapevine	1 × 112.5	Pre-flowering spray	Nectar	139.5	*	*	*	*	*	*	DuPont-30548
Cyantraniliprole 100 g/L SE	Grapevine	1 × 112.5	Pre-flowering spray	Pollen	491	10.2	*	*	*	5.3	*	DuPont-30548
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	2 × 150	Pre-flowering spray	Nectar	132.2	*	*	*	*	*	*	DuPont-30029
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	2 × 150	Pre-flowering spray	Pollen	107.8	5.5	*	*	*	*	*	DuPont-30029
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	1 × 150	Pre-flowering spray	Nectar	**836.5**	12.5	*	*	*	*	*	DuPont-27848, Revision No. 3
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	1 × 150	Pre-flowering spray	Pollen	2505	*	*	*	*	5.6	*	DuPont-27848, Revision No. 3
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	2 × 150	Pre-flowering spray	Nectar	40.8	*	*	*	*	*	*	DuPont-30028, Revision No. 1
Cyantraniliprole 100 g/L SE + codacide oil	Citrus	2 × 150	Pre-flowering spray	Pollen	1210	**39.4**	*	5.3	*	*	*	DuPont-30028, Revision No. 1
Cyantraniliprole 100 g/L SE + codacide oil	Nectarine	1 × 100	Pre-flowering spray	Nectar	47	*	*	*	*	*	*	DuPont-30026, Revision No. 1
Cyantraniliprole 100 g/L SE +	Nectarine	1 × 100	Pre flowering spray	Pollen	3450	*	*	16.6	*	15	*	DuPont-30026, Revision No.

Test substance	Crop	Rate g ai/ha	Use type	Matrix	Cyantraniliprole	IN-J9Z38	IN-JCZ38	IN-HGW87	IN-MLA84	IN-MYX98	IN-N7969	Reference
codacide oil												1
Cyantraniliprole 100 g/L SE + codacide oil	Nectarine	1 × 100	Flowering spray	Nectar	145.8	*	*	*	*	*	*	DuPont-30027
Cyantraniliprole 100 g/L SE + codacide oil	Nectarine	1 × 100	Flowering spray	Pollen	2915	*	*	*	*	*	*	DuPont-30027
Cyantraniliprole 100 g/L SE + codacide oil	Apple	1 × 150	Pre flowering spray	Nectar	14.2	*	*	*	*	*	*	DuPont-27847, Revision No. 2
Cyantraniliprole 100 g/L SE + codacide oil	Apple	1 × 150	Pre flowering spray	Pollen	1454	*	*	7.6	*	5.9	*	DuPont-27847, Revision No. 2
Cyantraniliprole 100 g/L SE + codacide oil	Apple	1 × 150	Pre flowering spray	Nectar	107.3	*	*	*	*	*	*	DuPont-28266
Cyantraniliprole 100 g/L SE + codacide oil	Apple	1 × 150	Pre flowering spray	Pollen	1588	10.1	*	6.3	*	5.3	*	DuPont-28266

Shaded residue values represent maximum values.
*Means residues <LOQ of 5.0 µg/kg.
N/A Not applicable
* These studies were not evaluated for Ecotoxicology in the Primary Review; their reliability depends on the evaluation in the Residues section.

Table 25 Screening level risk assessment for birds and mammals following a foliar application at the maximum cumulative rate of to 262.5 g a.i./ha (3 × 150 g a.i./ha with 5 day interval and a 5-d foliar half-life).

	Toxicity (mg a.i./kg bw/day)	Feeding Guild (food item)	EDE (mg a.i./kg bw)[a]	RQ
Small Bird (0.02 kg)				
Acute	225.00	Insectivore (small insects)	13.23	0.06
Reproduction	93.20	Insectivore (small insects)	13.23	0.14
Medium Sized Bird (0.1 kg)				
Acute	225.00	Insectivore (small insects)	10.32	0.05
Reproduction	93.20	Insectivore (small insects)	10.32	0.11
Large Sized Bird (1 kg)				
Acute	225.00	Herbivore (short grass)	10.77	0.05
Reproduction	93.20	Herbivore (short grass)	10.77	0.12
Small Mammal (0.015 kg)				
Acute	500.00	Insectivore (small insects)	7.61	0.02
Reproduction	1352.70	Insectivore (small insects)	7.61	0.01
Medium Sized Mammal (0.035 kg)				
Acute	500.00	Herbivore (short grass)	23.83	0.05
Reproduction	1352.70	Herbivore (short grass)	23.83	0.02
Large Sized Mammal (1 kg)				
Acute	500.00	Herbivore (short grass)	12.74	0.03
Reproduction	1352.70	Herbivore (short grass)	12.74	0.01

[a] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where:
FIR: Food Ingestion Rate (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): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{BW in g})^{0.651}$.
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{BW in g})^{0.822}$
BW: Generic Body Weight
EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.
RQ = Risk Quotient = EDE/Toxicity. The RQ is compared to a level of concern (LOC) of 1.

Table 26 Expanded risk assessment for birds and mammals exposed to treated seeds (rape seeds) at 10 mg a.i./ kg seeds (1000 mg a.i./100 kg seeds)

	Study Endpoint (mg a.i./kg bw/day / UF)	EDE (mg a.i./kg bw/day)	RQ	Number of seeds needed to reach endpoint[a]	Area required (m^2) [b]		
					100% available	3.3 % Available[c]	0.5% Available[d]
Small bird (0.02 kg)							
Acute	225.0	2539.4	11.3	225.0	1.2	36.1	238.2
Dietary	135.7	2539.4	18.7	135.7	0.7	21.8	143.7
Reproduction	93.2	2539.4	27.2	93.2	0.5	15.0	98.7
Medium bird (0.10 kg)							
Acute	225.0	1994.7	8.9	1125.0	6.0	180.5	1191.2
Dietary	135.7	1994.7	14.7	678.5	3.6	108.9	718.4
Reproduction	93.2	1994.7	21.4	466.0	2.5	74.8	493.4
Large bird (1.00 kg)							
Acute	225.0	581.5	2.6	11250.0	59.6	1804.8	11911.8
Dietary	135.7	581.5	4.3	6785.0	35.9	1088.5	7184.1
Reproduction	93.2	581.5	6.2	4660.0	24.7	747.6	4934.1

a: Number of seeds needed to reach endpoint:
- o Endpoint (mg a.i./kg bw/day) ÷ bird weight (0.02 kg, 0.10 kg or 1.00 kg) × mg a.i./seed
  - mg a.i./seed = seed treatment rate (mg a.i./kg seed)[c] ÷ number of seeds per kg (# seeds/kg)
  - # seeds/kg = 1/(kg/1000 seeds)[f]

b: Area required to reach endpoint (in m^2):
- o Number of seeds needed to reach endpoint ÷ seeding rate (kg seeds/ha) ÷ 10000 m^2/ha × # seeds/kg
  - Seeding rate (kg seeds/ha) = desired plant population (plants/m^2)[f] × 1000 kernel weight (g/1000 seeds)[f] ÷ seedling survival rate (0.90) ÷ 100

c: seeded using standard spring drilling (de Snoo and Luttik, 2004)
d: seeded using precision drilling (de Snoo and Luttik, 2004)
e: Accepted label rate
f: Alberta Department of Agriculture, Food and Rural Development. (http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex81?opendocument)

Table 27 Effects on terrestrial organisms (screening level assessment) – Excluding bees, birds and mammals

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Collembola	28 day PMRA # 2070816	NOEC (mortality): 0.08 mg a.i./kg dw soil Mortality was up to 33% at highest concentration 0.1200 mg cyantraniliprole/kg. The mean reproduction (% juveniles compared to control) ranged from 87 to 107%.	In field 0.195 mg/kg soil	2.4	YES
			Off field 74% (orchard)= 0.144 mg a.i./kg soil	1.8	YES
			Off field 59% (orchard)= 0.11 mg a.i./kg soil	1.4	YES
			Aerial 26% (both labels) = 0.05 mg a.i./kg soil	0.63	No
			11% (field use)=0.021 mg a.i./kg soil	0.27	No
	28 day	NOEC: 0.08 mg a.i./kg dw soil	Soil EEC for Verimark (soil drench): 0.13 mg/kg	1.6	YES
Hypoaspis aculeifer (soil predatory mite)	14 day PMRA # 2070805	NOEC 1000 mg a.i./kg dw soil	0.195 mg/kg soil	0.0002	No
Earthworm	14-d Acute TGAI PMRA # 2070827	LC_50 >500 mg a.i./kg dw soil (>1000 mg a.i./kg dw soil/2) NOEC = 1000 mg a.i./kg dw soil	0.195 mg/kg soil	0.00039	No
	56 day Chronic PMRA # 2070835	NOEC = 1000 mg a.i./kg dw soil (or 945 mg/kg based on purity) (highest concentration tested)	0.195 mg/kg soil	0.0002	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Earthworm	14-d Acute Cyantraniliprole 200 g/L SC PMRA # 2070318	LC_{50} >103.5 mg a.i./kg dw soil = >1000 mg Cyantraniliprole 200 g/L SC /kg dw soil = (207 mg a.i./kg soil/2) NOEC = 1000 mg Cyantraniliprole 200 g/L SC /kg dw soil	0.195 mg/kg soil (used rate higher than relevant EP, no risk therefore, no additional RA conducted at 300 g a.i./ha rate)	0.0019	No
	14-d Acute Cyantraniliprole 100 g/L OD PMRA # 2070522	LC_{50} >52.4 mg a.i./kg dw soil = >1000 mg Cyantraniliprole 100 g/L OD /kg dw soil = (104.8 mg a.i./kg/2) NOEC = 1000 mg Cyantraniliprole 100 g/L OD /kg dw soil	0.195 mg/kg soil	0.0037	No
	56 day Chronic Cyantraniliprole 100 g/L OD with codacide oil PMRA # 2070524	NOEC = 1000 mg Cyantraniliprole 100 g/L OD /kg dw soil + 1578 mg codacide soil/kg dry soil = 104.8 mg a.i./kg (highest concentration tested)	0.195 mg/kg soil	0.002	No
	14-d Acute Cyantraniliprole/ Thiamethoxam WG A16901B (20% each a.i.) PMRA # 2071404	LC_{50} >500 mg WG A16901B/kg (>1000 mg a.i./kg soil/2) NOEC (based on biomass) = 625 mg Cyantraniliprole WG A16901B /kg dw soil	0.067 mg/kg soil	0.0001	No
Earthworm	14-d IN-J9Z38 PMRA # 2070828	LC_{50} >500 mg IN-J9Z38/kg dw soil (>1000 mg IN-J9Z38/kg dw soil /2) (or 964 mg/kg based on purity) NOEC = 1000 mg IN-J9Z38/kg dw soil	0.19 mg/kg	0.00038	No
	56 day Chronic IN-J9Z38 PMRA # 2070841	NOEC: 1000 mg IN-J9Z38/kg dw soil (highest concentration tested)	0.19 mg/kg	0.00019	No
Hypoaspis aculeifer	14 day Acute IN-J9Z38 PMRA # 2070807	NOEC: 1000 mg IN-J9Z38/kg dw soil (highest concentration tested)	0.19 mg/kg	0.00019	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Collembola	28 day IN-J9Z38 PMRA # 2070803	NOEC: 500 mg IN-J9Z38/kg dw soil (highest concentration tested)	0.19 mg/kg	0.00038	No
Earthworm	14-d Acute IN-JCZ38 PMRA # 2070829	LC_{50}> 500 mg IN-JCZ38/kg dw soil (>1000 mg IN-JCZ38/kg dw soil/2) (or 921 mg/kg based on purity) NOEC = 1000 mg IN-JCZ38/kg dw soil	0.18 mg/kg	0.00036	No
	56 day Chronic IN-JCZ38 PMRA # 2070838	NOEC: 1000 mg IN-JCZ38/kg dw soil (highest concentration tested)	0.18 mg/kg	0.00018	No
Hypoaspis aculeifer	14-d IN-JCZ38 PMRA # 2070808	NOEC: 1000 mg IN-JCZ38/kg dw soil (highest concentration tested)	0.18 mg/kg	0.00018	No
Collembola	28 day IN-JCZ38 PMRA # 2070809	NOEC: 12 mg IN-JCZ38/kg dw soil	0.18 mg/kg	0.015	No
Earthworm	14-d Acute IN-JSE76 PMRA # 2070834	NOEC = 1000 mg IN-JSE76/kg dw soil	0.24 mg/kg	0.00024	No
	56 day Chronic IN-JSE76 PMRA # 2070837	NOEC = 1000 mg IN-JSE76/kg dw soil (highest concentration tested)	0.24 mg/kg	0.00024	No
Hypoaspis aculeifer	14-d IN-JSE76 PMRA # 2070812	NOEC = 1000 mg IN-JSE76/kg dw soil (highest concentration tested)	0.24 mg/kg	0.00024	No
Collembola	28 day IN-JSE76 PMRA # 2070814	NOEC = 250 mg IN-JSE76/kg dw soil	0.24 mg/kg	0.00096	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Earthworm	14-d Acute IN-K5A77 PMRA # 2070830	LC_{50}> 500 mg IN-K5A77/kg dw soil (=>1000 mg IN-K5A77/kg dw soil/2) (or 953 mg/kg based on purity) NOEC = 1000 mg IN-K5A77/kg dw soil	0.2 mg/kg	0.0004	No
	56 day chronic IN-K5A77 PMRA # 2070836	NOEC: 1000 mg IN-K5A77/kg dw soil (highest concentration tested)	0.2 mg/kg	0.0002	No
Hypoaspis aculeifer	14-d IN-K5A77 PMRA # 2070817	NOEC: 1000 mg IN-K5A77/kg dw soil (highest concentration tested)	0.2 mg/kg	0.0002	No
Collembola	28 day IN-K5A77 PMRA # 2070818	NOEC: 62.5 mg IN-K5A77/kg dw soil	0.2 mg/kg	0.0032	No
Earthworm	14-d Acute IN-K5A78 PMRA # 2070831	LC_{50}> 500 mg IN-K5A78/kg dw soil (=>1000 mg IN-K5A78/kg dw soil/2) (or 949 mg/kg based on purity) NOEC = 1000 mg IN-K5A78/kg dw soil	0.198 mg/kg	0.0004	No
	56 day Chronic IN-K5A78 PMRA # 2070839	NOEC: 1000 mg IN-K5A78/kg dw soil (highest concentration tested)	0.198 mg/kg	0.0002	No
Hypoaspis aculeifer	14-d IN-K5A78 PMRA # 2070813	NOEC: 1000 mg IN-K5A78/kg dw soil (highest concentration tested)	0.198 mg/kg	0.0002	No
Collembola	28 day IN-K5A78 PMRA # 2070810	NOEC: 1000 mg IN-K5A78/kg dw soil (highest concentration tested)	0.198 mg/kg	0.0002	No
Earthworm	14-d Acute IN-K5A79 PMRA # 2070832	LC_{50}> 500 mg IN- IN-K5A79/kg dw soil (=>1000 mg IN- IN-K5A79/kg dw soil/2) (or 844 mg/kg based on purity) NOEC = 1000 mg IN- IN-K5A79/kg dw soil	0.2 mg/kg	0.0004	No

Organism	**Exposure** **[PMRA number]**	**Endpoint value**	**EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)**	**RQ (EEC/endpoint)**	**LOC exceeded?**
	56 day chronic IN-K5A79 PMRA # 2070840	NOEC: 1000 mg IN-K5A79/kg dw soil (highest concentration tested)	0.2 mg/kg	0.0002	No
Hypoaspis aculeifer	14-d IN-K5A79 PMRA # 2070804	NOEC: 1000 mg IN-K5A79/kg dw soil (highest concentration tested)	0.2 mg/kg	0.0002	No
Collembola	28 day IN-K5A79 PMRA # 2070815	NOEC: 125 mg IN-K5A79/kg dw soil	0.2 mg/kg	0.0016	No
Earthworm	14-d Acute IN-PLT97 PMRA # 2070833	LC_{50}> 500 mg IN-PLT97/kg dw soil (=>1000 mg IN-PLT97/kg dw soil/2) (or 870 mg/kg based on purity) NOEC = 1000 mg IN-PLT97/kg dw soil	0.194 mg/kg	0.0004	No
	56 day chronic IN-PLT97 PMRA # 2070842	NOEC: 1000 mg IN-PLT97/kg dw soil (highest concentration tested)	0.194 mg/kg	0.00019	No
Hypoaspis aculeifer	14-d IN-PLT97 PMRA # 2070806	NOEC: 500 mg IN-PLT97/kg dw soil (highest concentration tested)	0.194 mg/kg	0.0004	No
Collembola	28 day IN-PLT97 PMRA # 2070811	NOEC: 1000 mg IN-PLT97/kg dw soil (highest concentration tested)	0.194 mg/kg	0.00019	No
Earthworm	56 day chronic IN-QKV54 PMRA # 2070843	NOEC: 100 mg IN-QKV54/kg dw soil (highest concentration tested) (98.3 mg/kg based on purity)	0.145 mg/kg	0.00145	No
Hypoaspis aculeifer	14 day IN-QKV54 PMRA # 2070822	NOEC: 100 mg IN-QKV54/kg dw soil (highest concentration tested)	0.145 mg/kg	0.00145	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Collembola	28 day IN-QKV54 PMRA # 2070819	NOEC: 98.3 mg IN-QKV54/kg dw soil (highest concentration tested)	0.145 mg/kg	0.00147	No
Earthworm	Subacute (4 week) plus 56 day chronic IN-RNU71 PMRA # 2070844	LC_{50}> 50 mg IN-RNU71/kg dw soil (=>100 mg IN-RNU71/kg dw soil/2) NOEC: 100 mg IN-RNU71/kg dw soil (highest concentration tested, no effects) (92.4 mg/kg based on purity)	0.18 mg/kg	0.0036	No
Hypoaspis aculeifer	14 day IN-RNU71 PMRA # 2070823	NOEC: 100 mg IN-QKV54/kg dw soil (highest concentration tested)	0.18 mg/kg	0.0018	No
Collembola	28 day IN-RNU71 PMRA # 2070820	NOEC: 12.5 mg IN-RNU71/kg dw soil	0.18 mg/kg	0.0144	No
Typhodromus pyri Predatory mite	7-d Contact Cyantraniliprole 100 g/L OD PMRA # 2070769	LR_{50} > 230 g a.i./ha (mortality) (>2300 mL cyantraniliprole 100 g/L OD/ha) There was 20.5% mortality in the highest test group (230 g a.i./ha)	<u>In-field</u> 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	<1.1	No
			<u>Off field</u> (11% drift)**= 28.9 g a.i./ha	<0.13	No
			<u>Off-field (aerial)</u> (26% drift)** = 68 g a.i./ha	<0.30	No
	14-d Contact Cyantraniliprole 200 g/L SC PMRA # 2070766	LR_{50} > 230 g a.i./ha (mortality, reproduction) (>1109 mL cyantraniliprole 200 g/L SC/ha) There was no "dose response" and mortality in highest test group was 5.7%.	<u>In-field</u> 300 g a.i./ha (off field risk not relevant for in-furrow)	<1.3	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
	14-d Contact 100 g/L SE PMRA # 2070767	LR_{50} > 300 g a.i./ha (mortality, reproduction) (>3000 mL cyantraniliprole 100 g/L SE/ha)	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	<0.87	No
			Off field (74% drift)**= 194 g a.i./ha	<0.65	No
Aphidius rhopalosiphi Parasitoid	48 hour Contact Cyantraniliprole 200 g/L SC PMRA # 2070763	LR_{50} =0.36 g a.i./ha (mortality) (1.74 mL cyantraniliprole 200 g/L SC/ha)	In-field 300 g a.i./ha (off field risk not relevant for in-furrow)	833	YES
	48 hour Contact Cyantraniliprole 100 g/L OD PMRA # 2070765	LR_{50} =0.1019 g a.i./ha (mortality) (1.019 mL cyantraniliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	2576	YES
			Off-field (11% drift)**= 28.9 g a.i./ha	284	YES
			Off-field (aerial) (26% drift)** = 68 g a.i./ha	667	YES
	48 hour Contact Cyantraniliprole 100 g/L SE PMRA # 2070764	LR_{50} =0.095 g a.i./ha (mortality) (0.95 mL cyantraniliprole 100 g/L SE/ha)	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	2763	YES
			Off -field (74% drift)**= 194 g a.i./ha	2042	YES

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Vascular plant	21-d Seedling emergence Cyantraniliprole 100 g/L OD PMRA 2070653	ER_{25} > 150 g a.i./ha (>1.43 L Cyantraniliprole 100 g/L OD/ha)	SOIL : In-field 3 × 150 g ai/ha using 130 day half life = 438.3 g a.i./ha	<2.9	Unable to determine, unlikely based on limited effects in study.
			Off-field (11% drift)** = 48.2 g a.i./ha	0.32	No
			Off-field (aerial) (26% drift)** = 114 g a.i./ha	0.76	No
	21-d Seedling emergence Cyantraniliprole 100 g/L OD	ER_{25} > 150 g a.i./ha (>1.43 L Cyantraniliprole 100 g/L OD/ha)	Off field (59% drift)**= 259 g a.i./ha	<1.7	Unable to determine, unlikely based on limited effects in study.
			Off field (74% drift)**= 324 g a.i./ha	<2.2	Unable to determine, unlikely based on limited effects in study.
	21-d Seedling emergence Cyantraniliprole 100 g/L OD with codacide oil PMRA 2070654	ER_{25} =123 g a.i./ha (tomato shoot dry weight) All other species were >150 g a.i./ha	SOIL : In-field 3 × 150 g a.i./ha using 130 day half life = 438.3 g a.i./ha	3.6	YES
			Off-field (11% drift)** = 48.2 g a.i./ha	0.39	No
			Off-field (aerial) (26% drift)** = 114 g a.i./ha	0.93	No

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
	21-d Seedling emergence Cyantraniliprole 100 g/L OD with codacide oil	ER_{25} =123 g a.i./ha (tomato shoot dry weight) All other species were >150 g a.i./ha	Off-field (59% drift)**= 258 g a.i./ha	2.1	YES
			Off-field (74% drift)**= 324 g a.i./ha	2.6	YES
	Vegetative vigour Cyantraniliprole 100 g/L OD PMRA 2070652	ER_{25} and ER_{50}> 150 g a.i./ha (>1.43 L Cyantraniliprole 100 g/L OD/ha) Note: onion and ryegrass had shoot dry weight inhibition of 22 and 20%, respectively.	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	<1.8	Unable to determine, however, up to 22% effect following one application.
			Off-field (11% drift)**= 28.9 g a.i./ha	0.19	No
			Off-field (aerial) (26% drift)**= 68 g a.i./ha	0.45	No
	Vegetative vigour Cyantraniliprole 100 g/L OD	ER_{25} and ER_{50}> 150 g a.i./ha (>1.43 L Cyantraniliprole 100 g/L OD/ha) Note: onion and ryegrass had shoot dry weight inhibition of 22 and 20%, respectively.	Off-field (59% drift)**= 258 g a.i./ha	<1.8	Unable to determine, however, up to 22% effect following one application.
			Off-field (74% drift)**= 324 g a.i./ha	<2.2	
	Vegetative vigour Cyantraniliprole 100 g/L OD with codacide oil (9.38, 18.8, 37.5,	ER_{25} and ER_{50}> 150 g a.i./ha (>1.5 L Cyantraniliprole 100 g/L OD/ha) All effects well below 5%	In-field 3 × 150 g a.i./ha using 5 day half life = 262.5 g a.i./ha	<1.8	Unable to determine, however, unlikely based on <5% effects observed in the study.

Organism	Exposure [PMRA number]	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
	75.0, and 150 g a.i./ha) PMRA 2070655		Off-field (11% drift)**= 28.9 g a.i./ha	0.19	No
			Off-field (aerial) (26% drift)**= 68 g a.i./ha	0.45	No
Note: although the study was conducted with the OD formulation, the % drift from the SE formulation would be 59 and 74%. The following is an assessment based on off-field drift from the SE formulation (Cyantraniliprole 100 g/L SE). The 26% aerial consideration was covered off under Benevia Insecticide.					
	Vegetative vigour Cyantraniliprole 100 g/L OD with codacide oil (9.38, 18.8, 37.5, 75.0, and 150 g a.i./ha)	ER_{25} and ER_{50}> 150 g a.i./ha (>1.5 L Cyantraniliprole 100 g/L OD/ha) All effects well below 5%	Off-field (59% drift)**= 258 g a.i./ha	<1.7	Unable to determine, however, unlikely based on <5% effects observed in the study.
			Off-field (74% drift)**= 324 g a.i./ha	<2.2	

Shaded cells indicate that the level of concern is exceeded.

Table 28 Effects on terrestrial organisms (refined level assessment) – Excluding bees

Organism	Exposure	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Tier II					
Collembola	28 day PMRA # 2070796	NOEC (mortality): 0.08 mg a.i./kg dw soil Mortality was up to 33% at highest concentration 0.1200 mg cyantraniliprole/kg. The mean reproduction (% juveniles compared to control) ranged from 87 to 107%.	<u>In field</u> 0.14 mg/kg soil × 0.9 soil fraction: 0.126 mg/kg (Washington half-life) 0.17 mg/kg soil × 0.9 soil fraction: 0.153 mg/kg (New York half-life)	1.6 1.9	YES
			<u>Off field</u> 74% (orchard)= 0.10 mg a.i./kg soil	1.3	YES
			<u>Off field</u> 59% (orchard)= 0.083 mg a.i./kg soil	1.0	YES
			<u>Off field (aerial – both labels)</u> 26%= 0.036 mg a.i./kg soil	0.46	No
			<u>Off field</u> 11% (field crops)= 0.015 mg a.i./.kg soil	0.19	No
			<u>In-field</u> Soil EEC for Verimark (soil drench): 0.13 mg/kg	1.6	YES
Collembola field study	The study exposed a community of collembola to three end-use products containing cyantraniliprole. Two applications were performed on short cut grass, the first application was done on 10 June 2010 and the second application took place 7 days later (17 June 2010). At the first application Cyantraniliprole was applied at 17.9 g a.i./ha, 142.2 g a.i./ha, 293.6 g a.i./ha and 1502.2 g a.i./ha for the test item treatments tmt1 (Cyantraniliprole 100 g/L OD), tmt2 (Cyantraniliprole 100 g/L OD + Codacide Oil), tmt3 (Cyantraniliprole 100 g/L SE + Codacide Oil), tmt4 (Cyantraniliprole –200 g/L SC, respectively). Two applications up to a maximum of 1000 g a.i./ha was applied. Initial transient effects were observed on some taxa (reduction in abundance). However, by the 4th and 5th samplings (159 and 368 DAT) no statistically significant abundance reductions were observed for any of the Collembola taxa groups in any of the test item treatment groups. Abundance increases were observed for Entomobryidae total for test item treatment T3 (Dunnett's t-test, $p < 0.05$, log transformed) and for *Isotomiella minor* for test item treatment tmt1 (Dunnett's t-test, $p < 0.05$, square root transformed). An increase in total Isotomidae was observed in tmt4 (Dunnett's t-test, $p < 0.05$, square root transformed). In conclusion, Collembola densities and species richness observed during this study were in the expected range of those reported earlier for German grassland soils for the first sampling (Chauvat et al. 2007, Salamon et al. 2004).				

Organism	Exposure	Endpoint value	EEC* (based on 3 × 150 g a.i./ha, unless otherwise stated)	RQ (EEC/endpoint)	LOC exceeded?
Aphidius rhopalosiphi Parasitoid	48 hour Contact Cyantraniliprole 200 g/L SC	LR_{50} =0.36 g a.i./ha (mortality) (1.74 mL cyantraniliprole 200 g/L SC/ha)	300 g a.i./ha (fraction for bare soil is 1.0) (off field risk not relevant for in-furrow)	833	YES
	48 hour Contact Cyantraniliprole 100 g/L OD	LR_{50} =0.1019 g a.i./ha (mortality) (1.019 ml cyantraniliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape)= 236 g a.i./ha	2316	YES
			Off-field (11% drift, 0.1 fraction)**= 2.9 g a.i./ha	28	YES
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	66	YES
	48 hour Contact Cyantraniliprole 100 g/L SE	LR_{50} =0.095 g a.i./ha (mortality) (0.95 ml cyantraniliprole 100 g/L SE/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit)= 210 g a.i./ha	2210	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	204	YES
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	163	YES
			Off-field (aerial) (26% drift × 0.1 fraction)*** = *6.8 g a.i./ha*	71	YES
Ladybird beetle *Coccinella septemunctata* L.	12 to 19-d Contact on sprayed leaves Cyantraniliprole 100 g/L OD	LR_{50} = 61.5 g a.i./ha (mortality) (615 mL cyantranliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape) 236 g a.i./ha	3.8	YES

	PMRA # 2070789		Off-field (11% drift, 0.1 fraction)**= 2.9 g a.i./ha	0.048	No
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	0.11	No
	12 to 19-d Contact on sprayed leaves Cyantraniliprole 100 g/L SE PMRA # 2070792	LR_{50} = 43.3 g a.i./ha (mortality) (433 mL cyantranliprole 100 g/L SE/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit) 210 g a.i./ha	4.8	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	0.45	No
			Off-field (59% drift × 0.1 fraction)*** = *15.5 g a.i./ha*	0.36	No
Green Lacewing, *Chrysoperla carnea*	12 to 19-d Contact on sprayed leaves Cyantraniliprole 100 g/L OD PMRA # 2070790	LR_{50} = 260.9 g a.i./ha (mortality) (2609 mL cyantranliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape) 236 g a.i./ha	0.9	No
			Off-field (11% drift, 0.1 fraction)**= 2.9 g a.i./ha	0.011	No
			Off-field (Aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	0.026	No
	12 to 19-d Contact on sprayed leaves Cyantraniliprole 100 g/L SE PMRA # 2070791	LR_{50} = 212.6 g a.i./ha (mortality) (2126 mL cyantranliprole 100 g/L SE/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit) 210 g a.i./ha	0.98	No
			Off-field (74% drift × 0.1 fraction)**= *19.4 g a.i./ha*	0.09	No
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	0.073	No

	28-d Contact with dried residues Cyantraniliprole 100 g/L SE with codacide oil PMRA # 2070786	No effects on mortality and reproduction following two applications of 150 g a.i./ha and 2500 mL codacide oil/ha (7 day interval) on apple tree leaves (after 2nd application, + 14 and +28 days after 2nd application). LR_{50}>150 g a.i./ha (up to 300 g a.i./ha for cumulative rate)	Not applicable for this type of study		
Aphidius rhopalosiphi Parasitoid	48 hour Contact with dried barley residues End-use product Cyantraniliprole 100 g/L OD (at 0.123, 0.370, 1.11, 3.33, 10.0 g a.i./ha) PMRA # 2070773	LR_{50} = 0.822 g a.i./ha (mortality) (8.22 mL cyantranliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape) = *236 g a.i./ha*	287	YES
			Off-field (11% drift, 0.1 fraction)**= *2.9 g a.i./ha*	3.5	YES
			Off-field (aerial) (26% drift, 0.1 fraction)**= *6.8 g a.i./ha*	8.3	YES
	27 d Contact with dried bean residues Cyantraniliprole 100 g/L OD with codacide oil (1 concentration) PMRA # 2070776	Treatment: two applications of 150 g a.i./ha and 2500 mL codacide oil/ha (7 day interval) on bean leaves (after 2nd application, + 13 and +27 days after 2nd application). Effects observed (87% mortality) for wasps exposed after 2nd application. However, no effects (<50% ESCORT trigger) on mortality and reproduction following 13 and 27 days after 2nd application.	Not applicable for this type of study		
	27 d Contact with dried residues on mummies (at two stages, 1–2 and 3–4 day old mummies)	NOEC based on reproduction is 25 g a.i./ha (for stage 3–4 mummies), however, all effects were <50% ESCORT trigger)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape)= 236 g a.i./ha	9.4	YES

	Cyantraniliprole 100 g/L OD with codacide oil (25, 50, 100, 150 g a.i./ha) PMRA # 2070778		Off-field (11% drift, 0.1 fraction)**= 2.9 g a.i./ha	0.116	No
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	0.27	No
	48 hour Contact with dried residues on barely Cyantraniliprole 100 g/L OD with codacide oil (2.2, 4.4, and 6.6 g a.i./ha) PMRA # 2070777	Corrected Mortality: 25, 46 and 63%, therefore, >50% ESCORT trigger in highest test concentration. Reproduction was not affected above the trigger value of 50% PMRA calculated LR_{50}: 4.7 g a.i./ha. The study author reported the LR/ER_{50} as > 4.4 g a.i./ha (the second highest concentration tested). Since there was up to 63% mortality, the PMRA will consider the LR_{50} as = 4.4 g a.i./ha for the risk assessment.	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.9 fraction for oilseed rape)= 236 g a.i./ha	53.6	YES
			Off-field (11% drift, 0.1 fraction)**= 2.9 g a.i./ha	0.66	No
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	1.5	Yes
	48 hour Contact with dried residues on barley Cyantraniliprole 100 g/L SE with 34.4 mL codacide oil/ha 0.032, 0.16, 0.8, 4.0, and 20.0 g a.i./ha PMRA # 2070772	LR_{50} = 2.06 g a.i./ha (mortality) (20.6 mL cyantranliprole 100 g/L OD/ha)	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit)= 210 g a.i./ha	102	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	9.4	YES
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	7.5	YES
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./.ha	3.3	YES

	48 hour Contact with dried residues on barley Cyantraniliprole 100 g/L SE with 36.7 to110 mL codacide oil/ha 2.2, 4.4, 6.6 g a.i./ha PMRA # 2070775	Corrected Mortality: 42.1%, 63.6%, 56.1% LR_{50}>2.2 g a.i./ha (considered = 2.2 g a.i./ha because of high mortality) ER_{50}<2.2 g a.i./ha Reproduction was affected at all rates above the trigger value of 50%	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit)= 210 g a.i./ha	95	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	8.8	YES
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	7	YES
			Off-field (aerial) (26% drift, 0.1 fraction)**= 6.8 g a.i./ha	3.1	YES
	End-Use product barley aged for 0, 2 and 7 days Cyantraniliprole 100 g/L SE with codacide oil (7.0, 13.0, 19.5, 26.0, and 32.6 g cyantraniliprole plus 116.7, 216.7, 325.0, 433.3, and 543.3 mL Codacide oil/ha) PMRA # 2150098	Bioassay 1 (fresh residue) LR_{50} = 19.8 g a.i./ha. reproductive ER_{50} > 19.5 g a.i./ha.	In-field 3 × 150 g a.i./ha using 5 day half-life = 262.5 g a.i./ha × 0.8 fraction for pome fruit)=210 g a.i./ha	10.6	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	0.98	No
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	0.78	No
		Bioassays 2 and 3 (2 and 7 days aging): variable reductions in mortality and/or reproduction seen but overall ER_{50} still >19.5 and <26.0 g a.i./ha.	In-field 3 × 150 g ai/ha using 5 day half-life = 262.5 g ai/ha × 0.8 fraction for pome fruit)= 210 g a.i./ha	8.1	YES
			Off-field (74% drift × 0.1 fraction)**= 19.4 g a.i./ha	0.75	No
			Off-field (59% drift × 0.1 fraction)*** = 15.5 g a.i./ha	0.60	No

	28 day Contact with dried residues on apple leaves Cyantraniliprole 100 g/L SE with codacide oil/ha (observations after 2nd application, +14 days and+28 days after 2nd application) 2 applications at 150 g a.i./ha PMRA # 2070770	Treatment: two applications of 150 g a.i./ha and codacide oil/ha (7 day interval) on apple leaves (after 2nd application, + 14 and +28 days after 2nd application). Effects observed (92.5% mortality) for wasps exposed after 2nd application. However, no effects (<50% ESCORT trigger) on mortality and reproduction following 14 and 28 days after 2nd application.	Not applicable for this type of study.		
Aleochara bilineata	Cyantraniliprole 200 g/L SC 13.4, 46.8, 164, 572 and 2005 mL/ha (=2.5, 8.75, 30.6, 107 and 375 g a.i./ha) PMRA # 2070783	$ER_{50\ (reproduction)}$= >56.4g a.i./ha	300 g a.i./ha	<5.3	Unable to determine
	Cyantraniliprole 200 g/L SC Aged residues for 2, 30 and 86 days after 2nd application 1 × 6.48 L/ha and 1 × 4.89 L/ha (7 day interval) followed by irrigation with 4 × 5000 L/ha = 1400 and 1000 g a.i./ha PMRA # 2070784	Effect on reproduction: 1st (aged for 2 days) = 100% 2nd (aged for 30 days) = –9.1% 3rd (aged for 86 days) 13.5 %	Not applicable for this type of study.		
Pardosa spiders	Cyantraniliprole 200 g/L SC 25, 50, 100, 200 and 400 g a.i./ha PMRA # 2070785	No effects >50% for mortality or reproduction up to 400 g a.i./ha ER_{50}: >400 g a.i./ha	300 g a.i./ha	0.75	No

Tier III			
Aphidius rhopalosiphi Parasitoid	48 hour outdoor barley plants Cyantraniliprole 100 g/L OD with codacide oil 22 mL cyantraniliprole 100 g/L OD/ha (2.2 g a.i./ha) × 1 application (+ 36.7 mL codacide oil/ha) PMRA # 2070774	Parastitism Only reproductive effect assessed: at 22.4% after 11 days exposure (i.e. <50%)	Not relevant. Effects in the field are compared to application rates for proposed Canadian use pattern. In this study, rates are below proposed Canadian rates.
	Cyantraniliprole 100 g/L OD with and without codacide oil 60 and 120 mL cyantraniliprole 100 g/L OD/ha without codacide oil (= 6 and 12 g a.i./.ha) & 60, 120 and 180 mL cyantraniliprole 100 g/L OD/ha (+166.7, 333.3 and 500 mL codacide oil/ha)(= 6, 12 and 18 g a.i./ha) PMRA # 2070779	Only effects > 50% for 6 g a.i./ha with no oil (41% reduction in reproduction) Effects (reproduction) were observed for all other treatment groups. 6 g a.i./ha without oil: 41% ↓ 6 g a.i./ha with oil: 59.9% ↓ 12 g a.i./ha without oil: 81% ↓ 12 g a.i./ha with oil: 90% ↓ 18 g a.i./ha with oil: 99.5% ↓	
	Cyantraniliprole 100 g/L SE with codacide oil (30, 60, 90, 120, and 180 mL plus 50, 100, 150, 200, and 300 mL codacide oil/ha) (= 3, 6, 9, 12, and 18 g a.i./ha) PMRA # 2070780	Parasitism rate was affected (>50%) at all dose rates 3 g a.i./ha: 100% ↓ reproduction 6 g a.i./ha: 100% ↓ reproduction 9 g a.i./ha: 98.9% ↓ reproduction 12 g a.i./ha: 99.1% ↓ reproduction 18 g a.i./ha: 90.7% ↓ reproduction	

Predatory mite *Typhlodromus pyri*	Field test on apple trees (99.6% *Typhlodromus pyri*, 0.4% *Euseius finlandicus*); Cyantraniliprole 100 g/L SE with codacide oil 2 × 1485 mL plus 2500 mL codacide oil/ha using a spray volume of 1100 L water/ha and 7day interval = 2 × 150 g a.i./ha PMRA # 2070781	Did not cause significant reduction in predatory mite population. Corrected mortality did not exceed 20.6% compared to control	
	Field test on grape vines 98.2% (*Kampimodromus aberrans*, 0.5% *Amblyseius andersonii*, 1.4% *Typhlodromus phialatus*) Cyantraniliprole 100 g/L SE plus codacide oil 2 × 1485 mL plus 2500 mL codacide oil/ha using a spray volume of 1100 L water/ha and 14 day interval = 2 × 150 g a.i./ha PMRA # 2070782	Did not cause significant reduction in predatory mite population. Corrected mortality did not exceed 19% compared to control	

Table 29 Summary of laboratory and higher Tier studies for pollinators.

Test material (dose used in study)	Oral LD_{50} (µg cyantraniliprole/ bee) (toxicity effects)	Contact LD_{50} (µg cyantraniliprole/bee) (toxicity effects)	Highest proposed Canadian application rate and crop	Formulation type	Reference (PMRA #)
Cyantraniliprole technical (oral: 0.0292, 0.0405, 0.510, 0.0703 and 0.1055 µg a.s./bee) (contact: 0.0243, 0.0340, 0.0477, 0.0667, and 0.0934 µg a.i./bee)	**>0.1055** (<2% mortality in all groups; 12% bees were apathetic in highest dose)	>0.0934 (34% mortality in highest dose)	N/A	Foliar Soil Seed	2070711
Cyantraniliprole 100 g/L OD (oral: 1.26, 2.72, 6.02, 13.6, and 29.1 µg Cyantraniliprole 100 g/L OD/bee (equivalent to 0.13, 0.28, 0.62, 1.40, and 3.0 µg a.i./bee)) (contact: 0.825, 1.84, 3.98, 8.83, and 19.4 µg Cyantraniliprole 100 g/L OD/bee (equivalent to 0.085, 0.19, 0.41, 0.91, and 2.0 µg a.i./bee))	0.39 (3.79 µg EP/bee) (87% mortality in highest test group)	0.65 (6.31 µg EP/bee) (77.8% mortality in highest test group)	Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola)	Foliar	2070710
Cyantraniliprole 200 g/L SC	0.404 (2.181 µg EP/bee) (77.6% mortality in highest test dose at 96 hours)	Not relevant since applied to soil (and ground dwelling bees not considered) 0.659 (3.558 µg EP/bee) (93% mortality in highest test dose at 96 hours)	Verimark Insecticide (Suspension Concentrate formulation) (In furrow rate of 200 g a.i./ha) In furrow and seed piece treatment use on fruiting veg, cucurbits	Soil	2070713
Cyantraniliprole 100 g/L SE (oral: 9.52, 18.09, 36.19, 71.43, 142.85, and 285.70 µg Cyantraniliprole 100 g/L SE/bee (equivalent to 1.0, 1.9, 3.8, 7.5, 15.0, and 30.0 µg a.i./bee)) (contact: 4.76, 9.52, 19.05, 38.09, 76.19, and 152.37 µg	0.92 (8.76 µg EP/bee) (92% mortality in highest test concentration at 72 and 96 hours)	2.78 (26.47 µg EP/bee) (94% mortality in highest test concentration at 96 hours)	Exirel Insecticide (Soluble Emulsion formulation). Foliar application by ground or air. 3 × 150 g a.i./ha for use on fruiting veg, cucurbits, pome, stone fruit, bushberries, tree nuts etc 3 × 150 g a.i./ha for use on greenhouse vegetables	Foliar	2070709

Test material (dose used in study)	Oral LD_{50} (µg cyantraniliprole/ bee) (toxicity effects)	Contact LD_{50} (µg cyantraniliprole/bee) (toxicity effects)	Highest proposed Canadian application rate and crop	Formulation type	Reference (PMRA #)
Cyantraniliprole 100 g/L SE/bee (equivalent to 0.5, 1.0, 2.0, 4.0, 8.0, and 16.0 µg a.i./bee))					
Cyantraniliprole with 100 g/L OD, and 100 g/L plus codacide oil, and 100 g/L SE, and 100 g/L SE + codacide oil, and only codacide oil (only 3 concentrations tested).	50% mortality with 100 g/L OD + codacide oil at highest concentration (0.4 µg a.i./bee), all other tests <20% mortality. No mortality with only codacide oil.	Results for highest concentration tested: 73% mortality for 100 g/L OD and 100 g/L OD + codacide oil; 100% mortality for 100 g/L SE and 10 g/L + codacide oil.	Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola) Label includes addition of mineral oil based adjuvant.	Foliar	2070704
Cyantraniliprole/thiamethoxam WG (A16901B) (oral: 0.014, 0.029, 0.049 and 0.051 µg EP/bee) (contact: 0.13, 0.25, 0.5, 1 and 2 µg product/bee)	**0.00639 µg a.s./bee** (0.031 µg EP/bee) (93% morality in highest test group at 24 and 48 hours) NOTE: oral LD_{50} for thiamethoxam is 0.005 µg a.i./ha	**0.0597 µg a.s./bee** (0.29 µg EP/bee) (100% mortality in highest test group. After 4 hours exposure, 86.7% mortality in highest test group.) NOTE: contact LD_{50} for thiamethoxam is 0.024 µg a.i./ha	A16901B WG Insecticide 759 g/ha/100 m row) Ground application (in furrow spray) use on fruiting veg, cucurbits Mainpring Insecticide (WG) Soil drench and foliar application (outdoor ornamental and greenhouse vegetables at 150 g a.i./ha; and soil drench at 0.375 g a.i./ha)	Soil Soil and foliar	2071403
IN-HGW87 (0.096, 0.172, 0.309, 0.556, 1.0, and 1.8 µg IN-HGW87/bee)	0.298 µg IN-HGW87/bee (97.9% mortality in highest test dose after 48 and 72 hours)	Not relevant, since they are transformation products translocated within plant.	(metabolite formed in plants)	Foliar Soil Seed (relevant for all application types since it is formed in plants)	2070706
IN-HGW87 (0.005, 0.009, 0.016, 0.029, and 0.053 µg IN-HGW87/bee)	>0.030[a] µg IN-HGW87/bee (0% mortality)		(metabolite formed in plants)	Foliar Soil Seed	2070707

Test material (dose used in study)	Oral LD_{50} (µg cyantraniliprole/ bee) (toxicity effects)	Contact LD_{50} (µg cyantraniliprole/bee) (toxicity effects)	Highest proposed Canadian application rate and crop	Formulation type	Reference (PMRA #)
				(relevant for all application types since it is formed in plants)	
IN-J9Z38 (one dose limit test) 9.25 ng IN-J9Z38/bee	>8.34 ng IN-J9Z38/bee (4% mortality after 24 and 48 hours)		(metabolite formed in plants and soil)	(formed in soil, relevant for soil application; and formed in plants, therefore relevant for all application types)	2070705
IN-K5A78 (3.125, 6.25, 12.5, 25 and 50 µg IN-K5A78/bee)	>45.61 µg IN-K5A78/bee		(metabolite formed in plants and soil)	(formed in soil, relevant for soil application; and formed in plants, therefore relevant for all application types)	2070708

Test material (dose used in study)	Oral LD_{50} (µg cyantraniliprole/ bee) (toxicity effects)	Contact LD_{50} (µg cyantraniliprole/bee) (toxicity effects)	Highest proposed Canadian application rate and crop		Formulation type	Reference (PMRA #)
Test item (application information)	**Highest proposed Canadian application rate and crop**	**Study type/species**	**Mortality**	**Behavioural effects**	**Comments from PMRA 2º review regarding study interpretation**	**Reference (PMRA #)**
Cyantraniliprole 100 g/L OD (1500 g Cyantraniliprole 100 g/L OD/ha (equivalent to 150 g cyantraniliprole a.i./ha))	Benevia Insecticide (Oil Dispersent formulation) (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola)	Extended Lab-Foliage residue toxicity test on Alfalfa/ *Apis mellifera*	No treatment related mortality during 24-hour exposure period	No treatment related behavioural abnormalities at 1- or 24-hour observation assessment	<13% mortality, no remarkable treatment related effects	2070762
Cyantraniliprole 100 g/L OD 200 g/L SC (chemigation: 3 × 100 g a.i./ha (SC) and spray (100 g/L OD with oil) at 3 × 100 g a.i./ha + codacide oil) before bees were foraging	Exirel Insecticide (Soluble Emulsion formulation) 3 × 150 g a.i./ha for use on fruiting veg, cucurbits, pome, stone fruit, bushberries, tree nuts etc 3 × 150 g a.i./ha for use on greenhouse vegetables	Extended Lab-Greenhouse study/*Bombus* sp.	* PMRA # 2070751			

*Different conclusion from secondary reviewer compared to study author.

Test item (Canadian rate for the EP formulation)	Rate(s) tested and timing	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Additional PMRA comments	Reference
Tier II Summary of honey bee semi-field trials							
Cyantraniliprole 100 g/L OD (Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups (including canola))	0.0954 L EP/ha (10 g a.s./ha) applied once after bee flight 0.954 L EP/ha (equivalent to 100 g a.s./ha) applied once after bee flight 0.0954 L EP/ha (10 g a.s./ha) applied once during bee flight 0.954 L EP/ha (equivalent to 100 g a.s./ha) applied once during bee flight	Semi-field/tunnel test/ wheat treated with sugar solution to simulate honeydew/ *A. m. mellifera*	A limited, short-term effect on mortality observed at both application rates, when applied during bee-flight. *	A limited, short-term effect on foraging activity observed at both application rates during and after bee flight.	Slight decrease in the number of brood combs and adult bee populations observed at both application rates during and after bee flight.	↓brood and size of adult population; paralyzed bees observed 1 day after application in all treatment groups.	PMRA # 2070760
	0.0954 L EP/ha (10 g a.s./ha) applied once after bee flight to the flowering crop 0.0954 L EP/ha (10 g a.s./ha) applied once during bee flight to the flowering crop 0.954 L EP/ha (equivalent to 100 g a.s./ha) applied once after bee flight to the flowering crop 0.954 L EP/ha (equivalent to 100 g a.s./ha) applied once during bee flight to the flowering crop	Semi-field/tunnel test/ *Phacelia tanacetifolia*/ *A. m. mellifera*	A limited, short-term effect on mortality observed at both application rates, when applied during bee-flight. No effect on mortality at lower rate when applied after bee-flight.	A limited, short-term effect on foraging activity observed at both application rates when applied during bee flight and after bee flight.	No difference between the amount of brood between treatments and control. No difference in bee populations between treatments and the control.	↑ adult mortality in most treatments for up to 2 days after application Additional note: Brood assessments were carried out until DAA+6.	PMRA # 2070761

Test item (Canadian rate for the EP formulation)	Rate(s) tested and timing	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Additional PMRA comments	Reference
Cyantraniliprole 100 g/L OD (only foliar uses are relevant to Canada)	4.5 L EP/ha applied once before sowing 4.5 L EP/ha applied once after sowing 4.5 L EP/ha applied once pre-flowering (foliar) 4.5 L EP/ha applied once during bee flight on the flowering crop	Semi-field/tunnel test/ *Phacelia tanacetifolia*/ *Apis mellifera carnica*	No significant increase in mortality when applied before and after sowing, and pre-flowering. Effect on honey bee mortality when applied during bee flight.	No effect on bee behaviour or flight when applied before and after sowing, and pre-flowering. An effect on honey bee behaviour and decreased flight intensity when applied during bee flight.	No impact to colony when applied before and after sowing, and pre-flowering. No impact on the colonies were observed when applications were made during bee flight.	No additional comments. Additional note: Brood assessments were carried out until DAA+21.	PMRA # 2070758
Cyantraniliprole 100 g/L OD (Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups ncluding canola))	95.4 mL EP/ha (10 g a.s./ha) once before flowering and once during flowering during bee flight 954 mL EP/ha (100 g a.s./ha) once before flowering and once during flowering during bee flight. Hives were moved in after 1st spray and 5 days after 2nd spray	Semi-field/tunnel test/ *Phacelia tanacetifolia*/ *A. m. carnica*	No significant impact on mortality with applications before flowering at two rates. An increase in mortality observed at highest rate during bee-flight.	Effect on flight activity was observed when applied during bee-flight at both rates. Both rates caused short lived intoxication symptoms.	No impact on brood development in either treatment at 2 application rates.	No additional comments.	PMRA # 2070759
	95.4 mL EP/ha (10 g a.s./ha) once before flowering and once during flowering during bee flight 954 mL EP/ha (100 g a.s./ha) once before flowering and once during flowering during bee flight	Semi-field/tunnel/ *Phacelia tanacetifolia/ Apis mellifera*	Not observed.*	No behavioural observations.*	No impact on brood development.	May have negative acute effects on foraging activity of honey bees immediately after application during bee flight, and on pollen and nectar stores. In a weight of evidence approach, the PMRA does not recommend that this trial have a large part in the risk assessment due to the poor health and performance of the	PMRA # 2070750

Test item (Canadian rate for the EP formulation)	Rate(s) tested and timing	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Additional PMRA comments	Reference
						control colony and the fact that this trial had no replication in the treatments tested.	
Cyantraniliprole 100 g/L OD plus codacide oil Benevia Insecticide (Label includes use of mineral oil based adjuvant)	1.5 L EP/ha (150 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight	Semi-field/tunnel test/ *Phacelia tanacetifolia/ Apis mellifera*	Short term effect on mortality up to 2 days for second application.*	Short term effect on behaviour. Reduced flight activity for up to 2 days following second application.	No effects on brood development.	↓foraging activity after application. Effects are not expected after 7 days of exposure. Spray application during pre-bloom had no short-term effect to bees.	PMRA # 2070716
	885.8 mL EP/ha (90 g a.s./ha) once before flowering and once during flowering after bee flight 885.8 mL EP/ha (90 g a.s./ha) plus 2.5 L codacide oil once before flowering and once during flowering after bee flight.	Semi-field/tunnel test/ *Phacelia tanacetifolia*/ *Apis mellifera*	Short term effect on mortality (1 day after 2nd application)*	No Short term effect on behavioural (flight) observations. Short term effect on foraging activity.	No impact on brood development.	Lack of appropriate controls (controls applied after flight) ↑transient mortality. Application before blooming had no effects. Application of Cyantraniliprole 100 g/L OD twice at a rate of 90 g a.i./ha with and without codacide oil had no remarkable difference on the effect to honey bees. However, both treatments increased the short-term adult mortality in 1 day after the 2nd spray application and decreased the foraging activity up to 2 days after the application. Such adverse effects were not detected after DAA+2. The 1st spray	PMRA # 2070746

Test item (Canadian rate for the EP formulation)	Rate(s) tested and timing	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Additional PMRA comments	Reference
						application during pre-bloom when bees were not foraging likely had no effect to bees.	
Cyantraniliprole 100 g/L SE and 100 g/L OD plus codacide oil Note: 100 g/L SE (Exirel Insecticide): Foliar application by ground or air. 3 × 150 g a.i./ha for use on fruiting veg, cucurbits, pome, stone fruit, bushberries, tree nuts etc 3 × 150 g a.i./ha for use on greenhouse vegetables	1.5 L EP[SE]/ha (150 g a.s./ha) plus 2.5 L codacide oil applied twice before flowering 1.5 L EP[OD]/ha (150 g a.s./ha) plus 2.5 L codacide oil applied twice before flowering	Semi-field/tunnel test/ *Brassica napus*/ *Apis mellifera carnica*	No effect on mortality with 2 applications applied before start of flowering in *Brassica napus* and before set-up of bee colonies.	No behavioural or flight activity effects with 2 applications before start of flowering in *B. napus* and before set-up of bee colonies.	No impact to brood development with 2 applications before start of flowering in *B. napus* and before set-up of bee colonies.	No additional comments.	PMRA # 2070749
Cyantraniliprole 100 g/L SE plus codacide oil Exirel Insecticide: Foliar application by ground or air. 3 × 150 g a.i./ha for use on fruiting	1.5 L EP/ha (150 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight	Semi-field/tunnel test/ Apple/ *Apis mellifera*	Short term increase in mortality during flowering after bee flight.*	Short term reduction in foraging activity during flowering after bee flight*	No effects on brood development.	Test colonies might be under stress during the test period, especially at the early exposure phase. Very low foraging activity prior to the 2nd application, reduction of larvae, eggs and total brood at	PMRA # 2070720

Test item (Canadian rate for the EP formulation)	Rate(s) tested and timing	Study type/ crop/species	Mortality	Flight activity and Behavioural effects	Impact on colonies	Additional PMRA comments	Reference
veg, cucurbits, pome, stone fruit, bushberries, tree nuts etc 3 × 150 g a.i./ha for use on greenhouse vegetables.						DAA +7, and high adult mortality in the controls were observed. No effects from pre-flowering.	
	980 mL EP/ha (100 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight	Semi-field/Tunnel test/ Nectarine/ *Apis mellifera*	Short term effect on mortality after 2nd application (on days 3, 5, 7).*	No behavioural abnormalities observed. No impact on flight activity.	No effects on brood development.	↑ mortality but did not reduce foraging; less brood cells at 7 days after application may indicate stress during exposure, but overall, no effect on brood development.	PMRA # 2070719
Cyantraniliprole 200 g/L SC		Semi-field residue trial/ tunnel test/Melon/ *Apis mellifera*	No effect on mortality with 3 applications at full flowering (melon), after bee-flight.	No behavioural impacts with 3 applications at full flowering (melon), after bee-flight. No impact on flight activity.	No impact on brood development with 3 applications at full flowering (melon), after bee-flight.		PMRA # 2070734
Cyantraniliprole 200 g/L SC Verimark Insecticide (Suspension Concentrate formulation) (In furrow rate of 200 g a.i./ha) In furrow and seed piece treatment use on fruiting veg, cucurbits		Semi-field/tunnel test/Melon/ *Apis mellifera*	No effect on mortality.	No behavioural impacts. No impact on flight activity.	May be some effects.* The reduction of colony strength in all hives during the entire study duration raises concerns about the quality of the test system and study conditions.	Lack of appropriate controls (test item applied after bee flight and controls applied during flight and different formulations (drip versus spray). Hive stress and a decrease in brood during exposure; ↓ colony strength	PMRA # 2070723

*Different conclusion from secondary reviewer compared to study author.

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
Cyantraniliprole 100 g/L OD (Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola))	tmt1: 1.5 L EP/ha (150 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once after flowering after bee flight tmt2: (12.5 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering during bee flight Residue results were not used for risk assessment.	Field/ *Brassica napus/ Apis mellifera carnica*	No impact on mortality as a result of the first application. Second applications after and during bee flight slightly increased mortality.*	No impact on flight activity or behaviour as a result of the first applications. Second applications after bee flight slightly reduced flight activity on the day following application. Second application during bee flight did not impact on flight activity. Some behavioural effects were seen after the second applications.	No effect on colony strength or brood developmen t.	The variation of the mortality and flight activity appeared to be high during the entire exposure period. Overall mortality and foraging activity in tmt1 and tmt2 during the entire exposure duration showed no remarkable treatment-related differences from the control. However, increase of short-term adult mortality was observed in tmt1 and tmt2 right after the 2nd spray application. A decrease of foraging activity right after the 2nd spray application was observed in tmt1 after the 2nd spray application. The potential treatment effect on such short-term changes can not be ruled out. Less effects were observed following "after foraging" exposure. Short-term brood effect was not observed. The following are observations from the study (1) No larvae or no brood at all was observed in two hives of each treatment (4tmt1, 6tmt1, 2tmt2 and 6tmt2) at DAA +124 and/or DAA+145, but no brood effect was shown in all control hives at all inspection dates prior to the overwintering; (2) in tmt1, egg laying and larva development were resumed at the next inspection date (DAA +145) after the disappearance of larvae at DAA+124, indicating queens were still laying eggs and not at the overwintering status. One hive in each tmt2 (2tmt2) and CK (5C) was found no brood after overwintering with very small number of adults, whereas other hives had large # of adults and brood. This may not be directly	PMRA # 2070754

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
						related to the treatment.	
Cyantraniliprole 100 g/L OD	1.5 L EP/ha (150 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight 0.125 L EP/ha (12.5 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering during bee flight Residues were not used in the risk assessment	Field/ *Brassica napus/ Apis mellifera carnica*	No impact on mortality as a result of the first applications. Second application of 150 g a.s./ha slightly increased mortality.	No impact on flight activity or behaviour as a result of the first applications. Second applications slightly reduced flight activity. Some behavioural effects were seen after the second applications.	No effect on colony strength or brood developmen t.	Zero eggs at some observation periods. Some brood and number of adults were lower before overwintering (but may not be treatment related). Some effects could be from varroa. Large variation in data. The variation of the mortality and flight activity appeared to be high during the entire exposure period. Overall mortality and foraging activity in tmt1 and tmt2 during the entire exposure duration showed no remarkable treatment-related differences from the control. Overall colony strength was similar between the control and treatment groups. Less effects were observed following “after foraging” exposure.	PMRA # 2070753

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
Cyantraniliprole 100 g/L OD (Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola))	1.5 L EP/ha (150 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight 0.125 L EP/ha (12.5 g a.s./ha) plus 2.5 L codacide oil applied once before flowering and once during flowering during bee flight	Field/ *Brassica napus/ Apis mellifera carnica*	Some potential short term mortality.*	Slight impact on flight activity after second application of 12.5 g a.s./ha. Flight activity was too consistently low in 150 g a.s./ha group to identify if an effect on flight activity had occurred. No effect on behaviour resulted from the first applications or second application of 12.5 g a.s./ha. The second application of 150 g a.s./ha had an effect on behaviour.	No effect on colony strength or brood developmen t.	Variation of the mortality and flight activity; ↑short-term adult mortality and foraging activity were observed in tmt1 and tmt2 right after the 2nd spray application. Hive death and decreased egg laying were found in all treatments and control. It is unknown whether there was treatment-related effect from the result of this study due to the poor hive conditions of the study. The variation of the mortality and flight activity appeared to be high during the entire exposure period. Overall mortality and foraging activity in tmt1 and tmt2 during the entire exposure duration showed no remarkable treatment-related differences from the control. However, increase of short-term adult mortality and foraging activity were observed in tmt1 and tmt2 right after the 2nd spray application on the same day. The potential treatment effect on such short-term changes can not be ruled out. First spray application appeared to have no effect on both adult mortality and foraging activity. Hive death and decreased egg laying were found in all treatments and control. It is unknown whether there was treatment-related effect from the result of this study due to the poor hive conditions of the study. Overall colony strength was similar between the control and treatment groups. Less effects were observed following "after foraging" exposure.	PMRA # 2070756

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
	90 g a.s./ha plus 2.5 L codacide oil applied once before flowering and once during flowering after bee flight. 90 g a.s./ha plus 2.5 L codacide oil applied once before flowering and once during flowering during bee flight. Note: exposure residue was measured 15 days after the 2nd spray application. Residues were not used in the risk assessment.	Field/ *Brassica napus/ Apis mellifera carnica*	No impact on mortality due to first applications or second application after bee flight. Impact on mortality due to second application during bee flight.	No impact on behaviour after first applications or second application after bee flight. Slight effect on behaviour after second application during bee flight. No impact on flight activity after first applications. Flight activity reduced for a few days after second applications.	No effect on colony strength or brood development.	Short term ↑ mortality, and ↓ foraging, decreased egg laying and some supercedures occurred. The variation of the mortality and flight activity appeared to be high during the entire exposure period. It appeared that tmt1 might have increased of adult mortality at DAA0, and decreased the foraging activity upto DAA +3. The tmt increased the adult mortality and decreased the foraging activity up to DAA+3 after the 2nd spray application. The first spray application appeared to have no effect on both adult mortality and foraging activity and adult behaviour. Queen supersedures (1 hives in tmt1, 2 hives in tmt2) and wax moth infestation were observed in both treatments. One queen supersedure was also observed in one control hive (5C). Overall colony strength was similar between the control and treatment groups. Less effects were observed following "after foraging" exposure.	PMRA # 2070757
Cyantraniliprole 100 g/L OD (Benevia Insecticide (Oil Dispersent formulation) Foliar application by ground or air. (3 × 150 g a.i./ha) for use on potatoes, 4 × 100 g a.i./ha for oilseed groups including canola))	90 g a.s./ha applied once before flowering and once during flowering after bee flight. 90 g a.s./ha applied once before flowering and once during flowering during bee flight. Residue results were not used in the risk assessment	Field/ *Brassica napus/ Apis mellifera carnica*	No impact on mortality due to first applications or second application after bee flight. Effect on mortality due to second application during bee flight.	No impact on flight activity due to first applications or second application after bee flight. No impact on or behaviour due to first applications. Slight impact on behaviour due to second application after bee flight. Slight impact on flight activity and	No effect on brood development due to applications after bee flight. No effect on colony strength due to applications after bee flight.	Effects on total number of brood; ↓ total number of brood cells. It appeared that tmt1 might have no remarkable effect on adult mortality but decreased the foraging activity upto DAA +2. tmt2 increased the adult mortality upto DAA+4 after the 2nd spray application and decreased the foraging activity for at least up to DAA+1. Less effects were observed following "after foraging" exposure. There was no flight activity during DAA+2 to +4 in all hives which	PMRA # 2070745

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
No brassica or melons on this label.				behaviour due to second application during bee flight.	Possible effect on overwintering capacity of colonies due to applications during bee flight, shown by lower mean colony strength after overwintering compared to control.	may contribute to unfavourable weather. The first spay application may have no remarkable effect on both adult mortality and foraging activity and adult behaviour. However, a slightly higher mortality was observed in tmt2 during DAA-8 to DAA-4. It is unknown if this was due to the unfavourable weather conditions, or the presence of residues detected in guttation liquid. This evaluated mortality was only observed in tmt2 not in tmt1 prior to the 2nd application. The control hives had stronger queens than in tmt1 and tmt2. Supersedure and queen replacement/insertion were required in both treatments (one queen insertion and one supersedure for each treatment of tmt1 and tmt2. but none for the control). The total # of brood cells in both treatments were lower when compared to the control for up to DAA+28. All hives appeared strong at the end of study (DAA+140). Some infestation with varrora mites were observed but detail level of infestation was not provided.	
	90 g a.s./ha plus 2.5 L codacide oil applied once at the beginning of flowering and once during full flowering after bee flight 90 g a.s./ha plus 2.5 L codacide oil applied once at the beginning of flowering and once	Field/ Melon/ *Apis mellifera*	No impact on mortality after first or second applications after bee flight. Slight impact on mortality after first application during bee flight. No impact on	No apparent effect on flight activity after first or second applications after bee flight. Possible effect on flight activity after first application during bee flight, by comparison to pre-application levels, but not compared	Some potential effects on brood – see next column for further data	Limited use because of low exposure to treated crops. Note: <1% of melon pollen in both treatments and 0% in the control. In honey stomach of forager bees, there was <1% of melon pollen in treatment and control in most of measuring dates except in tmt2, it reached up to 13% on DAA+2 Some intoxication symptoms (cramping) observed day after 2nd treatment, ↓ foraging in treatments	PMRA # 2150130

Tier III Summary of honey bee field trials							
Test item (Canadian rate for the EP formulation)	**Rate(s) tested and timing**	**Study type/ crop/species**	**Mortality**	**Flight activity and Behavioural effects**	**Impact on colonies**	**Additional PMRA comments**	**Reference**
	during full flowering during bee flight		mortality after second application during bee flight.	to the control. No apparent effect on flight activity after second application during flowering. Noted that control flight activity was very low. No behavioural effects seen after applications after bee flight. First application during bee flight had impact on behaviour, whereas second application during bee flight had no impact.		and control. Colony strength decreased during the exposure phase but increased after exposure at the monitoring site, which may indicate poor nutrient/condition for hive	

*Different (additional) conclusion from secondary reviewer compared to study author.

Table 30 Tier I risk for contact exposure from foliar application to forager bees.

Chemical	Max single application rate (EEC)	Koch and Weiber (adjustment factor)	Exposure* (EEC)	Toxicity endpoint	RQs (EEC/toxicity endpoint)	LOC exceeded?
	kg a.i./ha	µg a.i./bee per kg a.i./ha	µg a.i./bee	µg a.i./bee		
Technical Grade Active Ingredient						
Cyantraniliprole**	0.150	2.4	0.36	>0.0934	<3.9	YES
thiamethoxam	0.150	2.4	0.36	0.024	15	YES
End-Use Products						
100 g/L OD formulation (Benevia insecticide)	0.150	2.4	0.36	0.65	0.55	YES
100 g/L SE formulation (Exirel insecticide)	0.150	2.4	0.36	2.78	0.13	No
Cyantraniliprole/thiamethoxam WG (A16901B) formulation	0.150	2.4	0.36	0.0597	6.0	YES

*Exposure= application rate (kg a.i./ha) × adjustment factor (2.4 µg a.i./bee per kg a.i./ha)
**The screening level assessment considered the lowest endpoint (>0.0934 µg a.i./bee) but since it was a greater than value, additional endpoints were also considered.
Note: The single highest application rate is the same for all three end-use products (150 g a.i./ha × 1)
LOC for bee is set at 0.4, and is based on the historic average dose-response relationship for acute toxicity studies with bees and a 10% mortality level.

Table31 Refined Tier I dietary risk assessment for forager and nurse bees using maximum reported concentrations in pollen and nectar (excluding larvae).

		nectar consumption[d]	Highest nectar residue (mg/kg)	pollen consumption[d]	Highest pollen residue (mg/kg)	nectar exposure +	pollen exposure +	Total exposure ++	Oral toxicity endpoint	RQs (EEC/tox)	LOC exceeded?
Cyantraniliprole											
Caste of bees	Type of bees	mg/day	(Citrus 100 g/L SE + oil 1 × 150 (pre flowering))	mg/day	(sunflower 100 g/L OD 3 × 150 (pre flowering))			µg/bee/day	µg/bee/day		
Adults	forager-nectar	292	0.837	0.041	4.35	0.244	0.000178	0.245	>0.105	<2.3	Unknown (potentially)
	Nurse bees [a]	167	0.837	6.5	4.35	0.140	0.0283	0.168	>0.105	<1.6	Unknown (potentially)

		nectar consumption[d]	Highest nectar residue (mg/kg)	pollen consumption [d]	Highest pollen residue (mg/kg)	nectar exposure +	pollen exposure +	Total exposure ++	Oral toxicity endpoint	RQs (EEC/tox)	LOC exceeded?
	Nurse bees [b]	140	0.837	8.85	4.35	0.117	0.0385	0.155	>0.105	<1.5	Unknown (potentially)
End-use product toxicity data											
Cyantraniliprole 100 g/L OD formulation											
Adults	forager-nectar	292	0.837	0.041	4.35	0.244	0.000178	0.245	0.39	0.63	YES
	Nurse bees [a]	167	0.837	6.5	4.35	0.140	0.0283	0.168	0.39	0.43	YES
	Nurse bees [b]	140	0.837	8.85	4.35	0.117	0.0385	0.155	0.39	0.40	YES
Cyantraniliprole 100 g/L SE formulation											
Adults	forager-nectar	292	0.837	0.041	4.35	0.244	0.000178	0.245	0.92	0.27	No
	Nurse bees [a]	167	0.837	6.5	4.35	0.140	0.0283	0.168	0.92	0.18	No
	Nurse bees [b]	140	0.837	8.85	4.35	0.117	0.0385	0.155	0.92	0.17	No
Cyantraniliprole 200 g/L SC formulation (soil formulation)											
Adults	forager-nectar	292	0.837	0.041	4.35	0.244	0.000178	0.245	0.404	0.61	YES
	Nurse bees [a]	167	0.837	6.5	4.35	0.140	0.0283	0.168	0.404	0.42	No
	Nurse bees [b]	140	0.837	8.85	4.35	0.117	0.0385	0.155	0.404	0.38	No
IN-HGW87 transformation product											
Caste of bees	Type of bees	mg/day	LOQ	mg/day	(Zucchini 100 g/L OD soil 1 × 150 (pre flowering))	**nectar exposur e+**	**pollen exposure +**	**Total exposure ++**	**Oral toxicity endpoint**	**RQs (EEC/tox)**	**LOC exceeded?**
Adults	forager-nectar	292	0.005**	0.041	0.074	0.00146	0.0000030	0.00146	0.298	0.005	No
	Nurse bees [a]	167	0.005**	6.5	0.074	0.00083 5	0.00048	0.0013	0.298	0.004	No
	Nurse bees [b]	140	0.005**	8.85	0.074	0.0007	0.00065	0.0014	0.298	0.005	No

		nectar consumption[d]	Highest nectar residue (mg/kg)	pollen consumption [d]	Highest pollen residue (mg/kg)	nectar exposure +	pollen exposure +	Total exposure ++	Oral toxicity endpoint	RQs (EEC/tox)	LOC exceeded?
IN-J9Z38 transformation product											
Caste of bees	Type of bees	mg/day	(Citrus 100 g/L SE + oil 1 × 150 (pre flowering))	mg/day	(Oilseed rape 100 g/L SE 2 × 150 + oil (pre and flowering))	**nectar exposure+**	**pollen exposure +**	**Total exposure ++**	**Oral toxicity endpoint**	**RQs (EEC/tox)**	**LOC exceeded?**
Adults	forager-nectar	292	0.0125	0.041	0.0394	0.00365	1.6e-06	0.0037	>0.00834	<0.44	Unknown (potentially)
	Nurse bees [a]	167	0.0125	6.5	0.0394	0.0021	0.00026	0.002	>0.00834	<0.28	No
	Nurse bees [b]	140	0.0125	8.85	0.0394	0.0018	0.35	0.00035	>0.00834	<0.042	No
Thiamethoxam/cyantraniliprole product											
Caste of bees	Type of bees	mg/day	Using maximum cyantraniliprole residues	mg/day	Using maximum cyantraniliprole residues	**nectar exposure+**	**pollen exposure +**	**Total exposure ++**	**Oral toxicity endpoint**	**RQs (EEC/ tox)**	**LOC exceeded?**
Adults	forager-nectar	292	0.837	0.041	4.35	0.244	0.000178	0.245	0.00639 [c]	38	YES
	Nurse bees [a]	167		6.5		0.140	0.028	0.168	0.00639 [c]	26	YES
	Nurse bees [b]	140	0.837	8.85	4.35	0.117	0.0385	0.155	0.00639 [c]	24	YES

[a] Consumption rates adjusted to account for 50 g of sugar consumption per day and the 6.5 mg pollen consumption per day for nurse bees is from Rortais et al., assuming 30% of sugar content in nectar.
[b] Consumption rates from content presented in the White Paper in Support of the Proposed Risk Assessment Process for Bees
Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11 – 14, 2012.
[c] Toxicity endpoint from Mainspring insecticide (containing 20% each of thiamethoxam and cyantraniliprole)
[d] Consumption rates from Rortais et al. 2005.
+ Highest residue in nectar among all crops (equivalent to nectar consumption rate × nectar residues/1000); Highest residue in pollen among all crops (equivalent to pollen consumption rate × pollen residues/1000)
++ Total exposure is equal to nectar + pollen residues

Table 32 Effects on aquatic organisms (screening level assessment)

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
Daphnia	48 h acute TGAI* PMRA # 2070668	EC_{50} (immobility): 0.0102 mg/L (=0.0204 mg/L/2)	0.055 mg/L	5.4	YES
			Considering in furrow Verimark EP: 0.034 mg/L	3.3	YES
	21 day chronic TGAI PMRA # 2070689	NOEC (body length): 0.0065 mg/L	0.055 mg/L	8.5	YES
			Considering in furrow Verimark EP: 0.034 mg/L	5.2	YES
Mayfly	48 h acute TGAI PMRA # 2070680	LC_{50}: 0.036 mg/L (=0.0715 mg/L/2)	0.055 mg/L	1.5	YES
			Considering in furrow Verimark EP: 0.034 mg/L	0.94	No
Caddisfly	48 h acute TGAI PMRA # 2070681	LC_{50}: 0.0374 mg/L (=0.0748 mg/L/2)	0.055 mg/L	1.5	YES
			Considering in furrow Verimark EP: 0.034 mg/L	0.91	No
Stonefly	48 h acute TGAI PMRA # 2070679	LC_{50}: 7.0 mg/L (=14.0 mg/L/2)	0.055 mg/L	0.008	No
Gammarus pseudolimnaeus	48 h acute TGAI PMRA # 2070684	LC_{50}: 0.086 mg/L (=0.172 mg/L/2)	0.055 mg/L	0.63	No
Hyalella azteca	48 h acute TGAI PMRA # 2070683	LC_{50}: > 0.685 mg/L (=> 1.37mg/L/2)	0.055 mg/L	0.080	No
Ceriodaphnia dubia	7 day chronic (including 48 h) TGAI PMRA # 2070690	48 h LC_{50}: 0.02 mg/L (=0.04 mg/L/2) 7 day NOEC (adult survival): 0.005 mg/L	0.055 mg/L	2.8	YES
			Considering in furrow Verimark EP: 0.034 mg/L	1.7	YES
crayfish (Procambarus clarkii)	48 hour acute (static renewal) TGAI PMRA # 2070687	48 h LC_{50}: 2 mg a.i./L (=4 mg ai/L/2)	0.055 mg/L	0.028	No
Daphnia	48 h acute Cyantraniliprole 100 g/L OD PMRA # 2070514	EC_{50} (immobility): 0.0047 mg a.i./L (=0.0094 mg a.i./L/2) (0.126 mg cyantraniliprole 100 g/L OD/L)	0.055 mg/L	11.7	YES
	48 h acute Cyantraniliprole 100 g/L OD with codacide oil PMRA # 2070515	EC_{50} (immobility): 0.009 mg a.i./L (=0.018 mg a.i./L/2) (0.215 mg cyantraniliprole 100 g/L OD with oil/L)	0.055 mg/L	6.1	YES

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
	48 h acute Cyantraniliprole 100 g/L SE PMRA # 2070860	EC_{50} (immobility): 0.0116 mg a.i./L (=0.0232 mg a.i./L/2) (0.232 mg cyantraniliprole 100 g/L SE/L)	0.055 mg/L	4.7	YES
	48 h acute Cyantraniliprole 200 g/L SC PMRA # 2070309	EC_{50} (immobility): 0.0073 mg a.i./L (=0.0145 mg a.i./L/2) (0.0724 mg cyantraniliprole 200 g/L SC/L)	0.034 mg/L	4.7	YES
	48 h acute Cyantraniliprole/ thiamethoxam WG A16901B PMRA # 2071316	EC_{50} (immobility): 0.0054 mg a.i./L (=0.0108 mg a.i./L/2)	0.019 mg/L	3.5	YES
Daphnia	48 h acute IN-RNU71 PMRA # 2070677	EC_{50} (immobility):>1.35 mg IN-RNU71/L (>2.7 mg IN-RNU71/L/2)	0.052 mg/L	0.039	No
	48 h acute IN-JCZ38 PMRA # 2070672	EC_{50} (immobility): 0.925 mg IN-JCZ38/L (=1.85 mg IN-JCZ38/L/2)	0.0458 mg/L	0.046	No
	21 day chronic IN-J9Z38 PMRA # 2070691	NOEC (survival, growth and reproduction): 0.24 mg IN-J9Z38/L (highest concentration tested)	0.053 mg/L	0.22	No
	48 h acute IN-JSE76 PMRA #2070670	EC_{50} (immobility): 11.23 mg IN-JSE76/L (=22.46 mg IN-JSE76/L/2)	0.058 mg/L	0.005	No
	48 h acute IN-K5A77 PMRA # 2070676	EC_{50} (immobility): >0.425 mg IN-K5A77/L (=>0.85 mg IN-K5A77/L/2)	Minor TP (no EEC calculated) Using parent as approximation: 0.055 mg/L	0.13	No
	21 day chronic IN-K5A77	NOEC (body length): 0.117 mg IN-K5A77/L	Minor TP (no EEC calculated) Using parent as approximation: 0.055 mg/L	0.47	No

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
	48 h acute IN-K5A78 PMRA # 2070674	EC_{50} (immobility): >15.7 mg IN-K5A78/L/ (=>31.39 mg IN-K5A78/L/2)	0.056 mg/L	0.0036	No
	48 h acute IN-K5A79 PMRA # 2070673	EC_{50} (immobility): >15.8 mg IN-K5A79/L (=>31.57 mg IN-K5A79/L/2)	Minor TP (no EEC calculated) Using parent as approximation: 0.055 mg/L	0.0035	No
	48 h acute IN-NXX70 PMRA # 2070669	EC_{50} (immobility): >0.092 mg IN-NXX70/L (=>0.184 mg IN-NXX70/L/2)	0.018 mg/L	0.20	No
	48 h acute IN-PLT97 PMRA # 2070671	$EC5_0$ (immobility): 0.2 mg IN-PLT97/L (=0.40 mg IN-PLT97/L/2)	0.055 mg/L	0.28	No
	48 h acute IN-QKV54 PMRA # 2070667	EC_{50} (immobility): >0.14 mg IN-QKV54/L (=>0.287 mg IN-QKV54/L/2)	0.04 mg/L	0.29	No
Chironomus riparius	48 h acute TGAI PMRA #2070700	LC_{50}: 0.36 mg/L (=0.719 mg/L/2)	0.055 mg/L	0.15	No
	21 day chronic with spiked water TGAI PMRA # 2070701	**NOEC 0.01 mg a.i./L** (Overlying Water) LOEC: 0.01 mg a.i./L (Overlying Water) EC_{50} > 0.010 mg a.i./L (Overlying Water) (Impacts on emergence)	0.055 mg/L	5.5	YES
	21 day chronic with spiked sediment TGAI PMRA # 2070702	EC_{50} > 0.0095 mg/kg dry sediment (=>0.0190 mg/kg dry sediment/2) NOEC: 0.0190 mg/kg dry sediment	Not calculated	Unknown	Unknown

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
	Chronic study with thiamethoxam (ERC2007-01)	NOEC: 0.005 mg a.i./L*	0.019 mg/L	3.8	YES
Freshwater midge	Chronic study with thiamethoxam (ERC2007-01)	NOEC: 0.01 mg a.i./L	0.019 mg/L	3.0	YES
Lumbriculus variegatus	48 h acute TGAI PMRA # 2070699	$LC_{50:}$ >6.9 mg a.i./L (=>13.7mg/L/2) based on mean measured concentrations (limit of solubility)	0.055 mg/L	0.0080	No
Rainbow trout, *Oncorhynchus mykiss*	96 h acute static TGAI PMRA # 2070660	LC_{50}:1.26 mg a.i./L (>12.6 mg/L/10) mean measured (limit of solubility) NOEC: 12.6 mg/L	0.055 mg/L	0.04	No
	Chronic – Early life stage (90 days) TGAI PMRA # 2070664	NOEC: 10.7 mg a.i./L)	0.055 mg/L	0.0051	No
Bluegill sunfish, *Lepomis macrochirus*	96 h acute static-renewal TGAI PMRA # 2070661	LC_{50}>1.3 mg a.i./L (=>13 mg/L/10) mean measured (limit of solubility) NOEC: 13 mg/L	0.055 mg/L	0.042	No
Channel catfish *Ictalurus punctatus*	96 h acute flow through TGAI PMRA # 2070662	LC_{50}>1 mg a.i./L (=>10 mg/L/10) mean measured (limit of solubility) NOEC: 10 mg/L	0.055 mg/L	0.055	No
Amphibian+	96 h acute flow through TGAI	LC_{50}>1 mg a.i./L mean measured (limit of solubility) (>10 mg/L÷10)	15 cm depth: 0.29 mg/L	0.29	No
Amphibian+	Chronic – Early life stage (90 days) TGAI	NOEC (based on length of fish): (1.01 mg a.i./L)	15 cm depth: 0.29 mg/L	0.29	No

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
Pseudokirchneriella subcapitata	72 hour Cyantraniliprole 100 g/L OD PMRA # 2070517	72-h E_bC_{50} (cell density) = 0.59 mg/L 72-h E_bC_{50} (cell density) = (=1.18 mg a.i./L/2) (=11.4 mg Cyantraniliprole 100 g/L OD/L) (0.824 – 1.69) mg a.i./L NOEC: 0.295 mg a.i./L (Geo-mean measured concentrations)	0.055 mg/L	0.093	No
	72 hour Cyantraniliprole 100 g/L SE PMRA # 2070861	72-h E_bC_{50} (cell density) = 0.413 mg/L 72-h E_bC_{50} (cell density) = (=0.825 mg a.i./L/2) (0.583 – 1.17) mg a.i./L NOEC: 0.217 mg a.i./L (Geo-mean measured concentrations)	0.055 mg/L	0.13	No
	72 hour Cyantraniliprole 200 g/L SC PMRA # 2070310	72-h E_bC_{50} (cell density) = 3.7 mg/L 72-h E_bC_{50} (cell density) = (=7.37 mg a.i./L/2) (=39.4 mg Cyantraniliprole 200 g/L SC/L) (5.28 – 10.3) mg a.i./L Cyantraniliprole 200 g/L SC/L)	0.034 mg/L	0.009	No
	72 hour Cyantraniliprole/ Thiamethoxam WG A16901B (20% TGAI each) PMRA # 2071402	72-h E_bC_{50} (cell density) : 4.9 mg a.i./L 72-h E_bC_{50} (cell density) : (=9.8 mg a.i./L/2) (=49 mg EP/L)	0.019 mg/L	0.004	No
Duckweed *(Lemna gibba)*	Acute TGAI PMRA # 2070703	EC_{50} endpoints (all parameters): >6.05 mg a.i./L (=>12.1 mg a.i./L/2)	0.055 mg/L	0.009	No
Diatom *(Navicula pelliculosa)*	96 hour acute TGAI PMRA # 2070698	EC_{50} (density and growth rate): >7 mg a.i./L (=> 14 mg a.i./L/2)	0.055 mg/L	0.008	No
Mysid shrimp (*Americamysis bahia)*	96 hour acute (flow through) TGAI PMRA # 2070685	96-hour LC_{50} = 0.6 mg/L (=1.2 mg a.i./L/2) (based on mean measured concentrations and mortality) NOEC (mortality): 0.37 mg/L	0.055 mg/L	0.09	No

Organism	Exposure PMRA number	Endpoint value	EEC (mg/L) (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
Eastern oyster *(Crassostrea virginica*)	Acute TGAI PMRA # 2070688	96-hour EC_{50} = 0.225 mg/L (=0.45 mg a.i./L/2) (based on mean measured concentrations and inhibition of shell growth)	0.055 mg/L	0.24	No
Diatom *(Skeletonema costatum)*	72 hour PMRA # 2070696	72-h $E_bC_{50\ density}$ =1.6 mg a.i./L (=3.2 mg a.i./L/2), 72-h $E_rC_{50growth}$: > 10 mg a.i./L	0.055 mg/L	0.034	No
Sheepshead minnow	Acute 96 hour flow through PMRA # 2070663	LC_{50}: >1.2 mg/L (=>12 mg/L/10)	0.055 mg/L	0.046	No
	Early life stage PMRA # 2070665	NOEC (based on fish length): 2.9 mg a.i./L (mean measured concentration).	0.055 mg/L	0.019	No

a Based on United States Environmental Protection Agency classification scheme
+ using most sensitive endpoint from fish acute and chronic studies.
* TGAI = Technical grade active ingredient
Shaded cells indicate that the level of concern is exceeded.

Table 33 Effects on aquatic organisms (refined level assessment)

Organism	Exposure	Endpoint value	EEC (mg/L)* (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
Daphnia	48 h acute TGAI	EC_{50} (immobility): 0.0102 mg/L (=0.0204 mg/L/2) (10% immobility at 0.0149 mg/L and 95% immobility at 0.031 mg/L)	Refined with drift for orchard use (74%) = 0.041 mg/L	4.0	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	3.1	YES
			Refined with drift for field use (11%) = 0.0061 mg/L	0.60	No
			Refined with drift for field use (26%) = 0.014 mg/L	1.4	YES
			Refined with runoff EECs 0.017 mg/L (peak value)	1.7	YES
			Refined with run-off for in-furrow use (Verimark insecticide)=0.014 mg/L	1.4	YES
	21 day chronic TGAI	NOEC (body length): 0.0065 mg/L EC_{50} (adult survival): 0.056 mg/L (=0.1123 mg/L/2)	Refined with drift for orchard use (74%) = 0.041 mg/L	6.3	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	4.9	YES
			Refined with drift for field use (26%) = 0.014 mg/L	2.2	YES
			Refined with drift for field use (11%) = 0.0061 mg/L	0.94	No
			Refined with runoff EECs 0.017 mg/L (peak value)	2.6	YES
			Refined with run-off for in-furrow use (Verimark insecticide)= 0.014 mg/L	2.2	YES
Mayfly	48 h acute TGAI	LC_{50}: 0.036 mg/L (=0.0715 mg/L/2) (45% immobility at 0.0724 mg/L and 95% immobility at 0.145 mg/L)	Refined with drift for orchard use (74%) = 0.041 mg/L	1.1	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	0.89	No
			Refined with drift for field use (11%) = 0.0061 mg/L	0.17	No
			Refined with runoff EECs 0.017 mg/L (peak value)	0.47	No
			Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	0.39	No
Caddisfly	48 h acute TGAI	LC_{50}: 0.0374 mg/L (=0.0748 mg/L/2) (53% immobility at 0.0724 mg/L and 93% immobility at 0.155 mg/L)	Refined with drift for orchard use (74%) = 0.041 mg/L	1.1	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	0.86	No
			Refined with drift for field use (11%) = 0.0061 mg/L	0.16	No
			Refined with runoff EECs 0.017 mg/L (peak value)	0.45	No
			Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	0.37	No

Organism	Exposure	Endpoint value	EEC (mg/L)* (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
Ceriodaphnia dubia	7 day chronic (including 48 h) TGAI	48 hr LC_{50}: 0.02 mg/L (=0.04 mg/L/2) 7 day NOEC (adult survival): 0.005 mg/L	Refined with drift for orchard use (74%) = 0.041 mg/L	2.1	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	1.6	YES
			Refined with drift for field use (11%) = 0.0061 mg/L	0.30	No
			Refined with runoff EECs 0.017 mg/L (peak value)	0.85	No
			Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	0.70	No
Daphnia	48 h acute Cyantraniliprole 100 g/L OD	EC_{50} (immobility): 0.0047 mg/L (=0.0094 mg/L/2) (0.126 mg cyantraniliprole 100 g/L OD/L)	Refined with drift for field use (11%) = 0.0061 mg/L	1.3	YES
			Refined with drift for field use (26%) = 0.014 mg/L	2.9	YES
			Refined with runoff EECs 0.017 mg/L (peak value)	3.6	YES
	48 h acute Cyantraniliprole 100 g/L OD with codacide oil	EC_{50} (immobility): 0.009 mg/L) (=0.018 mg/L/2) (0.215 mg cyantraniliprole 100 g/L OD with oil/L)	Refined with drift for field use (11%) = 0.0061 mg/L	0.68	No
			Refined with drift for field use (26%) = 0.014 mg/L	1.6	YES
			Refined with runoff EECs 0.017 mg/L (peak value)	1.9	YES
	48 h acute Cyantraniliprole 100 g/L SE	EC_{50} (immobility): 0.0116 mg/L (=0.0232 mg/L/2) (0.232 mg cyantraniliprole 100 g/L SE/L)	Refined with drift for orchard use (74%) = 0.041 mg/L	3.5	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	2.8	YES
			Refined with drift for field use (26%) = 0.014 mg/L	1.2	YES
			Refined with runoff EECs 0.017 mg/L (peak value)	1.5	YES
	48 h acute Cyantraniliprole 200 g/L SC	EC_{50} (immobility): 0.0073 mg/L (=0.0145 mg/L/2) (0.0724 mg cyantraniliprole 200 g/L SC/L)	Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	1.9	YES
	48 h acute Cyantraniliprole/ thiamethoxam WG A16901B	EC_{50} (immobility): 0.0054 mg/L (=0.027 mg × (0.4) = 0.0108 EP/L/2) (40% immobility at 0.03 mg EP/L) and 100% immobility at 0.25 mg EP/L)	Refine with drift for field use (outdoor ornamentals) = 0.019 mg/L × 11% = 0.0021 mg a.i./L	0.39	No
			Refined with run-off for Verimark insecticide as conservative exposure (1 × 300 g a.i./ha) = 0.014 mg/L	2.6	YES
Chironomus riparius	21 day chronic with spiked water TGAI	NOEC >0.01 mg a.i./L (Overlying Water) LOEC: 0.01 mg a.i./L (Overlying Water) EC_{50} > 0.010 mg a.i./L (Overlying Water) (Effects on emergence)	Refined with drift for orchard use (74%) = 0.041 mg/L	4.1	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	3.2	YES
			Refined with drift for field use (26%) = 0.014 mg/L	1.4	YES
			Refined with drift for field use (11%) = 0.0061 mg/L	0.61	No
			Refined with runoff EECs 0.017 mg/L (peak value for water column)	1.7	YES

Organism	Exposure	Endpoint value	EEC (mg/L)* (in 80 cm unless otherwise stated)	RQ (EEC/ endpoint)	LOC exceeded?
			Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	0.61	No
	21 day chronic with spiked sediment TGAI	EC_{50} > 0.0095 mg/kg dry sediment (=>0.0190 mg/kg dry sediment/2) NOEC: 0.0190 mg/kg dry sediment	Sediment concentration= (K_{oc} × organic carbon/100) × pore water EEC =(151.4 × 0.016/100) × 0.0041 mg/L = 0.000099 mg/kg sediment	0.01	No
	Chronic study with thiamethoxam (ERC2007-01)	NOEC: 0.005 mg a.i./L	Refined with drift for field use (11%) = 0.0021 mg/L	0.42	No
SSD5 (for all aquatic organisms)**		HC_5: 0.0108 mg/L	Refined with drift for orchard use (74%) = 0.041 mg/L	3.3	YES
			Refined with drift for orchard use (59%) = 0.032 mg/L	2.6	YES
			Refined with drift for field use (26%) = 0.014 mg/L	1.1	YES
			Refined with drift for field use (11%) = 0.0061 mg/L	0.50	No
			Refined with runoff EECs 0.017 mg/L (peak value)	1.4	YES
			Refined with run-off for in-furrow use (Verimark insecticide) = 0.014 mg/L	1.1	YES

*EECs for run-off calculated using 3 × 150 g a.i./ha Exirel and Benevia rate for TGAI studies, unless otherwise stated.
** The following aquatic organisms were included in the SSD5 (HC_5) calculation:
For end-use products (converted to TGAI), daphnia exposed to Cyantraniliprole 100 g/L OD, 100 g/L OD with codacide oil, 100 g/L SE, 200 g/L SC and Cyantraniliprole/thiamethoxam;
For TGAI daphnia, mayfly, caddisfly, stonefly, *Gammarus, Hyalella*, *ceriodaphnia*, crayfish, chironomid, midge, and *lumbriculus*.
Note: The HC_5 value was used for buffer zone calculations for all end-use products.
Shaded cells indicate that the level of concern is exceeded.

Table 34 Proposed and Acceptable Label Claims

Claims proposed by applicant	Accepted claims
DUPONT VERIMARK INSECTICIDE (200 g cyantraniliprole/L)	
Potato	
Pests: Colorado potato beetle, Potato flea beetle, **Rate:** 9 mL product/100 m row in-furrow (1000 mL product/ha) OR 45 mL product/100 kg seed pieces (100 mL product/ha)	**Pests:** Colorado potato beetle, Potato flea beetle (early season control of spring adults) **Rate:** 6.75–9 mL product/100 m row in-furrow (750–1000 mL product/ha) OR 45 mL product/100 kg seed pieces (1000 mL product/ha)
Crop Group 5 – Brassica Vegetables	
Pests: Cabbage looper, Diamondback moth, Imported cabbageworm, Flea beetles, Swede midge **Rate:** 750–1000 mL product/ha	**Pest:** Control of Cabbage looper, Diamondback moth and Imported cabbageworm; Reduction of early season damage caused by Flea beetles and Swede midge **Rate:** 750–1000 mL product/ha
DUPONT BENEVIA INSECTICIDE (100 g cyantraniliprole/L)	
Potato	

Claims proposed by applicant	Accepted claims
Pest: Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** 7–14 days
Pests: European corn borer, Variegated cutworm **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days	**Accepted as proposed**
Pests: Potato aphid (suppression), green peach aphid **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Aphids **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
Crop Subgroup 20 – Oilseeds	
Pest: Diamondback moth **Rate:** 125–250 mL product/ha **Reapplication Interval:** Minimum 7 days	**Pest:** Diamondback moth **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
0Pest: Bertha armyworm **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days	**Pest:** Bertha armyworm **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Cabbage looper, Imported cabbageworm **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 7 days	**Pests:** Cabbage looper, Imported cabbageworm **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Cutworms, Sunflower head moth, Swede midge **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days	**Pests:** Sunflower head moth **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pests: Cutworms, Swede midge **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days
Pest: Cabbage seedpod weevil **Rate:** 500–1000 mL product/ha **Reapplication Interval:** Minimum 7 days	**Accepted as proposed**
DUPONT LUMIDERM INSECTICIDE SEED TREATMENT (625 g cyantraniliprole/L)	
Canola, Rapeseed and Oilseed Mustard	
Pests: Flea beetles and Cutworms (early season) **Rate:** 960–1600 mL product/100 kg seed	**Pests:** Early season protection from Flea beetle feeding damage **Rate:** 960–1600 mL product/100 kg seed
Pest: Cutworms (early season) **Rate:** 240–960 mL product/100 kg seed	**Pest:** Early season protection from Cutworm feeding damage **Rate:** 480–960 mL product/100 kg seed
DUPONT EXIREL INSECTICIDE (100 g cyantraniliprole/L)	
Crop Subgroup 1C – Tuberous and Corm Vegetables	
Pest: Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** 7–14 days
Pest: Diamondback moth **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Cabbage looper **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: European corn borer, Variegated cutworm, Tobacco hornworm, Tomato hornworm, Armyworm, Fall armyworm, Beet armyworm, Corn earworm **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** European corn borer **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days
	Pest: Variegated cutworm **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pests: Corn earworm; Suppression of Tobacco and Tomato hornworms **Rate:** 750 mL product/ha

<table>
<tr><th>Claims proposed by applicant</th><th>Accepted claims</th></tr>
<tr><td rowspan="2"></td><td>Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pests: Armyworm, Fall armyworm, Beet armyworm
Rate: 500 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pest: Green peach aphid
Rate: 500–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td rowspan="2">Pests: Aphids
Rate: 500–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td></tr>
<tr><td>Pest: Potato aphid
Rate: 750–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td></tr>
<tr><td colspan="2">Crop Group 3-07 – Bulb Vegetables</td></tr>
<tr><td>Pest: Thrips (suppression)
Rate: 1000–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td>Accepted as proposed</td></tr>
<tr><td colspan="2">Crop Group 4 – Leafy Vegetables</td></tr>
<tr><td rowspan="2">Pests: Cabbage looper, Cutworms
Rate: 500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td>Pest: Cabbage looper
Rate: 250–500 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pest: Cutworms
Rate: 500–750 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td rowspan="2">Pests: Armyworm, Fall armyworm, Beet armyworm, Corn earworm
Rate: 500–750 mL product/ha
Reapplication Interval: Minimum 5 days</td><td>Pests: Armyworm, Fall armyworm, Beet armyworm
Rate: 500 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pest: Corn earworm
Rate: 750 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pest: Green peach aphid
Rate: 500–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td rowspan="2">Pest: Aphids
Rate: 500–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td></tr>
<tr><td>Pest: Potato aphid
Rate: 750–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td></tr>
<tr><td>Pests: Leafminers (larvae)
Rate: 1000–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td>Pests: Dipteran leafminers (larvae)
Rate: 1000–1500 mL product/ha
Reapplication Interval: Minimum 5 days</td></tr>
<tr><td colspan="2">Crop Group 5 – Brassica Vegetables</td></tr>
<tr><td rowspan="2">Pests: Cabbage looper, Imported cabbageworm, Diamondback moth, Cutworms
Rate: 500 mL product/ha
Reapplication Interval: Minimum 5 days</td><td>Pests: Cabbage looper, Imported cabbageworm, Diamondback moth
Rate: 250–500 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pest: Cutworms
Rate: 500–750 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
<tr><td>Pests: Fall armyworm, Beet armyworm, Corn earworm, Swede midge
Rate: 500–750 mL product/ha</td><td>Pests: Fall armyworm, Beet armyworm
Rate: 500 mL product/ha
Reapplication Interval: Minimum 7 days</td></tr>
</table>

Claims proposed by applicant	Accepted claims
Reapplication Interval: Minimum 5 days	**Pest:** Corn earworm **Rate:** 750 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pest: Swede midge **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days
Pest: Green peach aphid **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Aphids **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
Pest: Cabbage aphid **Rate:** 750–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	
Pests: Leafminers (larvae) **Rate:** 1000–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Dipteran leafminers (larvae) **Rate:** 1000–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
Crop Group 8-09 – Fruiting Vegetables (except Cucurbits)	
Pests: Cabbage looper, Cutworms **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Cabbage looper **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pest: Cutworms **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Armyworm, Fall armyworm, Beet armyworm, Variegated cutworm, Tobacco hornworm, Tomato hornworm, Tomato fruitworm (Corn earworm), European corn borer **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Armyworm, Fall armyworm, Beet armyworm **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pest: Variegated cutworm **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pests: Suppression of Tobacco and Tomato hornworms **Rate:** 750 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pests: Tomato fruitworm (Corn earworm) **Rate:** 750 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pest: European corn borer **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days
Pest: Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Colorado potato beetle **Rate:** 750–1000 mL product/ha **Reapplication Interval:** 7–14 days
Pest: Green peach aphid **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Aphids **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
Pests: Potato aphid, Melon/Cotton aphid **Rate:** 750–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	

Claims proposed by applicant	Accepted claims
Crop Group 9 – Cucurbit Vegetables	
Pests: Cabbage looper, Cutworms **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Cabbage looper **Rate:** 250–500 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pest: Cutworms **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Armyworm, Fall armyworm, Corn earworm **Rate:** 500–750 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Armyworm, Fall armyworm **Rate:** 500 mL product/ha **Reapplication Interval:** Minimum 7 days
	Pests: Corn earworm **Rate:** 750 mL product/ha **Reapplication Interval:** Minimum 7 days
Pest: Green peach aphid **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Aphids **Rate:** 500–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
Pests: Potato aphid, Melon/Cotton aphid **Rate:** 750–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	
Pests: Leafminers (larvae), Thrips (suppression) **Rate:** 1000–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Dipteran leafminers (larvae) **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days
Crop Group 11-09 – Pome Fruit	
Pests: Codling moth, Oriental fruit moth, Spotted tentiform leafminer, Western tentiform leafminer **Rate:** 500–750 mL product/ha	**Accepted as proposed**
Pests: Leafrollers, Tufted apple bud moth **Rate:** 500–1000 mL product/ha	**Pests:** Obliquebanded, Threelined, Fruittree and European leafrollers, and Eyespotted and Tufted apple bud moths **Rate:** 500–1000 mL product/ha
Pest: Green peach aphid **Rate:** 500–1500 mL product/ha	**Pests:** Green peach aphid, Rosy apple aphid **Rate:** 750–1500 mL product/ha
Pest: Rosy apple aphid **Rate:** 750–1500 mL product/ha	
Pests: Apple maggot, Plum curculio, White apple leafhopper, Japanese beetle, European apple sawfly **Rate:** 1000–1500 mL product/ha	**Pests:** Apple maggot, Plum curculio, Japanese beetle **Rate:** 1000–1500 mL product/ha
	Pest: White apple leafhopper **Rate:** 750–1500 mL product/ha
	Pest: European apple sawfly **Rate:** 500–1000 mL product/ha
Reapplication Interval: Minimum 7 days **Maximum Number of Applications:** 4	**Accepted as proposed**

Claims proposed by applicant	Accepted claims
Crop Group 12-09 – Stone Fruits	
Pest: Leafrollers **Rate:** 500–1000 mL product/ha	**Pests:** Obliquebanded, Threelined, Fruittree and European leafrollers, and Eyespotted bud moth **Rate:** 500–1000 mL product/ha
Pests: Cherry fruit fly, Western cherry fruit fly, Oriental fruit moth, Peach twig borer **Rate:** 750–1000 mL product/ha	**Pests:** Cherry fruit fly, Western cherry fruit fly **Rate:** 750–1500 mL product/ha
	Pest: Peach twig borer **Rate:** 750–1000 mL product/ha
	Pest: Oriental fruit moth **Rate:** 500–750 mL product/ha
Pest: Green peach aphid **Rate:** 500–1500 mL product/ha	**Pests:** Green peach aphid, Plum aphid **Rate:** 750–1500 mL product/ha
Pest: Plum aphid **Rate:** 750–1500 mL product/ha	
Pests: Japanese beetle, Plum curculio **Rate:** 1000–1500 mL product/ha	**Accepted as proposed**
Reapplication Interval: Minimum 7 days **Maximum Number of Applications:** 4	**Accepted as proposed**
Crop Subgroup 13-07B – Bushberries	
Pest: Cranberry fruitworm **Rate:** 500–1000 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Cranberry fruitworm **Rate:** 500–1000 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Blueberry gall midge (cranberry tipworm), leafrollers **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pest:** Blueberry gall midge **Rate:** 750–1000 mL product/ha **Reapplication Interval:** Minimum 5 days
	Pests: Obliquebanded, Threelined, Fruittree and European leafrollers, and Eyespotted bud moth **Rate:** 500–1000 mL product/ha **Reapplication Interval:** Minimum 7 days
Pests: Blueberry maggot (suppression), Blueberry aphid, Plum curculio, Japanese beetle **Rate:** 1000–1500 mL product/ha **Reapplication Interval:** Minimum 5 days	**Pests:** Blueberry maggot (suppression), Plum curculio, Japanese beetle **Rate:** 1000–1500 mL product/ha **Reapplication Interval:** Minimum 5 days
	Pest: Blueberry aphid **Rate:** 750–1500 mL product/ha **Reapplication Interval:** Minimum 7 days
Maximum # Applications/Season: 4	**Maximum # Applications/Season:** 4
Crop Group 14-11 – Tree Nuts	
Pests: Codling moth **Rate:** 500–1000 mL product/ha	**Pests:** Codling moth, Oriental fruit moth **Rate:** 500–750 mL product/ha
Pests: Oriental fruit moth, Leafrollers, Peach twig borer **Rate:** 750–1000 mL product/ha	**Pests:** Obliquebanded, Threelined, Fruittree and European leafrollers, and Eyespotted bud moth **Rate:** 500–1000 mL product/ha
	Pests: Peach twig borer **Rate:** 750–1000 mL product/ha
Reapplication Interval: Minimum 7 days **Maximum Number of Applications:** 4	**Accepted as proposed**
SYNGENTA A17960A 600FS (600 g cyantraniliprole/L) and SYNGENTA A17960B 600FS (600 g cyantraniliprole/L)	
Crop: Potato **Pests:** Early to mid season protection from Colorado potato beetle **Rate:** 10–22.55 mL product/100 kg seed	**Crop:** Potato **Pests:** Early season protection from Colorado potato beetle **Rate:** 10–22.55 mL product/100 kg seed

Claims proposed by applicant	Accepted claims
SYNGENTA A16901B 40WG (20% cyantraniliprole, 20% thiamethoxam)	
Crop Group 4 – Leafy Vegetables	
Pests: Aphids, Beet armyworm, Cabbage looper, Corn earworm, Fall armyworm, Flea beetles, Leafhoppers, Leafminers (larvae) **Rate:** 750 g product/ha	**Pests:** Aphids, Cabbage looper (early season control), Leafhoppers, Dipteran leafminers, Flea beetles (early season suppression); Reduces damage caused by Beet armyworm, Corn earworm and Fall armyworm **Rate:** 750 g product/ha
Crop Group 5 – Brassica Vegetables	
Pests: Aphids, Beet armyworm, Cabbage looper, Corn earworm, Diamondback moth, Fall armyworm, Flea beetles, Imported cabbageworm, Leafminers (larvae), Thrips (foliage feeding) (early season suppression), Yellowstriped armyworm **Rate:** 750 g product/ha	**Pests:** Aphids, Dipteran leafminers; Early season control of Cabbage looper, Diamondback moth and Imported cabbageworm; Early season suppression of Flea beetles and Thrips; Reduces damage caused by Beet armyworm, Corn earworm, Fall armyworm and Yellowstriped armyworm **Rate:** 750 g product/ha
Crop Group 8-09 – Fruiting Vegetables (excluding Cucurbits)	
Pests: Aphids, Beet armyworm, Colorado potato beetle, Cucumber beetle, Fall armyworm, Flea beetles, Hornworms, Leafhoppers, Leafminers (larvae), Loopers, Potato psyllid, Thrips (foliage feeding) (early season suppression), Tomato fruitworm, Tomato pinworm, Yellowstriped armyworm **Rate:** 440–750 g product/ha	**Pests:** Aphids, Colorado potato beetle, Leafhoppers, Dipteran leafminers, Cabbage looper (early season control); Early season suppression of Flea beetles and Thrips **Rate:** 440–750 g product/ha
	Pests: Reduces damage caused by Beet armyworm, Fall armyworm, Tomato fruitworm and Yellowstriped armyworm **Rate:** 750 g product/ha
Crop Group 9 – Cucurbit Vegetables	
Pests: Aphids, Cucumber beetles (early season suppression), Flea beetles, Leafhoppers, Leafminers (larvae), Thrips (foliage feeding) (early season suppression) **Rate:** 750 g product/ha	**Pests:** Aphids, Leafhoppers, Dipteran leafminers; Early season suppression of Cucumber beetles, Flea beetles and Thrips **Rate:** 750 g product/ha
Potato	
Pests: Aphids, Colorado potato beetle, Flea beetles, Potato leafhopper **Rate:** 440–700 g product/ha	**Pests:** Aphids, Colorado potato beetle, Flea beetles (early season suppression), Potato leafhopper **Rate:** 440–700 g product/ha
SYNGENTA MAINSPRING (20% cyantraniliprole, 20% thiamethoxam)	
Outdoor Ornamentals – Foliar Application	
Pests: Aphids, Black vine weevil, Lace bugs, Leafhoppers, Leafminers, Mealybugs, Psyllids (including Asian citrus psyllid), Soft scales, Thrips (foliar feeding) (suppression), Whiteflies **Rate:** 37.5–75 g product/100 L **Maximum Number of Applications:** 1 at the high rate (75 g product/100 L), 2 at the low rate (37.5 g product/100 L); Allow 14 days between applications	**Pests:** Aphids, Black vine weevil, Lace bugs, Leafhoppers, Dipteran leafminers, Mealybugs, Psyllids, Soft scales; Suppression of Thrips **Rate:** 37.5–75 g product/100 L **Maximum Number of Applications:** As proposed
Greenhouse Ornamentals – Foliar Application	
Pests: Aphids, Leafminers, Mealybugs, Soft scales, Thrips (foliar feeding) (suppression), Whiteflies **Rate:** 37.5–75 g product/100 L **Maximum Number of Applications:** 2 Allow 14 days between applications	**Pests:** Aphids, Dipteran leafminers, Mealybugs, Soft scales; Suppression of Thrips and Whiteflies **Rate:** 37.5–75 g product/100 L **Maximum Number of Applications:** As proposed

Claims proposed by applicant	**Accepted claims**
Greenhouse Ornamentals – Drench Application	
Pests: Aphids, Leafminers, Mealybugs, Soft scales, Thrips (foliar feeding) (suppression), Fungus gnats, Root aphid, Whiteflies **Rate:** 50–75 g product/100 L **Maximum Number of Applications:** 1	**Pests:** Aphids, Dipteran leafminers, Mealybugs, Soft scales, Thrips (suppression), Fungus gnats, Root aphid, Whiteflies **Rate:** 50–75 g product/100 L **Maximum Number of Applications:** 1

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

All of the proposed Canadian MRLs are the same as that in the U.S. Cyantraniliprole has not been reviewed by Codex.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2070243	2011, Batch chromatograms from the analysis of cyantraniliprole (DPX-HGW86) technical, DACO: 2.13.3, CBI
2070244	2011, Batch analysis of IN-Q6S09 in cyantraniliprole (DPX-HGW86) technical, DACO: 2.13.3, CBI
2070245	2011, Batch analysis of cyantraniliprole (DPX-HGW86) technical, DACO: 2.13.3, CBI
2070246	2011, Characterization of cyantraniliprole toxicological sample DPX-HGW86-141, DACO: 2.13.3, CBI
2070247	2011, Characterization of cyantraniliprole toxicological sample DPX-HGW86-230, DACO: 2.13.3, CBI
2070248	2011, Characterization of cyantraniliprole toxicological sample DPX-HGW86-412, DACO: 2.13.3, CBI
2070249	2011, Characterization of cyantraniliprole toxicological sample DPX-HGW86-425, DACO: 2.13.3, CBI
2070250	2011, Characterization of cyantraniliprole toxicological sample DPX-HGW86-648, DACO: 2.13.3, CBI
2070251	2011, Technical grade cyantraniliprole, product identity and composition, material use to produce products, production process and formation of impurities, DACO: 2.11.1,2.11.3,2.11.4, CBI
2070252	2011, Cyantraniliprole (DPX-HGW86) certified limits, DACO: 2.12.1, 2.12.2, CBI
2070253	2006, DPX-HGW86: Laboratory study of melting, boiling and decomposition points, DACO: 2.14.13,2.14.4
2070254	2008, Photochemical oxidative degradation of DPX-HGW86, DACO: 8.2.3.3.3
2070255	2006, DPX-HGW86 technical insecticide: Laboratory study of explosive properties, flammability of solids, and the relative self-ignition (autoflammability) temperature, DACO: 2.16
2070256	2009, DPX-HGW86: Laboratory study of surface tension, DACO: 2.16
2070257	2008, DPX-HGW86: Laboratory study of oxidising properties, DACO: 2.16
2070259	2007, DPX-HGW86: Laboratory study of pH, DACO: 2.16
2070261	2010, DPX-HGW86: Laboratory study of storage stability and corrosion characteristics, DACO: 2.14.14
2070263	2009, DPX-HGW86: Stability to normal and elevated temperature, metals and metal ions, DACO: 2.14.13
2070264	2007, Laboratory determination of the n-octanol/water partition coefficients of DPX-HGW86 metabolites: Estimation by HPLC, DACO: 2.16
2070267	2010, IN-RNU71, IN-QKV54 and IN-NXX70 (photolysis products of DPX-HGW86): Laboratory determination of the n-octanol/water partition, DACO: 2.16

2070269 2010, IN-RNU71, IN-QKV54, and IN-NXX70 (photolysis products of DPX-HGW86): UV/visible absorption spectrum and molar absorptivity, DACO: 2.16

2070271 2007, DPX-HGW86: Laboratory study of appearance and relative density/bulk density, DACO: 2.14.1,2.14.2,2.14.3,2.14.6

2070273 2009, DPX-HGW86: Laboratory study of physical and chemical properties of appearance (physical state, colour, odor), relative density ,bulk density melting point and boiling point, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6

2070275 2007, DPX-HGW86: Laboratory study of vapor pressure, DACO: 2.14.9

2070277 2007, DPX-HGW85\6: Volatility, calculation of Henry's law constant, DACO: 2.16

2070279 2007, DPX-HGW86: Laboratory study of UV/visible absorption and molar absorptivity, DACO: 2.13.2,2.14.12

2070281 2008, DPX-HGW86: Spectra (mass spectrum, infrared spectrum, and NMR), DACO: 2.13.2

2070283 2007, DPX-HGW86: Laboratory study of water solubility, DACO: 2.14.7

2070285 2009, DPX-HGW86: Laboratory study of solubility in organic solvents, DACO: 2.14.8

2070287 2006, DPX-HGW86: Laboratory study of partition coefficient, DACO: 2.14.11

2070297 2007, DPX-HGW86: Laboratory study of dissociation constant, DACO: 2.14.10,8.2.3.2

2070303 2011, Validation of the analytical method for the determination of cyantraniliprole (DPX-HGW86) in technical grade cyantraniliprole and DPX-HGW86 end-use products, DACO: 2.13.1

2070301 2011, Determination of cyantraniliprole (DPX-HGW86) in technical grade cyantraniliprole and DPX-HGW86 end-use products, DACO: 2.13.1

2070303 2011, Validation of the analytical method for the determination of cyantraniliprole (DPX-HGW86) in technical grade cyantraniliprole and DPX-HGW86 end-use products, DACO: 2.13.1

2070305 2011, Description and validation of the analytical methods for determination of impurities in technical grade cyantraniliprole (DPX-HGW86), DACO: 2.13.4 CBI

2092889 2011, Technical grade cyantraniliprole, product identity and composition, material use to produce products, production process and formation of impurities, DACO: 2.11.1,2.11.3,2.11.4, CBI

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2229875 2012, Response to PMRAs Request for Additional Chemistry Data for DuPonts Cyantraniliprole Technical Material, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1, 2.12.2, 2.13.3,2.13.4,2.14.13,2.14.5,2.2,5.10,8.2.2.1,8.2.2.2,8.2.2.3

2070346 2006, Analytical method for the determination of DPX-HGW86 and metabolites in soil using LC/MS/MS, DACO: 8.2.2.1

2070350 2010, Independent laboratory validation of DuPont-15440 method for the determination of residues of DPX-HGW86 and metabolites in soil using LC/MS/MS, DACO: 8.2.2.1

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2070344 2010, Analytical method for the determination of DPX-HGW86 and photoproducts in soil using LC/MS/MS, DACO: 8.2.2.1

2070348 2010, Extraction efficiency of DPX-HGW86 from soil, DACO: 8.2.2.1

2070352 2010, Analytical method for the determination of DPX-HGW86 and metabolites in water (pond, stream, well, and tap) using LC/MS/MS, DACO: 8.2.2.3

2070354 2010, Independent laboratory validation of an analytical method for the determination of DPX-HGW86 and metabolites in water (surface, ground and tap) using LC-MS/MS, DACO: 8.2.2.3

2070357 2010, Sediment method validation (non-GLP) for HGW86 and metabolites, DACO: 8.2.2.2

2070302 2011, Product identity and composition of end-use product DPX-HGW86 200 g/L SC, DACO: 3.3.2

2070321 2010, Cyantraniliprole (DPX-HGW86) 200 g/Liter SC suspension concentrate formulation: Summary report of laboratory study of physical and chemical characteristics, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9

2070323 2008, DPX-HGW86 200 g/Liter SC suspension concentrate formulation: Laboratory study of physical and chemical properties, DACO: 3.5.1,3.5.10, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9,3.7,8.2.3.6

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2070324 2009, Cyantraniliprole 200 g/Liter SC Suspension concentrate formulation (DPX-HGW86): Laboratory study of flash point, explosive properties and auto-ignition temperature of liquids, DACO: 3.5.11,3.5.12

2070328 2011, DPX-HGW86 200 g/liter SC suspension concentrate formulation (in HDPE container): Laboratory study of shelf-life stability, DACO: 3.5.10

2070330 2011, DPX-HGW86 200 g/liter SC suspension concentrate formulation (in PET container): Laboratory study of shelf-life stability, DACO: 3.5.10

2070332 2010, Cyantraniliprole (DPX-HGW86) 200 g/Liter SC suspension concentrate formulation: Laboratory study of storage stability and corrosion characteristics, DACO: 3.5.10,3.5.14

2070508 2011, Product identity and composition of end-use product DPX-HGW86 100 g/L OD, DACO: 3.3.2

2070526 2009, Cyantraniliprole (DPX-HGW86) 100 g/Liter OD oil-based suspension concentrate formulation: Summary report of laboratory study of physical and chemical characteristics, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7, 3.5.8,3.5.9

2070527 2008, DPX-HGW86 100 g/Liter OD oil dispersion (oil-based suspension concentrate) formulation: Laboratory study of physical and chemical properties, DACO: 3.5.1,3.5.10,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7,8.2.3.6

2070530 2009, Cyantraniliprole 100 g/Liter OD Oil dispersion (oil-based suspension concentrate) formulation (DPX-HGW86): Laboratory study of flash point, explosive properties and auto-ignition temperature of liquids, DACO: 3.5.11,3.5.12,3.5.8

2070532 2011, DPX-HGW86 100 g/L OD oil dispersion (oil-based suspension concentrate) formulation (in PV/EVOH container): Laboratory study of shelf-life stability, DACO: 3.5.10

2070534 2011, DPX-HGW86 100 g/L OD oil dispersion (oil-based suspension concentrate) formulation (in PET container): Laboratory study of shelf-life stability, DACO: 3.5.10

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2229712 2012, Cyantraniliprole 100 g/L oil dispersion (OD) formulation (DPX-HGW86): Laboratory study of physical and chemical properties in a fluorinated high density polyethylene container, DACO: 3.5.10

2229714 2012, DPX-HGW86 100 g/liter OD oil dispersion (oil-based suspension concentrate) formulation (in PE/EVOH container): Laboratory study of shelf-life stability (3 years), DACO: 3.5.10

2071014 2011, Product identity and composition of end-use product DPX-HGW86 625 g/L FS, DACO: 3.3.2 CBI

2071016 2010, Cyantraniliprole 50FS (50% w/w active) flowable concentrate for seed treatment (DPX-HGW86): Laboratory study of physical and chemical properties, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9

2071019 2011, Cyantraniliprole 50FS (50% w/w active) flowable concentrate seed treatment (DPX-HGW86): Laboratory study of storage stability and corrosion characteristics, DACO: 3.5.10,3.5.14

2070858 2011, Product identity and composition of end-use product DPX-HGW86 100 g/L SE, DACO: 3.3.2

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4.0 Value

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B. Additional Information Considered

i) Published Information

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