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Proposed Registration Decision PRD2019-14

Tetraniliprole and Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino

(publié aussi en français) **30 December 2019**

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

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

Catalogue number: H113-9/2019-14E (print version)
H113-9/2019-14E-PDF (PDF version)

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Overview

Proposed Registration Decision for Tetraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Tetraniliprole Technical, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, containing the technical grade active ingredient tetraniliprole, to control a wide range of insect pests on labelled fruit and vegetable crops and turf.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of tetraniliprole and Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino.

What Does Health Canada Consider When Making a Registration Decision?

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

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

Before making a final registration decision on tetraniliprole and Tetraniliprole 200SC Insecticide, Tetraniliprole 480 FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, Health Canada's PMRA will consider any comments received from the public in response to this

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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."

consultation document.[3] Health Canada will then publish a Registration Decision[4] on tetraniliprole and Tetraniliprole 200SC Insecticide, Tetraniliprole 480 FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

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

What Is Tetraniliprole?

Tetraniliprole is an insecticide that is active by ingestion and contact. It is the active ingredient in the commercial class products Tetraniliprole 200SC Insecticide, Tetraniliprole 480 FS, Tetraniliprole 200SC Turf Insecticide and Tetrino.

Health Considerations

Can Approved Uses of Tetraniliprole Affect Human Health?

Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, containing tetraniliprole, are unlikely to affect your health when used according to label directions.

Potential exposure to tetraniliprole may occur through the diet (food and drinking water), when handling and applying the product, or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

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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*.

In laboratory animals, the technical grade active ingredient tetraniliprole was of low acute toxicity via the oral, dermal and inhalation routes. It was minimally irritating to the eyes and skin, but did cause an allergic skin reaction. Consequently, the hazard signal words “POTENTIAL SKIN SENSITIZER” are required on the label.

The end-use products Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, containing tetraniliprole, were of low acute toxicity via the oral, dermal and inhalation routes. They were non-irritating to the eyes and skin, and did not cause an allergic skin reaction.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of tetraniliprole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive endpoints for risk assessment included effects on body weight. The overall evidence suggests low concern for young animals and their sensitivity to tetraniliprole when compared to adult animals. There was no evidence that tetraniliprole damaged genetic material; however, there was equivocal evidence that it caused uterine tumours in rats.

The risk assessment protects against the effects noted above, and other potential effects, by ensuring that the level of human exposure is well below the lowest dose level at which these effects occurred in animal tests.

Residues in Water and Food

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

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and all population subgroups are expected to be exposed to less than 59% of the acceptable daily intake. Children 1 to 2 years old are the subpopulation expected to be subject to the highest exposures relative to body weight. Based on these estimates, the chronic dietary risk from tetraniliprole is not of health concern for all population subgroups.

On the strength of the overall information, it was determined that a threshold approach was appropriate for the cancer risk assessment based on the observed tumours (equivocal increase of uterine tumours in rats). Overall, the endpoints selected for non-cancer dietary risk assessment are considered to be protective of these findings.

Animal studies revealed no acute health effects. Consequently, a single dose of tetraniliprole is not likely to cause acute health effects in the general population (including infants and children).

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.

MRLs for tetraniliprole determined from the acceptable residue trials conducted throughout Canada and the United States on Crop Subgroup 1C, Crop Group 4-13, Crop Group 5-13, Crop Group 8-09, dry soybeans, Crop Group 10 (revised), Crop Group 11-09, Crop Group 12-09, Crop Subgroup 13-07F, Crop Group 14-11, field corn, sweet corn, and Crop Subgroup 20R-C can be found in the Science Evaluation section of this Consultation Document.

Occupational Risks From Handling Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide, and Tetrino

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of concern when tetraniliprole is used according to the proposed label directions.

Tetraniliprole 200SC Insecticide can be applied as a foliar spray to fruit trees in residential areas and Tetraniliprole 200SC Turf Insecticide and Tetrino can be applied to recreational areas such as golf courses and turf in residential areas. Therefore, there is the potential for adults, youth and children to be exposed via the dermal route as well as via the incidental oral route for children.

The exposure assessments conducted for adults, youth and children when contacting foliage and turf treated with tetraniliprole did not identify risks of concern when the label directions are followed.

Occupational Risks From Handling Tetraniliprole

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

Workers in commercial seed treatment facilities (and mobile treaters) and those planting and handling seed treated with Tetraniliprole 480FS can come into direct contact with tetraniliprole through residues on the skin. Therefore, the label states that treaters/applicators, baggers/sewers/stackers and forklift drivers in commercial seed treatment facilities (and mobile treaters) must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. Cleanout/repair personnel must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks. Corn and soybean seed can be treated using closed transfer systems only. Workers planting and handling treated seed must wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Farmers and custom applicators who mix, load and apply Tetraniliprole 200SC Insecticide as a foliar or soil treatment can come in direct contact with tetraniliprole residues on the skin and or through inhalation and workers entering treated fields can come in direct contact with tetraniliprole residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying tetraniliprole must wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. The label also requires that workers not enter treated fields for 12 hours after application.

Applicators who mix, load and apply Tetraniliprole 200SC Turf Insecticide or Tetrino to turf, including sod farms, golf courses and residential areas, and workers entering treated turf can come in direct contact with tetraniliprole residues on the skin and/or through inhalation. Therefore, the label specifies that anyone mixing/loading and applying tetraniliprole must wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. The label also requires that workers not enter treated sod fields for 12 hours after application and all other treated turf areas until sprays have dried.

Taking into consideration label statements and precautionary measures, it was determined that the risks to these individuals are not a concern.

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

Environmental Considerations

What Happens When Tetraniliprole Is Introduced Into the Environment?

When used according to label directions, the risks associated with tetraniliprole are acceptable from the viewpoint of environmental protection.

When tetraniliprole is used as a foliar application, in-furrow application or seed treatment to control insects, it can remain in the soil for a number of months depending on the soil type and conditions. It will not move from the treatment area to the air and, therefore, will not move to another area by movement through air. Tetraniliprole and its by-products can move downward in the soil, and, therefore, may reach groundwater. It can also move off the treatment area to reach surface waters such as ponds, streams and rivers. Once in water, tetraniliprole will not remain for a long period of time. Tetraniliprole is not expected to accumulate in plant or animal tissue.

Tetraniliprole can affect pollinators and beneficial insects following application. Because it is possible that tetraniliprole may enter ponds, streams and rivers after it is sprayed, it can affect aquatic life. Without precautions in place on how tetraniliprole should be used, the terrestrial and aquatic organisms listed above may be affected. Therefore, precautions are required to reduce the environmental exposure to tetraniliprole, thereby reducing the environmental risks. When tetraniliprole is used in accordance with the label and the required precautions, the resulting environmental risk is considered to be acceptable.

Value Considerations

What Is the Value of Tetraniliprole 200SC Insecticide?

Tetraniliprole 200SC Insecticide contains the new active ingredient tetraniliprole (200 g/L) and controls or suppresses numerous insect pests of field, fruit, tree nut and vegetable crops by foliar or in-furrow application.

Tetraniliprole 200SC Insecticide is a new commercial class product that is applied by foliar application by ground equipment to all listed crops, and also by aerial equipment to potato. It also can be applied in-furrow to tuberous and corm vegetables. It controls or suppresses important pests including aphids, Colorado potato beetle and grape berry moth. The product provides a new mode of action for mullein bug on pome fruit, aphids on tree nuts, and aphids and flea beetles on corn. Therefore, it may aid in resistance management of these pests on these crops.

What Is the Value of Tetraniliprole 480FS?

Tetraniliprole 480FS contains the new active ingredient tetraniliprole (480 g/L) and is a seed treatment that protects corn and soybean from certain soil-dwelling insects.

Tetraniliprole 480FS is a new commercial class seed treatment that protects corn and soybean from feeding damage by seedcorn maggot, wireworms and the larvae of European chafer, Japanese beetle and June beetles. These are important pests of corn and soybean. The product provides a new mode of action for use on soybean against these pests and may aid in resistance management.

What Is the Value of Tetraniliprole 200SC Turf Insecticide and Tetrino?

Tetraniliprole 200SC Turf Insecticide and Tetrino contain the new active ingredient tetraniliprole at 200 and 43 g/L, respectively, and control various insect pests of turf.

Tetraniliprole 200SC Turf Insecticide and Tetrino are new commercial class products that control annual bluegrass weevil, billbugs, chinch bugs and sod webworms, and control or suppress larvae of certain beetles on turf. These products provide a new mode of action against larvae of Asiatic garden beetle, northern masked chafer and oriental beetle on turf. Therefore, they may aid in resistance management of these turf pests.

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 Tetraniliprole Technical, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As direct contact with tetraniliprole on the skin or through inhalation can occur, anyone applying Tetraniliprole 480FS in commercial seed treatment facilities (and mobile treaters) must use closed transfer systems only. Also, treaters/applicators, baggers/sewers/stackers and forklift drivers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. Cleanout/repair personnel must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks. Workers planting and handling treated corn or soybean seed on farm must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Workers mixing, loading and applying Tetraniliprole 200SC Insecticide using ground application equipment and aerial applicators must wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. Chemical-resistant gloves are not required during application within a closed cab or cockpit. For aerial application, the field crew and the mixer/loaders must wear chemical-resistant gloves, coveralls and goggles or face shield during mixing/loading, clean-up and repair.

Workers mixing, loading and applying Tetraniliprole 200SC Turf Insecticide and Tetrino to turf using ground application equipment, including handheld equipment, must wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. Chemical-resistant gloves are not required during application within a closed cab.

Environment

- Label statements and no-spray buffer zones to reduce the risk of spray drift to aquatic ecosystems are required.
- Label statement indicating the potential for surface runoff from the soil surface is required.
- Label statement indicating the potential for movement to groundwater is required.
- Use restrictions to protect pollinators from exposure to tetraniliprole is required.

Next Steps

Before making a final registration decision on tetraniliprole, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other Information

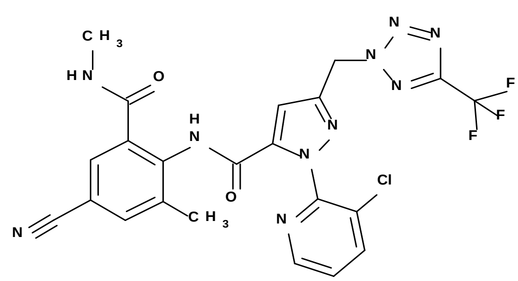
When the Health Canada makes its registration decision, it will publish a Registration Decision on tetraniliprole, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Tetraniliprole, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Tetraniliprole
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	2-(3-chloro-2-pyridyl)-N-[4-cyano-2-methyl-6-(methylcarbamoyl)phenyl]-5-[[5-(trifluoromethyl)tetrazol-2-yl]methyl]pyrazole-3-carboxamide
2. Chemical Abstracts Service (CAS)	1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2*H*-tetrazol-2-yl]methyl]-1*H*-pyrazole-5-carboxamide
CAS number	1229654-66-3
Molecular formula	$C_{22}H_{16}ClF_3N_{10}O_2$
Molecular weight	544.88 g/mol
Structural formula	
Purity of the active ingredient	96.77%

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

Technical Product—Tetraniliprole Technical

Property	Result
Colour and physical state	Light yellow solid
Odour	Odourless
Melting range	228.4-230.1°C under decomposition
Boiling point or range	No boiling point was determined until 235°C
Density	1.487–1.541 g/cm^3
Vapour pressure at 20°C	3.2×10^{-6} Pa
Ultraviolet (UV)-visible spectrum	conditions / λ_{max} (nm) / ε (L/mol.cm) neutral 204 45774 neutral 267 17237 acidic 204 47357 acidic 267 17171 basic 221 38595 basic 273 15969 basic 316 9645
Solubility in water at 20°C	pH / solubility (mg/L) dist. Water 1.2 4 1.0 7 1.0 9 1.3
Solubility in organic solvents at 20°C	solvent / solubility (g/L) Methanol 2.9 n-Heptane < 0.001 Toluene 0.17 Dichloromethane 5.3 Acetone 21.8 Ethyl acetate 6.4 Dimethyl sulfoxide > 280
n-Octanol-water partition coefficient (K_{ow})	pH / K_{ow} / log K_{ow} 4 at 25 °C 398 2.6 7 at 25 °C 398 2.6 9 at 25 °C 79 1.9
Dissociation constant (pK_a)	The dissociation constant (pK_a) for the active ingredient was determined in water with 10 % acetonitrile and was found to be pK_a. = 9.1
Stability (temperature, metal)	An exothermal effect was observed in the temperature range 230–410°C. The substance is thermally stable at ambient temperature under air.

End-use Product—Tetraniliprole 200SC Insecticide and its repack Tetraniliprole 200SC Turf Insecticide

Property	Result
Colour	Light beige
Odour	Musty odour
Physical state	Liquid
Formulation type	Suspension
Label concentration	200 g/L
Container material and description	Plastic, 0.25 to 1000 L
Specific Gravity	1.08–1.12
pH of 1% dispersion in water	3.5–5.5
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	Stable in HDPE containers at both accelerated (14 days at 54°C) and ambient (12 months) conditions.
Corrosion characteristics	Not corrosive to its HDPE packaging.
Explodability	Not explosive

End-use Product—Tetraniliprole 480FS

Property	Result
Colour	Beige
Odour	Weak aromatic odour
Physical state	Liquid
Formulation type	Suspension
Label concentration	480 g/L
Container material and description	Plastic, 0.25 to 1000 L
Specific Gravity	1.17–1.21
pH of 1% dispersion in water	4.0–6.0
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	Stable when stored for 14 days at 54°C in HDPE bottles.
Corrosion characteristics	Not corrosive to its HDPE packaging.
Explodability	Not explosive

End-use Product—Tetrino

Property	Result
Colour	Off-white
Odour	Slightly saponaceous odour
Physical state	Liquid
Formulation type	Suspension
Label concentration	43 g/L
Container material and description	Plastic jug, bottle and drum, 0.5 L to Bulk
Specific Gravity	1.03–1.07
pH of 1% dispersion in water	3.0–5.0
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.

Property	Result
Storage stability	Stable when stored for 14 days at 54°C in HDPE bottles.
Corrosion characteristics	Not corrosive to its HDPE packaging.
Explodability	Not explosive

1.3 Directions for Use

Tetraniliprole 200SC Insecticide is applied by foliar application to tuberous and corm vegetables, leafy vegetables, Brassica head and stem vegetables, fruiting vegetables, pome fruits, stone fruits, vine climbing berries and small fruits, tree nuts, corn (field, sweet and popcorn, including seed production) and soybean. It is applied by ground equipment to all listed crops, and also by aerial equipment to potato. It is also applied in-furrow to tuberous and corm vegetables. Pests vary by crop and include aphids, armyworms, codling moth, Colorado potato beetle, European corn borer, flea beetles, grape berry moth and oriental fruit moth. Foliar application rates are 150, 225 or 300 mL product/ha, depending on the pest. The in-furrow application rate is 6.75 mL product/100 m of row or 750 mL product/ha based on 90 cm row spacing. For full details, refer to the product label.

Tetraniliprole 480FS is applied as a seed treatment for corn (field, sweet and pop, including seed production) at an application rate of 42 mL product/80 000 seeds and for soybean at application rates of 13–20 mL/140 000 seeds. The product protects these crops from feeding damage by seedcorn maggot, wireworms and the larvae of European chafer, Japanese beetle and June beetles. For full details, refer to the product label.

Tetraniliprole 200SC Turf Insecticide and Tetrino are applied to turf to control or suppress larvae of Asiatic garden beetle, European chafer, Japanese beetle, June beetles, northern masked chafer and oriental beetle. The application rates against these pests for these two products are 5.0 and 23.2 mL/100 m^2, respectively. The two products also control annual bluegrass weevil, billbugs, chinch bugs, cutworms and sod webworms at rates of 2.5–5.0 and 11.6–23.2 mL/100 m^2, respectively. For full details, refer to the product labels.

1.4 Mode of Action

Tetraniliprole is a diamide insecticide in Group 28 of the Insecticide Resistance Action Committee mode of action classification. It modulates the ryanodine receptors of insects causing paralysis and death of the insect. Tetraniliprole has systemic activity when absorbed by the roots of plants and translaminar activity when absorbed by plant foliage.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Methods for Formulation Analysis

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

2.3 Methods for Residue Analysis

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

HPLC-MS/MS methods (Method 01414 in plant matrices and Method FV-002-A16-01 in animal matrices) were developed and proposed for data gathering and enforcement purposes for the analysis of tetraniliprole and BCS-CL73507-*N*-methyl-quinazolinone. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the method LOQ (0.01 ppm). Acceptable recoveries (70–120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in plant and animal matrices by an independent laboratory. Adequate extraction efficiencies of the parent compound were demonstrated using radiolabelled plant samples (apple fruit and leaves; rice kernels, forage, husks, and straw) analyzed with the enforcement method. Similar solvents were used in the livestock metabolism studies and the enforcement method for animal matrices.

Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Tetraniliprole (also known as BCS-CL73507 and BCS-CO80363) belongs to the anthranilic diamide class of pesticides. Pesticides of this class control insects through activation of ryanodine receptor channels, leading to internal calcium store depletion that impairs regulation of muscle contraction. Mammalian ryanodine receptors are substantially less sensitive to the effects of anthranilic diamides than insect ryanodine receptors.

A detailed review of the toxicological database for tetraniliprole was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. Additional studies included a uterotrophic assay and an in vitro steroidogenesis screen conducted with tetraniliprole, and acute toxicity, short-term toxicity, and genotoxicity studies conducted with metabolites of tetraniliprole. The required studies in the tetraniliprole database 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 characterize the potential hazards associated with tetraniliprole.

Toxicokinetic data consisted of studies in which rats were administered single low, mid or high doses via gavage of ^{14}C-tetraniliprole radiolabeled in the pyrazole-carboxamide position. Single low-dose gavage studies done with ^{14}C-tetraniliprole radiolabeled in the pyridinyl, phenyl-carbamoyl and tetrazolyl moieties were also conducted. A repeat-dosing regimen at a low-dose level consisting of 14 daily gavage doses of unlabelled tetraniliprole followed by a single gavage dose of ^{14}C-tetraniliprole radiolabelled in the pyrazole-carboxamide position was also conducted. The position of the radiolabel did not have a significant impact on the toxicokinetic profile.

Absorption was rapid, with peak plasma concentrations being reached between one and seven hours postdosing. Absorption, as determined by radioactive residues in bile, urine, and tissues, was low and decreased with increasing dose. Absorption at the low dose was slightly higher in males (41% and 29% of the administered dose (AD) in males and females, respectively, with the pyrazole-carboxamide label), but the area under the curve (AUC) was approximately double in females. At the mid- and high-dose levels, total absorption could not be estimated given that elimination via the bile was not measured at these dose levels. However, AUC values and levels of radioactivity in plasma indicated that absorption at the mid- and high-dose levels was very limited.

Elimination was rapid and nearly complete by 72 hours postdose. The half-life of elimination was slightly longer in males than in females at the low-dose level. Half-life of elimination values could not be calculated at the mid- and high-dose levels due to very low or non-detectable levels of radioactivity. For all dose levels, the fecal route was the predominant route of excretion. Biliary excretion at the low-dose level accounted for 25–39% of the AD, and elimination via the bile combined with feces accounted for 96–99% of the AD. At the low-dose level, excretion in urine accounted for 3–7% of the AD. Urinary excretion was negligible at the mid- and high-dose levels, again suggesting decreased absorption at higher dose levels. Elimination via expired air was negligible.

Residues in tissues were negligible at 72 hours postdosing, with levels greater in females than males. The highest levels of radioactivity were noted in the liver, followed by the kidneys. In females, levels were also relatively elevated in ovaries and perirenal fat.

A quantitative whole body autoradiography study confirmed the results noted above, with rapid but limited absorption, radioactivity distributing to the liver and kidney, with some distribution to glandular organs and fatty tissues, but overall low tissue burden. No significant sex-related differences in tissue distribution were noted.

Unchanged tetraniliprole was the major component excreted in urine and feces in all test groups, accounting for 51–71% of the AD at the low-dose level and over 90% of the AD at the mid- and high-dose levels. No unchanged tetraniliprole was found in the bile. The metabolite profiles were similar between sexes, although hydroxylation appeared to be a more significant process of transformation in males than in females.

The primary metabolites identified in excreta were (BCS-CL73507-) deshydrochloro-dihydrate, dihydroxy, and hydroxy-N-methyl metabolites. Other metabolites included the benzyl alcohol-glucuronide, hydroxypyridyl-glucuronide, deschloro-desmethyl-amide-dihydroxy, despyridyl, benzyl alcohol, pyridinyl-pyrazole-5-carboxylic acid, and hydroxypyridine metabolites. The identification of select metabolites is provided in Appendix I, Table 5.

The proposed metabolic pathway for tetraniliprole in rats involves hydroxylation in several positions including the pyridinyl moiety, the N-methyl moiety, and the methyl group of the phenyl moiety. Conjugation with glucuronic acid was noted following hydroxylation. Intramolecular condensation (cyclization) of parent molecule also occurred, yielding quinazolinone compounds, one of which was identified as BCS-CQ63359 (BCS-CL73507-N-methyl-quinazolinone), which was a primary plasma metabolite. Cleavage of the phenyl moiety yielding an amide was noted, followed by oxidation or methylation. Further cleavage reactions involving the pyridine and tetrazole ring also occurred.

An in vitro study compared the capacity of mouse, rat, rabbit, dog and human liver microsomes to metabolize tetraniliprole. Although this study was limited in scope, the results did suggest that the metabolism of tetraniliprole by human microsomes most closely resembled that of mouse liver microsomes when compared to the other species.

In a number of repeat-dose oral toxicity studies, plasma levels of tetraniliprole and the metabolite BCS-CQ63359 were determined. In rats and mice, plasma levels of tetraniliprole rose slightly with increasing dose level but in a non-proportional manner, and were notably more elevated in females than in males. This indicated that absorption of tetraniliprole was saturated in rodents over the range of dose levels tested. Levels of the metabolite BCS-CQ63359 in plasma of rodents were lower than those of tetraniliprole at low dose levels, but the opposite trend was observed at higher dose levels. Plasma levels of both tetraniliprole and the metabolite BCS-CQ63359 were higher in dogs than in rodents and were somewhat more dose-responsive, although saturation of absorption was still evident. Sex differences in plasma levels in dogs were slight. In pregnant rabbits, plasma levels of tetraniliprole rose slightly with increasing dose level but in a non-proportional manner; however, plasma levels of the metabolite BCS-CQ63359 increased in an almost dose-proportional manner.

In acute toxicity testing, the technical grade active ingredient tetraniliprole was of low acute toxicity via the oral, dermal and inhalation routes in rats. It was minimally irritating to the eyes and skin of rabbits. Tetraniliprole was positive for skin sensitization in mice when tested in the Local Lymph Node Assay (LLNA).

The end-use products Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide, and Tetrino were all of low acute toxicity via the oral, dermal and inhalation routes in rats. They were non-irritating to the eyes and skin of rabbits, and were negative for skin sensitization when tested in mice in the LLNA.

Repeat-dose dietary toxicity studies with tetraniliprole were available in mice, rats and dogs. In these studies, which involved short-term to longer-term testing, the most sensitive species for toxicity was the dog, followed by the rat and mouse. Effects in rodents, if any, usually occurred at dose levels approaching or exceeding the limit dose of testing. This species sensitivity may be the result of the higher absorption of tetraniliprole evident in dogs based on higher plasma levels of tetraniliprole and the metabolite BCS-CQ63359 when compared to rodents. The most sensitive endpoint of tetraniliprole was decreased body weight, which occurred in female dogs at the low-dose level and in males at the high-dose level in the one-year toxicity study. Other effects noted in the dog included slight adaptive effects on the liver (increased weight and alkaline phosphatase levels) as well as increased cholesterol levels. After one-year of dietary dosing, dogs of both sexes exhibited diffuse vacuolation of the zona glomerulosa of the adrenal gland, and male dogs displayed effects on the testes consisting of hypospermatogenesis, segmental tubular atrophy and hypoplasia.

In the repeat-dose oral toxicity studies, there was some evidence of increased toxicity with increased duration of dosing in dogs but not in rodents.

In a rat two-generation dietary reproductive toxicity study with tetraniliprole, no adverse impact on reproductive performance was observed. Slight body weight impairments were noted in F1 parental animals and offspring from both generations at the highest dose level tested. Delayed completion of vaginal opening was also observed in F1 female offspring. Although effects on F1 offspring occurred in the absence of effects in the P generation parental animals, concern with respect to potential sensitivity of the young is low given that the reduced body weight in F1 offspring was slight and occurred at a dose level exceeding the limit dose of testing. Furthermore, a delay in vaginal opening was not observed in F2 offspring that were maintained on study until sexual maturation.

An in vivo uterotrophic assay did not show any treatment-related effect of gavage administration of tetraniliprole on the day of vaginal opening or on the uterine weight of immature female rats. However, an in vitro steroidogenesis assay, using concentrations based on plasma levels measured in the chronic rodent toxicity studies and the one-year dog toxicity study, showed that both tetraniliprole and the metabolite BCS-CQ63359 caused increases in estradiol and cortisol secretion from human adrenocortical carcinoma cells.

In the developmental toxicity studies, some evidence of sensitivity of the young was noted in rats; a slight reduction in fetal weight and minor developmental effects (incomplete ossification of sternebrae) occurred in the absence of maternal toxicity. However, these effects occurred at the limit dose only. No adverse effects were noted in maternal animals or fetuses in the rabbit developmental toxicity study up to the limit dose of testing.

There was no evidence of genotoxicity in a battery of in vitro and in vivo genotoxicity studies conducted with tetraniliprole, nor was there evidence of oncogenicity in mice or male rats after long-term dietary administration. In the rat chronic toxicity/carcinogenicity toxicity study, the incidence of combined epithelial uterine tumours, including glandular polyps, endometrial adenocarcinomas, and adenosquamous carcinomas, was slightly elevated above concurrent and historical control incidences at the highest dose level tested. This finding was accompanied by treatment-related increases in associated pre-neoplastic findings, consisting of squamous cell hyperplasia of the cervix and vagina, and squamous cell metaplasia of the endometrium, at the same dose level. Other effects noted in female rats at the highest dose level tested were an increased incidence of vaginal prolapse and an increase in the severity of corpora lutea depletion. Although female reproductive organs appeared to be a target of toxicity at a very high dose level, the slightly increased tumour incidence was not statistically significant when compared to the concurrent control and occurred at the limit dose of testing. The increased incidence of uterine tumours was thus considered to be equivocal.

The toxicity of some metabolites and degradation products of tetraniliprole was investigated. Toxicity studies showed that these degradates had low acute oral toxicity and were not genotoxic. Two of these metabolites were also tested in 28-day rat dietary toxicity studies; no adverse effects were noted up to the highest dose level tested, which approached the limit dose of testing.

Results of the toxicology studies conducted on laboratory animals with tetraniliprole, its associated end-use products and select metabolites/degradation products, are summarized inAppendix I, Tables 2 and 3. The toxicology reference values for use in the human health risk assessment are summarized in Appendix I, Table 4. Select metabolites and degradates of tetraniliprole are identified in Appendix I, Table 5.

3.1.1 *Pest Control Products Act* Hazard Characterization

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

With respect to the completeness of the tetraniliprole toxicity database as it pertains to the toxicity to infants and children, the database contains the standard complement of required studies including gavage developmental toxicity studies in rats and rabbits, and a dietary two-generation reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, overall concern regarding sensitivity of the young was low. In the two-generation reproductive toxicity study, effects noted in the offspring included reduced body weight in both sexes of both generations and delayed sexual maturation in F1 females. These effects occurred at a dose level that was also associated with toxicity in the F1 maternal animals, manifest as reduced body weight. Although effects on F1 offspring occurred in the absence of effects in the P generation parental animals, concern with respect to potential sensitivity of the young is low given that the reduced body weight in F1 offspring was slight and the delay in vaginal opening was not observed in the subsequent generation. Furthermore, effects in the offspring only occurred at a dose level exceeding the limit dose of testing. In the rat developmental toxicity study, a slight reduction in fetal weight and minor developmental effects (incomplete ossification of sternebrae) were noted in in the absence of maternal toxicity, but these effects occurred at the limit dose only. No adverse effects were noted in the rabbit developmental toxicity study up to the limit dose.

Overall, endpoints in the young were well-characterized and not considered serious in nature. On the basis of this information, the *Pest Control Products Act* factor (PCPA factor) was reduced to onefold.

3.2 Acute Reference Dose

An acute reference dose (ARfD) was not established as an effect attributable to an acute exposure of tetraniliprole was not identified in the database.

3.3 Acceptable Daily Intake

To estimate risk following repeated dietary exposure, the one-year dietary toxicity study in dogs with a lowest observed adverse effect level (LOAEL) of 18 mg/kg bw/day was selected for risk assessment. At the LOAEL, effects included reduced body weight and body weight gain in females. A no observed adverse effect level (NOAEL) was not established. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. An additional uncertainty factor of threefold was applied due to the lack of a NOAEL in this study. As discussed in the PCPA Hazard Characterization section, the PCPA factor was reduced to onefold. The composite assessment factor (CAF) is thus 300.

The acceptable daily intake (ADI) is calculated according to the following formula:

$$ADI = \frac{LOAEL}{CAF} = \frac{18 \text{ mg/kg bw/day}}{300} = 0.06 \text{ mg/kg bw/day of tetraniliprole}$$

The ADI provides a margin of over 17 500 to the dose level at which an equivocal increase in uterine epithelial tumours was observed in rats.

Cancer Assessment

A slight increase in uterine epithelial tumours was noted in the two-year rat chronic toxicity/carcinogenicity study. This finding was considered equivocal based on the slight incidence and lack of statistical significance. Furthermore, the effect occurred above the limit dose, and there was no evidence of genotoxicity in the database. Based on these considerations, a threshold approach to the cancer assessment was considered appropriate. The selected reference values provide adequate margins to the dose level at which an equivocal increase in uterine epithelial tumours was observed in rats.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Reference Values

Short- and Intermediate-term Dermal

For the short- and intermediate-term dermal occupational and residential dermal risk assessment, the NOAEL of 1000 mg/kg bw/day from the 28-day dermal toxicity study in rats was selected, which was the highest dose level tested in this study. This study was conducted via the relevant route and was of an appropriate duration of exposure. For occupational and residential scenarios, the target margin of exposure (MOE) is 100, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. For residential scenarios, the PCPA factor was reduced to onefold as discussed in the *Pest Control Products Act* Hazard Characterization section. The selection of this study and target MOE is considered to be protective of all populations, including nursing infants and unborn children of exposed women.

Short- and Intermediate-term Inhalation

For short- and intermediate-term occupational inhalation risk assessments, the NOAEL of 126 mg/kg bw/day from the 90-day dog dietary toxicity study was selected. This endpoint was selected as there was no repeated exposure route-specific (inhalation) toxicity study available for tetraniliprole. At the LOAEL of 440/485 mg/kg bw/day, effects included reduced body weight and body weight gain in both sexes. The target MOE is 1000, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. Furthermore, a 10-fold uncertainty factor was applied to account for residual uncertainty with respect to differences in absorption when extrapolating from an oral toxicity study to the inhalation route of exposure. This uncertainty stems from the fact that the oral absorption of tetraniliprole was demonstrated to be quite low at the dose levels tested in the oral toxicity studies, while absorption via the inhalation route can be assumed to be near 100%. The selection of this study and the target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Short- to Intermediate-term Incidental (Non-dietary) Oral

For the short- and intermediate-term incidental oral risk assessment for children, the NOAEL of 126 mg/kg bw/day from the 90-day dog dietary toxicity study was selected. At the LOAEL of 440/485 mg/kg bw/day, effects included reduced body weight and body weight gain in both sexes. The target MOE is 100, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to onefold.

Short- to Intermediate-term Aggregate

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). For tetraniliprole, residential exposure via the inhalation route is not expected to occur, and it is not appropriate to include the dermal route based on the absence of effects following repeat-dermal exposure to tetraniliprole. Therefore, the aggregate assessment consisted of combining oral exposure from dietary (food and drinking water) and non-dietary sources only. For aggregating short- and intermediate-term exposure via the dietary and non-dietary oral routes, the NOAEL of 126 mg/kg bw/day from the 90-day dog dietary toxicity study was selected. At the LOAEL of 440/485 mg/kg bw/day, effects included reduced body weight and body weight gain in both sexes.

The target MOE is 100, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to onefold.

Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for tetraniliprole. Tetraniliprole belongs to the anthranilic diamide class of pesticides. Although other pesticides of the same class that are known to target the insect ryanodine receptors are registered in Canada, there is insufficient evidence to link the apical endpoints observed in the toxicology databases for the anthranilic diamide class of pesticides with activation of mammalian ryanodine receptors. Furthermore, the observed effects with tetraniliprole are indicative of more generalized toxicity, and a common mechanism of toxicity has not been identified. Therefore, no cumulative health risk assessment is required at this time.

3.4.1.1 Routes and Durations of Exposure

Tetraniliprole 480FS

Commercial seed treatment workers, mobile treaters, planters and anyone handling seed treated with Tetraniliprole 480FS are expected to be exposed via the dermal and inhalation routes. The duration of exposure for those working in commercial seed treatment facilities handling Tetraniliprole 480FS and seeds treated with tetraniliprole is expected to be short- to intermediate-term. For mobile treaters and those planting and handling treated seed on farm, exposure is expected to be short-term in duration.

Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide, Tetrino

Workers are expected to be exposed via the dermal and inhalation routes during mixing, loading and application of Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide and Tetrino. Workers entering treated fields or orchards or people entering treated turf areas are expected to be exposed via the dermal route and in addition, children (1 < 2 years) may also be exposed via the incidental oral route. Following commercial treatment of residential fruit trees, adults and children (6<11 years) may be exposed by the dermal route.

The duration of exposure for Tetraniliprole 200SC Insecticide is expected to be short-term in duration for farmers and postapplication workers but intermediate-term for custom applicators. The exposure duration to Tetraniliprole 200SC Turf Insecticide and Tetrino is expected to be short- to intermediate-term in duration for mixer/loader/applicators (M/L/As) and people entering treated areas. The intermediate-term duration of exposure may occur because 4 applications are possible at intervals of 4 weeks. The duration of exposure to treated fruit trees in residential areas is short-term in duration based on 3 applications at 7 day re-treatment intervals.

3.4.1.2 Dermal Absorption

A dermal absorption study was submitted but was not required in the risk assessment as the dermal NOAEL was derived from a dermal toxicological study representing the durations of exposure relevant to the proposed end-use products.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Tetraniliprole 480FS

Corn and soybeans can be treated with Tetraniliprole 480FS in commercial seed treatment facilities or by commercial mobile treaters. Exposure duration is expected to be short- to intermediate-term in duration for workers in commercial facilities and short-term for mobile treaters, and to occur primarily by the dermal and inhalation routes.

Chemical-specific data for assessing exposures during pesticide handling activities in commercial treatment facilities were not submitted. For assessing exposure during seed treatment in commercial operations, a surrogate passive dosimetry study, measuring the exposure of mixers/loaders/calibrators (treaters), baggers/sewers/stackers and cleaners at commercial facilities treating corn and canola with a variety of active ingredients, was used. Using this study, dermal and inhalation exposures were determined for workers performing commercial seed (canola and corn) treatment activities using closed transfer systems.

A dust-off study was provided which compared the dust-off potential of corn and soybean seeds treated with Tetraniliprole 480FS with the dust-off potential of seeds treated with formulations used in the surrogate passive dosimetry studies. The results of the study indicated that dust-off potential of Tetraniliprole 480FS treated corn and soybeans is equal to or higher than that from surrogate test material-treated crops. Therefore, the surrogate seed treating and planting studies may underestimate exposure to workers treating or planting tetraniliprole-treated corn and soybean seeds.

Exposure estimates were derived for treaters/applicators applying tetraniliprole to corn and soybean seeds using closed transfer systems including closed mixing, loading, calibrating and closed treatment equipment. The exposure estimates were based on treaters/applicators, baggers/sewers/stackers, cleaners and planters wearing a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Default commercial seed treatment throughput capacities for corn (125 000 kg seed/day) and soybean (63 000 kg seed/day) were combined with the maximum application rates to calculate the amount of product handled over a typical 8-hour day.

Dermal and inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the NOAEL to obtain the MOE; the target MOE is 100 for dermal and 1000 for inhalation. Inhalation and dermal risks to workers were not of concern (MOEs were above the target MOE; Appendix I, Table 6). The risk assessment is presented for corn only but is representative of exposure to soybean as the application rate and daily throughput are higher for corn than soybean. Similarly, exposure to workers in commercial treatment facilities is representative of that of mobile treaters because of the larger seed throughput capacities in commercial facilities. Considering the large differences between the calculated MOEs and the target MOEs, the exposure to workers in a commercial seed treatment facility (and mobile treaters) is not likely to be underestimated despite the difference in the dust-off potential noted in the dust-off study.

Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide, Tetrino

Individuals have the potential to be exposed to tetraniliprole during the mixing, loading and application of Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide and Tetrino. Exposure is expected to be short- to intermediate-term in duration and occur primarily by the dermal and inhalation routes.

Dermal and inhalation exposure estimates were derived for mixers/loaders/applicators applying tetraniliprole to a variety of crops using open cab groundbooms and mechanically-pressurized sprayers, using unit exposure values from the Pesticide Handler Exposure Database (PHED) v3.1. and the Agricultural Handlers Exposure Task Force (AHETF) database. All exposure estimates are based on mixers/loaders/applicators using equipment and wearing personal protective equipemnt (PPE) that is in keeping with label instructions.

For the treatment of turf, including sod farms, golf courses and residential areas, dermal and inhalation exposure estimates were derived for workers mixing/loading and applying tetraniliprole using open cab groundbooms, turf gun, backpack and manually-pressurized sprayers. Unit exposure values were derived from PHED, AHETF and the Outdoor Residential Exposure Task Force (ORETF) and considered the PPE that is in keeping with label instructions.

Exposure estimates were compared to the NOAELs to obtain the MOE; the target MOE is 100 for dermal and 1000 for inhalation. Inhalation and dermal risks to workers were not of concern (Appendix I, Table 7).

3.4.2.2 Exposure and Risk Assessment for Planters of Treated Seed

Individuals have the potential to be exposed to tetraniliprole while planting treated seed through dermal and inhalation routes. Exposure is expected to be short-term in duration. Chemical-specific data for assessing exposure during the planting or handling of treated seed were not submitted.

A previously reviewed surrogate passive dosimetry study that measured the exposure of workers loading and planting treated seed was used to assess exposure to workers handling tetraniliprole-treated seeds. Workers were monitored opening bags, loading seed into a hopper and planting seeds (closed-cab), and during clean-up and repair while wearing a single layer and gloves. Exposure values were normalized for the amount of active ingredient handled per day.

Commercially-treated corn and soybean seed are either bagged or shipped in bulk containers whereas corn seed in the surrogate exposure study was only transferred from bags. However, exposures to bulk transferred seed are not expected to be underestimated by exposure from handling bags of treated seed because there is less direct handling of seed in bulk containers.

The default seeding rate of 90 kg/ha and 100 ha planted per day were used to calculate the amount of a.i. handled per day for soybeans. For corn, the seeding rates of 32 kg seed/ha and 80 ha planted per day by custom planters were used to calculate the amount of product handled per day.

Dermal and inhalation exposures were estimated by coupling the unit exposure values with the amount of product handled per day. Exposures were normalized to mg/kg bw/day by using an 80 kg adult body weight.

Exposure estimates were compared to the NOAELs to obtain the MOE; the target MOE is 100 for dermal and 1000 for inhalation. Inhalation and dermal risks to workers were not of concern (Appendix I, Table 8). Due to the large differences between the calculated MOEs and the target MOEs, the exposure to workers handling and planting tetraniliprole-treated seeds is not likely to be underestimated despite the difference in the dust-off potential noted in the dust-off study. Furthermore, the closed cab requirement for planters can be waived.

3.4.2.3 Exposure and Risk Assessment for Workers Entering Treated Areas

There is the potential for workers entering treated areas to be exposed to tetraniliprole after the application to crops or turf to perform activities such as hand harvesting, girdling, thinning, setting irrigation lines by hand, mowing, watering and slab harvesting. Given the nature of activities performed, dermal contact with treated crops and turf should be short- to intermediate-term in duration. Inhalation exposure is not expected to be of concern given the non-volatile nature of tetraniliprole and restricted-entry interval (REI) of 12 hours.

Tetraniliprole 200SC Insecticide

Potential dermal exposures to workers entering treated areas were estimated by coupling dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients (TCs). Activity specific TCs are based on data from the Agricultural Re-entry Task Force (ARTF). Chemical-specific DFR data were not submitted so the default deposition value of 25% of the application rate with a daily dissipation value of 10% were used.

Exposure estimates were compared to the dermal NOAEL to obtain the MOE; the target MOE is 100. Dermal risks to workers were not of concern (Appendix I, Table 9).

Tetraniliprole 200SC Turf Insecticide and Tetrino

Chemical-specific data were not submitted to support the registration of the end-use products for use on turf so the default transferable turf value of 1% of the maximum application rate and a daily dissipation of 10% were used. The transferable turf residues (TTR) were based on 2 applications at the maximum rate and a 28-day re-treatment interval. Dermal exposures were calculated for postapplication workers entering treated turf to complete activities in golf courses and sod farms. The calculated dermal MOEs are presented in Appendix I, Table 10 and exceed the target MOE of 100, and thus not of concern.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

The proposed end-use products are all of the commercial marketing class, therefore a residential applicator risk assessment is not required.

3.4.3.2 Postapplication Exposure and Risk

Tetraniliprole 200SC Insecticide

Tetraniliprole 200SC Insecticide may be applied by commercial applicators to fruit trees on residential properties. As such, a postapplication dermal risk assessment for adults (16 years +) and children (6<11 years) is required to estimate exposure from contacting treated trees in residential areas.

Exposures were calculated using the maximum application rate and number of applications per year for pome and stone fruits. The DFR value was derived using the default 25% of the application rate retained on the foliage and a daily dissipation rate of 10%. Dermal exposure for adults and children were estimated by combining the DFR value with the default TC values from the 2012 USEPA Residential Standard Operating Procedure (SOP) (Section 4) and duration of exposure per day. Unlike occupational postapplication activities, the SOP has established a single TC value covering all potential activities residents may engage in (thinning, harvesting, etc). Using the dermal NOAEL for short- to intermediate-term duration, the calculated MOEs on the day of application were above the target MOE of 100, and thus not of concern (Appendix I, Table 11).

Tetraniliprole 200SC Turf Insecticide and Tetrino

Tetraniliprole 200SC Turf Insecticide and Tetrino can be used on turfgrass in residential properties, parks, athletic fields, playgrounds, golf courses, etc. As such, there is potential for recreational and residential postapplication exposure. Exposure was assessed according to equations and parameters stated in the 2012 USEPA Residential SOP (Section 3). Dermal exposure while golfing was assessed for adults (16 years +), youth (11 < 16 years) and children (6<11 years). Dermal exposures from high contact lawn activities were assessed for adults and children (1 to <2 years) and for adults and youth when mowing. Incidental oral exposures from hand-to-mouth (HtM), object-to-mouth (OtM) and soil ingestion were assessed for children (1< 2 years). The TTR value was derived using the default 1% of the application rate retained on turf and a daily dissipation rate of 10%. It was then used to assess postapplication exposure on the day of application.

Using the available toxicological reference values for dermal and incidental oral routes of exposure for short- to intermediate-term duration, the calculated MOEs on the day of application were above the target MOE of 100 (Appendix I, Tables 12 and 13). Appendix I, Table 14 presents the calculated MOEs on the day of application for incidental oral exposures to children, which are above the target MOE of 100, and thus not of concern.

3.4.3.3 Aggregate Exposure

The use of Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide and Tetrino in residential areas requires that an aggregate risk assessment be conducted. The dermal route is not included in the aggregate assessment based on the toxicological reference values so only the incidental oral and dietary (food + drinking water) routes of exposure were combined. As such, only an aggregate risk assessment for children (1 < 2 years) was necessary. Not all of the incidental oral routes of exposure were included as they are unlikely to co-occur on the same day. As a result, only HtM was aggregated with chronic dietary exposure and compared to the short- to intermediate-term NOAEL to estimate aggregate risk. The MOE for children was greater than the target MOE of 100, and thus not of concern (Appendix I, Table 15).

3.4.3.4 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to only when the potential for drift to non-target areas of human habitation and human activity is minimal. The applicator must take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

3.5 Exposure from Drinking Water

3.5.1 Concentrations in Drinking Water

Modelling estimates

Environmental concentrations of tetraniliprole were estimated using numerical models for human health risk assessment. Modelling was conducted using the Pesticides in Water Calculator (PWC) version 1.52, using standard PMRA scenarios, which take into account regional weather and soil characteristics as well as relevant plant properties.

Environmental water monitoring data can complement modelling estimates and are considered in conjunction with each other when estimating the potential exposure to humans. Monitoring information was not available for tetraniliprole.

Application Information and Model Inputs

A subset of labelled use patterns, intended to cover off the entire use pattern, are selected for modelling. The selection of modelled use patterns considers factors such as the application rates, intervals and crop area.

Two use patterns were modelled for tetraniliprole: four foliar applications of 45 g a.i./ha with a three day interval and two foliar applications of 100 g a.i./ha with a 28 day interval. In addition, single in-furrow application of 150 g a.i./ha (used on potatoes and sweet potatoes) was used for groundwater modelling.

For drinking water, tetraniliprole was modelled as a combined residue with the transformation products BCS-CQ63359, BCS-CR74541, BCS-CU81055, and BCS-CT30673. Modelling inputs are listed in Table 3.5.1 below:

Table 3.5.1 Major fate inputs for the drinking water modelling

Fate Parameter	Value (drinking water)
Residues modelled	Tetraniliprole + BCS-CQ63359 + BCS-CR74541 + BCS-CU81055 + BCS-CT30673
K_{oc}	16.2 L/kg
Water half-life	stable
Sediment half-life	1700 days, at 20°C
Photolysis half-life	10.6 days
Hydrolysis	stable
Soil half-life	883 days at 20°C

3.5.2 Estimated Concentrations in Drinking Water Sources

Estimated environmental concentrations (EECs) in potential drinking water sources are calculated for both groundwater and surface water (Table 3.5.2). Surface water EECs are calculated for a 274 hectare watershed adjacent to a 5.3 hectare reservoir having a 2.7m depth. EECs in groundwater are calculated by simulating leaching through a layered soil profile and reporting the average concentration in the top 1m of a water table that is 2 to 5 m deep.

Table 3.5.2 Level 1 estimated environmental concentrations of tetraniliprole in potential drinking water sources

Use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
All proposed use patterns	312	311	9	2

[1] 90th percentile of daily average concentrations
[2] 90th percentile of 365-day moving average concentrations
[3] 90th percentile of the peak concentrations from each year
[4] 90th percentile of yearly average concentrations

3.6 Food Residues Exposure Assessment

3.6.1 Residues in Plant and Animal Foodstuffs

The residue definition for enforcement in plants (primary and secondary), processed commodities and animal commodities is tetraniliprole. The residue definition for risk assessment is tetraniliprole for poultry and plant (primary and secondary) commodities; and tetraniliprole and BCS-CL73507-*N*-methyl-quinazolinone (BCS-CQ63359) in processed commodities and ruminant matrices. The data gathering/enforcement analytical method is valid for the quantitation of tetraniliprole and BCS-CL73507-*N*-methyl-quinazolinone residues in crops, processed commodities, and livestock matrices. The residues of tetraniliprole and BCS-CL73507-*N*-methyl-quinazolinone are stable in representative matrices from five commodity categories (high water, high oil, high protein, high starch and high acid content) for up to 24 months when stored at ≤-18°C. Therefore, tetraniliprole and BCS-CL73507-*N*-methyl-quinazolinone residues are considered stable in all frozen crop matrices and processed crop fractions for up to 24 months.

The raw agricultural commodities (RAC) potatoes, tomatoes, oranges, apples, plums, grapes, dry soybeans, field corn, undelinted cottonseeds were processed, but wheat, canola, and sunflower RAC were not processed due to the lack of quantifiable residues in the RAC. Residues of tetraniliprole concentrated in the following processed commodities: citrus oil (8.6-fold), prunes (4.1-fold), tomato paste (3.5-fold), raisins (1.2-fold), and corn flour (1.1-fold).

A ruminant feeding study was carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Quantifiable residues are not expected to occur in hen matrices with the current use pattern. Crop field trials conducted throughout Canada and the United States using end-use products containing tetraniliprole at approved or exaggerated rates in or on Crop Subgroup 1C, Crop Group 4-13, Crop Group 5-13, Crop Group 8-09, dry soybeans, Crop Group 10 (revised), Crop Group 11-09, Crop Group 12-09, Crop Subgroup 13-07F, Crop Group 14-11, field corn, sweet corn, and Crop Subgroup 20R-C are sufficient to support the proposed maximum residue limits.

Field rotational crop studies were conducted in/on onions, wheat, barley, sorghum, legumes, cucurbits, alfalfa, sunflowers and canola. The data are adequate to demonstrate that a 30-day plant-back interval is appropriate for Crop Group 3-07, Crop Group 6 and Crop Group 7 (except soybeans), Crop Group 9, Crop Group 15 and Crop Group 16 (except corn), Crop Subgroup 20A, Crop Subgroup 20B, alfalfa; and a 120-day plant-back interval is appropriate for other non-labelled crops.

3.6.2 Dietary Risk Assessment

Chronic (cancer/non-cancer) dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 4.02, 05-10-c), which incorporates consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) for the year 2005-2010 available through the Centers for Disease Control and Prevention’s (CDC) National Center for Health Statistics (NCHS).

3.6.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic (cancer and non-cancer) analysis for tetraniliprole: 100% crop treated, default processing factors, proposed MRLs on crops and livestock matrices. The chronic dietary exposure from all supported tetraniliprole food uses (alone) for the total population is 18% (0.010892 mg/kg bw/day) of the acceptable daily intake (ADI). The highest exposure and risk estimate is for children 1-2 years of age at 44% (0.026562 mg/kg bw/day) of the ADI. Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure (cancer and non-cancer) to tetraniliprole from food and drinking water is 29% (0.017176 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1–2 years of age at 59% (0.035204 mg/kg bw/day) of the ADI.

3.6.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.6.3 Aggregate Exposure and Risk

The dietary exposure values, food plus drinking water chronic exposure for specific subpopulations for tetraniliprole, were aggregated with the residential exposure.

3.6.4 Maximum Residue Limits

Table 3.6-1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Leafy vegetables (CG4-13)	20
Citrus oil	7.0
Brassica head and stem vegetable group(CG5-13), lemons/limes (Revised) CSG10B, small fruits vine climbing, except fuzzy kiwifruit (CSG13-07F), tomato paste	1.5
Oranges (Revised) CSG10A, stone fruits (CG12-09)	1.0
Grapefruits (Revised) CSG10C	0.9
Pome fruits (CG11-09)	0.5
Fruiting vegetables (CG8-09), cottonseeds (Revised) (CSG20R-C)	0.4
Meat byproducts of cattle, goats, horses, and sheep	0.3
Dry soybeans	0.2
Milk	0.05
Fat of cattle, goats, horses, and sheep	0.04
Tree nuts (CG14-11)	0.03
Meat of cattle, goats, horses and sheep	0.02
Tuberous and corm vegetables (CSG1C)	0.015

Eggs, fat, meat, and meat by-products of poultry, fat, meat, meat by-products of hogs, field corn, popcorn grain, sweet corn kernels plus cob with husks removed	0.01

MRLs are proposed for each commodity included in the listed Crop Groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides portion of the Canada.ca website.

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 methodologies, field trial data, and the chronic dietary risk estimate are summarizedin Appendix I, Tables 1, 16 and 17.

Incident Reports

Tetraniliprole is pending registration for use in Canada, and there are no incident reports in the PMRA database at this time. Once registered, the PMRA will conduct routine monitoring for any incidents related to the active ingredient.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Environmental fate properties of tetraniliprole and its transformation products are summarized in Appendix I, Tables 18.1 to 18.3.

Terrestrial environment: In the terrestrial environment, tetraniliprole can undergo hydrolysis in the presence of water. Tetraniliprole can transform rapidly via hydrolysis under alkaline conditions and environmentally relevant temperatures. However, at neutral and acidic pHs hydrolysis is slower. Photolysis is not a major route of transformation in soils. Laboratory and field studies indicate that depending on soil type, tetraniliprole can be persistent in soils. Tetraniliprole can transform more rapidly under anaerobic conditions in soil as compared to aerobic conditions. Depending on the soil type, tetraniliprole ranges from moderately persistent to persistent under aerobic soil conditions and is moderately persistent under anaerobic soil conditions. The major transformation product, BCS-CL73507-N-methyl-quinazolinone (BCS-CQ63359) is a common transformation product produced under various processes including hydrolysis, phototransformation and biotransformation. Other major transformation products formed during biotransformation include BCS-CL73507-Carboxylic acid (BCS-CR74541), BCS-CL73507-desmethyl-amide-carboxylic acid (BCS-CU81055) and BCS-CL73507-N-methyl-quinazolinone-carboxylic acid (BCS-CT30673). These transformation products were also observed under field conditions. Tetraniliprole has a low potential for residue carry over under field conditions.

A potential for tetraniliprole and its transformation products to reach groundwater was identified based on terrestrial field dissipation and laboratory studies, mobility studies and consideration of the criteria of criteria of Cohen *et al.* (1984) and groundwater ubiquity score (GUS).

Aquatic environment: In the aquatic environment, tetraniliprole transforms rapidly via hydrolysis under alkaline conditions and environmentally relevant temperatures, however, at neutral and acidic pHs hydrolysis is slower. Photolysis is a route of transformation in water. One major transformation product, BCS-CL73507-deschloro-oxazine (BCS-CY28900) was formed when exposed to light in water. The transformation product, BCS-CL73507-N-methyl-quinazolinone (BCS-CQ63359) resulting from many transformation processes phototransformed rapidly at neutral pH (half-life 1.3 d) in aquatic systems. Tetraniliprole is persistent in water-sediment systems under aerobic and anaerobic conditions. Two major transformation products, BCS-CL73507-N-methyl-quinazolinone (BCS-CQ63359) and BCS-CL73507-N-methyl-quinazolinone-amide (BCS-CT30672) were detected in the aquatic systems.

Based on log K_{ow} values and fish bioaccumulation studies, tetraniliprole is not expected to bioaccumulate.

Air: Tetraniliprole has a low vapor pressure and a low Henry's law constant which indicate that it has a low potential for volatilization from moist soil and water surfaces under field conditions. The low half-life of tetraniliprole in air (0.27–0.40 days) indicates that it has a low potential for long range atmospheric transport.

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. EECs are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level). The endpoints from the ecotoxicity effect studies are listed in Appendix I, Tables 19.1 to 19.11.

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints.

Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A risk assessment for tetraniliprole was conducted for terrestrial organisms. For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints. A summary of terrestrial toxicity data for tetraniliprole, various transformation products and formulations containing tetraniliprole is presented in Appendix I, Tables 19.1 to 19.6. The screening level risk assessment and further characterization of risk for tetraniliprole is presented in Appendix I: Foliar application: Tables 20.1 to 20.6; In-furrow application: Tables 20.7 to 20.9; Seed treatment application: Tables 20.10 to 20.18.

The proposed registration includes three different application methods, foliar application, in-furrow application, and seed treatment. These application methods result in different exposure scenarios for terrestrial organisms, as such, the potential risks associated with these different application methods are presented separately.

In summary, when used according to approved label directions, risks associated with tetraniliprole are acceptable for the following terrestrial organisms when applied as foliar, in-furrow or seed treatment application:

- Earthworms
- Birds
- Wild mammals
- Terrestrial vascular plants

The risk exceeds the LOC for tetraniliprole when applied as a foliar, in-furrow and seed treatment application to the following terrestrial organisms:

- Pollinators
- Non-target arthropods

However, with the addition of preventative measures and use restrictions to reduce exposure, therisks are acceptable for these organisms.

4.2.1.1 Screening level conclusions for terrestrial organisms exposed to foliar applications (Tables 20.1 to 20.3)

The foliar application screening level risk assessment for earthworms, birds and mammals does not exceed the LOC (see Tables 20.1 and 20.2 for further information regarding the screening level risk assessments). The RQ determined for terrestrial vascular plants was at the level of concern (Table 20.1), and therefore, a 1 m buffer will be required for some terrestrial habitats to manage this risk. The environmental risks to earthworms, birds, mammals and terrestrial vascular plants are, therefore, acceptable from foliar application of tetraniliprole when label directions are followed.

The foliar application screening level risk assessment, conducted according to the *Guidance for Assessing Pesticide Risks to Bees*, determined that the risk to pollinators exceeded the level of concern. The screening level risk assessment also exceeded the level of concern for foliar-dwelling non-target arthropods. Below are detailed summaries of both the pollinator and foliar-dwelling non-target arthropod screening risk assessments.

Pollinators (Table 20.3)
During foliar application, pollinators may be exposed by contacting tetraniliprole spray droplets during flight or through contacting dried spray residues on plants. They can also be exposed orally by feeding on pollen and nectar after spray droplets were deposited on open flowers or from systemic movement of tetraniliprole residues to pollen and nectar following application before and during bloom. Sometimes if an active ingredient is very persistent, residues can be seen in pollen and nectar the following year even if an application is made after bloom. An acute and chronic foliar application screening level risk assessment for bees was conducted using the single maximum application rate of Tetraniliprole 200SC Insecticide (for orchard crops = 60 g a.i./ha) and Tetraniliprole 200SC Turf Insecticide/Tetrino (for turf = 100 g a.i./ha).

The results of the screening level risk assessment for the lower rate from the orchard use (60 g a.i./ha) showed:

Acceptable risk:

- To adult bees from contact exposure
- To adult bees from contact and oral exposure to transformation products

Risk exceeds the level of concern, and further risk characterization is needed:

- To adult bees from acute and chronic oral exposure
- To bee larvae from acute and chronic exposure

The results of the screening level risk assessment for the higher rate from the turf use (100 g a.i./ha) showed:

Acceptable risk:

- To adult bees from contact and oral exposure to transformation products

Risk exceeds the level of concern, and further risk characterization is needed:

- To adult bees from acute contact and oral exposure, and chronic exposure
- To bee larvae from acute and chronic exposure

In most exposure pathways the screening level risk quotients for pollinator exposure to foliar applied tetraniliprole exceeded the level of concern. Therefore the risk was further characterized using pollen and nectar residue levels and higher tier semi-field studies. No potential for risk was identified from transformation products.

Non-Target Arthropods (Table 20.1)
The screening level risk assessment was conducted using data for the most sensitive species of parasitic wasp and predatory mite exposed to tetraniliprole on glass plates. The most sensitive species were *Aphidius rhopalosiphi*, a parasitic wasp, for acute exposure and *Typhlodrimus pyri*, a predatory foliar dwelling mite, for reproductive exposure. The estimated environmental concentration used to assess risk was calculated with the maximum cumulative foliar application from Tetrino and Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. This amounts to a total yearly rate of 195 g a.i./ha when considering the soil half life of 380 days. The screening level risk quotients for non-target arthropods resulting from acute and reproductive exposure to foliar applied tetraniliprole exceeded the level of concern. Therefore, a refined risk assessment analysis was conducted where non-target arthropods were exposed to leaves treated with tetraniliprole in the laboratory. These are referred to as extended laboratory tests.

4.2.1.1.2 Further characterization of risks to terrestrial organisms from foliar applications (Tables 20.4, 20.5 and 20.6)

The foliar application screening level risk assessment determined that the risk to pollinators and non-target arthropods exceeded the level of concern. Below are detailed summaries of how the risks to both pollinators and non-target arthropods were further characterized.

Pollinators (Table 20.4)

Tier I Refined

A total of 12 studies contained residue data for use in the Tier I refined risk assessment. The acute and chronic risks identified at the Tier I screening level were further refined by looking at the EEC in crop pollen and nectar. Pollen and nectar residues of tetraniliprole and the related transformation products were determined following foliar application to different crops, and with different application timing. The pollen and nectar residue samples were collected either using honey bees or bumble bees, or directly from flowers during bloom. Acute and chronic risk estimates were calculated for each crop selected for use in the risk assessment by comparing the residue exposures with the effect endpoints.

Where residue information was not available for a specific crop, the risk to bees was estimated by using the residue data that was the most relevant and available as a surrogate. For crops that were identified as having negligible pollinator exposure, a Tier I refined risk assessment was not conducted.

These included leafy vegetables (Crop Group 4-13) and brassica vegetables (Crop Group 5-13) which are harvested before bloom, and which are not grown for seed in Canada; therefore no pollen or nectar is available for foraging with these crops. Additionally, tuberous and corm vegetables (Crop Subgroup 1C) are also harvested before bloom, excluding potato and sweet potato.

The results of the Tier I refined risk assessment showed the following based on pollen and nectar residue levels:

Acceptable risk:

1. PRE-BLOOM

- Considering residues from potato pollen, there is negligible risk from **pre-bloom** application to tuberous and corm vegetables (potato and sweet potato) and to soybean and corn when using potato residues as a surrogate.
    - Tuberous and corm vegetables (Crop Subgroup 1C) (potato and sweet potato)
    - Soybean
    - Corn

2. POSTBLOOM

- Considering apple and cherry residues, there is negligible risk from **postbloom** application to orchard crops (pome fruit and stone fruit) and berry and small fruit when using apple and cherry as a surrogate.
    - Stone fruits (Crop Group 12-09) and pome fruits (Crop Group 11-09)
    - Berry and small fruits (Crop Subgroup 13-07F)

Risk exceeds the level of concern, and further risk characterization is needed:

1. PRE-BLOOM

- Considering residues in clover and tomato, there is potential risk from **pre-bloom** application to turf when considering bee attractive plants which may be present in turf such as clover, and for fruiting vegetables. For fruiting vegetables, there is potential risk considering only one of two available tomato residue studies.
    - Turf
    - Fruiting vegetables (Crop Group 8-09)

2. DURING BLOOM

- There is a potential risk from foliar application **during bloom** for all crops.

3. POSTBLOOM

- Considering residues in almond, there is a potential risk from **postbloom** application to tree nuts.
  - Tree nuts (Crop Group 14-11)

Tier II

Risk was identified in the Tier I refined assessment from pre-bloom applications (turf and fruiting vegetables), during bloom (all proposed crops) and postbloom (tree nuts). The Tier II data submitted and reviewed to address these risks included 5 semi-field foliar application studies. Three of these studies assessed potential effects following application during bloom while bees were actively foraging, and two assessed potential effects following pre-bloom application. All of the semi-field studies were on the flowering plant *Phacelia tanacetifolia* which is highly attractive to pollinators. One open-feeding colony study was reviewed that looked at the chronic effects to honey bees for 293 days after being fed sucrose solution that contained different doses of tetraniliprole.

Open-feeding Colony Study
A colony feeding study looked at the chronic effects of a six-week exposure to tetraniliprole in food (sucrose solution). Honey bee colonies were dosed with sucrose solution at 81, 158, 318, and 624 µg a.i./kg solution (measured), or 1720 µg a.i./kg solution (prepared with formulated product). Results from this study showed that at the highest concentration of 1720 µg a.i./kg solution tested, a reduction in colony performance and an increase in colony loss were seen. Over the course of the study, colony survival in controls was 50% and these losses occurred mainly during the overwintering period. As such, the overwintering success of the colonies could not adequately be assessed in this study. Therefore, for nectar exposure, the no observed effect level (NOEL) for this study was set to 624 µg a.i./kg solution and the lowest observed effect level (LOEL) was set at 1720 µg a.i./kg solution.

Pre-bloom Tunnel Studies
The data reviewed to address the risk from turf and fruiting vegetables after pre-bloom applications included two semi-field studies where small honey bee hives were exposed for 7–8 days to *Phacelia tanacetifolia* plants. The plants were treated pre-bloom with foliar applications of either 21 or 62.9 g a.i./ha. The hives were introduced into the tunnels 5–13 days after application. After applications of 21 g a.i./ha, residues in pollen from the comb contained up to 28 µg a.i./kg and pollen from forager bees contained up to 25 µg a.i./kg. Therefore, there appeared to be exposure to bees in the study, and levels found in the comb were consistent with those found collected on forager bees. Residues in nectar in combs and from forager bees were much lower at measured amounts of less than 0.4 µg a.i./kg. Residues were not analysed after applications of 62.9 g a.i./ha. No effects on mortality were observed in either study, however, effects on brood were seen in the hives placed 5 days after application at the higher rate but not in the hives placed 13 days after application at the lower rate. The effects on brood after application of 62.9 g a.i./ha included a significant decrease in brood development.

During Bloom Tunnel Studies
Three semi-field studies on honey bees were reviewed to address the risk from all proposed crops from foliar applications during bloom. Small honey bee hives were exposed for 7–8 days

to *Phacelia tanacetifolia* plants. The plants were treated during bloom and during bee flight with foliar applications of either approximately 2.6, 5.0 or 10.0 g a.i./ha. The hives were observed for 26–29 days after application. After applications of 10.0 g a.i./ha, significant negative effects on mortality were seen in two of the three studies, on foraging activity in one study, and on food stores in one study. One out of the three studies showed negative effects on mortality after applications of 5.0 g a.i./ha. None of the studies showed effects on honey bees after applications of 2.6 g a.i./ha. Residues were not analysed in any of these studies.

Given the effects observed at low levels (5–10 g a.i./ha), it is expected that effects could occur with application during bloom to any bee attractive crops at proposed label rates.

Pre-bloom Foliar Application Risk Assessment Conclusion

Overall the results from the Tier I, Tier I refined and Tier II studies are as follows based on the proposed use pattern:

1. **Crop Subgroup 1C: Tuberous and corm vegetables (excluding potato and sweet potato)**
   Crop Group 4-13: Leafy vegetable
   Crop Group 5-13: Brassica vegetable
   Because these crops are harvested before bloom, there is minimal potential for pollinator exposure through pollen and nectar. Therefore, based on crop production practices, the risks to pollinators are acceptable from foliar applications to tuberous and corm vegetable (excluding potato and sweet potato), leafy vegetable and brassica vegetable crops.

2. **Corn, Soybean, Potato and Sweet Potato**
   Potato (pollen only), corn (pollen only), sweet potato and soybean (pollen and nectar) plants have low/moderate attractiveness to bees, and overall there is low to moderate potential for pollinator exposure. Based on low residue levels (potato), and results from pre-bloom tunnel studies and colony feeding study, the risks to pollinators from pre-bloom application on corn, soybean, potato and sweet potato are expected to be minimal and managed by mitigation measures on the label.

3. **Crop Group 8-09: Fruiting vegetables**
   Fruiting vegetable blooms are moderately attractive to some pollinators, and overall there is moderate potential for exposure through pollen and nectar. Based on residue levels (tomato pollen), the decline in pollen residues over time, and the results from pre-bloom tunnel studies, the risks to pollinators from pre-bloom application on fruiting vegetables are expected to be managed by mitigation measures on the label.

4. **Turf**
   The potential for pollinator exposure in turf is dependent on the presence of flowering weeds and plants in the turf area to be treated. This results in a range of negligible to high potential for exposure through pollen and nectar, depending on the presence and the type of flowering plants in turf. Based on the pollen and nectar residue levels in clover, and

the effects seen in pre-bloom tunnel studies, there may be potential risks to pollinators from pre-bloom application on turf, but these risks are expected to be managed by mitigation measures on the label.

During Bloom Foliar Application Risk Assessment Conclusion

Overall the results from the Tier I, Tier I refined and Tier II studies show the following based on the proposed use pattern:

1. **Crop Subgroup 1C: Tuberous and corm vegetables (excluding potato and sweet potato)**
   Crop Group 4-13: Leafy vegetable
   Crop Group 5-13: Brassica vegetable
   Because these crops are harvested before bloom, there is minimal potential for pollinator exposure through pollen and nectar. Therefore, based on crop production practices, the risks to pollinators are acceptable from foliar applications to tuberous and corm vegetable (excluding potato and sweet potato), leafy vegetable and brassica vegetable crops.

2. **All other crops**
   There is a potential for risk for during bloom foliar application based on the Tier I refined assessment, the Tier II colony feeding study assessment, and the tunnel studies at all proposed application rates. This potential for risk can be managed by label mitigation. Appropriate label mitigation may consider the potential for pollinator exposure. High pollinator exposure is expected for orchard crops (pome and stone fruit), small fruit and vine climbing berry crops excluding grapes, and certain tree nuts. Low to moderate pollinator exposure is expected for corn, soybean, fruiting vegetable, potato, sweet potato, and grape.

Postbloom Foliar Application Risk Assessment Conclusion

Overall, considering all the results from the Tier I refined and Tier II colony feeding studies compared to available residues from postbloom application to cherry, apple, and almond, risk from postbloom application was shown to be acceptable for:

Crop Group 11-09: Pome fruits
Crop Group 12-09: Stone fruits
Crop Subgroup 13-07F: Berry and small fruits
Crop Group 14-11: Tree nuts

Additionally, postbloom application is acceptable for all annual crops harvested at the end of the season.

Non-Target Arthropods (Tables 20.5 and 20.6)

Extended Laboratory Studies (Table 20.5)

The refined risk quotients for non-target arthropods from acute and reproductive exposure to tetraniliprole in extended laboratory tests exceed the level of concern. Therefore, the risk was further refined by considering semi-field and full field studies.

Semi-field and Full-field Studies (Table 20.6)

In semi-field studies, the risks to non-target arthropods were acceptable when foliar application rates of 60 g a.i./ha were applied in a greenhouse cropping system. After an application of 60 g a.i./ha, the parasitic wasp populations recovered by 16 days after application. In an on-field study, where 40 g a.i./ha was applied to apple trees, the parasitic wasp populations did not recover within 14 days. The proposed use pattern on pome and stone fruit has a seasonal maximum application of 180 g a.i./ha, which is higher than the effect level seen in the on-field study. However, the single application on both pome and stone fruit is lower at 30 g a.i./ha. At off-field foliar application rates of 4 g a.i./ha, effects to specific non-target arthropod taxa were seen, but they recovered within two months of exposure and the population levels were not affected.

Non-target Arthropod Foliar Application Risk Assessment Conclusion

The effect data submitted indicated that tetraniliprole at all levels from screening to field poses risks at different levels to non-target arthropods. However, recovery occurs within an acceptable time period, as demonstrated at lower rates expected through off-field drift, as well as at higher rates in some cases. Therefore, based on laboratory, semi-field, on-field and off-field studies, the risks to non-target arthropods are expected to be managed by mitigation measures on the label.

4.2.1.2 Screening level conclusions for terrestrial organisms exposed to in-furrow applications (Tables 20.7 and 20.8)

The screening level risk assessment for in-furrow application on earthworms and soil-dwelling non-target arthropods did not exceed the level of concern (Table 20.7). For birds, mammals and terrestrial vascular plants, a screening level risk assessment for tetraniliprole was not conducted due to the limited exposure of these terrestrial organisms with this application method. Therefore, the environmental risk to earthworms, soil-dwelling non-target arthropods, birds, mammals and terrestrial vascular plants from in-furrow application of tetraniliprole is acceptable from the viewpoint of environmental protection.

The screening level pollinator risk assessment for in-furrow use exceeded the level of concern (Table 20.8). Below is a more detailed summary of the pollinator screening or Tier I level risk assessment for in-furrow application.

Pollinators (Table 20.8)
The primary route of exposure from soil applied products is through the diet via systemic transport of pesticide residues (including parent and transformation products) from the soil into the pollen and nectar of the plant. For these application types, it is assumed that honey bees will not be directly exposed through contact because pesticide residues are not expected to be present on the surface of the soil or plant. An acute and chronic in-furrow risk assessment on bees was conducted using the single maximum application rate of Tetraniliprole 200SC Insecticide (for tuberous and corm crops = 150 g a.i./ha).

The results of the screening level risk assessment for the tuberous and corm crop in-furrow use (150 g a.i./ha) showed:

Acceptable risk:

- To adult bees from acute oral exposure to transformation products

Risk exceeds the level of concern. Further risk refinement is needed:

- To adult bees from acute and chronic oral exposure
- To bee larvae from acute and chronic exposure

4.2.1.2.2 Further characterization of risks to terrestrial organisms from in-furrow applications (Table 20.9)

The in-furrow application screening level risk assessment determined that the risk to pollinators exceeded the level of concern. Below are detailed summaries of how the risks to pollinators were further characterized.

Pollinators (Table 20.9)

Tier I Refined

A total of 8 studies contained residue data for use in the Tier I refined risk assessment. The acute and chronic risks identified at the Tier I screening level were further refined by looking at the EEC in crop pollen and nectar. Pollen and nectar residues of tetraniliprole and the related transformation products in samples were measured after in-furrow applications to various crops. The pollen and nectar residue samples were collected using either using honey bees or bumble bees or directly from flowers during bloom. Acute and chronic risk estimates were calculated for each crop selected for use in the risk assessment by comparing the residue exposures with the effect endpoints. Residues in soil and in guttation fluid (the sap that is sometimes present on the edges of leaves) were also available from a bare soil application study.

The results of the Tier I refined risk assessment showed the following results based on pollen and nectar residue levels:

Acceptable risk:

- There is negligible risk from in-furrow application to tuberous and corm vegetables (Crop Subgroup 1C), including potato.
    - There is negligible risk from in-furrow application based on residues from potato at relevant application rates. As well, in-furrow corn and one tomato study indicated negligible risk at relevant application rates. One tomato soil drench study indicated risk for one soil-type located in Indiana. Corn and tomato are not proposed for in-furrow applications, but residue information was available and considered for the potato use pattern.
    - Because tuberous and corm vegetables (excluding potato and sweet potato) are harvested before bloom, there is minimal potential for pollinator exposure through pollen and nectar. Therefore, based on crop production practices the risks to pollinators are acceptable from foliar applications to tuberous and corm (excluding potato and sweet potato).

- There is negligible risk from carryover of residues, or from other plants grown in soils with high residues.
    - Buckwheat (pollen and nectar) and canola (pollen and nectar) grown after potato treated at 1 × 200 g ai/ha in-furrow.
    - Buckwheat (pollen and nectar), mustard (pollen and nectar), corn (pollen and guttation fluid) grown on bare soil treated with a total of 150 g ai/ha

Tier II

The risk identified in the Tier I refined assessment from in-furrow application to potato is acceptable. However, since potatoes only produce pollen (and corn and tomato also produce pollen only), the risk assessment (based on pollen residues) may underestimate potential exposure to other tuberous and corm vegetables that produce both pollen and nectar and are attractive to pollinators (sweet potato). Therefore, Tier II data that was submitted was reviewed to address these risks. There were 2 semi-field studies which applied tetraniliprole by in-furrow application. Both of these studies assessed potential effects following pre-bloom application to *Phacelia tanacetifolia* which is highly attractive to pollinators. One open-feeding colony study described under the foliar application risk assessment was also used for the in-furrow risk assessment. The study looked at the chronic effects to honey bees for 293 days after being fed sucrose solution that contained different doses of tetraniliprole.

Open-feeding Colony Study
See study description in foliar application risk assessment in Section 4.2.1.1.2.

In-furrow Tunnel Studies
The data reviewed to address the risk from in-furrow treatments on tuberous and corm vegetables included two semi-field studies where small honey bee hives were exposed for 29–30 days to *Phacelia tanacetifolia* plants in bloom. The plants were treated pre-bloom with in-furrow applications of 60 g a.i./ha. The hives were introduced into the tunnels 4–5 days after application when the plants were in flower. In one study, no significant differences were determined for total

mortality, larval and pupal mortality, flight intensity, brood index, compensation index, or termination rate. A significant decrease in the number of combs with brood was seen 1 day after start of exposure. A significant decrease in the total number of bees at 11 days after exposure was also seen. Other than these two instances, colony strength was not affected by exposure. Therefore, these effects were thought to be transient, and not treatment related. No residues of tetraniliprole or its transformation product BCS-CQ63359 were detected in treated flowers, pollen from treated forager bees, or nectar from treated forager bees. Therefore, there appears to be limited exposure to bees in this study from soil application close to bloom. In the other study, increases in mortality were detected at 27 days after bees were exposed. Slight decreases in brood index were detected at two middle time points, and decreases in the percentage of eggs at the 4th of 5 colony condition assessment were observed. The brood termination rate was higher in the treatment than the control. Decreases in foraging activity were also noted at one early time point. Effects to brood were considered transient with evidence of recovery. Residues were not measured in this study to establish exposure. The application rate in both of the studies (60 g ai/ha) was below the proposed Canadian rate for in-furrow application (150 g ai/ha).

In-furrow Risk Assessment Conclusion

Overall the results from the Tier I, Tier I refined and Tier II studies show the following based on the proposed use pattern:

1. **Crop Subgroup 1C: Tuberous and corm vegetables (excluding potato and sweet potato)**
   Because these crops are harvested before bloom, there is minimal potential for pollinator exposure through pollen and nectar. Therefore, based on crop production practices, the risks to pollinators from in-furrow application on tuberous and corm vegetables excluding potato and sweet potato are acceptable.

2. **Potato and sweet potato**
   Potato and sweet potato blooms have low/moderate attractiveness to pollinators, and overall there is low to moderate potential for exposure through pollen and nectar. Based on the low pollen and nectar residue levels and a lack of effects that were not transient in the tunnel studies, the risks to pollinators from in-furrow application on potato and sweet potato are acceptable.

Screening level conclusions for terrestrial organisms exposed to seed treatment applications (Tables 20.11 to 20.13)

The screening level risk assessment for seed treatment on earthworms, soil-dwelling non-target arthropods, mammals, and acute exposure to birds did not exceed the level of concern (Tables 20.11 and 20.12). For terrestrial vascular plants, a screening level risk assessment was not conducted due to the limited exposure to terrestrial plants with this application method. Therefore, the environmental risk to earthworms, soil-dwelling non-target arthropods, mammals, terrestrial vascular plants and acute exposure to birds from seed treatment application of tetraniliprole is acceptable.

The screening level seed treatment risk assessment for reproductive effects on birds exceeded the level of concern. The screening level pollinator risk assessment for seed treatment use exceeded the level of concern (Table 20.13). Below is a more detailed summary of the bird reproductive screening and the pollinator screening or Tier I level risk assessment for seed treatment application.

Birds (Table 20.12)
An acute and reproduction screening level risk assessment on birds was conducted using the highest application rate of 0.25 mg a.i./seed for corn. This application rate amounts to a maximum estimated environmental concentration of 825 mg a.i./kg seed which is based on 0.25 mg a.i./seed with 3300 corn seeds/kg. This is the most conservative exposure estimate. To define bird exposure, the concentration of tetraniliprole on various food items is used to determine the amount of pesticide residues in the diet, or estimated daily exposure (EDE). Because exposure is dependent on the body weight of the bird and the amount and type of food consumed, a set of generic bird body weights is used to represent a range of bird species. In addition, specialized feeding guilds are considered for each category of bird body weights. In this assessment, the most conservative feeding guilds were used.

The results of the screening level risk assessment for an exposure to corn seed treated with 0.25 mg a.i./seed showed acceptable risk to small, medium and large birds from acute oral exposure. The level of concern for reproductive effects was exceeded for small, medium and large birds.

Therefore, the risk was further characterized by looking at the number of seeds and the area-size needed to reach an adverse effect.

Pollinators (Table 20.13)
The primary route of exposure from seed treatment products is through the diet via systemic transport of pesticide residues (including parent and transformation products) from the seed into the pollen and nectar of the plant. Contact exposure is not expected from systemic transport. Bees may also be exposed from dust generated during planting of treated seeds for some seed types, including corn and soybean. An acute and chronic seed-treatment risk assessment on bees was conducted using a default exposure value of 1 mg a.i./kg concentration for pesticide residues in nectar and pollen. Tetraniliprole 480 FS is for use as a seed treatment on soybean at 0.0675 mg ai/kernel (20 mL per 140 000 unit of seed) and corn at 0.25 mg ai/kernel (42 mL per 80 000 unit of seed).

The results of the screening level risk assessment for an exposure of 1 mg a.i./kg of seed showed:

Acceptable risk:

- To adult bees from acute oral exposure to transformation products

Risk exceeds the level of concern. Further characterization is needed:

- To adult bees from acute and chronic oral exposure
- To bee larvae from acute and chronic exposure

4.2.1.3.2 Further characterization of risks to terrestrial organisms from seed treatment applications (Tables 20.10, 20.14 to 20.17)

The seed treatment application screening level risk assessment determined that the risk from reproductive effects on birds and the risk to pollinators exceeded the level of concern. Below are detailed summaries of how the risks to bird reproductive effects, and pollinators were further characterized.

Birds, Reproductive Effects (Tables 20.14 to 20.17)

The refined analysis of seed treatment exposure first looked at the number of seeds needed to reach an endpoint and the differences in drilling type (Table 20.14). The expanded risk assessment exceeded the level of concern for small, medium and large birds.

Therefore, to further refine the risk, an additional reproductive NOAEC was considered (Table 20.15) followed by a defined LOAEL endpoint value (Table 20.16 and 20.17). When using the NOAEC from the mallard duck study, the risk quotients calculated for small, medium and large birds exceeded the level of concern (RQ > 1). The LOAEL value from the same study on mallard ducks resulted in risk quotients for small and medium birds marginally exceeding the level of concern (RQ >1). In order for this risk to be realized in the environment, 100% of a bird's diet would need to consist of treated seed (see seeding details in Table 20.17). For large birds, this amounts to over 500 seeds. Small and medium size birds do not consume large corn or soybean seeds so, although the amount of seeds these birds will need to consume in order to reach an endpoint is smaller, their biology indicates this is not likely to happen. Precision drilling used to plant corn and soybean seeds is quite deep, and only large birds are physically capable of digging down to this level of planting. Another indicator that the risk is low is the area required on which a bird would need to forage to achieve a level of concern. The area required for a large bird is almost 9900 m^2. It is very unlikely that a large bird would be exposed to only treated seed over such a large area and not fly to a new foraging location. Therefore, the reproductive risk to wild birds from the proposed uses is considered to be minimal and the risks are acceptable from an environmental perspective.

Pollinators (Table 20.18)

Tier I Refined

A total of 2 studies contained residue data for use in the Tier I refined risk assessment. The acute and chronic risks identified at the Tier I screening level were further refined by looking at the EEC in crop pollen and nectar. Pollen and nectar residues of tetraniliprole and the related transformation products in samples were measured after bare soil or seed treatment applications were made. The pollen and nectar residue samples were collected using honey bees or directly from flowers during bloom. Acute and chronic risk estimates were calculated for each crop selected for use in the risk assessment by comparing the pollen and nectar residues with the effect endpoint. Residues in soil and in guttation fluid (the sap that is sometimes present on the edges of leaves) were also available from the bare soil application study.

The results of the Tier I refined risk assessment showed the following results based on residue levels from related studies:

Acceptable risk:

- There is negligible risk from **seed treatment** application
  - Corn and soybean
  - Buckwheat (pollen and nectar), mustard (pollen and nectar), corn (pollen and guttation fluid) grown on bare soil treated with a total of 150 g ai/ha
    Although residues in soil were high after direct bare soil application, there was very low translocation of residues into plant pollen and nectar and guttation fluid (maximum of 1.2 ppb in buckwheat). Guttation fluid residues were below 0.3 ppb. All of these residues are below those where effects to bees were seen.

Tier II

No Tier II data on seed treatment application was submitted for review. One open-feeding colony study described under the foliar application risk assessment was also used for the seed treatment risk assessment. The study looked at the chronic effects to honey bees for 293 days after being fed sucrose solution that contained different doses of tetraniliprole.

Open-feeding Colony Study
See study description in foliar application risk assessment in Section 4.2.1.1.2.

Seed-Treatment Risk Assessment Conclusion for translocation to pollen and nectar

Overall, the results from the Tier I, Tier I refined and the Tier II open-feeding colony study show that based on the proposed use pattern:

> **Corn and Soybean**
> Corn plants only produce pollen that is low/moderately attractive to bees; there is low to moderate potential for pollinator exposure through corn pollen. Based on low pollen and guttation residue levels, very little translocation of soil residues into pollen or nectar, and no exposure levels exceeding effects levels, the risks to pollinators from seed treatment application are acceptable. Standard pollinator label statements will apply.

Seed-Treatment Risk Assessment Conclusion for exposure to dust during planting

Exposure from corn and soybean seed treatment planting dust was assessed for risk to pollinators. The registrant provided a laboratory dust-off study investigating the dust generated without a lubricant, using talc and with the use of a fluency agent. This study demonstrated that the total amount of dust from treated corn and soybean was greatest when talc planter lubricant was used. When the fluency agent or no planter lubricant was used, the amount of total dust decreased for both corn and soybean.

The amount of tetraniliprole present in the dust decreased very little between the three corn trials (0.020 – 0.024 g a.i./ha), whereas a difference in the amount of tetraniliprole in the dust generated was observed when soybean was planted (the highest level of 0.014 g a.i./ha when no lubricant was used, 0.010 g a.i./ha when talc was used to the lowest level of 0.007 g a.i./ha when the fluency agent lubricant was used).

When the results of the tetraniliprole dust-off study were compared to a similar study using another seed treatment insecticide, it was shown that the levels of dust and active ingredient released are an order of magnitude lower in the tetraniliprole study. The toxicity of tetraniliprole to other seed treatment pesticides that require the use of fluency agent was compared demonstrating that tetraniliprole is much less toxic to adult honey bees based on contact, acute oral, chronic oral and chronic larvae endpoints by at least an order of magnitude.

Therefore, based on this weight of evidence risk assessment, when used according to approved label directions, risks associated with tetraniliprole are acceptable for pollinators when applied as a seed treatment application.

4.2.2 Risks to Aquatic Organisms

A risk assessment for tetraniliprole was conducted for freshwater and marine aquatic organisms based on available toxicity data. A summary of aquatic toxicity data is presented in Appendix I, Table 19.7 to 19.11.

For acute toxicity studies, uncertainty factors of 1/2 and 1/10 of the EC_{50} (LC_{50}) are typically used for aquatic plants and invertebrates, and fish species, respectively, when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. For groups where the level of concern (LOC) is exceeded (thus, if RQ $\geq$ 1), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and runoff separately. The screening level risk quotients for tetraniliprole are summarized in Appendix I, Tables 20.19 to 20.21. The risk quotients for the Tier 1 assessment of tetraniliprole are presented in Appendix I, Table 20.23 (runoff only) and Table 20.24 (spray drift only).

When used according to approved label directions, the risks to the following aquatic organisms from the use of tetraniliprole applied as a foliar, in-furrow and seed treatment application are acceptable:

- Freshwater
    - Fish
    - Amphibians
    - Aquatic vascular plants
    - Algae
- Marine
    - Invertebrates
    - Fish
    - Algae

The level of concern for tetraniliprole applied as a foliar, in-furrow and seed treatment application was exceeded for the following freshwater organisms:

- Aquatic invertebrates

However, with the addition of preventative measures to reduce drift and and precautionary measure to inform users of the potential for runoff, the risks are acceptable for these organisms.

4.2.2.1 Screening level conclusions for aquatic organisms (Tables 20.19 to 20.21)

For all aquatic organisms, the screening level risk assessment was based on the highest maximum seasonal application rate for the foliar application use pattern since it resulted in a higher maximum application rate (197.9 g a.i./ha) when compared to the in-furrow application rate of 150 g a.i./ha or the seed treatment application rate of 26.4 g a.i./ha.

The screening level risk assessment for acute exposure of freshwater pelagic (*Daphnia* sp.) and for chronic exposure to both freshwater benthic and pelagic invertebrates (*Chironomus* sp. and *Daphnia* sp., respectively) exceeded the level of concern (Appendix I, Table 20.19). Therefore, the acute and chronic risk identified for pelagic invertebrates and chronic exposure to benthic invertebrates will be further characterized by considering drift and run-off exposure.

For all other organism groups, the level of concern was not exceeded in the screening level risk assessment (see Tables 20.19 to 20.21 for further information). Therefore, the environmental risks from application of tetraniliprole to freshwater fish, amphibians, aquatic vascular plants, algae, and from short-term exposure of freshwater benthic invertebrates are acceptable when used according to label directions. The environmental risk to marine invertebrates, fish and algae is also acceptable when used according to label directions.

4.2.2.2 Further characterization of risk to aquatic organisms (Tables 20.22 to 20.24)

Freshwater invertebrates

Screening level risk assessment was conducted with a conservative scenario of direct foliar application of tetraniliprole into a body of water. This assessment indicated a potential acute risk to pelagic (*Daphnia* sp.) and chronic risk to pelagic and benthic (*Daphnia* sp. and *Chironomus* sp.) freshwater invertebrates. The risk was further characterized by estimating EECs from spray drift and runoff from treated areas into a receiving water body.

Foliar Spray Drift: The potential risk to aquatic organisms was determined based on the percentage of spray drift expected from the application methods (Table 20.24). The LOC was exceeded for ground, airblast and aerial applications; therefore, buffer zones ranging from 3 to 55 m will be required.

Run-off: Environmental concentrations of tetraniliprole in runoff water were estimated using numerical models. Estimated environmental concentrations for ecological risk assessment were modelled for tetraniliprole only. A subset of the foliar uses was modelled corresponding to:

- highest foliar cumulative application rate in agriculture
- highest foliar cumulative application rate in turf

Table 4.2-1 Major fate inputs for the ecological modelling

Fate Parameter	Value
Residues modelled	Tetraniliprole
K_{oc}	228 L/kg
Water half-life	429 days at 20°C
Sediment half-life	217 days at 20°C
Photolysis half-life	10.6 days at 33.6°
Hydrolysis	60 days
Soil half-life	139 days at 20°C

For the ecological risk assessment, EECs in water are calculated for a ten hectare field adjacent to a one hectare water body with a depth of 80 cm to represent a permanent water body. The model calculates the amount of pesticide entering the water body by runoff and the subsequent degradation of the pesticide in the water and sediment. Deposition of pesticide on the water body due to spray drift is not included. The model is run for 50 years.

In-furrow application and seed treatment are expected to result in lower exposure, therefore, foliar modeled EECs are protective of seed treatment and in-furrow uses. The highest runoff EECs estimated from water models are presented in Table 20.22.

Based on the modelling EECs, acute and chronic risk quotients to *Daphnia* sp were calculated using the peak runoff EEC of 0.0098 and 21-d EEC of 0.0087 mg a.i./L (Table 20.23). The risk quotients did not exceed the level of concern.

To assess the potential chronic/long-term risk to the sediment-dwelling *Chironomus* sp. larvae, two exposure scenarios were considered: 1) exposure to modelled 21-d pore water EEC of 0.0038 mg a.i./L, and 2) exposure to modelled 21-d overlying water EEC of 0.0087 mg a.i./L. These values represent the 90th percentile of the year maximum 21-d concentrations determined over 50 years. Using these 21-d EECs, the calculated risk quotients exceeded the level of concern for both overlying and pore water exposure (Table 20.23). The 90th percentile value used in the risk assessment represents the 1 in 10 year exposure value assuming that the users are applying the maximum number of applications in each of 50 years to the same location. The chronic chironomid studies reviewed evaluated the emergence of the midges. Chironomids hatch throughout the open-water period, but emergence is heaviest in the spring and the maximum 21-d EECs used in the risk assessment were derived in the fall. Given the conservatisms in the risk assessment, the PMRA does not anticipate effects on benthic invertebrate populations. Standard precautionary label statements alerting users of the potential for runoff will be included on all product labels for tetraniliprole.

4.2.3 Incident Reports

Tetraniliprole is pending registration for use in Canada and the United States; therefore, there have not been any incidents reported in either the United States or Canada.

5.0 Value

Over 140 field trials, along with scientific rationales, were provided to support the uses of Tetraniliprole 200SC Insecticide, Tetraniliprole 480 FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, with over 100 of these trials provided for Tetraniliprole 200SC Insecticide. This information demonstrated that the products controlled or suppressed the listed insect pests on the listed crops or sites when used as directed.

Isolated cases of resistance to Group 28 insecticides have been reported for codling moth in Germany and for diamondback moth, armyworms and cutworms in Asia. These pests are listed on the label of Tetraniliprole 200SC Insecticide. No resistance to Group 28 insecticides has been reported for the insect pests listed on the labels of the seed treatment or the turf products. Resistance management recommendations are included on the labels of all four products to decrease the potential for the development of insecticide resistance.

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, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, tetraniliprole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-031[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that tetraniliprole and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Table 20.25 for further information on the TSMP assessment.

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

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations, including the Toxic Substances Management Policy[1] and Formulants Policy,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that tetraniliprole and its end-use products do not contain any formulants or contaminants identified in the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted is adequate to characterize the potential hazards associated with tetraniliprole. Overall, tetraniliprole demonstrated low toxicity in short-term and chronic studies on laboratory animals. The dog was the most sensitive species, demonstrating reduced body weight and body weight gain along with effects on the testes and spermatogenesis, and mild effects on the liver and adrenal gland. There was equivocal evidence of carcinogenicity in female rats after longer-term dosing, based on a slightly increased incidence of uterine epithelial tumours at the limit dose only. No evidence of genotoxicity, or of oncogenicity in mice or male rats, was demonstrated. There was evidence of increased sensitivity of the young in developmental toxicity studies, with delays in ossification of the sternebae observed at dose levels that were not overtly toxic to maternal animals. However, the overall level of concern for this finding was low as it occurred at the limit dose only. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose level at which these effects occurred in animal tests.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is tetraniliprole in plant products and in animal matrices. The proposed use of tetraniliprole on Crop Subgroup 1C, Crop Group 4-13, Crop Group 5-13, dry soybean seed, Crop Group 8-09, Crop Group 11-09, Crop Group 12-09, Crop Subgroup 13-07F, Crop Group 14-11, field corn and sweet corn and the importation of undelinted cottonseeds and Crop Group 10-R

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

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

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*

does not constitute a risk of concern for chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs. The PMRA recommends that the following MRLs be specified for residues of tetraniliprole:

Commodity	Recommended MRL (ppm)
Leafy vegetables (Crop Group 4-13)	20
Citrus oil	7.0
Brassica head and stem vegetable group (Crop Group 5-13), lemons/limes (Revised) Crop Subgroup 10B, small fruits vine climbing, except fuzzy kiwifruit (Crop Subgroup 13-07F), tomato paste	1.5
Oranges (Revised) Crop Subgroup 10A, stone fruits (Crop Group 12-09)	1.0
Grapefruits (Revised) Crop Subgroup 10C	0.9
Pome fruits (Crop Group 11-09)	0.5
Fruiting vegetables (Crop Group 8-09), cottonseeds (Revised) (Crop Subgroup 20R-C)	0.4
Meat byproducts of cattle, goats, horses, and sheep	0.3
Dry soybeans	0.2
Milk	0.05
Fat of cattle, goats, horses, and sheep	0.04
Tree nuts (Crop Group 14-11)	0.03
Meat of cattle, goats, horses and sheep	0.02
Tuberous and corm vegetables (Crop Subgroup 1C)	0.015
Eggs, fat, meat, and meat by-products of poultry, fat, meat, meat by-products of hogs, field corn, popcorn grain, sweet corn kernels plus cob with husks removed	0.01

Commercial workers in seed treatment facilities (and mobile treaters) and farmers planting and handling treated corn and soybean seeds are not expected to be exposed to levels of tetraniliprole that will result in an unacceptable risk when used according to label directions. The personal protective equipment on the product label for workers in commercial seed treatment facilities (and mobile treaters) is a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. In addition to the above listed PPE, cleaners must also wear coveralls. Corn and soybean seeds can only be treated in closed treatment systems. Workers planting or handling treated seed must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Mixers, loaders and applicators handling tetraniliprole and workers entering treated fields are not expected to be exposed to levels of tetraniliprole that will result in an unacceptable risk when the products are used according to label directions and the required restricted entry intervals are adhered to. Those mixing, loading and/or applying Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide and Tetrino must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Exposures to the general public from engaging in activities in treated recreational or residential areas are not expected to result in unacceptable risks when Tetraniliprole 200SC Insecticide, Tetraniliprole 200SC Turf Insecticide and Tetrino are used according to label directions.

Bystander exposure is not of concern.

7.2 Environmental Risk

The risks to wild mammals, birds, fish, amphibians and terrestrial and aquatic plants associated with the use of Tetraniliprole 200SC Insecticide, Tetraniliprole 480 FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, containing the active ingredient tetraniliprole, at the proposed label rates are acceptable from the environmental perspective when label directions are followed. The use of these products may, however, pose a risk to bees, beneficial predatory and parasitic arthropods, and freshwater invertebrates. Risks to these organisms can be mitigated with label statements and spray buffer zones to protect sensitive terrestrial and aquatic habitats from spray drift. Risks to bees will be mitigated by restricting application timing during the pre-bloom and blooming period on a crop specific basis. To reduce the potential risk to bees resulting from the use of tetraniliprole as a seed treatment on corn and soybean, best management practices during planting of treated seed will be required. The appropriate cultural practices will be required following application to turf in order to reduce exposure of bees to residues of tetraniliprole on any flowering weeds that may be present. Statements are required on the labels for tetraniliprole products to inform users of the potential risks of run-off, leaching and persistence of tetraniliprole.

7.3 Value

Tetraniliprole 200SC Insecticide is a new commercial class product that is applied by foliar application to various crops. It is applied by ground application to all listed crops, and also by aerial application to potato. It can be applied in-furrow to tuberous and corm vegetables. It controls or suppresses important insect pests including aphids, Colorado potato beetle and flea beetles. It provides a new mode of action for mullein bug on pome fruit, aphids on tree nuts and aphids and flea beetles on corn. Therefore, this product may aid in resistance management of these pests on these crops.

Tetraniliprole 480FS is a new commercial class seed treatment that protects corn and soybean from feeding damage by certain soil-dwelling insects. It provides a new mode of action for use on soybean against these pests which may aid in resistance management.

Tetraniliprole 200SC Turf and Tetrino are new commercial class products that control or suppress certain insect pests of turf. These products provide a new mode of action against larvae of Asiatic garden beetle, northern masked chafer and oriental beetle on turf. Therefore, these products may aid in resistance management of these turf pests.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Tetraniliprole Technical, Tetraniliprole 200SC Insecticide, Tetraniliprole 480FS, Tetraniliprole 200SC Turf Insecticide and Tetrino, containing the technical grade active ingredient tetraniliprole, to control a wide range of insect pests on labelled fruit and vegetable crops, and turf.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

Additional Information Being Requested

Since the technical product, Tetraniliprole Technical, is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production will be required as postmarket information after registration.

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
AD	Administered dose
ADI	acceptable daily intake
AHETF	Agricultural Re-entry Task Force
ALP	alkaline phosphatase
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
ATPD	area treated per day
AUC	area under the curve
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
bwg	body weight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
cm	centimetres
CMAX	maximum plasma concentration
DF	dry flowable
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
dw	dry weight
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
ER_{25}	effective rate for 25% of the population
F1	first generation
F2	second generation
FOB	functional observational battery
g	gram
h	hour(s)
ha	hectare(s)
HDPE	high-density polyethylene
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
HtM	hand-to-mouth
IC_{XX}	inhibition concentration on XX% of the population

IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
kg bw	kilogram body weight
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre
mg	milligram
MIS	maximum irritation score
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
M/L/A	mixer/loader/applicators
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
ORETF	Outdoor Residential Exposure Task Force
OtM	object-to-mouth
P	parental generation
PBI	plantback interval
PCPA	*Pest Control Product Act*
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal generation
PPE	personal protective equipment
ppm	parts per million
REI	restricted entry interval
RSD	relative standard deviation

SC	soluble concentrate
SOP	standard operating procedure
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TC	transfer coefficient
Tmax	time to maximum plasma concentration
TP	transformation product
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
µM	mocromolar
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
wt	weight
♂	male
♀	female
↑	increased
↓	decreased

Appendix I Tables and Figures

Table 1 Residue Analysis

<table>
<tr><th>Matrix</th><th>Method ID</th><th>Method Type</th><th>Analytes</th><th>LOQ</th><th>Reference</th></tr>
<tr><td colspan="6">Soil and Sediment</td></tr>
<tr><td>Soil and sediment</td><td colspan="2">HPLC-MS/MS</td><td>Parent, BCS-CQ63359, BCS-CR60014, BCS-CR74541, BCS-CU81055, BCS-CT30673, BCS-CU81056</td><td>2 µg/kg</td><td>PMRA# 2731912, 2731911</td></tr>
<tr><td colspan="6">Water</td></tr>
<tr><td>Water</td><td colspan="2">HPLC-MS/MS</td><td>Parent, BCS-CQ63359, BCS-CR60014, BCS-CR74541, BCS-CU81055, BCS-CU81056, BCS-CY28900, BCS-CY28897, BCS-CY28906</td><td>0.1 µg/L</td><td>PMRA# 2731917, 2731915</td></tr>
<tr><td colspan="6">Plant</td></tr>
<tr><td>Tomatoes; Rapeseed; Grapes; Wheat grain; Dry bean seed</td><td>01414</td><td>Data Gathering and Enforcement Method- Plant Commodities/ LC-MS/MS</td><td>BCS-CL73507[1]
BCS-CQ63359[2]</td><td>0.01 ppm for each analyte in all matrices</td><td>PMRA# 2732152</td></tr>
<tr><td>Oranges; Broccoli (stems and heads)</td><td>01414</td><td>ILV of Enforcement Method- Plant Commodities/ LC-MS/MS</td><td>BCS-CL73507[1]
BCS-CQ63359</td><td>0.01 ppm for each analyte in all matrices</td><td>PMRA# 2732156</td></tr>
<tr><td>Apple; Rice (grain, forage, straw) from [pyrazole-carboxamide]-^{14}C-BCS-CL73507</td><td colspan="2">Extraction efficiency: HPLC with radiometric, UV-detection and HPLC-MS/MS confirmation</td><td>BCS-CL73507[1]
BCS-CQ63359</td><td>0.01 ppm for each analyte in all matrices</td><td>PMRA# 2731904
PMRA# 2731899</td></tr>
<tr><td colspan="6">Animal</td></tr>
<tr><td>Cattle (muscle, liver, kidney, fat); milk; cream</td><td rowspan="4">Method FV-002-A16-01</td><td rowspan="2">Enforcement and Data Gathering Method- Livestock Commodities/LC-MS/MS</td><td>BCS-CL73507[1]
BCS-CQ63359[2]</td><td>0.01 ppm for each analyte in all matrices</td><td>PMRA# 2732153</td></tr>
<tr><td>Poultry (muscle); Cattle (milk, kidney, fat, liver)</td><td>BCS-CL73507[1]
BCS-CQ63359[2]</td><td>0.01 ppm for each analyte in all matrices</td><td>PMRA# 2732155</td></tr>
<tr><td>Cattle (milk, liver)</td><td rowspan="2">ILV of Enforcement Method- Livestock Commodities/LC-MS/MS</td><td>BCS-CL73507[1]
BCS-CQ63359[2]</td><td rowspan="2">0.01 ppm for each analyte in all matrices</td><td>PMRA# 2732157</td></tr>
<tr><td>Eggs; poultry liver</td><td>BCS-CL73507[1]</td><td>PMRA# 2732154</td></tr>
</table>

Matrix	Method ID	Method Type	Analytes	LOQ	Reference
Goat: milk, liver, kidney, muscle, and fat Hen: eggs, liver, muscle, and fat	Similar solvents were used in the livestock metabolism studies and the enforcement method for animal matrices.				PMRA# 2731888-2731890 PMRA# 2731891-2731893

[1] Tetraniliprole; [2]BCS-CL73507-*N*-methyl-quinazolinone

Table 2 Toxicity Profile of End-use Products Containing Tetraniliprole

(Effects are known or assumed to occur in both sexes unless otherwise noted)

Study Type/Animal/PMRA#	Study Results
TETRANILIPROLE 200SC INSECTICIDE, TETRINO, TETRANILIPROLE 200SC TURF INSECTICIDE	
Acute oral toxicity (Up and down) Rat, Wistar PMRA# 2732143	LD_{50} (♂/♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity
Acute dermal toxicity Rat, Wistar PMRA# 2732144	LD_{50} (♂/♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
Acute inhalation toxicity (nose-only) Rat, Wistar PMRA# 2732145	LC_{50} (♂/♀) > 4.49 mg/L Low acute toxicity Laboured respiration and red-brown staining and/or wet fur were noted in all animals on the day of exposure, all animals recovered by the following day.
Eye Irritation Rabbit, NZW PMRA# 2732146	MIS = 7.33 at 1 h MAS = 0 Non-irritating
Dermal Irritation Rabbit, NZW PMRA# 2732147	MAS = 0 MIS = 0 Non-irritating
Dermal sensitization (LLNA) Mouse, CBA/J Rj PMRA# 2732148	Not a dermal sensitizer

Study Type/Animal/PMRA#	Study Results
TETRANILIPROLE 480 FS	
Acute oral toxicity (Up and down) Rat, Sprague-Dawley derived PMRA# 2733943	LD_{50} (♀) > 5000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
Acute dermal toxicity Rat, Sprague-Dawley derived PMRA# 2733944	LD_{50} (♂/♀) > 5000 mg/kg bw Low acute toxicity Erythema at dosing site on day one and two only.
Acute inhalation toxicity (nose-only) Rat, Sprague-Dawley derived PMRA# 2733945	LC_{50} (♂/♀) > 5.10 mg/L Low acute toxicity Irregular respiration on day one and two only.
Eye Irritation Rabbit, NZW PMRA# 2733946	MIS = 3.33 at 1 h MAS = 0 Non-irritating
Dermal Irritation Rabbit, NZW PMRA# 2733947	MIS = 0.67 at 1 h MAS = 0 Non-irritating
Dermal sensitization (LLNA) Mouse, CBA/J PMRA# 2733948	Not a dermal sensitizer Hair loss noted at the dosing site in animals in the 100% dosing group.

Table 3 Toxicity Profile of Technical Tetraniliprole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted. Effects above the LOAEL(s) have not been reported in this table for most studies for reasons of brevity.)

Study Type/Animal/PMRA#	Study Results
Toxicokinetic Studies	
Absorption, distribution, excretion and metabolism (gavage) Rat, Wistar PMRA# 2731870	Single (2, 20, 200 mg/kg bw) dose of [pyrazole-carboxamide-^{14}C]-BCS-CL73507 and repeated doses (14 daily doses of 2 mg/kg bw) of unlabelled test material followed by a single dose of [pyrazole-carboxamide-^{14}C]- BCS-CL73507; animals sacrificed 72 h after administration of the radiolabelled dose. **Absorption:** Absorption was rapid (Tmax = 1 h regardless of dosing regimen, except for 20 mg/kg bw ♀ with Tmax = 7 h). Absorption in bile duct-cannulated animals at 2 mg/kg bw was 41%/29% of the AD in ♂/♀. No radioactivity was detected in plasma at 200 mg/kg bw, or at ≥48 h at 20 mg/kg bw. The AUC for ♀ at 2 mg/kg bw (single dose) was twofold greater

	than for ♂. AUC values at 20 mg/kg bw were approximately 5% of those at 2 mg/kg bw, suggesting more limited absorption at 20 mg/kg bw. **Elimination:** Plasma concentrations declined to <2% of Cmax by 72 h postdose (study termination). The $t_{1/2}$ of elimination at 2 mg/kg bw was 28/18 h in ♂/♀. The fecal route was the predominant route of excretion. At 2 mg/kg bw, biliary excretion accounted for 25 – 39% of the AD, and bile combined with feces accounted for 96-99% of the AD; excretion in urine was 5 – 7% of the AD. Urinary excretion was negligible at 20 and 200 mg/kg bw, suggesting decreased absorption at higher dose levels. Elimination was completed by 48 h postdose in most dosing regimens, with the exception of the 200 mg/kg bw ♀ for which excretion was complete by 72 h. **Distribution:** Radioactivity remaining in the carcass (including the gastrointestinal tract) was <1% of the AD at study termination. Multiple dosing at 2 mg/kg bw did not lead to increased radioactivity in any tissues or organs. Residues in organs were greater in ♀ compared to ♂. The greatest concentrations were in liver. **Metabolism:** Unchanged tetraniliprole was the major component in urine and feces in all test groups, accounting for 51 – 66% of the AD for the 2 mg/kg bw groups and approximately 89% and 108% of the AD for the 200 or 20 mg/kg bw groups. Unchanged parent was not found in the bile. Metabolite profiles were similar between sexes. Major metabolites (1 – 9% of the AD) included the (BCS-CL73507-) deshydrochloro-dihydrate (feces/bile), dihydroxy (urine/feces), and hydroxy-N-methyl metabolites (urine/feces/bile). Other prominent metabolites (1-4% of the AD) included the benzyl alcohol-glucuronide (feces bile), hydroxypyridyl-glucuronide (bile), deschloro-desmethyl-amide-dihydroxy (feces/bile), despyridyl (urine/feces/bile), benzyl alcohol (urine/feces), pyridinyl-pyrazole-5-carboxylic acid (urine/feces/bile), and hydroxypyridine (feces/bile) metabolites. Not all metabolites were fully elucidated due to uncertainty regarding the exact position of hydroxylation.
Absorption, distribution, excretion and metabolism (gavage) – continued from above Rat, Wistar PMRA# 2731870	The primary metabolic reactions involved hydroxylation in the pyridinyl moiety, the N-methyl moiety, and the methyl group of the phenyl moiety, yielding mono- and/or dihydroxy components, with hydroxylation greater in ♂ compared to ♀. Hydroxylation in other positions was also detected, but the locations were not determined. Conjugation with glucuronic acid was observed as a secondary reaction after hydroxylation. Another major reaction was the intra-molecular condensation (cyclization) of tetraniliprole, yielding quinazolinone compounds, one of which was identified as BCS-CQ63359 (BCS-CL73507-N-methyl-quinazolinone). Cleavage of the phenyl moiety was also observed, yielding an amide, with subsequent oxidation to a carboxylic acid or methylation to an N-methyl amide. Additional cleavage reactions involving the pyridine and tetrazole rings were noted. Cleavage of the tetrazole ring was followed by oxidation yielding a carboxylic acid. Minor metabolic reactions included demethylation of the N-methyl group and deschlorodination in the pyridine ring. Additionally, two separate conjugations of tetraniliprole (after deschlorodination) with glutathione occurred, followed by degradation of one of the glutathione groups to the mercapto-alcohol.
Absorption, distribution, excretion and metabolism (gavage) Rat, Wistar PMRA# 2731872	Single (2 mg/kg bw) gavage dose administration of [pyridinyl-2-^{14}C]-BCS-CL73507; animals sacrificed 48 h postdose. **Absorption:** Absorption was rapid (Cmax reached within 2 h postdosing). Absorption was slightly faster in ♂ than in ♀. The calculated mean AUC values were similar for ♂ and ♀. **Elimination:** Plasma concentrations declined to ≤3% of Cmax by 72/48 h in ♂/♀. The $t_{1/2}$ of elimination was 36/11 h in ♂/♀. The majority of radioactivity was excreted in feces (102% of the AD) with elimination essentially complete within 72 h (most occurring by 24 h). Urinary excretion accounted for 3% of the AD in ♂ and ♀. **Distribution:** Residues in organs and tissues at 72 h postdose were minimal, with residues greater in ♀ compared to ♂. The largest concentrations were detected in liver. **Metabolism:** Unchanged tetraniliprole was the major component in excreta, accounting for 62/71% of the AD in ♂/♀. Metabolite profiles were similar between sexes. Hydroxylated metabolites appeared to be slightly more abundant in ♂ compared to ♀. Major metabolites were BCS CL73507 hydroxy-N-methyl and BCS CL73507-5-hydroxypyridine, ranging from 3% to 8% of the AD. Other prominent metabolites included BCS CL73507-deshydrochloro-dihydrate, dihydroxy (♂), BCS CL73507-deschloro desmethyl amide-dihydroxy, BCS

	CL73507-benzylalcohol (♂), BCS CL73507-pyridinyl-pyrazole-5-carboxylic acid (♂), and BCS CL73507-N methyl-quinazolinone (♀), ranging from 2% to 3% of the AD. The remainder of the identified metabolites each accounted for ≤2% of the AD. Results suggested similar metabolic reactions to those observed in PMRA# 2731870.
Absorption, distribution, excretion and metabolism (gavage) Rat, Wistar PMRA# 2731871	Single (2 mg/kg bw) gavage dose administration of [Phenyl-carbamoyl-^{14}C]-BCS-CL73507; animals sacrificed 72 h postdose. **Absorption:** Absorption was rapid with Cmax reached within 1 h after administration. The calculated mean AUC value for ♀ was approximately 1.8-fold greater than in ♂. **Elimination:** Mean plasma concentrations declined to <2% of the maximum concentration by 72 h postdosing. The $t_{1/2}$ of elimination was 25/23 h in ♂/♀. The majority of radioactivity was excreted by 24 to 48 h; excretion was essentially complete by 72 h postdosing. Fecal elimination was the major route of excretion (96% of the AD). Urinary excretion accounted for 4/5% of the AD in ♂/♀. **Distribution:** Residues in organs and tissues at 72 h postdose were minimal, with residues greater in ♀ compared to ♂. The largest concentrations were detected in liver. Kidneys in both sexes, and ovaries and perirenal fat in ♀ also contained notable residues. **Metabolism:** Unchanged tetraniliprole comprised the majority of identified radioactivity in excreta of both sexes (53/60% of the AD in ♂/♀). Metabolite profiles were similar between sexes, with the exception that hydroxylated metabolites were more abundant in ♂ compared to ♀. Major metabolites were BCS CL73507-deshydrochloro-dihydrate, BCS-CL73507-dihydroxy (♂), BCS CL73507-despyridyl (♀), BCS-CL73507-benzylalcohol, BCS CL73507 hydroxy N-methyl, and BCS-CL73507-hydroxypyridine, ranging from 3% to 7% of the AD. Other prominent metabolites were BCS-CL73507-dihydroxy (♀), BCS-CL73507-deschloro desmethyl-amide-dihydroxy, and BCS CL73507 despyridyl (♂), ranging from 2% to 3% of the AD. The remainder of the identified metabolites amounted to <2% of the AD. Results suggested similar metabolic reactions to those observed in PMRA# 2731870.
Absorption, distribution, excretion and metabolism (gavage) Rat, Wistar PMRA# 2731873	Single (2 mg/kg bw) gavage dose administration of [tetrazolyl-^{14}C]-BCS-CL73507; animals sacrificed 72 h postdose. **Absorption:** Absorption was rapid and extensive with Cmax reached within 1 h after dosing and declining to < 2% of the peak level by 72 h. **Elimination:** An initial fast elimination phase was followed by a slower elimination phase approximately 24 h later. The majority of radioactivity was excreted within 24 h postdosing, and was essentially complete by 72 h. Excretion was mainly via the fecal route and amounted to approximately 96/98% of the AD for ♂/♀. Urinary excretion represented approximately 5/6% of the AD for ♂/♀. The $t_{1/2}$ of elimination was 32/25 h in ♂/♀. **Distribution:** Radioactivity was widely distributed and tissues of both sexes contained low levels. The highest concentrations were detected in the liver. Radioactivity was detected in perirenal fat of ♀ only. **Metabolism:** The major metabolites were BCS-CL73507-hydroxy-N-methyl (both sexes) and BCS-CL73507-dihydroxy (♂ only) and ranged from 4 to 10% of the AD. Results suggested similar metabolic reactions to those observed in PMRA# 2731870.
Quantitative whole body autoradiography (gavage) Rat, Wistar PMRA# 2731869	Single (5 mg/kg bw) gavage dose administration [pyrazole-carboxamide-^{14}C]-BCS-CL73507; examinations at various intervals up to 168 h postdose. Absorption from the GI tract was rapid in both sexes, but was limited leading to low levels in tissues, blood, and excreta. Peak concentrations of radioactivity in most organs and tissues occurred at approximately 1 h postdosing, except in testis and nasal mucosa, where peak concentration occurred at 4 h postdosing. Slight delays in peak concentrations were observed for some organs and tissues of ♀ rats compared to ♂.

	Radioactivity was widely and rapidly distributed with clear preference for liver and kidney; some radioactivity was also detected in glandular organs (for example, adrenal gland) and fatty tissues. At the 168 h sacrifice, radioactivity was almost completely eliminated, with only trace amounts in liver and renal cortex of ♂ and in the liver of ♀. Excretion was predominantly by the fecal route (> 95% of the AD within 48 h of dosing) for both sexes. There were no significant sex-related differences concerning blood or tissue concentrations. Whole-body autoradiography indicated similar absorption, distribution and excretion behavior in both sexes. Radioactivity remaining in tissues and organs was negligible after 168 h, and less than 0.01% of the AD was expired in air. In urine, feces, plasma, liver and kidney, unchanged tetraniliprole was the prominent component. Metabolites included BCS-CL73507-N-methyl-quinazolinone. A small increase of the metabolite BCS-CL73507-N-methyl-quinzolinone occurred during storage of plasma for all investigated samples. Unchanged tetraniliprole remained the most prominent component at all time points.
Blood plasma kinetics study (dietary), seven-day administration Rat, Wistar PMRA# 2731874	145/163 mg/kg bw/day for ♂/♀ The purpose of this study was to determine the optimal time for sampling by determining the plasma Tmax after repeated dosing. It was determined by the study authors that under environmental conditions of the long-term studies (light period: 7 am to 7 pm and dark period: 7 pm to 7 am), a blood sampling time of approximately 8 am should give a good indication of the maximum plasma concentration of the test item. However, there were too few blood sampling time-points and high inter-animal variability to allow for obtaining sufficient data points for determining Tmax or Cmax.
Toxicity and Biokinetic Screening study Rat, Wistar PMRA# 2731875	2/sex, single 150 mg/kg bw gavage dose administration of BCS-CO80363; 5/sex/group, dosed for 14 days with BCS-CO80363 at 0, 150 mg/kg bw/day via gavage. In plasma after single dose, Tmax was 7h in ♂, 3h in ♀. Cmax was slightly higher in ♀ compared to ♂ (1.3-fold). At 24 h, plasma concentration was still elevated in ♀ compared to ♂ (3.7-fold), and fat concentration was 2.8-fold in ♀ compared to ♂. 24 h following the last repeat dose, plasma and fat concentration was higher in ♀ compared to ♂ (2.0-fold and 2.3-fold, respectively). Plasma concentrations were comparable to those seen 24 h after the single dose, but fat concentrations were 2.0/1.7-fold in ♂/♀ after repeat dosing compared to a single dose. No metabolites were identified in plasma. No mortalities, treatment related clinical signs, effects on bw or fc, or histopathology findings were noted in any group. In the 150 mg/kg bw/day repeat dose group: non s.s. ↑ thyroid wt (17 – 21%); no associated histopathology. No analysis of dose preparation was performed, and information pertaining to methods used for the determination of BCS-CO80363 concentrations in plasma and fat or identification of metabolites was not included.
In vitro inter-species liver microsome metabolic comparison Mouse, CD-1; Rat, Wistar; Rabbit, New Zealand; Dog, Beagle, Human HLM cells PMRA# 2731885, 2731886, 2731887	10 µM of [Pyrazole-carboxamide-^{14}C]BCS-CL73507, [Tetrazolyl-4-^{14}C]BCS-CL73507 or [Pyridinyl-2-^{14}C]-BCS-CL73507, incubation of 0, 30 and 60 minutes. A total 5 metabolites were identified by HPLC (BCS-1, BSC-2, BCS-3, BCS-4 and BCS-5) but their structures were not elucidated. In the incubation buffer, 98.6% of radioactivity was unchanged BCS-CL73507 following 60 min incubation, with 1.4% BCS-5, indicating that it was a degradation product and that BCS-CL73507 was stable in the buffer solution. The labeling position had little impact on the results. The most active microsomes were those of the mouse and human, with 73 – 82% and 74 – 78%, respectively, of unchanged BCS-CL73507 remaining following a 60 min incubation. The least active microsomes were those of ♀ rats, with 98% BCS-CL73507compound remaining, indicating minimal transformation. In all species, BCS-3 was the primary

	metabolite, present at 3.8 – 25.1% (with the exception of the ♀ rats due to minimal transformation) No unique metabolite was detected following incubation of BCS-CL73507 with human liver microsomes compared with the other animal species. Qualitatively human microsomes were most similar to ♂ rabbits; quantitatively they were most similar to the mouse. Results following 30 min incubation were similar to the results at 60 min, except that slightly more unchanged BCS-CL73507 was present with the 30 min incubation.
Acute Toxicity Studies	
Acute oral toxicity (Acute toxic class) Rat, Wistar PMRA# 2731825	LD_{50} (♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
Acute oral toxicity (Acute toxic class) Rat, Wistar PMRA# 2731826	LD_{50} (♂) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
Acute dermal toxicity Rat, Wistar PMRA# 2731827	LD_{50} (♂/♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
Acute inhalation toxicity (nose-only) Rat, Wistar PMRA# 2731828	LC_{50} (♂/♀) > 5.01 mg/L Low acute toxicity Sneezing, labored respiration, decreased activity and hunched posture. All signs recovered by day three, with the exception of one female with fur loss around the eye, which cleared on day 11.
Eye Irritation Rabbit, NZW PMRA# 2731829	MIS = 11.33 at 1 h MAS = 1.11 Minimally irritating
Dermal Irritation Rabbit, NZW PMRA# 2731830	MIS = 1 at 1 h MAS = 0.22 Minimally irritating
Dermal sensitization (LLNA) Mouse, CBA/J Rj PMRA# 2731831	Potential dermal sensitizer
Dermal sensitization (LLNA) Mouse, CBA/CaOlaHsd PMRA# 2731832	Potential dermal sensitizer
Short-Term Toxicity Studies	
28-day oral toxicity (diet) Mouse, C57BL/6J	NOAEL ≥ 1010/1159 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested.

PMRA# 2731838	
90-day oral toxicity (diet) Mouse, C57BL/6J PMRA# 2731834	NOAEL ≥ 973/1224 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested. Plasma concentrations of unchanged tetraniliprole ↑ slightly with ↑ dose, but in a non-proportional manner. ♀ plasma concentrations were more ↑ than those of ♂, even when comparing the lowest dose level tested in ♀ to the highest dose level tested in ♂.
28-day oral toxicity (diet) Rat, Wistar PMRA# 2731837	NOAEL ≥ 599/700 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested.
90-day oral toxicity (diet) Rat, Wistar PMRA# 2731833	NOAEL ≥ 608/723 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested. Slight ↑ in plasma concentrations of unchanged tetraniliprole in ♂ with ↑ dose, but in a non-proportional manner. In ♀, the plasma concentrations of the test compound were higher than ♂ and were similar among dose groups despite an 11-fold ↑ in dose. No treatment-related findings in FOB assessment.
28-day oral toxicity (diet), Range-finding Dog, Beagle PMRA# 2731841	NOAEL and LOAEL not established as this was a dose range-finding study. ≥190/222 mg/kg bw/day: ↑ cholesterol; ↑ salivation (♀) The plasma concentrations of unchanged tetraniliprole were similar among all treated groups, with increasing dose only resulting in a marginal, if any, ↑ in plasma concentration. The plasma concentrations in ♀ were highly variable.
90-day oral toxicity (diet) Dog, Beagle PMRA# 2731835	NOAEL = 126/138 mg/kg bw/day (♂/♀) LOAEL = 440/485 mg/kg bw/day (♂/♀) Effects at LOAEL: salivation, ↓ bw, ↓ bwg, ↑ALP; ↑ liver wt (♂) Plasma concentrations of unchanged tetraniliprole and of the metabolite BCS-CQ63359 ↑ slightly with ↑ dose, but in a non-proportional manner; a 16-fold ↑ in dose resulted in 2-fold and 4-fold ↑ plasma concentrations of unchanged tetraniliprole and the metabolite, respectively. Results were similar in both sexes.
One-year oral toxicity (diet) Dog, Beagle PMRA# 2731836	NOAEL ♂ = 20 mg/kg bw/day LOAEL ♂ = 91 mg/kg bw/day NOAEL ♀ not established as adverse effects were observed at the lowest dose level tested. LOAEL ♀ = 18 mg/kg bw/day Effects at LOAEL: ↑ salivation, diffuse vacuolation of adrenal zona glomerulosa, hypospermatogenesis and segmental tubular atrophy/hypoplasia of the testes, ↑ cholesterol (♂); ↓ bw ↓ bwg (♀). Plasma concentrations of unchanged tetraniliprole and the metabolite BCS-CQ63359 ↑ slightly with ↑ dose, but in a non-proportional manner; a 20-fold ↑ in dose resulted in 3- and 8-fold ↑ plasma concentrations of unchanged tetraniliprole and the metabolite, respectively. Results were similar in both sexes.
28-day dermal toxicity Rat, Wistar PMRA# 2731839	NOAEL ≥ 1000 mg/kg bw/day LOAEL not established as no adverse effects were observed up to the highest dose level tested.
Repeat-dose inhalation toxicity PMRA# 2731840	Waiver request was based on low volatility (3.2×10^{-9} kPa), low acute oral, dermal and inhalation toxicity, negligible irritancy, and high inhalation MOEs for the proposed use patterns and exposure scenarios. The waiver was accepted; however, a 10-fold uncertainty factor was applied to repeat exposure scenarios to account for residual uncertainty with respect to differences in absorption when extrapolating from an oral toxicity study to the inhalation route of exposure.

Chronic Toxicity/Oncogenicity Studies	
18-month carcinogenicity (diet) Mouse, C57BL/6J PMRA# 2731843	NOAEL ≥ 825/1073 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested. Plasma concentrations of neither tetraniliprole nor the metabolite BCS-CQ63359 increased in a dose-proportional manner. A 25-fold ↑ in dose level resulted in ↑ of approximately twofold and 10-fold for tetraniliprole and the metabolite, respectively. Concentrations in ♀ were slightly higher than in ♂. No evidence of oncogenicity
Two-year chronic toxicity/carcinogenicity (diet) Rat, Wistar PMRA# 2731842	NOAEL ♂ = 741 mg/kg bw/day LOAEL ♂ not established as no adverse effects were observed up to the highest dose level tested. NOAEL ♀ = 221 mg/kg bw/day LOAEL ♀ = 1052 mg/kg bw/day Effects in ♀ at LOAEL: ↓ bw, ↓ bwg, ↑ prolapsed vagina, ↑ squamous cell hyperplasia in cervix/vagina, ↑ squamous cell metaplasia of the endometrium, ↑ severity of corpora lutea depletion, equivocal ↑ uterine epithelial tumours (glandular polyp, endometrial adenocarcinoma, adenosquamous carninoma; total incidence 3, 0, 0, 6; 5.1%, 0%, 0%, 10%). Plasma concentrations of unchanged tetraniliprole ↑ slightly with ↑ dose level, but in a non-proportional manner. Plasma concentrations of metabolite BCS-CQ63359 were lower than parent at the low- and mid-dose levels, but higher at the high-dose level. Plasma concentrations of unchanged tetraniliprole and the metabolite were higher in ♀ than ♂ at the corresponding dose levels. Equivocal evidence of oncogenicity
Developmental/Reproductive Toxicity Studies	
Two-generation reproductive toxicity (diet) Rat, Wistar PMRA# 2731844	**Parental** NOAEL = 196/224 mg/kg bw/day (♂/♀) LOAEL = 896/1032 mg/kg bw/day (♂/♀) Effects at LOAEL: ↓ F1 parental bw **Offspring** NOAEL = 224 mg/kg bw/day LOAEL = 1032 mg/kg bw/day Effects at LOAEL: ↓ pup bw (F1 PND 14, 21; F2 PND 7, 14, 21); delayed completion of vaginal opening (F1) (♀) **Reproductive** NOAEL ≥ 896/1032 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested. No evidence of sensitivity of the young
Developmental toxicity (gavage) Rat, Sprague-Dawley PMRA# 2731847	**Maternal** NOAEL ≥ 1000 mg/kg bw/day LOAEL not established as no adverse effects were observed up to the highest dose level tested. **Developmental** NOAEL = 250 mg/kg bw/day LOAEL = 1000 mg/kg bw/day Effects at LOAEL: slight ↓ fetal bw, ↑ incomplete ossification of 5th and 6th sternebrae (fetal basis), ↑ unossified 5th and 6th sternebrae (fetal and litter basis). No evidence of treatment-related malformations

	Evidence of sensitivity of the young
Developmental toxicity (gavage) Rabbit, NZW PMRA# 2731848	**Maternal** NOAEL ≥ 1000 mg/kg bw/day LOAEL not established as no adverse effects were observed up to the highest dose level tested. **Developmental** NOAEL ≥ 1000 mg/kg bw/day LOAEL not established as no adverse effects were observed up to the highest dose level tested. Plasma concentrations of neither tetraniliprole nor the metabolite BCS-CQ63359 increased in a dose-proportional manner. A 16-fold ↑ in dose level resulted in ↑ of approximately twofold and 7.5-fold for tetraniliprole and the metabolite, respectively. Concentrations in ♀ were slightly higher than in ♂. No evidence of treatment-related malformations No evidence of sensitivity of the young
Genotoxicity Studies	
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731849	Negative Tested up to precipitating and limit concentrations.
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731850	Negative Tested up to precipitating and limit concentrations.
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731852	Negative Tested up to precipitating and limit concentrations.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731857	Negative Tested up to precipitating and cytotoxic concentrations.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731858	Negative Tested up to precipitating concentrations.
In vitro chromosomal aberration assay Chinese hamster lung (V79) cells PMRA# 2731862	Negative Tested up to cytotoxic and/or precipitating concentrations.
In vivo micronucleus assay Mouse, NMRI PMRA# 2731867	Negative No clinical signs of toxicity.
In vitro micronucleus assay	Negative

Human lymphocytes PMRA# 2731868	Tested up to precipitating concentrations.
Neurotoxicity Studies	
Acute and subchronic neurotoxicity PMRA# 2731845	Waiver requested based on lack of evidence of neurotoxicity in other studies, including the FOB performed in the rat 90-day oral toxicity study, and the rat 28-day dermal toxicity study. The waiver request was accepted.
Studies on Metabolite BCS-CR74541	
Acute oral toxicity (Acute toxic class) Rat, Wistar PMRA# 2731880	LD_{50} (♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
28-day oral toxicity (diet) Rat, Wistar PMRA# 2731879	NOAEL ≥ 775/884 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested.
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731851	Negative Tested up to precipitating and limit concentrations.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731856	Negative Tested up to precipitating concentrations.
In vitro chromosomal aberration assay Chinese hamster lung (V79) cells PMRA# 2731864	Negative Tested up to precipitating concentrations.
Studies on Metabolite BCS-CU81055	
Acute oral toxicity (Acute toxic class) Rat, Wistar PMRA# 2731881	LD_{50} (♀) > 2000 mg/kg bw Low acute toxicity No clinical signs of toxicity.
28-day oral toxicity (diet) Rat, Wistar PMRA# 2731878	NOAEL ≥ 768/845 mg/kg bw/day (♂/♀) LOAEL not established as no adverse effects were observed up to the highest dose level tested.
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731853	Negative Tested up to precipitating and limit concentrations.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731861	Negative Tested up to precipitating concentrations.

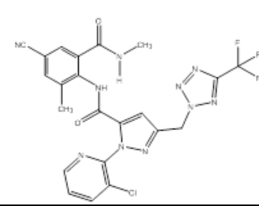
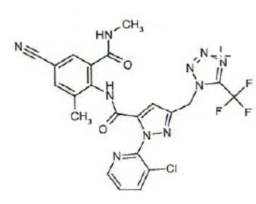
In vitro chromosomal aberration assay Chinese hamster lung (V79) cells PMRA# 2731866	Negative Tested up to the limit concentration.
Studies on Metabolite BCS-CT30673	
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731854	Negative Tested up to precipitating and limit concentrations.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731860	Negative Tested up to cytotoxic and/or precipitating concentrations.
In vitro chromosomal aberration assay Chinese hamster lung (V79) cells PMRA# 2731863	Negative Tested up to precipitating concentrations.
Studies on Metabolite BCS-CU81056	
Bacterial reverse mutation assay S. typhimurium TA98, TA100, TA1535, TA1537, and TA102 PMRA# 2731855	Negative Tested up to the limit concentration.
In vitro gene mutation assay in mammalian cells Chinese hamster lung (V79) cells PMRA# 2731859	Negative Tested up to precipitating concentrations.
In vitro chromosomal aberration assay Chinese hamster lung (V79) cells PMRA # 2731865	Negative Tested up to precipitating concentrations.
Special Studies (non-guideline)	
In vitro steroidogenesis screen H295R human adrenocortical carcinoma cells PMRA# 2731877	Cells exposed to tetraniliprole or the metabolite BCS-CQ63359. Concentrations based on plasma concentrations measured in ♀ rats and mice at the end of the cancer bioassays and on ♂ dogs at the end of the one-year toxicity study. Tetraniliprole: ↑ estradiol and cortisol secretion ≥3 µM; marginal ↑ in testosterone and progesterone ≥3 µM BCS-CQ63359: ↑ estradiol and cortisol secretion ≥1 µM; marginal ↑ in testosterone ≥8 µM Supplemental
Uterotrophic assay (gavage) Rat, Sprague-Dawley; 19-day old PMRA# 2731876	No treatment-related effects on day of vaginal opening or on uterine wt when dosed at 600 mg/kg bw/day of BCS-C080363for 20 days or 800 mg/kg bw/day for three days. Supplemental

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

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary	An ARfD was not established as an effect attributable to a single exposure of tetraniliprole was not identified in the database.		
	ARfD not required		
Repeated dietary	One-year dietary toxicity study in the dog	LOAEL = 18 mg/kg bw/day, based on reduced body weight and body weight gain in ♀ (NOAEL not established)	300
	ADI = 0.06 mg/kg bw/day		
Short- and intermediate-term dermal	28-day dermal toxicity study in rats	NOAEL = 1000 mg/kg bw/day, no adverse effects at highest dose level tested	100
Short- and intermediate-term inhalation[2]	90-day dietary toxicity study in the dog	NOAEL = 126 mg/kg bw/day, based on reduced body weight and body weight gain in both sexes	1000
Non-dietary oral ingestion (short- and intermediate-term)	90-day dietary toxicity study in the dog	NOAEL = 126 mg/kg bw/day, based on reduced body weight and body weight gain in both sexes	100
Short- and intermediate-term aggregate (oral)	90-day dietary toxicity study in the dog	NOAEL = 126 mg/kg bw/day, based on reduced body weight and body weight gain in both sexes	100
Cancer	Equivocal increase in uterine epithelial uterine tumours in female rats. Threshold approach was considered appropriate. The ADI provides a margin of over 17 500 to the dose level at which an equivocal increase in uterine epithelial tumours was observed in rats.		

[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, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation. See main text for further discussion on this issue.

Table 5 Identification of Select Metabolites and Degradates of Tetraniliprole

Code	Identity	Structure
BCS-CL73507	Tetraniliprole (parent compound) 2-(3-chloro-2-pyridyl)-N-[4-cyano-2-methyl-6-(methylcarbamoyl)phenyl]-5-[[5-(trifluoromethyl)tetrazol-2-yl]methyl]pyrazole-3-carboxamide	
BCS-CO80363	Mixture of tetraniliprole and 1 isomer, BCS-CN61675 (96.8% tetraniliprole, 3.2% isomer)	

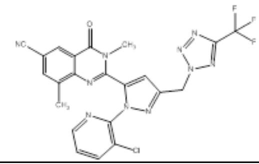
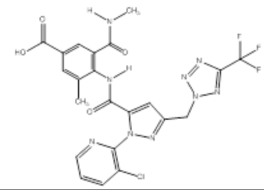
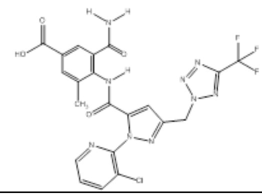
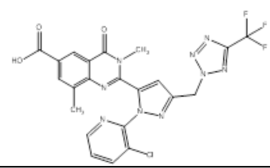
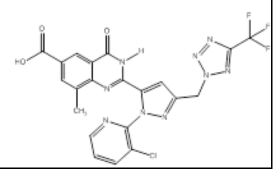
Code	Identity	Structure
BCS-CQ63359	BCS-CL73507-N-methyl-quinazolinone	
BCS-CR74541	BCS-CL73507- carboxylic acid	
BCS-CU81055	BCS-CL73507- desmethylamide- carboxylic acid	
BCS-CT30673	BCS-CL73507-N-methylquinazolinone- carboxylic acid	
BCS-CU81056	BCS-CL73507- quinazolinone-carboxylic acid	

Table 6 Exposure and risk estimates for workers in commercial corn seed treatment facilities

Scenario	kg a.i. handled per day	Unit Exposure[2] (µg/kg a.i. handled)		Exposure[3,4] (mg/kg bw/day)		MOE	
		Dermal	Inhalation	Dermal	Inhalation	Dermal[5]	Inhalation[6]
Treater/Applicator	137.5	256	3.72	0.440	0.00639	2270	19700
Bagger/Sewer/ Stacker		114	54.5	0.196	0.0937	5100	1350
Cleanout Personnel	Application Rate[1]: 111 g a.i./100 kg seed	127 µg/g a.i./100 kg seed	24.1 µg/g a.i./100 kg seed	0.176	0.0334	5670	3770

[1] The application rate for cleanout personnel (g a.i./100 kg seed) = 4400 seeds/kg × (20.2 g a.i./ 80 000 unit of seed) × 100kg/100 kg seed

[2] Unit exposures for a single layer of PPE with chemical-resistant gloves.

[3] For treaters/applicators and baggers/sewers/stackers:

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{80\text{ kg bw} \times 1000\text{ µg/mg}}$$

[4] For Cleanout personnel, unit exposures are normalized for application rate therefore:

$$\text{Exposure (mg/kg bw/day)} = \frac{\text{Unit exposure (µg/g a.i./100 kg seed/day)} \times \text{application rate (g a.i./100 kg seed)}}{80 \text{ kg bw} \times 1000 \text{ µg/mg}}$$

[5] MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure (mg/kg bw/day); Target MOE = 100
[6] MOE = Inhalation NOAEL of 126 mg/kg bw/day ÷ Inhalation Exposure (mg/kg bw/day); Target MOE = 1000

Table 7 Dermal and Inhalation Exposure and Risks to Tetraniliprole from Foliar and In-furrow Application to Terrestrial Food and Feed Crops and Foliar Application to Turf

Scenario	Amount of ai handled per day (kg a.i./day) [1]	Dermal unit exposure (µg /kg a.i. handled)[2]	Dermal Exposure (mg a.i./kg bw/day)[3]	Dermal MOE[4]	Inhalation unit exposure (µg /kg a.i. handled)[2]	Inhalation Exposure (mg a.i./kg bw/day)[3]	Inhalation MOE[5]
Terrestrial Food and Feed Crops							
Liquid M/L + groundboom							
M/L (open)/A (open cab)	10.8	83.9	0.0113	88 500	2.31	0.000312	404 000
Liquid M/L + open cab airblast							
M/L (open)/A (open cab)	1.2	3827.8	0.0574	17 400	9.71	0.000146	863 000
Aerial Application (liquid/closed cockpit)							
M/L (open)	12	58.5	0.0088	114 000	0.63	0.000095	1 330 000
Pilot	12	2.67	0.000401	2 490 000	0.00969	0.00000145	86 900 000
Mechanically-pressurized handgun (orchard crops)							
M/L/A	1.0	5585.49	0.0698	143 00	151	0.001888	66 700
In-Furrow Application (liquid)							
M/L (open)/A (open cab)	15.6	83.9	0.0164	61 000	2.31	0.000450	280 000
Turf							
Liquid M/L + groundboom							
M/L (open)/A (open cab)	3	83.9	0.003146	318 000	2.31	0.000087	1 450 000
Liquid M/L/A turf gun							
M/L/A (turf gun)	0.2	1103	0.00276	363 000	3.4	0.0000085	14 800 000

[1] Exposure was only calculated for highest amount handled for each equipment type.
[2] Based on PHED, AHETF and ORETF databases for the baseline PPE of a single layer and chemical-resistant gloves.
[3] Exposure (mg/kg bw/day) = Amount Handled per Day × Unit Exposure / 80 kg bw / 1000 µg/mg
[4] Dermal MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure (mg/kg bw/day); Target MOE = 100
[5] Inhalation MOE = Inhalation NOAEL of 126 mg/kg bw/day ÷ Inhalation Exposure (mg/kg bw/day); Target MOE = 1000

Table 8 Exposure and risk estimates from planting commercially treated corn and soybean seeds

Seed	kg a.i. handled per day[1]	Unit Exposure (µg/kg a.i. handled) [2]		Exposure (mg/kg bw/day) [3]		MOE	
		Dermal	Inhalation	Dermal	Inhalation	Dermal[4]	Inhalation[5]
Corn	2.8	1515	82.83	0.05303	0.002899	18 900	43 500
Soybean	4	1515	82.83	0.07575	0.004142	13 200	30 400

[1] Based on the application rate × seeding rates
[2] Surrogate passive dosimetry study on planting of treated corn seed.
[3] $\text{Exposure (mg/kg bw/day)} = \dfrac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{80 \text{ kg bw} \times 1000 \text{ µg/mg}}$
[4] MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure (mg/kg bw/day); Target MOE = 100
[5] MOE = Inhalation NOAEL of 126 mg/kg bw/day ÷ Inhalation Exposure (mg/kg bw/day); Target MOE = 1000

Table 9 Postapplication occupational risk assessment foliar application

Crop /Crop Group (CG)	Application Rate (µg/cm²)	Activity	TC (cm²/hr)	DFR (µg/cm²)	Exposure (mg/kg bw/day) [1]	MOE [2]
CSG 1C, including potato	0.30	Hand-set Irrigation	1750	0.101	0.0177	56 497
CG 4-13	0.45	Hand-set Irrigation	1750	0.298	0.0522	19 157
CG 8-09	0.30	Hand-set Irrigation	1750	0.161	0.0282	35 461
CG 5-13	0.45	Hand harvesting	5150	0.241	0.1241	8058
Corn	0.30	Hand harvesting	8800	0.136	0.1197	8354
Soybean	0.30	Scouting	1100	0.130	0.0143	69 930
CG 11-09, CG 12-09	0.60	Thinning	3000	0.256	0.0768	13 021
CSG 13-07 F	0.45	Girdling/turning	19 300	0.204	0.3937	2540
CG 14-11	0.60	Scouting	580	0.272	0.0158	63 291

[1] REI of 0 days used to calculate the worst-case exposure scenario
[2] MOE = NOAEL of 1000 mg/kg bw/day; Target MOE = 100

Table 10 Postapplication MOEs for workers exposed to turf/sod treated with tetraniliprole

Activity	Application Rate (µg/cm²)	# of Applications	Turf Transferable Residue (TTR) (µg/cm²)	TC (cm²/hr)[1]	Exposure Time (ET) (hr/day)	Dermal Exposure (mg/kg bw/day)[2]	Dermal MOE[3]
Golf Courses							
Mowing, watering, cup changing, irrigation repair and miscellaneous grooming	1	2	0.0105	3500	8	0.0039	2.56×10^5
Sod Farms							
Slab harvesting, transplanting/planting	1	2	0.0105	6700	8	0.0074	1.35×10^5

[1] Source: ARTF database

[2] Dermal Exposure (mg/kg bw/day) = TTR × TC × ET ÷ 80 kg bw ÷ Conversion Factor

[3] Dermal MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure; Target MOE = 100.

Table 11 Dermal exposure during postapplication activities following commercial treatment of fruit trees in residential areas

Lifestage	DFR (ug/cm²)	Transfer Coefficient (cm²/hr)	Exposure Time (hr)	Dermal Exposure (mg/kg bw/day)	Dermal MOE
Adult (16+ yrs)	0.256	1700	1	5.44×10^{-3}	184 000
Children (6 <11 yrs)	0.256	930	0.5	3.72×10^{-3}	269 000

[1] The DFR value was calculated based on three applications of the maximum rate.

[2] Dermal Exposure (mg/kg bw/day) = DFR × TC × ET ÷ kg bw ÷ Conversion Factor

[3] Dermal MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure; Target MOE = 100.

Table 12 Dermal exposure to the general public from treated golf courses

Lifestage	TTR (µg/cm²)[1]	Transfer Coefficient (cm²/hr)	Exposure Time (hr/day)	Dermal Exposure (mg/kg/day)[2]	Dermal MOE[3]
Adult (16+ yrs)	0.0105	5300	4	0.00279	359 000
Youth 11 <16 yrs	0.0105	4400	4	0.00325	308 000
Children 6 <11 yrs	0.0105	2900	4	0.00381	262 000

[1] The TTR value was calculated based on two applications of the maximum rate.

[2] Dermal Exposure (mg/kg bw/day) = TTR × TC × ET ÷ kg bw ÷ Conversion Factor

[3] Dermal MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure; Target MOE = 100.

Table 13 Residential postapplication exposure to treated turf

Life Stage	Activity	TTR (µg/cm²)[1]	Transfer Coefficient (cm²/hr)	Hours of Exposure (hr)	Dermal Exposure (mg/kg/day)[2]	Dermal MOE[3]
Adult (16+ yrs)	High Contact	0.0105	180000	1.5	0.0355	28 200
	Mowing		5500	1	0.000723	1 380 000
Youth (11 < 16 yrs)	Mowing		4500	1	0.000831	1 200 000
Child (1 < 2 yrs)	High Contact		49000	1.5	0.0703	14 200

[1] The TTR value was calculated based on two applications of the maximum rate.

[2] Dermal Exposure (mg/kg bw/day) = TTR × TC × ET ÷ kg bw ÷ Conversion Factor

[3] Dermal MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Dermal Exposure; Target MOE = 100.

Table 14 Incidental oral exposure for children (1 < 2 years)[1]

	Residue	Surface Area Mouthed / Event	Exposure Time (hours/ day)	Replenishment intervals per hr (intervals/ hr)	Extraction by Saliva	Events per hour	Incidental Oral Exposure (mg/kg/day)	MOE
HtM	0.0155 mg/hr	13%	1.5	4	0.48	14	0.000246	511 000
OtM	0.01052 $\mu g/cm^2$	10 cm^2				9	0.0000442	2 850 000
Soil Ingestion	0.67 µg/g	Ingestion Rate = 50 mg/day					0.00000305	41 400 000

[1] Refer to Section 3 of the 2012 USEPA Residential SOP for an explanation of the default calculations and parameter inputs.

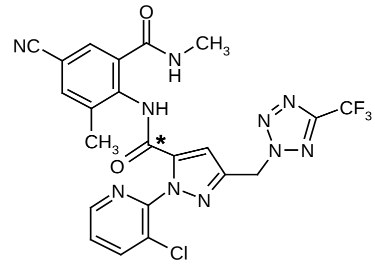
Table 15 Aggregate exposure for tetraniliprole

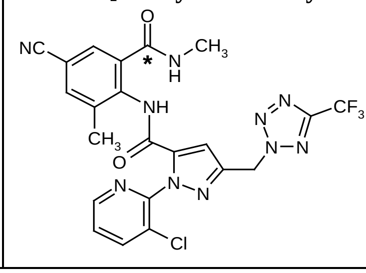
Life Stage	Exposure (mg/kg bw/day)			Aggregate MOE [1]
	Incidental Oral (HtM)	Dietary	Aggregate	
Children (1 < 2 years)	0.000246	0.03520	0.03545	3550

[1] The aggregate short- to intermediate – term NOAEL of 126 mg/kg bw/day; target MOE = 300
The aggregate MOE = NOAEL (mg/kg bw/day) ÷ Aggregate Exposure (mg/kg bw/day)

Table 16 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN TOMATO, APPLE, POTATO, LETTUCE AND RICE		PMRA # 2731894-2731899/2731900-2731906/2731908
Radiolabel Position	**[Pyrazole-carboxamide-^{14}C]-**	**[Phenyl-carbamoyl-^{14}C]-**



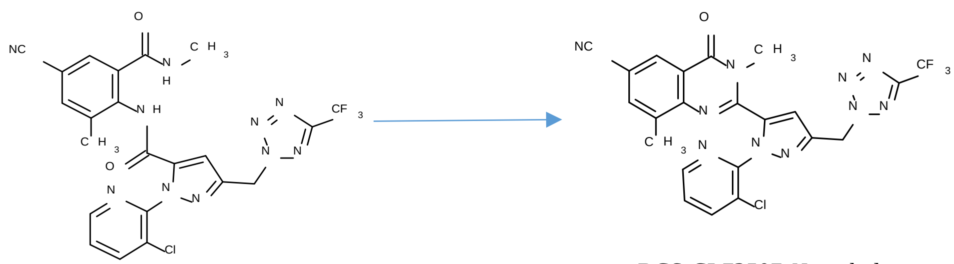


Test Site	In individual pots in greenhouse	
Treatment/Rate	Tomato: 1 drench treatment: 153 – 156 g a.i./ha/season Apple: 2 foliar application: 159 – 161 g a.i./ha/season Potato: 2 foliar applications:207 g a.i./ha/season 1 seed treatment in-furrow: 200g a.i./ha/season Lettuce: 2 foliar applications:119 g a.i./ha/season Paddy Rice: 2 foliar applications:101 – 103 g a.i./ha/season 1 granular application:205 – 211 g a.i./ha/season Field corn: Seed treatment: 63 g ai/ha/season and 150 g a.i./ha/season	
Formulation	Suspension concentrate (SC) formulation	

Matrices	**PHI (days)**	**[Pyrazole-carboxamide-^{14}C]-**	**[Phenyl-carbamoyl-^{14}C]-**
		Overall TRRs (ppm)	**Overall TRRs (ppm)**
Tomato fruit (Soil drench)	83-99	<0.001	<0.001
Tomato leaves (Soil drench)	99	0.005	0.006
Apple fruit (Foliar)	64-65	0.183	0.252
Apple leaves (Foliar)	66	99.406	-
Potato tubers (Foliar) (Seed piece in-furrow)	14 151	<0.001 <0.001	<0.001 -
Lettuce (Foliar)	7	4.063	4.122
Paddy rice forage Foliar Granular	13 64	1.306 0.011	2.579 0.008
Paddy rice grain Foliar Granular	56 150	0.040 0.003	0.024 0.004
Paddy rice husks Foliar Granular	56 150	2.519 0.026	2.110 0.018
Paddy rice straw Foliar Granular	56 150	4.317 0.098	4.566 0.069
Field corn forage - Seed treatment	98	63 g a.i./ha: 0.003; 150 g a.i./ha:0.006	-
Field corn stover - Seed treatment	145	63 g a.i./ha: 0.004; 150 g a.i./ha:0.008	-
Field corn grain - Seed treatment	145	63 g a.i./ha: <0.001; 150 g a.i./ha:<0.001	-

Matrices	Major Metabolites (≥10% of the TRRs) - [Pyrazole-Carboxamide-^{14}C]/ [Phenyl-Carbamoyl-^{14}C]-
Tomato leaves and fruits- Soil drench	Tetraniliprole; BCS-CL73507-N-methyl- quinazolinone
Apple leaves and fruits- Foliar	Tetraniliprole
Potato tubers- Foliar	Tetraniliprole; BCS-CL73507-N-methyl- quinazolinone
Lettuce - Foliar	Tetraniliprole
Paddy rice forage– Foliar	Tetraniliprole
Paddy rice forage- Granular	Tetraniliprole; BCS-CL73507-*N*-methyl- quinazolinone
Paddy rice grain – Foliar or Granular	Tetraniliprole
Paddy rice husks – Foliar or Granular	Tetraniliprole
Paddy rice straw – Foliar	Tetraniliprole
Paddy rice straw- Granular	Tetraniliprole; BCS-CL73507-N-methyl- quinazolinone
Field corn stover- Seed treatment	Tetraniliprole; BCS-CL73507-N-methyl- quinazolinone

Proposed Metabolic Pathway in Plants



Tetraniliprole
(BCS-CL73507)

BCS-CL73507-*N*-methyl-
quinazolinone
(BCS-CQ63359)

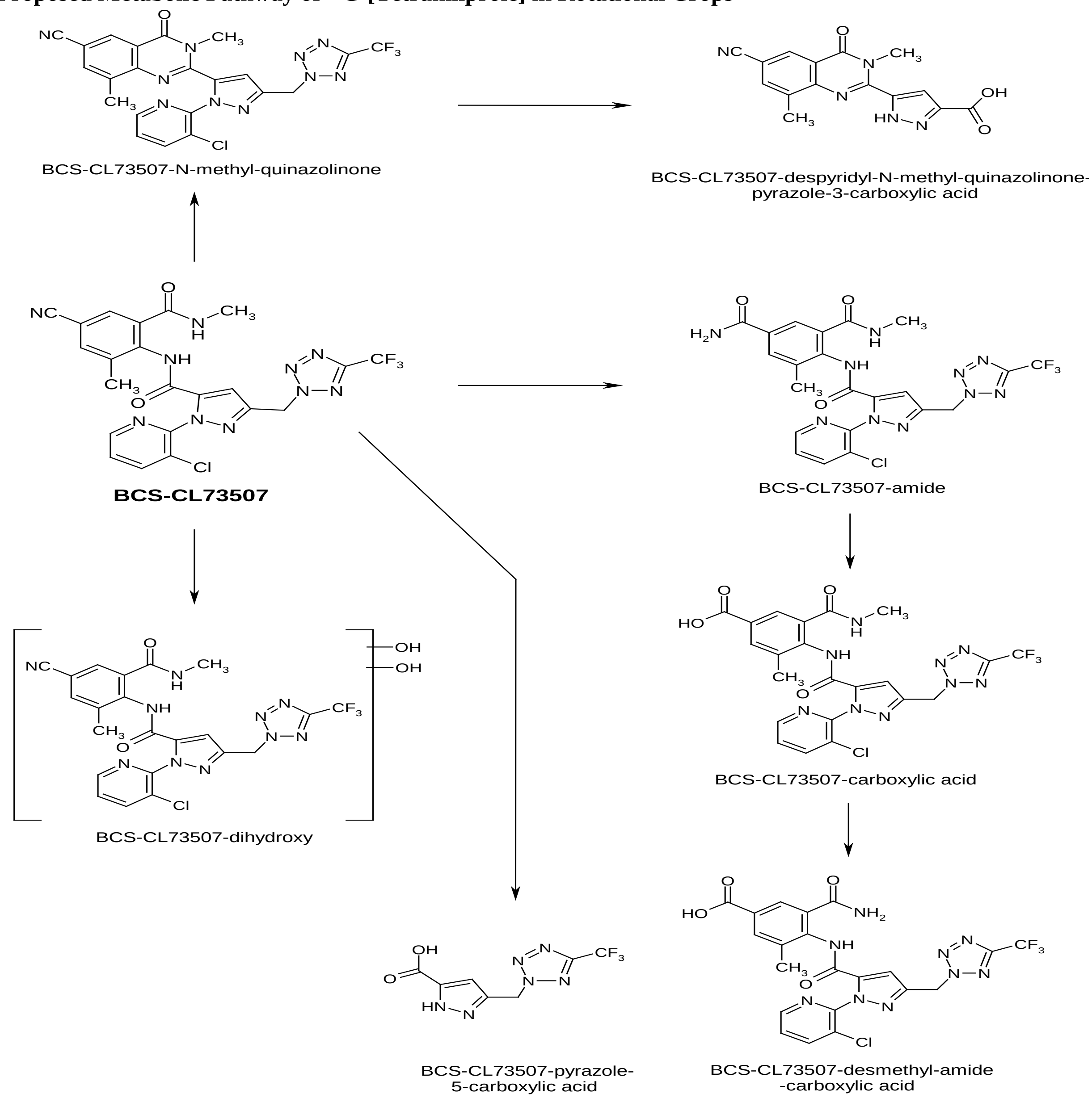
CONFINED ACCUMULATION IN ROTATIONAL CROPS- [Wheat, Turnip, and Swiss chard]	PMRA# 2732178/2732179
Radiolabel position	[Pyrazole-carboxamide-^{14}C] and [Phenyl-carbamoyl-^{14}C]
Test Site	A planting container (area 1 m^2) was filled with a sandy loam soil 'Monheim 4'was placed in a greenhouse during the aging period of the soil (30 days after treatment) and during the plant cultivation.
Soil type	Sandy loam: 1.2% organic carbon; pH ($CaCl_2$) of 6.8; CEC = 8.2 meq/100g
Treatment	Spray application onto bare soil at 209-213 g ai/ha/season

Radiolabel	**[Pyrazole-carboxamide-^{14}C]**			**[Phenyl-carbamoyl-^{14}C]**		
	Overall TRRs [ppm]			**Overall TRRs [ppm]**		
PBI (days)	**30**	**168**	**286**	**30**	**168**	**286**
Wheat forage	0.057	0.030	0.014	0.060	0.024	0.007
Wheat hay	0.208	0.062	0.064	0.160	0.063	0.028
Wheat straw	0.256	0.104	0.110	0.116	0.067	0.035
Wheat grain	0.006	0.007	0.007	0.001	0.004	0.002
Turnip leaves	0.007	0.002	0.007	0.006	0.004	0.003
Turnip roots	0.004	0.008	0.002	0.002	0.001	0.001
Swiss chard (immature)	0.056	0.020	0.014	0.056	0.016	0.012
Swiss chard (at maturity)	0.052	0.023	0.016	0.047	0.014	0.008

TRRs from both radiolabels were not further analyzed in wheat grain (all PBIs), and turnip (leaves and roots) from 2nd and 3rd rotation as residues were <0.01 ppm. Swiss chard at maturity and wheat forage (phenyl label only) at the 3rd rotation were not further analyzed.

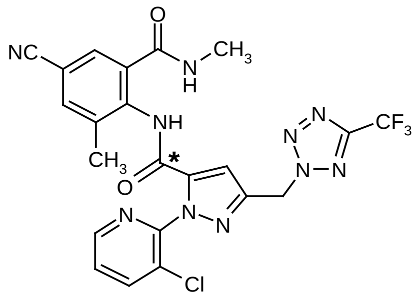
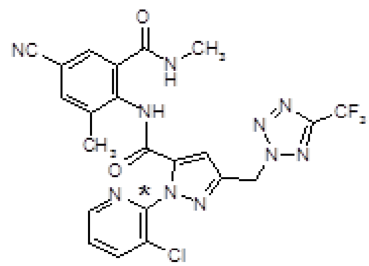
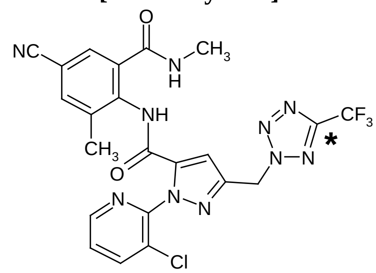
Summary of Major Metabolites (>10% of the TRRs) in Rotated Crops			
Rotated crops	**1st Rotation – 30d PBI**	**2nd Rotation - 168d PBI**	**3rd Rotation - 286d PBI**
	[Pyrazole-carboxamide-^{14}C]/ [Phenyl-carbamoyl-^{14}C]	**[Pyrazole-carboxamide-^{14}C]/ [Phenyl-carbamoyl-^{14}C]**	**[Pyrazole-carboxamide-^{14}C]/ [Phenyl-carbamoyl-^{14}C]**
Wheat forage	Tetraniliprole	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid
Wheat hay	Tetraniliprole; BCS-CL73507-*N*-methyl quinazolinone	Tetraniliprole; BCS-CL73507-*N*-methyl quinazolinone; BCS-CL73507-desmethyl-amide-carboxylic acid	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid; BCS-CL73507-*N*-methyl quinazolinone
Wheat straw	Tetraniliprole	Tetraniliprole; BCS-CL73507-*N*-methyl quinazolinone; BCS-CL73507-carboxylic acid	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid; BCS-CL73507-*N*-methyl quinazolinone
Turnip leaves	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid	Not analyzed	Not analyzed
Turnip roots	Tetraniliprole; BCS-CL73507-*N*-methyl quinazolinone; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid	Not analyzed	Not analyzed
Swiss chard (immature)	Tetraniliprole; BCS-CL73507-despyridyl-*N*-methyl-quinazolinone-pyrazole-3-carboxylic acid	Tetraniliprole; BCS-CL73507-carboxylic acid; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-*N*-methyl quinazolinone	Tetraniliprole; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid; BCS-CL73507-*N*-methyl-quinazolinone
Swiss chard (at maturity)	Tetraniliprole; BCS-CL73507-despyridyl-*N*-methyl-quinazolinone-pyrazole-3-carboxylic acid	Tetraniliprole; BCS-CL73507-carboxylic acid; BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-despyridyl-*N*-methyl-quinazolinone-pyrazole-3-carboxylic acid	BCS-CL73507-desmethyl-amide-carboxylic acid; BCS-CL73507-carboxylic acid

Proposed Metabolic Pathway of ^{14}C-[Tetraniliprole] in Rotational Crops



NATURE OF THE RESIDUE IN LAYING HEN	**PMRA# 2731891-2731893**

Six laying hens were dosed orally each with [Pyrazole-carboxamide-^{14}C]-, [Pyridinyl-2-^{14}C]-, and [Tetrazolyl-^{14}C]-Tetraniliprole at 17.94 to 18.66 mg/kg feed using 0.5% Tragacanth suspension once daily for 14 consecutive days. Samples of excreta were collected daily. Samples of eggs were collected once daily. The hens were euthanized 6 hours after administration of the final dose. Residues in eggs appeared to plateau after day 9 (0.08-0.09 ppm) for all radiolabels.

[Pyrazole-carboxamide-^{14}C]-	[Pyridinyl-2-^{14}C]-	[Tetrazolyl-^{14}C]-
		

Matrices	[Pyrazole-Carboxamide-^{14}C]	[Pyridinyl-2-^{14}C]	[Tetrazolyl-^{14}C]	[Pyrazole-Carboxamide-^{14}C]	[Pyridinyl-2-^{14}C]	[Tetrazolyl-^{14}C]
	Overall TRRs (ppm)			% of Administered Dose		
Excreta (Day 1 – 13.25)	---	---	---	92.49	92.32	91.25
Eggs (Day 1 – 13.25)	0.063	0.069	0.067	0.18	0.19	0.16
Partly Formed Eggs	0.218	0.236	0.245	0.03	0.03	0.05
Liver	0.485	0.734	0.766	0.08	0.13	0.12
Kidney	0.098	0.332	0.172	<0.01	0.01	0.01
Fat	0.046	0.028	0.095	0.04	0.02	0.08
Muscle	0.017	0.025	0.031	0.05	0.07	0.09
Skin	0.035	0.047	0.078	0.01	0.01	0.02
Total	**---**	**---**	**---**	**92.88**	**92.79**	**91.81**

Matrices	**Major Metabolites (>10% of the TRRs) – [Pyrazole-carboxamide-^{14}C]/[Pyridinyl-2-^{14}C]/[Tetrazolyl-^{14}C]**
Eggs	Tetraniliprole; BCS-CL73507-despyridyl-*N*-methyl-quinazolinone
Muscle	Tetraniliprole; BCS-CL73507-pyrazole-5-amide; BCS-CL73507-pyrazole-5-*N*-methyl-amide
Fat	Tetraniliprole; BCS-CL73507-despyridyl-*N*-methyl-quinazolinone
Liver	BCS-CL73507-despyridyl-*N*-methyl-quinazolinone

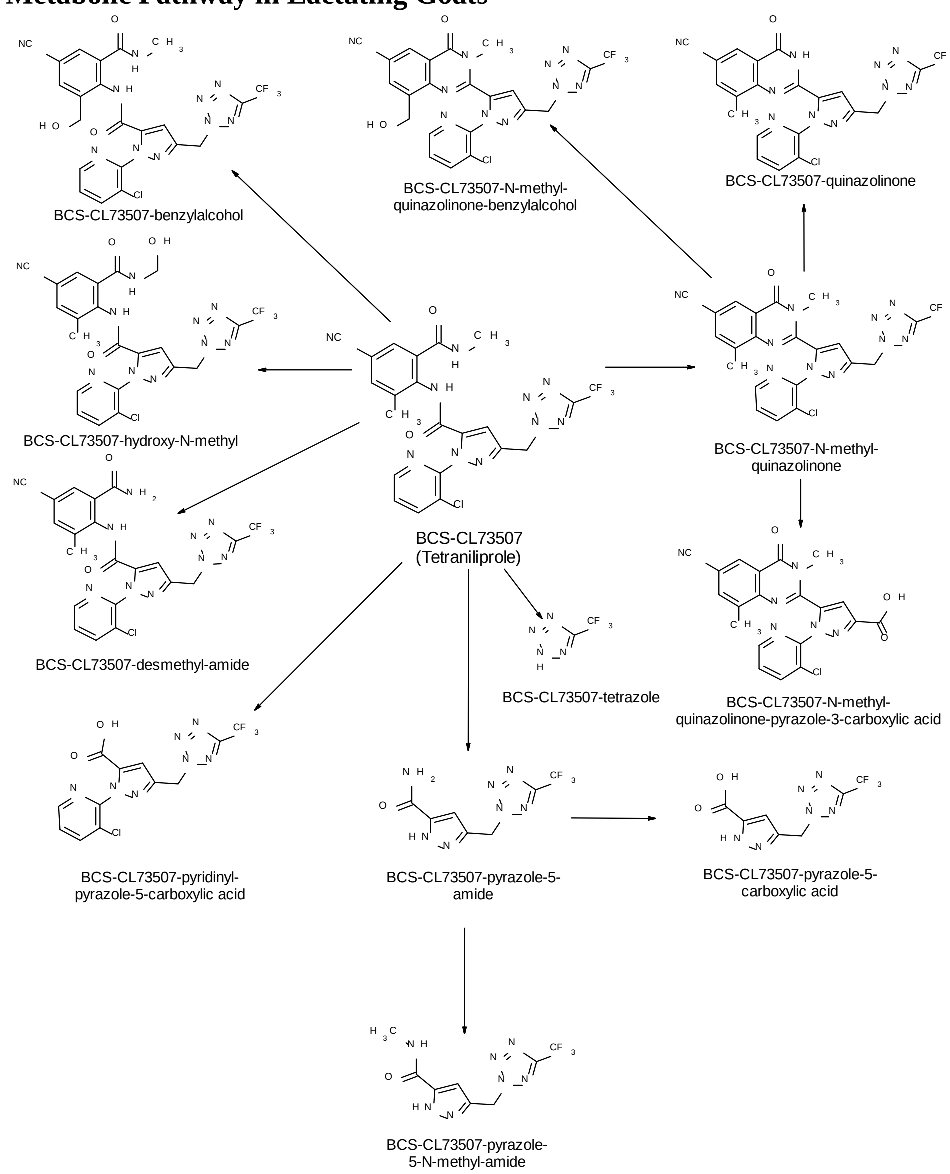
NATURE OF THE RESIDUE IN LACTATING GOATS	**PMRA# 2731888-2731890**

Three lactating goats were dosed orally each with [Pyrazole-carboxamide-^{14}C]-, [Pyridinyl-2-^{14}C]-, and [Tetrazolyl-^{14}C]-Tetraniliprole at an average of 21 to 38 mg/kg feed by gelatin capsule once daily for 5 consecutive days. Samples of excreta were collected daily and milk was collected twice daily. The goats were euthanized at approximately 6 hours after administration of the final dose. There was no evidence of a plateau of residues in milk for any of the radiolabels. The majority of the radioactivity was found in skim milk (94 – 98% of the TRRs; 0.397 – 0.496 ppm) in comparison to cream (2 – 6% of the TRRs; 0.010 – 0.024 ppm).

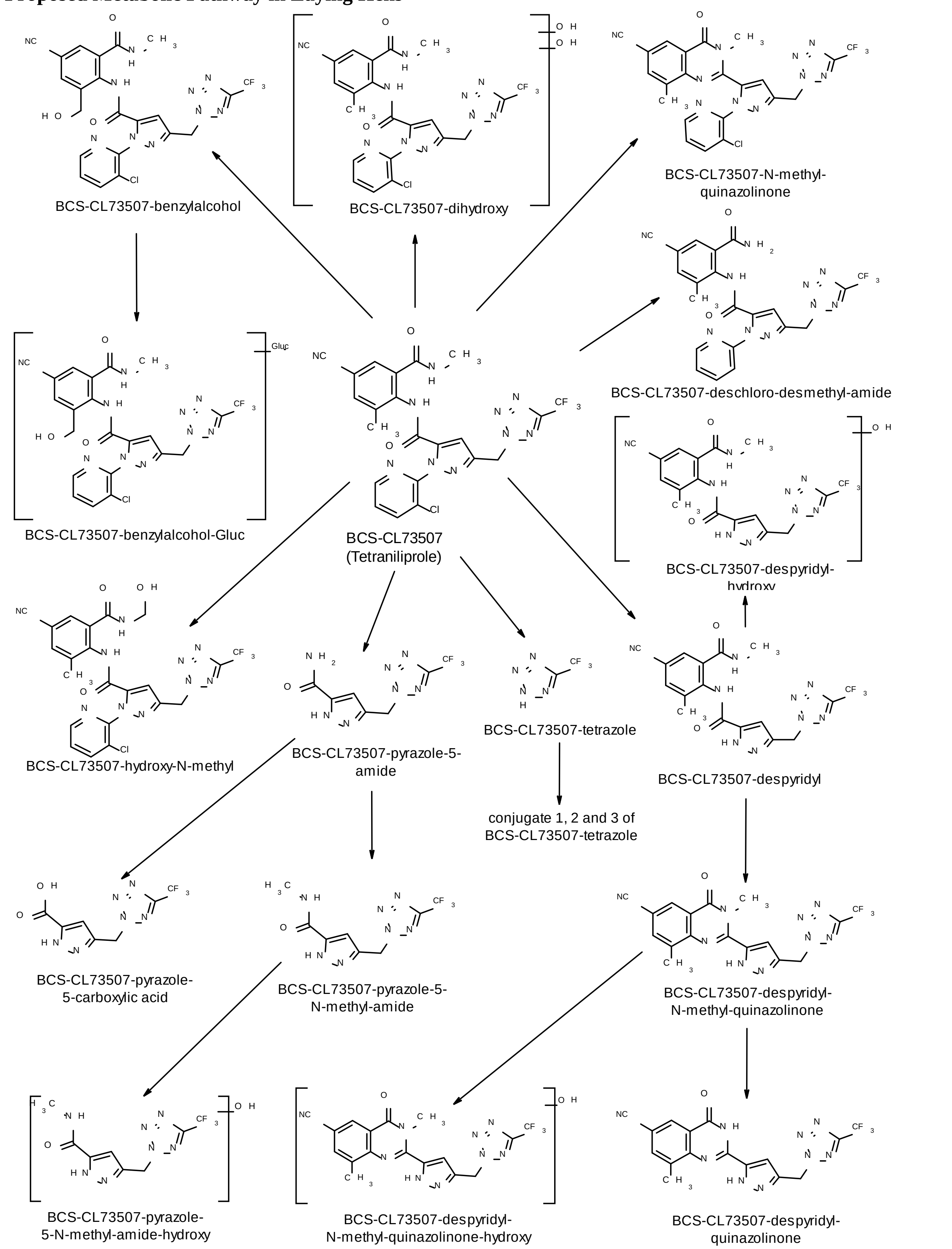
Matrices	[Pyrazole-Carboxamide-^{14}C]	[Pyridinyl-2-^{14}C]	[Tetrazolyl-^{14}C]	[Pyrazole-Carboxamide-^{14}C]	[Pyridinyl-2-^{14}C]	[Tetrazolyl-^{14}C]
	Overall TRRs (ppm)			% of Administered Dose		
Liver	0.998	0.878	1.211	0.42	0.44	0.57
Kidney	0.253	0.243	0.331	0.01	0.02	0.02
Muscle	0.099	0.086	0.123	0.56	0.49	0.72
Fat	0.598	0.387	0.473	1.36	0.89	1.11
Milk	0.326	0.223	0.368	1.24	1.32	1.10
Urine	---	---	---	2.13	2.03	3.25
Feces	---	---	---	67.28	68.98	60.87
Total excreted	---	---	---	69.41	71.02	64.12
Total Administered	**---**	**---**	**---**	**73.0%**	**74.2%**	**67.6%**

Matrices	Major Metabolites (>10% of the TRRs) – [Pyrazole-carboxamide-^{14}C]/[Pyridinyl-2-^{14}C]/[Tetrazolyl-^{14}C]
Liver	Tetraniliprole
Muscle	Tetraniliprole, BCS-CL73507-*N*-methyl-quinazolinone
Fat	Tetraniliprole, BCS-CL73507-*N*-methyl-quinazolinone
Kidney	Tetraniliprole, BCS-CL73507-*N*-methyl-quinazolinone
Whole milk	Tetraniliprole, BCS-CL73507-benzylalcohol, BCS-CL73507-*N*-methyl-quinazolinone

Proposed Metabolic Pathway in Lactating Goats



Proposed Metabolic Pathway in Laying Hens



FREEZER STORAGE STABILITY				PMRA # 2732158
The stability of BCS-CL73507-*N*-methyl-quinazolinone was also tested, but results are not reported herein.				
Tested Matrices	**Analyte**	**Tested Intervals (months)**	**T°C**	**Category**
Tomato	Tetraniliprole (BCS-CL73507)	4, 6, 12, 19, 24	≤-18	High-water
Dry bean seed				High-protein
Wheat grain				High-starch
Rapeseed				High-oil
Grapes				High-acid
Animal matrices: Freezer storage stability data was not required as the samples in the feeding study were analyzed within 30 days of sampling.				

Summary of Residues from Crop Field Trials Conducted with Tetraniliprole.

Crop field trials were conducted in North America (2014-2015) with a variety of crops using either Tetraniliprole 200SC (200 g ai/L Soluble Concentrate) or Tetraniliprole 480 FS (480 g ai/L Flowable Suspension). All trials were conducted at ±25% of GAP. Adjuvants (COC and NIS) were used in/on lettuce, spinach, fruiting vegetables, stone fruits, grapes, tree nuts, field corn, sweet corn, and cottonseeds. Different treatments were applied to various crops (foliar, in-furrow, seed, directed chemigation soil application). Foliar applications were made using ground equipment with concentrated and/or dilute spray volumes. The number and geographic distribution of trials were generally in accordance with Health Canada's DIR2010-05. Independence of trials was assessed for each representative crop from the various Crop Groups. Residues of tetraniliprole generally decreased with increasing PHIs. Adequate storage stability data are available on diverse crop types to support the storage intervals of the crop field trials. Samples were analyzed using a validated analytical method. Residues of BCS-CL73507-*N*-methyl-quinazolinone were also quantified but not reported herein.

Crop Matrix	Total Application Rate (kg ai/ha)	PHI (days)	n	Tetraniliprole Residues (ppm)				
				LAFT	HAFT	Median	Mean	SDEV
Potato (Crop Subgroup 1C: Tuberous and Corm Vegetables)						**PMRA# 2732162**		
Potato tuber (in-furrow)	0.19–0.22	75–146	26	<0.010	0.015	0.010	0.010	0.001
Potato tuber (foliar)	0.12	13–14	26	<0.010	<0.010	<0.010	<0.010	NA
Leaf Lettuce, Head Lettuce, Spinach, Mustard Greens (Crop Group 4-13: Leafy Vegetables)						**PMRA# 2732161/2732168-2732170**		
Lettuce leaves	0.179–0.183	1	11	<0.010	7.980	2.940	2.952	1.942
Head lettuce with wrapper leaves	0.179–0.182		6	0.434	2.730	1.255	1.367	0.886
Head lettuce without wrapper leaves			6	<0.010	0.871	0.021	0.178	0.342
Spinach	0.173–0.183	1	9	0.246	8.660	5.580	4.896	3.040
Mustard leaves	0.18–0.19	1	5	3.210	7.270	4.030	4.468	1.616
Broccoli, Cauliflower, Cabbage (Crop Group 5-13, Brassica Head and Stem Vegetables)						**PMRA# 2732160**		
Broccoli	0.18	1	5	0.110	0.240	0.150	0.166	0.050
Cauliflower			5	0.036	0.190	0.110	0.112	0.064
Cabbage head with wrapper leaves			10	0.046	1.070	0.135	0.276	0.314
Cabbage head without wrapper leaves			10	<0.01	0.026	0.011	0.015	0.006

Dry Soybeans						**PMRA# 2732176**		
Soybean seed (Foliar)	0.197–0.205	13–14	20	<0.010	0.136	0.026	0.036	0.036
Tomato, Pepper, Non-Bell Pepper (Crop Group 8-09: Fruiting Vegetables)						**PMRA# 2732171/2732174**		
Crop Matrix	**Total Application Rate (kg ai/ha)**	**PHI (days)**	**n**	**Tetraniliprole Residues (ppm)**				
				LAFT	**HAFT**	**Median**	**Mean**	**SDEV**
Tomato	0.173–0.184	1	19	0.030	0.323	0.064	0.085	0.072
Bell pepper	0.173–0.183	1	10	<0.010	0.198	0.076	0.079	0.057
Non-bell pepper	0.178–0.183	1	3	0.011	0.106	0.087	0.068	0.050
Oranges, Lemons, Grapefruits (Crop Group 10 Revised: Citrus Fruits)						**PMRA# 2734115**		
Crop Matrix	**Total Application Rate (kg ai/ha)**	**PHI (days)**	**n**	**Tetraniliprole Residues (ppm)**				
				Min.	**Max.**	**Median**	**Mean**	**SDEV**
Orange (Drip Soil + 1 Foliar)*	0.18	1	8	0.015	0.071	0.032	0.038	0.021
Orange (Foliar Dil.)	0.18–0.19	1	8	0.041	0.148	0.105	0.099	0.039
Orange (Foliar Conc.)	0.18–0.19	1	8	0.017	0.170	0.105	0.096	0.060
Mandarin (Drip Soil + 1 Foliar)*	0.18	1	4	0.028	0.210	0.054	0.087	0.083
Mandarin (Foliar Dil.)	0.18	1	4	0.123	0.499	0.165	0.238	0.175
Mandarin (Foliar Conc.)	0.18	1	4	0.062	0.224	0.180	0.161	0.070
Lemon (Drip Soil + 1 Foliar)*	0.18	1	5	0.023	0.048	0.041	0.038	0.010
Lemon (Foliar Dil.)	0.18	1	5	0.058	0.202	0.099	0.111	0.059
Lemon (Foliar Conc.)	0.18	1	5	<0.010	0.767	0.142	0.224	0.314
Grapefruit (Drip Soil + 1 Foliar)*	0.18	1	6	0.011	0.046	0.025	0.027	0.014
Grapefruit (Foliar Dil.)	0.18	1	6	0.038	0.105	0.071	0.071	0.024
Grapefruit (Foliar Conc.)	0.18–0.19	1	6	0.023	0.493	0.055	0.140	0.183
*For the drip soil + 1 foliar application, duplicate samples were analyzed, therefore values reported are LAFT and HAFT.								
Apples and Pears (Crop Group 11-09, Pome Fruits)						**PMRA# 2732163**		
Apples (Foliar Conc.)	0.18–0.19	6 to 8	15	0.064	0.195	0.115	0.120	0.036
Apples (Foliar Dil.)			15	0.051	0.198	0.109	0.120	0.039
Pears (Foliar Conc.)	0.18–0.20	5 to 7	10	0.022	0.238	0.075	0.111	0.076
Pears (Folair Dil.)			10	0.040	0.143	0.086	0.092	0.037
Cherry, Peach, Plum (Crop Group 12-09: Stone Fruits)						**PMRA# 2732166/2732167/2732173**		
Crop Matrix	**Total Application Rate (kg ai/ha)**	**PHI (days)**	**n**	**Tetraniliprole Residues (ppm)**				
				LAFT	**HAFT**	**Median**	**Mean**	**SDEV**
Cherries	0.178–0.184	5	12	0.085	0.660	0.283	0.337	0.174
Peaches	0.175–0.182	5	16	0.030	0.380	0.088	0.109	0.087
Plums	0.175–0.184	4 to 5	10	<0.010	0.129	0.034	0.051	0.045
Grapes (Crop Subgroup 13-07F: Fruit, small vine climbing, except fuzzy kiwifruit)						**PMRA# 2732175**		
Grapes	0.176–0.185	14	14	0.057	0.923	0.264	0.318	0.243
Almonds, Pecans (Crop Group 14-11: Tree Nuts)						**PMRA# 2732164-2732165**		
Almond nutmeat	0.178–0.181	10	5	<0.010	0.016	<0.010	0.011	0.003
Almond hulls		10	5	0.219	1.81	0.844	0.931	0.579

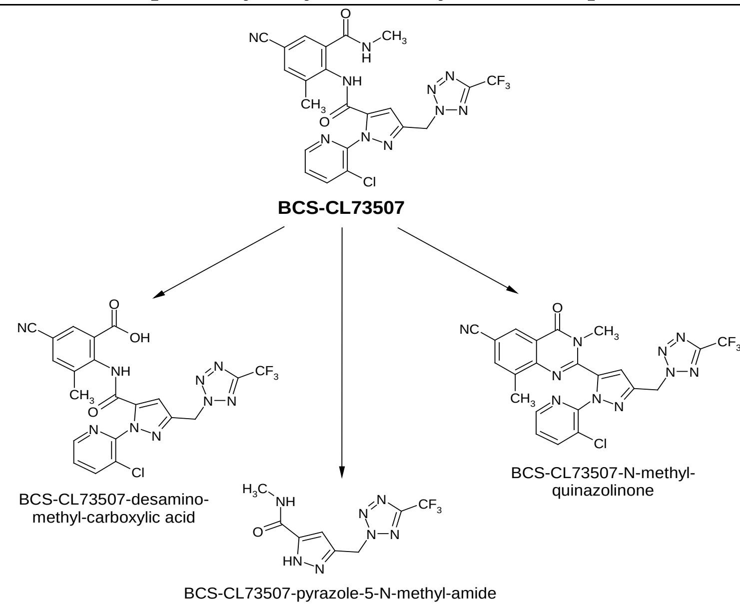
Pecan nutmeat	0.180–0.182	10	8	<0.010	<0.010	<0.010	<0.010	NA
Field Corn						**PMRA# 2732177**		
Crop Matrix	**Total Application Rate (kg ai/ha)**	**PHI (days)**	**n**	**Tetraniliprole Residues (ppm)**				
				LAFT	**HAFT**	**Median**	**Mean**	**SDEV**
Field Corn Forage (Foliar)	0.196–0.219	14	21	<0.010	3.11	0.533	0.816	0.745
Field Corn Forage (Seed Treat.)	0.030–0.048	93–100	3	<0.010	0.674	<0.010	0.231	0.383
Field Corn Grain (Foliar)	0.196–0.219	14	21	<0.010	0.010	<0.010	<0.010	NA
Field Corn Grain (Seed Treat.)	0.029–0.048	128–150	3	<0.010	<0.010	<0.010	<0.010	NA
Field Corn Grain (Seed+Foliar)	0.179–0.201	14	3	<0.010	0.010	<0.010	<0.010	NA
Field Corn Stover (Foliar)	0.196–0.219	14	21	<0.010	10.1	2.91	3.42	2.80
Field Corn Stover (Seed Treat.)	0.029–0.048	128–150	3	<0.010	<0.010	<0.010	<0.010	NA
Field Corn Stover (Seed+Foliar)	0.179–0.201	14	3	1.14	5.28	1.40	2.60	2.32
Sweet Corn						**PMRA# 2732172**		
K+CWHR (Foliar)	0.194–0.208	1	15	<0.010	<0.010	<0.010	<0.010	NA
Forage (Foliar)		1	15	0.064	3.43	1.71	1.77	0.929
Stover (Foliar)		14–31	14	<0.010	15.7	1.31	2.65	4.09
K+CWHR (Seed Treat.)	0.049–0.063	73–85	3	<0.010	<0.010	<0.010	<0.010	NA
Forage (Seed Treat.)		73–85	3	<0.010	<0.010	<0.010	<0.010	NA
Stover (Seed Treat.)		102–115	3	<0.010	0.012	<0.010	0.011	0.001
K+CWHR (Seed+Foliar)	0.203–0.212	1	3	<0.010	<0.010	<0.010	<0.010	NA
Forage (Seed+Foliar)		1	3	0.507	2.52	2.25	1.76	1.09
Stover (Seed+Foliar)		29 31	3	0.079	10.8	1.13	4.01	5.93
Undelinted Cottonseeds (Crop Subgroup 20R-C: Cottonseeds) as Rotational Crop						**PMRA# 2734117**		
Seed	0.198–0.205	21	12	<0.010	0.213	0.072	0.085	0.074
Gin byproducts			5	0.604	11.4	2.18	4.85	5.05
RESIDUE DATA IN ROTATIONAL CROPS								
Rotational crop trials (onions, wheat, barley, sorghum, legumes, cucurbits, alfalfa, sunflowers and canola) with a 30-day PBI were conducted in both the United States and Canada during the 2014 – 2015 growing season. One broadcast application was made to bare soil with Tetraniliprole 200SC. No adjuvant was used at any of the trial sites. The number and geographic distribution of trials were generally in accordance with Health Canada's DIR2010-05. In addition, a limited rotational crop study was undertaken with wheat and soybean with multiple PBIs (30, 120, and 365 days). Adequate storage stability data are available on diverse commodity categories to support the storage intervals of the rotational crop field trials. Samples were analyzed using a validated analytical method. Residues of BCS-CL73507-*N*-methyl-quinazolinone were also quantified but not reported herein.								
Commodity	**Total Application Rate (kg ai/ha)**	**PBI (days)**	**Tetraniliprole Residue Levels (ppm)**					
			n	**LAFT**	**HAFT**	**Median**	**Mean**	**SDEV**
Dry Bulb Onion (Crop Subgroup 3-07A: Bulb Onions)						**PMRA# 2732195**		
Dry bulb onions	0.19–0.21	25–30	11	<0.010	<0.010	<0.010	<0.010	NA
Snow Peas and Snap Beans (Crop Subgroup 6A: Edible-Podded Legume Vegetables)						**PMRA# 2732190**		
Snow Peas	0.20	26–29	7	<0.010	<0.010	<0.010	<0.010	NA
Snap Beans	0.20	25–30	9	<0.010	<0.010	<0.010	<0.010	NA

Garden Peas and Lima Beans (Crop Subgroup 6B: Succulent Shelled Pea and Bean)						**PMRA# 2732197**		
Garden Peas	0.20–0.22	25–31	8	<0.010	<0.010	<0.010	<0.010	NA
Lima Beans	0.19–0.20	25–30	8	<0.010	<0.010	<0.010	<0.010	NA
Dry Peas and Dry Beans (Crop Subgroup 6C: Dried Shelled Pea and Bean (except soybean))						**PMRA# 2732198**		
Dry Peas - Forage	0.20	26–30	7	<0.010	<0.010	<0.010	<0.010	NA
Dry Peas - Hay			7	<0.010	0.010	<0.010	0.010	NA
Dry Peas - Dry Seeds			7	<0.010	<0.010	<0.010	<0.010	NA
Commodity	**Total Application Rate (kg ai/ha)**	**PBI (days)**	**n**	**Tetraniliprole Residue Levels (ppm)**				
				LAFT	**HAFT**	**Median**	**Mean**	**SDEV**
Dry Beans - Forage	0.20	25–31	9	<0.010	0.017	<0.010	0.011	NA
Dry Beans - Hay			9	<0.010	<0.010	<0.010	<0.010	NA
Dry Beans - Dry Seeds			9	<0.010	<0.010	<0.010	<0.010	NA
Cucumber, Summer Squash, Melon (Crop Group 9: Cucurbit Vegetables)						**PMRA# 2732199**		
Cucumber	0.19–0.21	25–30	8	<0.010	<0.010	<0.010	<0.010	NA
Summer Squash			9	<0.010	<0.010	<0.010	<0.010	NA
Melon			10	<0.010	<0.010	<0.010	<0.010	NA
Wheat (Crop Group 15: Cereal Grains); (Crop Group 16: Forage, Fodder, and Straw of Cereal Grains)						**PMRA# 2732192**		
Wheat - Forage	0.20–0.21	25–30	12	<0.010	0.012	0.010	0.010	0.001
Wheat - Grain			12	<0.010	<0.010	<0.010	<0.010	NA
Wheat - Hay			12	<0.010	0.032	0.010	0.014	0.008
Wheat - Straw			12	<0.010	0.092	0.010	0.021	0.024
Barley (Crop Group 15: Cereal Grains); (Crop Group 16: Forage, Fodder, and Straw of Cereal Grains)						**PMRA# 2732191**		
Barley - Hay	0.19–0.21	25–31	9	<0.010	0.018	0.010	0.012	0.003
Barley - Straw			9	<0.010	0.017	0.010	0.011	0.002
Barley - Grain			9	<0.010	<0.010	<0.010	<0.010	NA
Sorghum (Crop Group 15: Cereal Grains); (Crop Group 16: Forage, Fodder, and Straw of Cereal Grains)						**PMRA# 2732200**		
Sorghum - Forage	0.19–0.21	25–31	7	<0.010	<0.010	<0.010	<0.010	NA
Sorghum- Grain			7	<0.010	<0.010	<0.010	<0.010	NA
Sorghum- Fodder			7	<0.010	<0.010	<0.010	<0.010	NA
Alfalfa (Crop Group 18: Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay)						**PMRA# 2732201**		
Alfalfa Forage (1st cutting)	0.19–0.21	25–30	22	<0.010	0.012	<0.010	0.010	0.001
Alfalfa Forage (2nd cutting)			22	<0.010	<0.010	<0.010	<0.010	NA
Alfalfa Forage (3rd cutting)			22	<0.010	<0.010	<0.010	<0.010	NA
Alfalfa Hay (1st cutting)	0.19–0.21	25–30	22	<0.010	0.046	0.013	0.015	0.010
Alfalfa Hay (2nd cutting)			22	<0.010	0.012	0.010	0.010	0.001
Alfalfa Hay (3rd cutting)			22	<0.010	<0.010	<0.010	<0.010	NA
Canola (Crop Subgroup 20A: Rapeseeds (Revised))						**PMRA# 2732193**		
Canola Seed	0.20	25–30	7	<0.010	<0.010	<0.010	<0.010	NA

Sunflower (Crop Subgroup 20B: Sunflowers (Revised))						**PMRA# 2732194**		
Sunflower Seed	0.19–0.20	25–31	6	<0.010	<0.010	<0.010	<0.010	NA
Wheat and Soybeans – Limited Field Accumulation						**PMRA# 2732202**		
Commodity	**Total Application Rate (kg ai/ha)**	**PBI (days)**	**n**	**Tetraniliprole Residue Levels (ppm)**				
				LAFT	**HAFT**	**Median**	**Mean**	**SDEV**
Wheat forage	0.20–0.21	22–29	3	<0.010	0.027	<0.010	0.016	0.010
	0.20	108–119	3	<0.010	0.016	<0.010	0.012	0.003
	0.20–0.21	334–365	3	<0.010	<0.010	<0.010	<0.010	NA
Wheat hay	0.20–0.21	22–29	3	<0.010	0.014	<0.010	0.011	0.002
	0.20	108–119	3	<0.010	0.023	<0.010	0.014	0.008
	0.20–0.21	334–365	3	<0.010	<0.010	<0.010	<0.010	NA
Wheat grain	0.20–0.21	22–29	3	<0.010	<0.010	<0.010	<0.010	NA
Wheat straw	0.20–0.21	22–29	3	<0.010	0.011	0.010	0.010	0.001
	0.20	108–119	3	<0.010	0.013	0.012	0.012	0.002
	0.20–0.21	334–365	3	<0.010	<0.010	<0.010	<0.010	NA
Soybean forage	0.20–0.21	25–29	3	<0.010	0.024	0.010	0.015	0.008
	0.19–0.20	117–119	3	<0.010	0.039	<0.010	0.020	0.017
	0.20–0.21	348–365	3	<0.010	0.050	<0.010	0.023	0.023
Soybean hay	0.20–0.21	25–29	3	<0.010	0.154	0.021	0.062	0.080
	0.19–0.20	117–119	3	<0.010	0.162	0.012	0.061	0.087
	0.20–0.21	348–365	3	<0.010	0.083	<0.010	0.034	0.042
Soybean seed	0.20–0.21	25–29	3	<0.010	<0.010	<0.010	<0.010	NA

HIGH-TEMPERATURE HYDROLYSIS STUDY			**PMRA# 2731907**
The radiolabelled test compounds [pyrazole-carboxamide-^{14}C]-BCS-CL73507 and [phenyl-carbamoyl-^{14}C]-BCS-CL73507 were used for hydrolysis investigations with a tetraniliprole concentration of approximately 1 mg/L (solubility limit of tetraniliprole). As the pH and hydrolysis temperature increases, the % radioactivity of tetraniliprole decreases, while that of the metabolite BCS-CL73507-*N*-methyl quinazolinone (BCS-CQ63359) increases.			
Processing	**Pasteurization**	**Baking, brewing and boiling**	**Sterilization**
Conditions	pH 4/90°C/20 min	pH 5/100°C/60 min	pH 6/120°C/20 min
Major metabolites (>10% of the TRRs)	Tetraniliprole	Tetraniliprole; BCS-CL73507-*N*-methyl-quinazolinone	BCS-CL73507-*N*-methyl-quinazolinone

Proposed Hydrolysis Pathway of Tetraniliprole



PROCESSED FOOD AND FEED – Potatoes, Oranges, Apples, Tomatoes, Grapes, Plums, Soybeans, Field Corn, Cottonseeds	PMRA# 2732173-2732177; 2732206-2732207; 2734117-2734118

Processing studies were conducted in two distinctive NAFTA regions using Tetraniliprole 200SC at 0.89–1.15 kg ai/ha (fivefold of maximum single seasonal use rate) in/on potatoes, oranges, apples, plums, tomatoes, grapes, soybeans, field corn and undelinted cottonseeds. In addition, processing studies were conducted with rotational crops (wheat, canola, sunflower) using Tetraniliprole 200SC applied to soil at 1 kg ai/ha 30 days prior to planting these crops. Since no residues were observed in wheat grain, canola seed, and sunflower seed, samples were not processed further as there was no expectation of residues in the processed fractions. Adequate storage stability data are available on diverse crop types to support the storage intervals of the processed food and feed. Samples were analyzed using a validated analytical method. Residues of BCS-CL73507-*N*-methyl-quinazolinone were also quantified but not reported herein.

RAC	Processed Fractions	RAC HAFT (ppm)	Average Processing Factor	Anticipated Residues of Tetraniliprole (ppm)
Potatoes [CSG1C]	Chips	0.015	0.4	0.006
	Flakes		0.4	0.006
	Starch		0.4	0.006
Oranges (Revised) [CSG10A]	Juice	0.170	0.03	0.005
	Citrus Oil	0.767 (lemons)	8.6	6.596
	Dried pulp	0.170	1.1	0.187
Apples [CG11-09]	Juice	0.198	0.4	0.079
	Dried		0.03	0.006
Plums [CG12-09]	Prunes	0.129	4.1	0.529
Tomato [CG8-09]	Paste	0.323	3.5	1.131
	Purée		0.85	0.275
Grapes [CSG13-07F]	Juice	0.923	0.2	0.185
	Raisins		1.2	1.108
Soybean	Meal	0.136	0.5	0.068
	Hulls		2.6	0.354
	Oil		0.5	0.068
Field corn	Flour	0.01	1.1	0.011

	Meal		1.1	0.011
	Starch		0.8	0.008
	Oil		0.8	0.008
Cottonseeds (Revised) [CSG20R-C]	Meal	0.213	0.01	0.002
	Hulls		0.1	0.021
	Oil		0.01	0.002

LIVESTOCK FEEDING – Dairy cattle	**PMRA #2732208**

Lactating dairy cows were administered tetraniliprole at dose levels of 0.9 ppm, 9 ppm, 27 ppm and 90 ppm in the feed for 28 consecutive days. Animals were sacrificed approximately 3.5 to 8 hours after the last dose. A depuration study was conducted using the 90 ppm dosing group and selected animals were sacrificed at 3, 7, 10, 14 and 21 days after the last dose for milk collection; and 8, 15, and 22 days for liver, kidney, muscle, and fat collection. Residues of tetraniliprole were less than LOQ by the end of the depuration study. Residues of BCS-CL73507-*N*-methyl-quinazolinone were also quantified but not reported herein.

Matrices/Collection Day	**Feeding Level (ppm)**	**Maximum Tetraniliprole Residues (ppm)**
Whole milk/28	0.9	<0.010
	9	0.051
	27	0.151
	90	0.206
Perirenal fat/29	0.9	<0.010
	9	0.063
	27	0.116
	90	0.223
Omental fat/29	0.9	<0.010
	9	0.052
	27	0.117
	90	0.198
Subcutaneous fat/29	0.9	<0.010
	9	0.033
	27	0.094
	90	0.196
Kidney/29	0.9	<0.010
	9	0.067
	27	0.187
	90	0.276
Liver/29	0.9	0.037
	9	0.372
	27	0.875
	90	1.539
Muscle/29	0.9	<0.010
	9	0.023
	27	0.060
	90	0.090

Anticipated Residues in Animal Matrices

Matrices	**Residue Definition**	**Dietary Burden (ppm)**	**Anticipated Residues of Tetraniliprole (ppm)**
Beef/Dairy Cattle			
Whole milk	Tetraniliprole	5.84	0.048
Fat			0.037
Kidney			0.058
Liver			0.264

Muscle			0.019
Swine			
Fat			
Kidney			
Liver			
Muscle			

LIVESTOCK FEEDING – Laying Hens				**PMRA# 2732209**
A request to waive the feeding study was provided based on the low dietary burden. Therefore, the hen metabolism study was used to estimate the anticipated residues in the relevant poultry matrices.				
Commodity	**Feeding Level (ppm)**	**Highest Residues of Tetraniliprole (ppm)**	**Dietary Burden (ppm)**	**Anticipated Residues of tetraniliprole (ppm)**
Eggs	18.7	0.012	0.01	<0.01
Fat		0.025		<0.01
Liver		0.032		<0.01
Muscle		0.003		<0.01

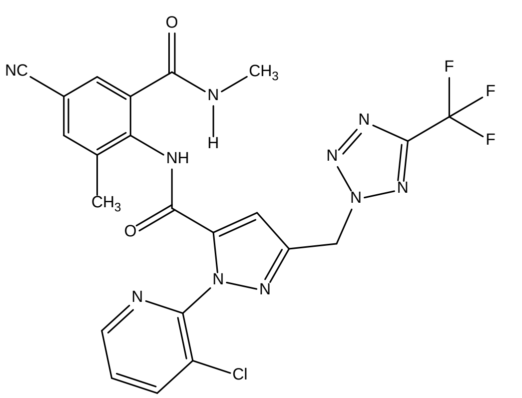
Table 17 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

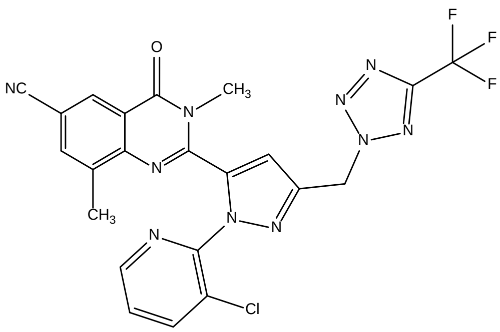
PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (Apple, field corn, lettuce, paddy rice, potato, and tomato)** **Rotational crops (Swiss chard, turnips, wheat)** **Processed commodities**	Tetraniliprole
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops (Apple, field corn, lettuce, paddy rice, potato, and tomato)** **Rotational crops (Swiss chard, turnips, wheat)**	Tetraniliprole
Processed commodities	Tetraniliprole + BCS-CL73507-*N*-methyl-quinazolinone
METABOLIC PROFILE IN DIVERSE CROPS	Similar
ANIMAL STUDIES	
ANIMALS	**Ruminant and Poultry**
RESIDUE DEFINITION FOR ENFORCEMENT **Poultry, Ruminants**	Tetraniliprole
RESIDUE DEFINITION FOR RISK ASSESSMENT **Poultry**	Tetraniliprole
Ruminants	Tetraniliprole + BCS-CL73507-*N*-methyl-quinazolinone
METABOLIC PROFILE IN ANIMALS **Goat, hen, rat**	Similar
FAT SOLUBLE RESIDUE	No

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Alone	Food and Water
Basic chronic (cancer and non-cancer) dietary exposure analysis **ADI = 0.06 mg/kg bw/day** **Estimated chronic drinking water concentration = 0.311 ppm**	**All infants < 1 year**	15.7	54.8
	Children 1–2 years	44.3	58.7
	Children 3–5 years	34.6	46.3
	Children 6–12 years	19.6	28.3
	Youth 13–19 years	13.8	21.2
	Adults 20–49 years	16.2	26.6
	Adults 50+ years	17.3	27.4
	Total population	18.2	28.6

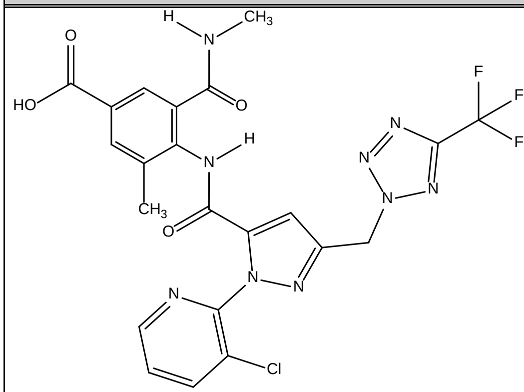
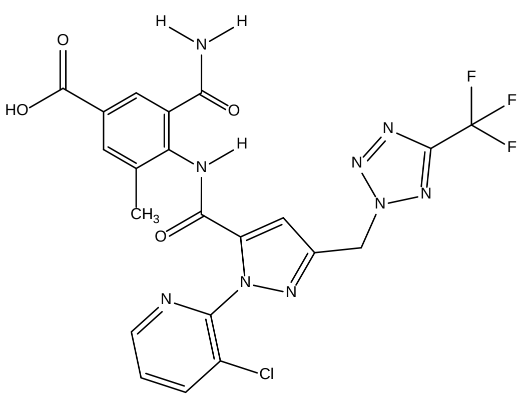
Table 18 Fate and Behaviour in the Environment

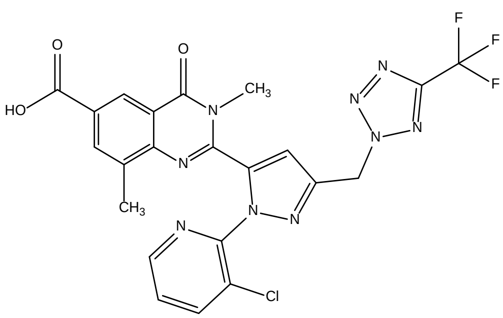
Table 18.1 Tetraniliprole and its environmental transformation products identified in laboratory and field dissipation studies

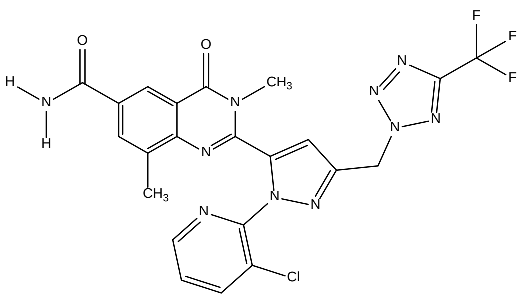
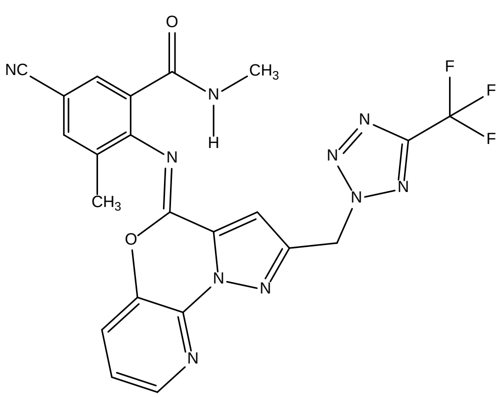
Compound Structure Chemical Name	Study Type	Maximum %AR (day)	Final %AR (study length)	PMRA#
Tetraniliprole (BCS-CL73507)  **IUPAC:** 2-(3-chloro-2-pyridyl)-N-[4-cyano-2-methyl-6-(methylcarbamoyl)phenyl]-5-[[5-(trifluoromethyl)tetrazol-2-yl]methyl]pyrazole-3-carboxamide **CAS:** 1-(3-Chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamide	835.2120 Hydrolysis	NA	NA	2731921
	835.2240 Aqueous photolysis	NA	NA	2731924 2731925 2731927 2731926
	835.2410 Soil photolysis	NA	NA	2731922
	835.4100 Aerobic soil metabolism	NA	NA	2731930 2731929 2731931 2731932
	835.4200 Anaerobic soil metabolism	NA	NA	2731933
	835.4300 Aerobic aquatic metabolism	NA	NA	2731934
	835.4400 Anaerobic aquatic metabolism	NA	NA	2731935
	835.6100 Terrestrial field dissipation	NA	NA	2732221 2732218 2732219

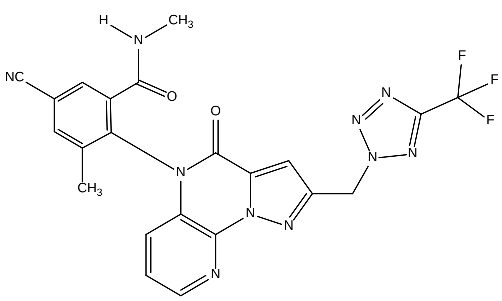
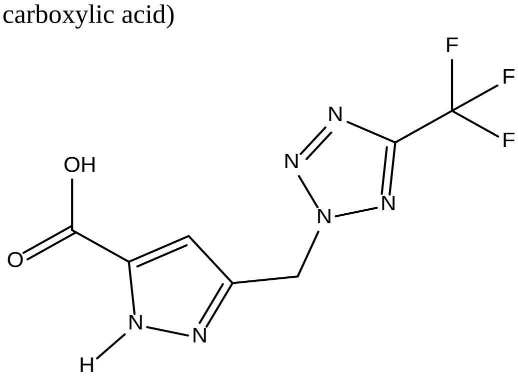
Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
CAS No.: 1229654-66-3 **Formula:** $C_{22}H_{16}ClF_3N_{10}O_2$ **MW:** 544.88 g/mol					2732222 2732220 2732217 2735496
Major Transformation Products (> 10%)					
BCS-CQ63359 (BCS-CL73507-N-methyl-quinazolinone)  **IUPAC:** 2-[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile **Formula:** $C_{22}H_{14}ClF_3N_{10}O$ **MW:** 526.87 g/mol	835.2120 Hydrolysis	pH 4 (20°C)	3.3% (30 d)	3.3% (30 d)	2731921
		pH 7 (20°C)	**27.1%** (30 d)	**27.1%** (30 d)	
		pH 9 (20°C)	**100.4%** (30 d)	**100.4%** (30 d)	
		pH 4 (25°C)	6.5% (30 d)	6.5% (30 d)	
		pH 7 (25°C)	**40.2%** (30 d)	**40.2%** (30 d)	
		pH 9 (25°C)	**97.8%** (30 d)	**97.8%** (30 d)	
		pH 4 (50°C)	**76.7%** (30 d)	**76.7%** (30 d)	
		pH 7 (50°C)	**97.0%** (30 d)	**97.0%** (30 d)	
		pH 9 (50°C)	**99.9%** (2.04 d)	**97.8%** (2.04 d)	
	835.2240 Aqueous photolysis	Natural water (pH 8)	**38.6%** (0.25 d)	ND (10 d)	2731925
	835.2410 Soil photolysis	Silt loam	8.2% (9 d)	7.5% (11 d)	2731922
	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	**14.0%** (62 d)	**13.6%** (119 d)	2731930
		Loam (pH 7.3)	**10.1%** (9 d)	4.8% (119 d)	
		Silt loam (pH 5.3)	6.8% (119 d)	6.8% (119 d)	
		Silt loam (pH 6.4)	**15.3%** (119 d)	**15.3%** (119 d)	
		Silt loam (pH 5.8)	**14.2%** (120 d)	**14.2%** (120 d)	2731929
		Silt loam (pH 6.5)	**18.2%** (120 d)	**18.2%** (120 d)	
		Sandy loam (pH 6.2)	**18.8%** (120 d)	**18.8%** (120 d)	
		Clay loam (pH 6.4)	**12.4%** (91 d)	**11.4%** (120 d)	

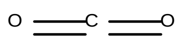
Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
		Loamy sand (pH 7.1)	**36.2%** (120 d)	**36.2%** (120 d)	
		Clay loam (pH 7.3)	9.0% (120 d)	9.0% (120 d)	
	835.4200 Anaerobic soil metabolism	Sandy loam	**34.7%** (150 d)	**34.7%** (150 d)	2731933
		Silt loam	**34.1%** (150 d)	**34.1%** (150 d)	
		Loam	**17.8%** (134 d)	**17.8%** (134 d)	
	835.4300 Aerobic aquatic metabolism	Water:sand	**86.6%** (59 d)	**80.4%** (101 d)	2731934
		Water:silt loam	**33.6%** (101 d)	**33.6%** (101 d)	
	835.4400 Anaerobic aquatic metabolism	Pond water: loam	**19.7%** (104 d)	**19.7%** (104 d)	2731935
		Water:loamy sand	**47.0%** (104 d)	**47.0%** (104 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	**34.8%** (274 d)	**28.5%** (560 d)	2732221
		Washington (Bare)	**28.6%** (179 d)	**20.7%** (540 d)	2732218
		Iowa (Bare)	**19.6%** (272 d)	**17.7%** (346 d)	2732219
		California (Bare)	**29.2%** (180 d)	**14.5%** (538 d)	2732222
		New York (Bare)	**12.3%** (269 d)	**11.2%** (440 d)	2732220
		New York (Turf)	**20.6%** (269 d)	**17.9%** (440 d)	2732220
		Ontario (Bare)	**21.3%** (368 d)	**13.6%** (519 d)	2732217
		Prince Edward Island (Bare)	5.5% (423 d)	5.0% (514 d)	2773549
BCS-CR74541 (BCS-CL73507-carboxylic acid)	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	**29.1%** (119 d)	**29.1%** (119 d)	2731930
		Loam (pH 7.3)	**48.1%** (62 d)	**43.3%** (119 d)	
		Silt loam (pH 5.3)	**20.1%** (119 d)	**20.1%** (119 d)	
		Silt loam (pH 6.4)	**36.0%** (119 d)	**36.0%** (119 d)	
		Silt loam (pH 5.8)	**19.3%** (120 d)	**19.3%** (120 d)	
		Silt loam (pH 6.5)	**27.6%** (120 d)	**27.6%** (120 d)	

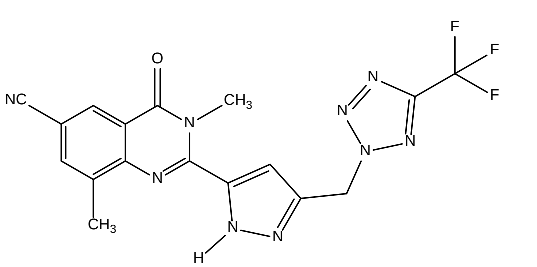
Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
 **IUPAC:** 4-({[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]carbonyl}amino)-3-methyl-5-(methylcarbamoyl)benzoic acid **Formula:** $C_{22}H_{17}ClF_3N_9O_4$ **MW:** 563.88 g/mol		Sandy loam (pH 6.2)	**17.2%** (120 d)	**17.2%** (120 d)	2731929
		Clay loam (pH 6.4)	**25.5%** (120 d)	**25.5%** (120 d)	
		Loamy sand (pH 7.1)	**10.2%** (120 d)	**10.2%** (120 d)	
		Clay loam (pH 7.3)	**35.3%** (120 d)	**35.3%** (120 d)	
	835.4200 Anaerobic soil metabolism	Sandy loam	**20.0%** (91 d)	**19.0%** (150 d)	2731933
		Silt loam	**21.6%** (91 d)	**19.4%** (150 d)	
		Loam	**44.6%** (73 d)	**38.3%** (134 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	3.6% (560 d)	3.6% (560 d)	2732221
		Washington (Bare)	1.6% (91 d)	0.0% (540 d)	2732218
		Iowa (Bare)	4.3% (346 d)	4.3% (346 d)	2732219
		California (Bare)	4.9% (120 d)	0.0% (538 d)	2732222
		New York (Bare)	6.5% (269 d)	4.8% (440 d)	2732220
		New York (Turf)	9.2% (180 d)	7.2% (440 d)	
		Ontario (Bare)	7.9% (175 d)	2.6% (519 d)	2732217
		Prince Edward Island (Bare)	**11.2%** (423 d)	9.2% (514 d)	2773549
BCS-CU81055 (BCS-CL73507-desmethyl-amide-carboxylic acid) 	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	4.4% (119 d)	4.4% (119 d)	2731930
		Loam (pH 7.3)	**10.7%** (119 d)	**10.7%** (119 d)	
		Silt loam (pH 5.3)	1.1% (91 d)	1.0% (119 d)	
		Silt loam (pH 6.4)	**12.3%** (119 d)	**12.3%** (119 d)	
		Silt loam (pH 5.8)	4.4% (120 d)	4.4% (120 d)	2731929
		Silt loam (pH 6.5)	3.5% (120 d)	3.5% (120 d)	
		Sandy loam (pH 6.2)	1.2% (42 d)	0.6% (120 d)	
		Clay loam (pH 6.4)	3.1% (120 d)	3.1% (120 d)	

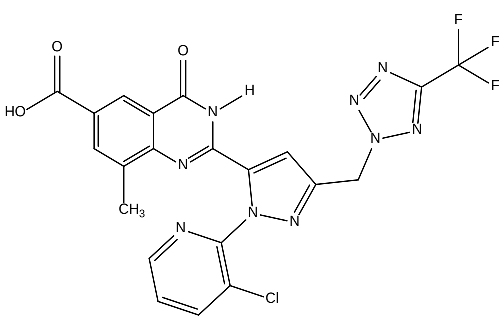
Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
IUPAC: 3-carbamoyl-4-({[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]carbonyl}amino)-5-methylbenzoic acid **Formula:** $C_{21}H_{15}ClF_3N_9O_4$ **MW:** 549.9 g/mol		Loamy sand (pH 6.2)	0.7% (30 d)	<LOQ (120 d)	
		Clay loam (pH 7.3)	2.9% (91, 120 d)	2.9% (120 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	1.8% (121 d)	0.0% (560 d)	2732221
		New York (Bare)	0.9% (440 d)	0.9% (440 d)	2732220
		New York (Turf)	6.0% (180 d)	3.1% (440 d)	
		Ontario (Bare)	4.9% (429 d)	4.0% (519 d)	2732217
		Prince Edward Island (Bare)	1.7% (423 d)	1.6% (514 d)	27735549
BCS-CT30673 (BCS-CL73507-N-methyl-quinazolinone-carboxylic acid)  **IUPAC:** 2-[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carboxylic acid **Formula:** $C_{22}H_{15}ClF_3N_9O_3$ **MW:** 545.9 g/mol	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	1.4% (119 d)	1.4% (119 d)	2731930
		Loam (pH 7.3)	**11.0%** (119 d)	**11.0%** (119 d)	
		Silt loam (pH 5.3)	0.5% (119 d)	0.5% (119 d)	
		Silt loam (pH 6.4)	4.7% (119 d)	4.7% (119 d)	
		Silt loam (pH 5.8)	1.1% (120 d)	1.1% (120 d)	2731929
		Silt loam (pH 6.5)	2.8% (120 d)	2.8% (120 d)	
		Sandy loam (pH 6.2)	0.8% (120 d)	0.8% (120 d)	
		Clay loam (pH 6.4)	1.6% (120 d)	1.6% (120 d)	
		Loamy sand (pH 7.1)	0.7% (120 d)	0.7% (120 d)	
		Clay loam (pH 7.3)	2.9% (120 d)	2.9% (120 d)	
	835.4200 Anaerobic soil metabolism	Sandy loam	4.1% (150 d)	4.1% (150 d)	2731933
		Silt loam	4.6% (150 d)	4.6% (150 d)	
		Loam	**11.5%** (134 d)	**11.5%** (134 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	2.1% (560 d)	2.1% (560 d)	2732221
		Washington (Bare)	0.8% (540 d)	0.8% (540 d)	2732218

Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
		California (Bare)	9.4% (538 d)	9.4% (538 d)	2732222
		New York (Bare)	1.7% (366 d)	1.2% (440 d)	2732220
		New York (Turf)	3.4% (440 d)	3.4% (440 d)	
		Ontario (Bare)	2.1% (519 d)	2.1% (519 d)	2732217
		Prince Edward Island (Bare)	0.6% (514 d)	0.6% (514 d)	2773549
BCS-CT30672 (BCS-CL73507-N-methyl-quinazolinone-amide)  **IUPAC:** 2-[2-(3-chloro-2-pyridyl)-5-[[5-(trifluoromethyl)tetrazol-2-yl]methyl]pyrazol-3-yl]-3,8-dimethyl-4-oxo-quinazoline-6-carboxamide **Formula:** $C_{22}H_{16}ClF_3N_{10}O_2$ **MW:** 544.9 g/mol	835.4300 Aerobic aquatic metabolism	Water:sand	**9.7%** (101 d)	**9.7%** (101 d)	2731934
		Water:silt loam	1.4% (101 d)	1.4% (101 d)	
BCS-CY28900 (BCS-CL73507-deschloro-oxazine)  **IUPAC:** 5-cyano-N,3-dimethyl-2-{[(4Z)-2-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-4H-pyrazolo[1,5-d]pyrido[3,2-	835.2240 Aqueous photolysis	pH 4	**73.1%** (11 d)	**73.1%** (11 d)	2731924

Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
b][1,4]oxazin-4-ylidene]amino}benzamide **Formula:** $C_{22}H_{15}F_3N_{10}O_2$ **MW:** 508.4 g/mol					
BCS-CY28897 (BCS-CL73507-deschloro-pyrazine)  **IUPAC:** 5-cyano-N,3-dimethyl-2-((4-oxo-2-((5-(trifluoromethyl)-2H-tetrazol-2-yl)methyl)pyrazolo[1,5-a]pyrido[3,2-e]pyrazin-5(4H)-yl)methyl)benzamide **Formula:** $C_{22}H_{15}F_3N_{10}O_2$ **MW:** 508.43 g/mol **SMILES:**	835.2240 Aqueous photolysis	Natural water (pH 8)	**38.9%** (2 d)	1.5% (10 d)	2731925
		Natural water (pH 8.5)	**40.6%** (2 d)	0.9% (11 d)	2731926
BCS-CY28906 (BCS-CL73507-pyrazole-5-carboxylic acid)  **IUPAC:** 3-((5-(trifluoromethyl)-2H-tetrazol-2-yl)methyl)-1H-pyrazole-5-carboxylic acid	835.2240 Aqueous photolysis	Natural water (pH 8)	**19.8%** (10 d)	**19.8%** (10 d)	2731925

Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
Formula: $C_7H_5F_3N_6O_2$ **MW:** 262.15 g/mol					
Carbon dioxide  **IUPAC:** Carbon dioxide **Formula:** CO_2 **MW:** 44 g/mol	835.2240 Aqueous photolysis	pH 4	0.4% (11 d)	0.4% (11 d)	2731924
		Natural water (pH 8)	**11.2%** (10 d)	**11.2%** (10 d)	2731925
		Natural water (pH 8.5)	**39.7%** (11 d)	**39.7%** (11 d)	2731926
	835.2410 Soil photolysis	Silt loam	0.9% (11 d)	0.9% (11 d)	2731922
	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	1.0% (119 d)	1.0% (119 d)	2731930
		Loam (pH 7.3)	2.7% (119 d)	2.7% (119 d)	
		Silt loam (pH 5.3)	0.6% (119 d)	0.6% (119 d)	
		Silt loam (pH 6.4)	2.3% (119 d)	2.3% (119 d)	
		Silt loam (pH 5.8)	1.3% (120 d)	1.3% (120 d)	2731929
		Silt loam (pH 6.5)	1.1% (91, 120 d)	1.1% (120 d)	
		Sandy loam (pH 6.2)	1.0% (120 d)	1.0% (120 d)	
		Clay loam (pH 6.4)	0.7% (120 d)	0.7% (120 d)	
		Loamy sand (pH 7.1)	0.8% (120 d)	0.8% (120 d)	
		Clay loam (pH 7.3)	3.0% (120 d)	3.0% (120 d)	
	835.4200 Anaerobic soil metabolism	Sandy loam	0.3% (0-150 d)	0.3% (0-150 d)	2731933
		Silt loam	0.4% (0-150 d)	0.4% (0-150 d)	
		Loam	0.1% (0-134 d)	0.1% (0-134 d)	

Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
	835.4300 Aerobic aquatic metabolism	Water:sand	0.2% (101 d)	0.2% (101 d)	2731934
		Water:silt loam	0.2% (101 d)	0.2% (101 d)	
	835.4400 Anaerobic aquatic metabolism	Pond water: loam	0.3% (12 d)	<LOD (104 d)	2731935
		Water:loamy sand	0.1% (12, 20, 40 & 82 d)	<LOD (104 d)	
Unextractable residues	835.4100 Aerobic soil metabolism	Loam (pH 7.3)	**14.0%** (119 d)	**14.0%** (119 d)	2731930
		Silt loam (pH 5.8)	**10.6%** (91 d)	**10.4%** (120 d)	2731929
		Clay loam (pH 6.4)	**14.2%** (91 d)	**12.4%** (120 d)	
		Clay loam (pH 7.3)	**19.3%** (120 d)	**19.3%** (120 d)	
	835.4200 Anaerobic soil metabolism	Silt loam	**10.6%** (150 d)	**10.6%** (150 d)	2731933
	835.4300 Aerobic aquatic metabolism	Water:silt loam	**15.9%** (29 d)	**11.0%** (101 d)	2731934
	835.4400 Anaerobic aquatic metabolism	Pond water: loam	**11.8%** (82 d)	**9.7%** (104 d)	2731935
MINOR (<10%) TRANSFORMATION PRODUCTS					
BCS-CY28894 (BCS-CL73507-despyridyl-N-methyl-quinazolinone)  **IUPAC:** 3,8-dimethyl-4-oxo-2-(3-((5-(trifluoromethyl)-2H-tetrazol-2-yl)methyl)-1H-pyrazol-5-yl)-3,4-dihydroquinazoline-6-carbonitrile **Formula:** $C_{17}H_{12}F_3N_9O$	835.2240 Aqueous photolysis	Natural water (pH 8)	8.0% (2 d)	6.3% (10 d)	2731925

Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
MW: 415.34 g/mol					
BCS-CU81056 (BCS-CL73507-quinazolinone-carboxylic acid)  **IUPAC:** 2-[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]-8-methyl-4-oxo-3,4-dihydroquinazoline-6-carboxylic acid **Formula:** $C_{21}H_{13}ClF_3N_9O_3$ **MW:** 531.84 g/mol	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	0.4% (0 d)	ND (119 d)	2731930
		Loam (pH 7.3)	6.6% (119 d)	6.6% (119 d)	
		Silt loam (pH 5.3)	0.6% (6 d)	ND (119 d)	
		Silt loam (pH 6.4)	1.0% (119 d)	1.0% (119 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	2.2% (121 d)	0.0% (560 d)	2732221
		California (Bare)	0.9% (1 d)	0.0% (538 d)	2732222
		New York (Turf)	0.5% (440 d)	0.5% (440 d)	2732220
		Ontario (Bare)	1.0% (519 d)	1.0% (519 d)	2732217
BCS-CR60014 (BCS-CL73507-amide)	835.4100 Aerobic soil metabolism	Loamy sand (pH 6.2)	4.2% (16 d)	1.2% (119 d)	2731930
		Loam (pH 7.3)	3.6% (2 d)	<LOD (119 d)	
		Silt loam (pH 5.3)	7.0% (62 d)	6.2% (119 d)	
		Silt loam (pH 6.4)	5.4% (16 d)	2.0% (119 d)	

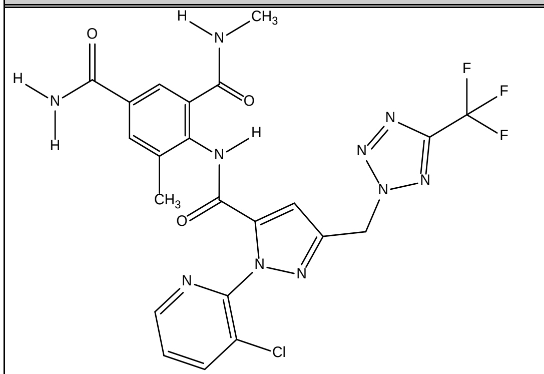
Compound Structure Chemical Name	Study Type		Maximum %AR (day)	Final %AR (study length)	PMRA#
 **IUPAC:** 4-({[1-(3-chloropyridin-2-yl)-3-{[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl}-1H-pyrazol-5-yl]carbonyl}amino)-N3,5 dimethylisophthalamide **Formula:** $C_{22}H_{18}ClF_3N_{10}O_3$ **MW:** 562.9 g/mol		Silt loam (pH 5.8)	3.0% (42 d)	1.8% (120 d)	2731929
		Silt loam (pH 6.5)	2.1% (14 d)	0.9% (120 d)	
		Sandy loam (pH 6.2)	5.0% (91 d)	4.2% (120 d)	
		Clay loam (pH 6.4)	3.4% (42 d)	2.0% (120 d)	
		Loamy sand (pH 7.1)	4.6% (63 d)	2.9% (120 d)	
		Clay loam (pH 7.3)	2.8% (30 d)	1.4% (120 d)	
	835.6100 Terrestrial field dissipation	Florida (Bare)	4.5% (90 d)	2.4% (560 d)	2732221
		Washington (Bare)	2.5% (91, 120 d)	0.0% (540 d)	2732218
		Iowa (Bare)	2.2% (28 d)	1.8% (346 d)	2732219
		California (Bare)	2.0% (28 d)	0.0% (538 d)	2732222
		New York (Bare)	1.9% (59 d)	0.8% (440 d)	2732220
		New York (Turf)	3.3% (28 d)	0.7% (440 d)	
		Ontario (Bare)	2.2% (92 d)	0.0% (519 d)	2732217
		Prince Edward Island (Bare)	4.2% (88 d)	2.7% (514 d)	2773549

Table 18.2 Fate and Behaviour in the Environment: Transformation

Characteristic	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	Transformation Products (maximum % of applied	PMRA #
Hydrolysis	Tetraniliprole	**20°C: (SFO)** pH 4 – stable pH 7 – 59.8 d pH 9 – 1.29 d **25°C (SFO)** pH 4 – stable pH 7 – 39.7 d pH 9 – 0.76 d **50°C (SFO)** pH 4 – 11 d pH 7 – 3.84 d pH 9 – 0.04 d	Sterile buffer (20ºC)	BCS-CQ63359 (100.4%, at 30 days, pH 9 and 20°C)	2731921
Phototransformation on soil	Tetraniliprole	DT_{50}: 210 d (SFO) – Phoenix, AZ	1 EU soil (20º C); Silt Loam pH 6.4, %OC 1.8	BCS-CQ63359 (8.2%, 9 days)	2731922
Phototransformation in water	Tetraniliprole	DT_{50}: 10.6 d (SFO) – Phoenix, AZ (7.7 h of irradiation/d)	pH 4 aqueous buffered solutions	BCS-CY28900 (73.1% AR, 11 d)	2731924
	BCS-CQ63359	DT_{50}: 1.26 d (SFO) – Phoenix, AZ (7.9 hours of irradiation/d)	sterilized pH 7 aqueous buffered solutions	ND	2731927
Biotransformation: aerobic soil	Tetraniliprole	DT_{50}: 380 d (DFOP) DT_{90}: 949 d	Laacher Hof AXXa Loamy sand soil (20°C, pH 6.2)	BCS-CQ63359 (15.3%, 119 d) BCS-CR74541 (48.1%, 62 d) BCS-CU81055 (12.3%, 119 d) BCS-CT30673 (11.0%, 119 d) Unextracted residues (14.0%, 119 d)	2731930
		DT_{50} : 25.1 d (IORE) DT_{90} :83.4 d	Dollendorf II Loam soil (20°C, pH 7.3)		
		DT_{50}:241 d (DFOP) DT_{90}: 733 d	Hanscheiderhof Silt loam soil (20°C, pH 5.3)		
		DT_{50}:53.2 d (IORE) DT_{90}: 177 d	Hoefchen Am Hohenseh 4a Silt loam soil (20°C, pH 6.4)		
	Tetraniliprole	DT_{50} :114 d (DFOP) DT_{90} : 366 d	Kansas USA Silt loam soil (20°C, pH 5.8)	BCS-CQ63359 (36.2%, 120 d) BCS-CR74541 (35.3%, 120 d)	2731929
		DT50 :76.3 d (SFO);	Nebraska USA		

Characteristic	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	Transformation Products (maximum % of applied	PMRA #
		DT_{90} :254	Silt loam soil (20°C, pH 6.5)	Unextracted residues (19.3%, 120 d)	
		DT_{50}:144 d (DFOP) DT_{90} ::446 d	California USA Sandy loam soil (20°C, pH 6.2)		
		DT_{50}: 108 (DFOP) DT_{90} : 341 d	North Dakota USA Clay loam soil (20°C, pH 6.4)		
		DT_{50}: 113 d (DFOP) DT_{90} : 350 d	California USA Loamy sand soil (20°C, pH 7.1)		
		DT_{50}: 69.1 d (DFOP) DT_{90}: 209 d	North Dakota USA Clay loam soil (HCB) (20°C, pH 7.3)		
	BCS-CU81055	DT_{50}: 4060 d (IORE) DT_{90}: 13471 d	Laacher Hof AXXa Sandy loam soil (20°C, pH 6.4)	BCS-CU81056 (10.3%, 120 d) Unextracted residues (18.0%, 59 d)	2731931
		DT_{50}: 4100 d (IORE) DT_{90} : 13626 d	Hoefchen Am Hohenseh Silt loam soil (20°C, pH 6.5)		
		DT_{50}: 6080 d (IORE) DT_{90} : 20201 d	Hanscheider Hof Silt loam soil (20°C, pH 5.8)		
	BCS-CT30673	DT_{50}: 414 d (SFO)	Laacher Hof AXXa Loamy sand soil (20°C, pH 6.0)	Unextracted residues (18.0%, 120 d)	2731932
		DT_{50}: 398 d (SFO) DT_{90} :1321 d	Hoefchen Am Hohenseh Silt loam soil, (20°C, pH 6.3)		
		DT_{50}:566 d (DFOP) DT_{90} : 1719 d	Hanscheider Hof Loam soil (20°C, pH 5.4)		

Characteristic	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	Transformation Products (maximum % of applied	PMRA #
Biotransformation: anaerobic soil	BCS-CL73507	DT_{50} : 177 d (DFOP) DT_{90} : 533 d	Laacher Hof AXXa Sandy loam soil (20°C, pH 6.3)	BCS-CQ63359 (34.7%, 150 d) BCS-CR74541 (44.6%, 73 d) BCS-CT30673 (11.5%, 134 d)	2731933
		DT_{50} : 160 d (DFOP) DT_{90} : 486 d	Hoefchen Am Hohenseh 4a Silt loam soil (20°C, pH 6.1)		
		DT_{50} : 174 d (DFOP) DT_{90} : 484 d	Dollendorf II Loam soil (20°C, pH 7.1)		
Biotransformation: aerobic water/sediment system	Tetraniliprole	DT_{50} : 11.2 d (SFO) DT_{90} : 37.3 d	Water:sand sediment (20°C, water pH 7.8, sediment pH 7.2)	BCS-CL73507-N-methyl-quinazolinone (86.6%, 59 d) BCS-CL73507-N-methyl-quinazolinone-amide (9.7%, 101 days); Unextracted residues (15.9%, 29 days)	2731934
		DT_{50} : 925 d (DFOP) DT_{90} : 2260	Water:silt loam sediment (20°C, water pH 7.7, sediment pH 5.5)		
		DT_{50}: 1.33 days (IORE)	Water alone (20°C, water pH 8.0)	BCS-CQ63359 (104.5%, 45 d)	2731992
Biotransformation: anaerobic water/ sediment system	Tetraniliprole	DT_{50}: 218 (SFO) DT_{90} : 724 d	North Carolina, USA; water:loam sediment (20°C, water pH 6.9, sediment pH 4.6)	BCS-CL73507-N-methyl-quinazolinone (47.0%, 104 d) Unextracted residues (11.8%, 82 days)	2731935
		DT_{50}: 104 d (SFO) DT_{90} : 346	California Water:loamy sand sediment (20°C, water pH 9.0, sediment pH 7.7)		
Transformation in air	Tetraniliprole	Half-life: 0.27-0.404 days	Structure- activity relationship by Atkinson *et al* and assessed with a computer model AOPWIN (USEPA, 2010)		2731947

Characteristic	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	Transformation Products (maximum % of applied	PMRA #
Terrestrial field dissipation (half-life)	End-use product: Tetraniliprole SC 200: (American soils)	DT_{50}:30 d (SFO); DT_{90}:99.6 d	**California Bare Plot Sandy loam pH 7.9	BCS-CQ63359 (*34.8%, 274 d) (Canadian relevant: 28.6%, 179 d) BCS-CT30673 (*9.4%, 538 d) (Canadian relevant: 3.4%, 440 d)	2732222
		DT_{50}:334 d (DFOP); DT_{90}:740 d DT_{90}: 740 d	**Florida Bare Plot; Sand pH 6.3		2732221
		DT_{50}: 39.2 (SFO) DT_{90}: 130 d	Iowa Bare Plot Clay loam pH 6.8		2732219
		DT_{50}: 271-359 d (DFOP); DT_{90}: 727 d	New York Bare Plot Sandy loam pH 5.8		2732220
		DT_{50}: 228 d (IORE); DT_{90}:758 d	New York Turf Plot Sandy loam pH 5.8		2732220
		DT_{50}: 47 d (IORE) DT_{90}: 156 d	Washington Bare Plot Sand pH 7.7		2732218
	End-use product: Tetraniliprole SC 200; Canada soils	DT_{50}:141 d (IORE) DT_{90}: 468 d	Ontario Bare Plot Sandy loam pH 6.9	BCS-CQ63359 (*21.3%, 368 d) BCS-CR74541 (*11.2%, 423 d)	2732217
		DT_{50}: 1000 d (DFOP) DT_{90}: 1958 d	PEI Bare Plot Sandy loam pH 5.6		2773549

*Percent of applied amount; d: days
**California and Florida field studies are not considered by the PMRA as they do not represent Canadian field use conditions

Table 18.3 Fate and Behaviour in the Environment: Mobility

Study	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	PMRA#
Adsorption/Desorption	Tetraniliprole	K_d: 4.70; K_{oc}: 261 K_F: 3.89; K_{FOC}: 216	Laacher Hof AXXa Loamy sand (1.8% OC, pH 6.2)	2731944
		K_d: 8.06; K_{oc}: 299 K_F: 6.10; K_{FOC}: 226	Hoefchen Am Hohenseh 4a Silt loam (2.7% OC, pH 6.4)	
		K_d: 6.10; K_{oc}: 226 K_F: 5.68; K_{FOC}: 210	Hanscheiderhof Silt loam (2.7% OC, pH 5.3)	

Study	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	PMRA#
		K_d: 12.15; K_{oc}: 238 K_F: 10.65; K_{FOC}: 209	Dollendorf II Loam (5.1% OC, pH 7.3)	
Adsorption/Desorption	Tetraniliprole	K_d: 8.50; K_{oc}: 472 K_F: 6.53; K_{FOC}: 363	NE Silt loam (1.8% OC, pH 6.5)	2731943
		K_d:1.37; K_{oc}: 152 K_F: 1.23; K_{FOC}: 137	CA Sandy loam (0.90% OC, pH 6.2)	
		K_d: 7.08; K_{oc}: 2082 K_F: 6.93; K_{FOC}: 2037	KS Silty clay loam (0.34% OC, pH 7.5)	
Adsorption/Desorption	BCS-CR60014	K_d: 2.87; K_{oc}: 137 K_F: 2.73; K_{FOC}: 130	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731936
		K_d: 3.63; K_{oc}: 191 K_F: 3.50; K_{FOC}: 184	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 3.67; K_{oc}: 160 K_F: 3.56; K_{FOC}: 155	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 7.59; K_{oc}: 149 K_F: 7.32; K_{FOC}: 144	Dollendorf II Loam (5.1% OC, pH 7.2)	
Adsorption/Desorption	BCS-CT30673	K_d: 11.69; K_{oc}: 557 K_F: 11.64; K_{FOC}: 554	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731937
		K_d: 11.92; K_{oc}: 627 K_F: 10.50; K_{FOC}: 553	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 18.42; K_{oc}: 801 K_F: 16.41; K_{FOC}: 713	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 19.32; K_{oc}: 379 K_F: 15.90; K_{FOC}: 312	Dollendorf II Loam (5.1% OC, pH 7.2)	
Adsorption/Desorption	BCS-CU81055	K_d: 0.50; K_{oc}: 24 K_F: 0.51; K_{FOC} : 24	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731938
		K_d: 0.58; K_{oc}: 31 K_F: 0.55; K_{FOC}: 29	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 1.21; K_{oc}: 53 K_F: 1.16; K_{FOC}: 51	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 1.05; K_{oc}: 21 K_F: 0.90; K_{FOC}: 18	Dollendorf II Loam (5.1% OC, pH 7.2)	

Study	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	PMRA#
Adsorption/Desorption	BCS-CU81056	K_d: 29.68; K_{oc}: 1413 K_F: 21.48; K_{FOC}: 1023	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731939
		K_d: 27.0; K_{oc}: 1421 K_F: 22.85; K_{FOC}: 1203	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 35.97; K_{oc}: 1564 K_F: 25.38; K_{FOC}: 1104	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 41.60; K_{oc}: 816 K_F: 29.60; K_{FOC}: 580	Dollendorf II Loam (5.1% OC, pH 7.2)	
Adsorption/Desorption	BCS-CR74541	K_d: 0.41; K_{oc}: 20 K_F: 0.37; K_{FOC}: 18	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731940
		K_d: 0.36; K_{oc}: 19 K_F: 0.36; K_{FOC}: 19	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 0.61; K_{oc}: 27 K_F: 0.60; K_{FOC}: 26	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 0.63; K_{oc}: 12 K_F: 0.58; K_{FOC}: 11	Dollendorf II Loam (5.1% OC, pH 7.2)	
Adsorption/Desorption	BCS-CQ63359	K_d: 117.13; K_{oc}: 5578 $K_{F:}$ 109.34; K_{FOC}: 5207	Laacher Hof AXXa Loamy sand (2.1% OC, pH 6.0)	2731941
		K_d: 265.04; K_{oc}: 13949 K_F: 231.35; K_{FOC}: 12176	Hoefchen Am Hohenseh 4a Silt loam (1.9% OC, pH 6.3)	
		K_d: 213.46; K_{oc}: 9281 K_F: 195.82; K_{FOC}: 8514	Hanscheiderhof Loam (2.3% OC, pH 5.4)	
		K_d: 432.18; K_{oc}: 8474 K_F: 451.46; K_{FOC}: 8852	Dollendorf II Loam (5.1% OC, pH 7.2)	
Adsorption/Desorption	BCS-CT30672	K_d: 222.52; K_{oc}: 7673 K_F: 267.56; K_{FOC}: 9226	Hanscheider Hof Silt loam (2.9% OC, pH 5.4)	2731942
		K_d: 357.57; K_{oc}: 18819 K_F: 447.60; K_{FOC}: 23558	Hoefchen am Hohenseh 4a Silt loam (1.9% OC, pH 6.1)	
		K_d: 531.42; K_{oc}: 11071 K_F: 577.07; K_{FOC}: 12022	Dollendorf II Clay loam (4.8% OC, pH 7.3)	

Study	Test substance	Value (half-life, DT_{50} or DT_{90})	Comment	PMRA#
		K_d: 140.02; K_{oc}: 9335 K_F: 151.40; K_{FOC}: 10093	Laacher Hof AXXa Sandy loam (1.5% OC, pH 6.5)	

*Percent of applied amount; d: days

Table 19 Toxicity to Non-Target Species

Non-Target Terrestrial Organisms

Table 19.1 Effects on earthworms

Organism	Exposure	Test substance	Endpoint value	PMRA#
Earthworm (*Eisenia fetida*)	Acute, 14-day	Tetraniliprole	LC_{50}: >896 mg a.i./kg soil dw NOAEC ≥896 mg a.i./kg soil dw	2731996
Earthworm (*Eisenia fetida*)	Mortality and biomass (4-week) and reproduction (8-week)	TP: BCS-CR 74541	LC_{50}: >100 mg a.i./kg soil dw NOAEC: 100 mg a.i./kg soil dw	2731994
Earthworm (*Eisenia fetida*)	Mortality and biomass (4-week) and reproduction (8-week)	TP: BCS-CQ 63359	LC_{50}: >100 mg a.i./kg soil dw NOAEC: 100 mg a.i./kg soil dw	2731995
Earthworm (*Eisenia fetida*)	Acute, 14-day	End-use product: Tetraniliprole FS 480 G	LC_{50}: >404 mg a.i./kg soil dw NOAEC ≥404 mg a.i./kg soil dw	2733964
Earthworm (*Eisenia fetida*)	Acute, 14-day	End-use product: Tetraniliprole SC 200 G	LC_{50}: >185 mg a.i./kg soil dw NOEC ≥ 185 mg a.i. /kg soil dw	2732259
Earthworm (*Eisenia fetida*)	Chronic, 28-day	End-use product: Tetraniliprole SC 200 G	NOAEC: 182 mg a.i./kg soil dw LOAEC: >182 mg a.i./kg soil dw	2732260

TP: Transformation product

Table 19.2a Effects on non-target arthropods

Organism	Exposure	Test substance	Endpoint value	PMRA#
Treated glass surface with End-use product				
Parasitoid wasp (*Aphidius rhopalosiphi)*	48h acute (treated glass surface)	End-use product: Tetraniliprole SC 200 G	LR_{50}: 0.627 g a.i./ha NOER: < 0.5 g a.i./ha	2732257
Predatory mite (*Typhlodromus pyri)*	reproduction (treated glass surface)	End-use product: Tetraniliprole SC 200 G	LR_{50}: >44 g a.i./ha ER_{50}: > 44 g a.i./ha NOER: ≥ 44 g a.i./ha	2732252
Soil mite (*Hypoaspis aculeifer)*	14 d (mortality and reproduction (artificial soil)	BCS-CL73507 SC 200 G	NOEC for reproduction: ≥182 mg a.i./kg LOEC for reproduction: >182 mg g a.i./kg	27322254
Collembolan species (*Folsomia candida)*	28 d reproduction (artificial soil)	BCS-CL73507 SC 200 G	reproduction: NOEC: 58.34 mg a.i./kg soil dw LOEC: 103.76 mg a.i./kg soil dw weight	2732258
Extended laboratory test				
Parasitoid wasp (*Aphidius rhopalosiphi)*	reproduction (apple leaves) (Extended laboratory test)	End-use product: Tetraniliprole SC 200 G	No end points were defined (83.3% mortality due to high rates)	2732256

Organism	Exposure	Test substance	Endpoint value	PMRA#
Parasitoid wasp (*Aphidius rhopalosiphi*	reproduction (barley) (Extended laboratory test)	End-use product: Tetraniliprole SC 200	LR_{50} (mortality): 0.7 g a.i./ha NOER (mortality) < 0.3 g a.i./ha ER_{50} (reproduction) : 0.4 g a.i./ha NOER (reproduction): < 0.3 g a.i./ha	2732255
Green lacewing (*Chrysoperla carnea)*	reproduction (beans) (extended laboratory test)	End-use product: Tetraniliprole SC 200 G	LR_{50}: ≥ 44 g a.i./ha NOER: ≥ 44 g a.i./ha NOER(reproduction): ≥ 44 g a.i./ha	2732251
Ladybird (*Coccinella Septempunctata* L.)	mortality and reproduction effects (extended laboratory test)	End-use product: Tetraniliprole SC 200 G	Mortality: The LR_{50} > 44 and NOER ≥ 44 g a.i./ha Reproduction: no effects up to 44 g a.i./ha	2732253
Transformation products				
Collembolan (*Folsomia candida)*	reproduction (artificial soil)	TP: BCS-CQ63359	NOEC: ≥ 562 mg p.m./kg d.w	27332009
Predatory mite (*Hypoaspis aculeifer)*	reproduction (artificial soil)	TP: BCS-CQ63359	NOEC: ≥ 100 mg p.m./kg d.w (limit test)	2730007
Collembolan (*Folsomia candida)*	28 d reproduction (artificial soil)	TP:BCS-CR74541	NOEC: ≥ 100 mg p.m./kg d.w (limit test)	2732010
Predatory mite (*Hypoaspis aculeifer*)	14 d reproduction (artificial soil)	TP:BCS-CR74541	NOEC: ≥ 100 mg p.m./kg d.w (limit test)	2732008

TP: Transformation product

Table 19.2b Effects of Tetraniliprole and the End-use Product Tetraniliprole SC 200 G on Non-target Arthropods based on Semi-field and Full-field Studies

Organism	Study design	Conclusions	Uncertainties	PMRA #
SEMI-FIELD STUDY				
Parasitic wasp (*Aphidius colemani*)	End-use product: Tetraniliprole (25 g/L) Application: Test: 60 g a.s./ha (2400 mL product/ha) to zucchini and Savoy cabbage in a greenhouse Toxic reference: lambda-cyhalothrin at 12.5 g a.s./ha (125 mL product/ha) Control: untreated Assessment: parasitization of aphids was measured for up to 19 days after application (DAA)[1]	The exposure to 60 g a.s./ha under semi-field conditions for up to 19 DAA indicates adverse effects on both parasitization rate and reproduction. The highest levels of effects seen were: •0 DAA Immediately after application: - moderately harmful (>50%) to parasitization •3-19 DAA: - 2 slightly harmful (25 – 50%) to parasitization and reproduction	This is a non-standard test therefore there are no validity guidelines to follow. The application rate was not verified. The greenhouse environmental conditions were not noted. The parasitization rates in one control plot were inconsistent.	2732263

Organism	Study design	Conclusions	Uncertainties	PMRA #
Parasitic wasp (*Encarsia formosa*)	End-use product: Tetraniliprole (25 g/L) Application: Test: 60 g a.s./ha (2400 mL product/ha) to tomato in a greenhouse Toxic reference: lambda-cyhalothrin at 12.5 g a.s./ha (125 mL product/ha) Control: untreated Assessment: parasitization of aphids was measured for up to 16 DAA	The exposure to 60 g a.s./ha under semi-field conditions indicates no unacceptable adverse effects on parasitation rate and reproduction. The highest levels of effects were: - >50% for a short-term duration and remained <50% at samplings later than 5 DAA over all studies. The overall classification is determined to be moderately harmful at 0 DAA until 5 DAA and slightly harmful until 16 DAA in postapplication samplings.	This is a non-standard test therefore there are no validity guidelines to follow. The application rate was not verified. The greenhouse environmental conditions were not noted.	2732265
Parasitic wasp (*Eretmocerus eremicus*)	End-use product: Tetraniliprole (200 g/L) Application: Test: 2 × 20 g a.s./ha at a 7 day interval to eggplant in a greenhouse Toxic reference: lambda-cyhalothrin at 12.5 g a.s./ha Control: untreated Assessment: parasitization of aphids was measured for 28 days after the first application and 21 days after last second application	The exposure to a total of 40 g a.s./ha under semi-field conditions indicates no unacceptable adverse effects on parasitation rate and reproduction. At the test item rate of 2 × 20 g tetraniliprole/ha, effects remain <25% in all samplings during the study period. The classification is determined to be harmless in postapplication sampling.	This is a non-standard test therefore there are no validity guidelines to follow. The application rate was not verified. The greenhouse environmental conditions were not noted.	2732266
ON-FIELD EXPOSURE FULL-FIELD STUDY				
Parasitic wasps (*Aphelinus mali*)	End-use products: Study 1 : Tetraniliprole (25 g/L) Study 2-5 : Tetraniliprole (200 g/L) Application to apple trees: Test: Study 1: 1 × 20 g a.s./ha/m canopy height Study 2-4: 2 × 20 g a.s./ha/m ch Study 5: 2 × 10 g a.s./ha/m ch Toxic reference: Study 1: clothianidin at 37.5 g a.s./ha/m ch Study 2-5: lambda-cyhalothrin at 12.5 g a.s./ha/m ch Control: untreated	The exposure to tetraniliprole in apple orchards under field conditions indicates no unacceptable adverse effects on parasitization rate and reproduction. At the test item rates of up to 2 × 20 g a.s./ha, effects remained <50% compared to untreated controls. The classifications are determined to be harmless and slightly harmful in postapplication samplings.	This is a non-standard test therefore there are no validity guidelines to follow. The application rate was not verified. The field environmental conditions were not noted.	2732264

Organism	Study design	Conclusions	Uncertainties	PMRA #
	Assessment: parasitization of aphids was measured for up to 56 days after application			
OFF-FIELD EXPOSURE FULL FIELD STUDY				
Non-target, surface- and plant-dwelling, arthropods of a grassland habitat (off-crop) in The Netherlands	End-use product: Tetraniliprole SC 200 G Application: Test: 0.2, 0.4, 0.8, 1.6 and 4.0 g a.s./ha equivalent to typical drift values for various use pattern of the test item. Toxic reference: lambda-cyhalothrin 40 g a.s./ha (100 g/L) Control: tap water Assessment: arthropod counts from various sampling methods were taken before application, and 3 days and approximately 1, 2, 4 and 8 weeks after application; initial effects followed by full recovery within the test period of 8 weeks was deemed an ecologically acceptable effect	The short-term exposure of naturally occurring surface- and plant-dwelling arthropods to tetraniliprole SC 200 G applied at the rate of up to 4 g a.s./ha did not cause significant adverse effects at the population level in The Netherlands. Statistically significant adverse effects at the population level were observed, but recovery of all populations occurred within one month after treatment and were therefore deemed ecologically acceptable effects.	This is a non-standard test therefore there are no validity guidelines to follow.	2732261
Non-target, surface- and plant-dwelling, arthropods of a grassland habitat (off-crop) in Southwestern France	End-use products: Tetraniliprole SC 200 G Application: Test: 0.2, 0.4, 0.8, 1.6 and 4.0 g a.s./ha equivalent to typical drift values for various use pattern of the test item. Toxic reference: lambda-cyhalothrin 40 g a.s./ha (100 g/L) Control: tap water Assessment: arthropod counts from various sampling methods were taken before application, and 3 days and approximately 1, 2, 4 and 8 weeks after application; initial effects followed by full recovery within the test period of 8 weeks was deemed an ecologically acceptable effect	The short-term exposure of naturally occurring surface- and plant-dwelling arthropods to Tetraniliprole SC 200 G applied at the rate of up to 4 g a.s./ha did not cause significant adverse effects at the population level in France. Statistically significant adverse effects at the population level were observed, but recovery of all populations occurred within two months after treatment and were therefore deemed ecologically acceptable effects.	This is a non-standard test therefore there are no validity guidelines to follow.	2732262

[1] DAA = days after application

Table 19.3a Effects on pollinators

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	PMRA#
Laboratory Studies					
Honey bee, *Apis mellifera*	Acute, adult oral, 72-hr	Tetraniliprole	LD_{50} = 0.010 µg a.i./bee	Highly toxic	2731999
	Acute, adult, oral, 48-hr	TP: BCS-CQ63359	LD_{50} > 53.3 µg t.p./bee	Relatively non-toxic	2732001
	Acute, adult, oral, 96-hr	End-use product: Tetraniliprole SC 200 G	LD_{50} = 0.0479 µg a.i./bee	Highly toxic	2732227
	Acute, adult, oral, 96-hr	End-use product: Tetraniliprole FS 480 G	LD_{50} = 0.045 µg a.i./bee	Highly toxic	2733962
	Acute, adult, oral, 96-hr	End-use product: Tetraniliprole FS 480 G	LD_{50} = 0.0557 µg a.i./bee	Highly toxic	2733960
	Adult, contact, 96-hr	Tetraniliprole	LD_{50} = 0.39 µg a.i./bee	Highly toxic	2731999
	Adult contact, 48-hr	TP: BCS-CQ63359	LD_{50} > 100 µg t.p./bee	Relatively non-toxic	2732001
	Adult, contact, 96-hr	End-use product: Tetraniliprole SC 200 G	LD_{50} = 0.406 µg a.i./bee	Highly toxic	2732227
	Adult, contact, 96-hr	End-use product: Tetraniliprole FS 480 G	LD_{50} = 0.090 µg a.i./bee	Highly toxic	2733962
	Adult, contact, 96-hr	End-use product: Tetraniliprole FS 480 G	LD_{50} = 0.0662 µg a.i./bee	Highly toxic	2733960
	Chronic, adult, oral, 10-day	End-use product: Tetraniliprole SC 200 G	NOAEL = 7.23 ng a.i./bee/day (39.1 ng product/bee/day) (mortality and food consumption)	Highly toxic	2732297
	Single exposure, larvae	Tetraniliprole	LD_{50} = 13 ng a.i./larva	Highly toxic	2732076
	Repeated exposure, larvae, 22-day	Tetraniliprole	NOAEL = 0.88 ng a.i./larva/day (emergence and mortality)	Highly toxic	2732080
	Foliage residue exposure, up to 104 g a.i./ha	End-use product: Tetraniliprole 200SC	RT_{25} < 3 h for 30, 57, and 104 g a.i./ha	No classification	2732285

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	PMRA#
Acute Non-*Apis* Laboratory Studies					
Bumble bee, *Bombus terrestris*	Acute, adult, oral, 72-hr	Tetraniliprole	LD_{50} = 0.043 µg a.i./bee	Highly toxic	2732003
	Acute, adult, oral, 48-hr	End-use product: Tetraniliprole SC 200 G	LD_{50} = 0.046 µg a.i./bee	Highly toxic	2732229
	Adult, contact, 96-hr	Tetraniliprole	LD_{50} = 23.1 µg a.i./bee	Relatively non-toxic	2731997
	Adult, contact, 96-hr	End-use product: Tetraniliprole SC 200 G	LD_{50} = 85 µg a.i./bee	Relatively non-toxic	2732229

Table 19.3b Effects and residues of Tetraniliprole, the End-use Product Tetraniliprole SC 200 G and the Transformation Product BCS-CQ63359 on Honey Bees based on Tier II and Exposure Studies

Study design	Conclusion	Uncertainties	PMRA#
Tier II (Semi-field)			
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects in honey bee colonies Tunnel area: 80 m^2 Exposure period: 8 days Observation period: 28 days Colony size: 4000 to 6000 bees Replicates: 3 Application rates: 2.6, 5.2, or 10.1 g a.i./ha (actual applied) *Phacelia tanacetifolia* were sprayed by foliar application during full flowering when bees were actively foraging.	There were significant increases in mortality in 5 and 10 g a.i./ha groups. Foraging activity was decreased in the 10 g a.i./ha group. Based on this study, the NOAEL is 2.5 g a.i./ha for applications of tetraniliprole to honey bee colonies actively foraging.	Brood index, termination rate, and compensation index were not determined. No residue monitoring was conducted. The application rates used were well below those for foliar (single rate of 60 g a.i./ha) or turf (single rate of 100 g a.i./ha).	2732238
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects and residues in honey bee colonies Tunnel area: 100 m^2 Exposure period: 8 days Observation period: 28 days Colony size: 7865 to 15 665 bees (for biological assessment) Replicates: 4 Application rate: 20.9 or 20.7 g a.i./ha (actual applied) *Phacelia tanacetifolia* were sprayed by foliar application	No test-item related adverse effects on mortality, flight intensity, behaviour, food storage, or colony strength were observed. There was too much variability in the test item data to determine an effect on brood in comparison with the control. Based on this study, the NOAEL is 20 g a.i./ha for applications of tetraniliprole prior to the start of flowering. Residues of tetraniliprole: Pollen from combs: up to 28 µg a.i./kg pollen	The test substance was applied before bees were introduced to the test tunnels. As such, this scenario is relevant for pre-bloom foliar application. There was no acclimation period to the tunnels prior to test substance exposure. The application rates used were well below those for foliar (single rate of 60 g a.i./ha) or turf (single rate of 100 g a.i./ha).	2732241

Study design	Conclusion	Uncertainties	PMRA#
just before onset of flowering. Bees were introduced 13 days later (for tetraniliprole treatment).	Pollen from forager bees: up to 25 µg a.i./kg pollen Nectar from combs: <0.4 µg a.i./kg nectar Nectar from forager bees: ≤1 µg a.i./kg nectar Treated bees wax: up to 6.3 µg a.i./kg bees wax Fresh bees wax: up to 2.2 µg a.i./kg bees wax Residues of TP: BCS-CQ63359: either not quantifiable (< 1 µg met./kg) or not detectable (< 0.4 µg met./kg) in all bee-relevant matrices		
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects in honey bee colonies Tunnel area: 200 m^2 Exposure period: 10 days Observation period: 29 days Colony size: 7280 to 14 950 bees Replicates: 4 Application rate: 60 g a.i./ha *Phacelia tanacetifolia* were treated by drip application (for tetraniliprole treatment) before full flowering. Bees were introduced 5 days later (for tetraniliprole treatment).	No significant differences were determined for total mortality, larval and pupal mortality, flight intensity, brood index, compensation index, or termination rate. There was a significant decrease in the number of combs with brood at 1 day after start of exposure and the total number of bees at 11 days after exposure. Other than these two instances, colony strength was not affected by exposure. Therefore, these effects were thought to be transient, and not treatment related. Based on this study and the noted lack of biologically significant effects, the NOAEL is 60 g a.i./ha for drip applications of tetraniliprole prior to the start of flowering and bee flight. No residues of tetraniliprole or its transformation product tetraniliprole-N-methyl-quinazolinone were detected in treated flowers, pollen from treated forager bees, or nectar from treated forager bees.	The test substance was applied before bees were introduced to the test tunnels by drip irrigation. As such, this scenario is relevant for pre-bloom soil application. There was no acclimation period to the tunnels prior to test substance exposure. The application rate used was well below that for soil (single rate of 150 g a.i./ha) or turf (single rate of 100 g a.i./ha).	2732249
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Spain) to determine effects in honey bee colonies Tunnel area: 100 m^2 Exposure period: 7 days	No biologically significant effect on mortality. Brood development was significantly affected by treatment with tetraniliprole (brood index, brood compensation index, and brood termination index). Based on this study, the NOAEL	The test substance was applied before bees were introduced to the test tunnels. As such, this scenario is relevant for pre-bloom foliar application. There was no acclimation period to the tunnels prior to test	2732242

Study design	Conclusion	Uncertainties	PMRA#
Observation period: 28 days Colony size: 7500 to 9000 bees Replicates: 4 Application rate: 62.9 g a.i./ha (actual applied) *Phacelia tanacetifolia* were sprayed by foliar application during pre-flowering. Bees were introduced 5 days later (for tetraniliprole treatment).	is <60 g a.i./ha for applications of tetraniliprole prior to the start of flowering.	substance exposure. No residue monitoring was conducted. The application rate used was below that for turf (single rate of 100 g a.i./ha). However, the rate is consistent with the single maximum orchard and berry application rates.	
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Spain) to determine effects in honey bee colonies Tunnel area: 100 m^2 Exposure period: 7 days Observation period: 29 days Colony size: 2500 to 8700 bees Replicates: 3 Application rates: 2.7, 5.1, or 10.0 g a.i./ha (actual applied) *Phacelia tanacetifolia* were sprayed by foliar application during full flowering when bees were actively foraging.	At 10.0 g a.i./ha, significant increases in mortality were detected at 1 and 6 days after test substance application, and significant decreases in food stores were detected at 21 and 29 days after application. Based on this study and the noted effects to adult worker bee mortality and reductions in food stores, the NOAEL is 5.1 g a.i./ha for applications of tetraniliprole while bees were actively foraging.	Brood index, termination rate, and compensation index were not determined. No residue monitoring was conducted. The application rates used were well below those for foliar (single rate of 60 g a.i./ha) or turf (single rate of 100 g a.i./ha).	2732235
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects in bumble bee colonies Tunnel area: 60 m^2 Exposure period: 26 days Observation period: 26 days Colony size: mean of 109.5 bees per replicate Replicates: 5 Application rate: 8 g a.i./ha (foliar) or 200 g a.i./ha (in-furrow) Potatoes were either treated by two foliar applications during pre-flowering or one in-furrow application during planting. Bees were introduced 8 days later (foliar) or 47 days later (in-furrow).	The total exposure phase was 26 days and the main food source was pollen from potato flowers. Although it was supplemented with sugar solution, a confinement period of this long severely impacted the bumble bees. The bumble bee colonies developed weakly due to insufficient and restricted food supply in the tunnels. Queen mortality was observed in both control and treatment groups, and therefore, bumble bees did not enter the reproduction phase. Residue of tetraniliprole (bumble bee forager collected pollen): From foliar application: 7.7 µg a.i./kg pollen, 4.6 µg a.i./kg pollen and < LOQ (<1 µg a.i./kg pollen) at 3, 7 and 20 days after exposure, respectively. From in-furrow application: 1.4 µg a.i./kg pollen, 1.2 µg a.i./kg pollen and < LOQ (<1 µg a.i./kg	This study was deemed not reliable by the USEPA and PMRA. The exposure period of the test was 26 days in the tunnels, which significantly impacted the bees, resulting in insufficient food supply and weak colony development and queen mortality in both controls and treatments. The test substance was applied before bees were introduced to the test tunnels, with the study examining effects from pre-bloom applications by foliar or in-furrow soil application. There was no acclimation period to the tunnels prior to test substance exposure. A concurrent reference item group in	2732247

Study design	Conclusion	Uncertainties	PMRA#
	pollen) at 3, 7 and 20 days after exposure, respectively.	the field was not used; only a laboratory reference test was run. The foliar application rates used were well below those for turf (single rate of 100 g a.i./ha) or in-furrow (single rate of 150 g a.i./ha).	
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects on brood development in honey bee colonies Tunnel area: 108 m^2 Exposure period: 7 days Observation period: 26 days Colony size: 6110 to 6679 bees Replicates: 4 Application rate: 2.5 or 5.0 g a.i./ha *Phacelia tanacetifolia* were sprayed by foliar application during full flowering when bees were actively foraging.	No significant effects on mortality (adults and pupae), foraging, behaviour, colony strength, food storage, and brood development were observed.	This study was deemed unreliable by the USEPA but not by the PMRA. Bees were placed into the tunnels 13 days before application, therefore staying for a total of 20 days, potentially impacting the integrity of the study data. No residue monitoring was conducted. The foliar application rates used were well below those for turf (single rate of 100 g a.i./ha) or in-furrow (single rate of 150 g a.i./ha).	2732231
Test substance: End-use product: Tetraniliprole SC 200 G Semi-field study (Germany) to determine effects on brood development in honey bee colonies Tunnel area: 125 m^2 Exposure period: 10 days Observation period: 30 days Colony size: 5648 to 7616 bees Replicates: 4 Application rate: 60 g a.i./ha *Phacelia tanacetifolia* were treated by soil drench application before full flowering. Bees were introduced 4 days later (for tetraniliprole treatment).	Increases in mortality were detected at 27 days after bees were exposed to test material. Slight decreases in brood index were detected at two middle time points. Decreases in foraging activity were noted at one early time point. Decreases in the percentage of eggs present at the 4th of 5 colony condition assessment were observed. Finally, the brood termination rate was higher in the treatment than the control. These effects were considered transient with evidence of recovery. Based on this study, the NOAEL is 60 g a.i./ha for soil drench applications of tetraniliprole prior to the start of flowering and bee flight. Residues of tetraniliprole: Nectar from hive and from	The test substance was applied before bees were introduced to the test tunnels. As such, this scenario is applicable to pre- bloom soil applications. There was no acclimation period to the tunnels prior to test substance exposure. Sampling for residues did not start until 7 days after the application of the test material. The study rate was below the maximum single soil rate in Canada (150 g a.i./ha).	2732245

Study design	Conclusion	Uncertainties	PMRA#
	foraging bees: <LOD (<0.3 µg a.i./kg nectar) Pollen from hive: up to 2.3 µg a.i./kg pollen Pollen from foraging bees: up to 6.9 µg a.i./kg pollen Residues of tetraniliprole-N-methyl-quinazolinone: Nectar from hive and from foraging bees: <LOD (<0.3 µg a.i./kg nectar) Pollen from hive: <LOD (<0.3 µg a.i./kg pollen) Pollen from foraging bees: <LOQ (<1 µg a.i./kg pollen)		
Tier II (Colony feeding study)			
Test substance: End-use product: Tetraniliprole SC 200 G or Tetraniliprole Colony feeding study to determine chronic effects on honey bee colonies Exposure period: 6 weeks Observation period: 293 days Replicates: 12 (for tetraniliprole treatments) Exposure concentrations: 81, 158, 318, and 624 µg a.i./kg solution (measured), or 1720 µg a.i./kg solution (prepared with formulated product). Formulated end-use product was used in order to test above the limit of solubility. A sucrose solution containing tetraniliprole was provided to the bee hives during the exposure period.	Exposure to Tetraniliprole SC 200 at 1720 µg a.i./kg solution resulted in reductions in colony performance and increased colony loss. Overall colony survival in the controls throughout the study was 50%, with almost all colony losses occurring during the overwintering period. As such, the overwintering success could not be properly evaluated in this study. Based on the results of this study prior to overwintering, the overall NOAEC was determined to be 624 µg a.i./kg sucrose solution. Residues of tetraniliprole: Uncapped nectar: medians ranged from 37 to 1,486 µg a.i./kg nectar Capped honey: medians ranged from 1.3 to 1162 µg a.i./kg honey Bee bread: medians ranged from 12.6 to 501 µg a.i./kg bee bread	Queen ("swarm") cells and supercedure cells were present, as well as queen bees not being present (colonies no longer queen right), in multiple control and treatment hives. Overwintering success could not be properly evaluated in this study owing to high overwinter mortality in control hives.	2732005
Dust Characterization			
Test substance: End-use product: Tetraniliprole FS 480 Corn seed was treated with Tetraniliprole FS 480 at 0.25 mg ai/seed and soybean seed was treated with Tetraniliprole FS 480 at 0.0675 mg a.i./seed. The seeds were also treated with a typical treatment system and rates including fungicides, coatings, and colorant currently commercially applied by the	John Deere Vacuum Meter: Because the John Deere Vacuum Meter produced more total dust and higher active ingredient content for both corn and soybean than the Heubach Dust Meter and is considered more relevant to the dust generation occurring in the field during planting, these results will be used in our risk assessment for corn and soybean seed treated with tetraniliprole.	Raw data was not available (study design mentioned 2 replicates/treatment – both replicates or only means were available). Study was conducted in a GLP facility but study not subjected to GLP requirements. Study was not conducted under a guideline.	2997519

Study design	Conclusion	Uncertainties	PMRA#
major corn and soybean seed producers. Corn and soybean total dust and Tetraniliprole dust fraction were characterized with either no planter lubricant, talc (John Deere) or Fluency Agent Advanced (Bayer) using both a Heubach Dust Meter and a John Deere vacuum meter on a planter test stand. Replicates: The dust from 1 kg sample of "planted" seed is collected in vacuum (3 replicates/treatment and seed source; 3 seed sources).	The mean total amount of dust from treated corn and soybean was from the talc planter lubricant which was 0.54 g dust/ha and 0.69 g dust/ha, respectively. The amount of total dust decreased in both corn and soybean when the fluency agent was used or when no planter lubricant was used at all. However the amount of tetraniliprole present in the dust decreased very little between all three corn treatments (0.020 – 0.024 g a.i./ha). The amount of tetraniliprole present in the dust from the soybean treatment appeared to decreased in response to the planting lubricant with the highest level of 0.014 g a.i./ha when no lubricant was used, 0.010 g a.i./ha when talc was used to the lowest level of 0.007 g a.i./ha when the fluency agent lubricant was used.		

Table 19.4 Effects on birds

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	PMRA#
Northern Bobwhite Quail (*Colinus virginianus*)	Acute	End-use product: Tetraniliprole SC 200	LD_{50}: >2000 mg formulation/kg bw; >370 a.i./kg bw	Practically non-toxic	2732272 2732273
Canary (*Serinus canaria*)	Acute	Tetraniliprole	LD_{50}: >2000 mg a.i./kg	Practically non-toxic	2732058
Northern Bobwhite Quail (*Colinus virginianus*)	Acute, oral	Tetraniliprole	LD_{50}: >2000 mg a.i./kg	Practically non-toxic	2732057
Northern Bobwhite Quail (*Colinus virginianus*)	Acute, oral	End-use product: Tetraniliprole FS 480G	LD_{50}: >2000 mg formulation/kg bw; >808 a.i./kg bw	Practically non-toxic	2733969
Northern Bobwhite Quail (*Colinus virginianus*)	Dietary, 8-day	Tetraniliprole	Daily dietary dose LC_{50}: >740 mg a.i./kg bw/day Concentration in diet LC_{50}: >5130 mg ai/kg diet	Practically non-toxic based on concentration in diet	2732059
Mallard Duck (*Anas platyrhynchos*	Dietary, 8-day	Tetraniliprole	Daily dietary dose LC_{50}: >1405 mg a.i./kg bw/day	Practically non-toxic based on	2732060

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	PMRA#
			Concentration in diet LC_{50}: >4952 mg a.i./kg diet	concentration in diet	
Mallard Duck (*Anas platyrhynchos*	Reproduction, 20-week	Tetraniliprole	NOAEC: 323 mg a.i./kg feed; 42.9 mg a.s./kg bw/day LOAEL: 940 mg a.s./kg bw/day; 129.5 mg a.s./kg bw/day	No classification	2732063 2732064
Northern Bobwhite Quail (*Colinus virginianus*)	Reproduction, 23-week	Tetraniliprole	NOAEC: 1045 mg a.s./kg feed; 78 mg a.s./kg bw/day LOAEL: >1045 mg a.s./kg bw/day; >78 mg a.s./kg bw/day	No classification	2732061 2732062

TP: Transformation product

Table 19.5 Effects on mammals

Organism	Exposure	Test Substance	Endpoint value	PMRA#
Rat	Acute, oral	Tetraniliprole	LD_{50} > 2000 mg/kg bw, (♂/♀)	2731825 2731826
Rat	Oral, 28-day	Tetraniliprole	NOAEL ≥ 599/700 mg/kg bw/day (♂/♀)	2731837
Mouse	Oral, 28-day	Tetraniliprole	NOAEL ≥ 1010/1159 mg/kg bw/day(♂/♀)	2731838
Rat	Oral, 90-day	Tetraniliprole	NOAEL ≥ 608/723 mg/kg bw/day (♂/♀)	2731833
Mouse	Oral, 90-day	Tetraniliprole	NOAEL ≥ 973/1224 mg/kg bw/day (♂/♀)	2731834
Dog	Oral, 90-day	Tetraniliprole	NOAEL ≥ 126/138 mg/kg bw/day (♂/♀)	2731835
Dog	Oral, 1-year	Tetraniliprole	NOAEL = 91.2/18.3 mg/kg bw/day (♂/♀)	2731836
Rat	Chronic	Tetraniliprole	NOAEL ♂ ≥ 741 mg/kg bw/day; NOAEL ♀ = 221 mg/kg bw/day	2731842
Mouse	Chronic	Tetraniliprole	NOAEL ≥ 825/1073 mg/kg bw/day (♂/♀)	2731843
Rat	Reproduction, 2-generation	Tetraniliprole	NOAEL = 196/224 mg/kg bw/day (♂/♀)	2731844

Table 19.6 Effects on Non-Target Terrestrial Plants

Organism	Exposure	Test Substance	Endpoint value	PMRA #
Sugar beet, Oilseed rape, Cucumber, Soybean, Sunflower, Tomato, Onion, Oat, Wheat, Corn	Tier 1 seedling emergence, 21-day	End-use product: Tetraniliprole SC 200	ER_{25}: >201.6 g a.i./ha Oilseed rape NOAEL: <201.6 g a.i./ha All other plants NOAEL: 201.6 g a.i./ha	2732274 2732275

Oilseed rape	Tier 2 seedling emergence, 21-day	End-use product: Tetraniliprole SC 200	ER_{25}: >201.6 g a.i./ha NOAEL: 201.6 g a.i./ha	2732276 2732278
Sugar beet, Oilseed rape, Cucumber, Soybean, Sunflower, Tomato, Onion, Oat, Wheat, Corn	Tier 1 vegetative vigor, 21-day	End-use product: Tetraniliprole SC 200	ER_{25}: >201.6 g a.i./ha Tomato NOAEL: < 201.6 g a.i./ha All other plants NOAEL: 201.6 g a.i./ha	2732279 2732280
Tomato	Tier 2 vegetative vigor, 21-day	End-use product: Tetraniliprole SC 200	ER_{25}: >201.6 g a.i./ha NOAEL: 201.6 g a.i./ha	2732281 2732282

Non-Target Aquatic Organisms

Table 19.7 Effects on freshwater invertebrates: *Daphnia* sp.

Organism	Exposure	Test Substance	Endpoint value	Degree of	PMRA #
Waterflea (*Daphnia magna*)	Acute, static, 48-hr	Tetraniliprole	EC_{50}: 143 µg a.i./L	Highly toxic	2732012
Waterflea (*Daphnia magna*)	Acute, static, 48-hr	Tetraniliprole	EC_{50}: 254 µg a.i./L	Highly toxic	2732011
Waterflea (*Daphnia magna*)	Chronic, static-renewal, 21-day	Tetraniliprole	NOEC: 12.5 µg a.i./L LOEC: 23.1 µg a.i./L µg a.i./L 13.3 µg	No classification	2732013
Waterflea (*Daphnia*	Acute, static, 48-hr	End-use product: Tetraniliprole FS	EC_{50}: 72µg formulation/L; 29 µg a.i./L	Highly toxic	2733965
Waterflea (*Daphnia*	Acute, static, 48-hr	End-use product: Tetraniliprole SC	EC_{50}: 365.3 µg formulation/L;	Highly toxic	2732267 2732268

Table 19.8 Acute and Chronic Effects on Freshwater Fish and Amphibians

Organism	Exposure	Test	Endpoint value	Degree of	PMRA#
Fathead minnow (*Pimephales*	Acute, static, 96-hr	Tetraniliprole	LC_{50}: >10.9 mg a.i./L (limit test)	Slightly toxic	2732052
Rainbow trout (*Oncorhynchus*	Acute, static, 96-hr	Tetraniliprole	LC_{50}: > 10.9 mg a.i./L	Slightly toxic	2732050
Fathead minnow (*Pimephales*	Chronic early life stage, flow- through,	Tetraniliprole	NOEC = 0.646 mg a.i./L LOEC = 1.33 mg a.i./L (based on total length)	No classification	2732054
Clawed Frog (*Xenopus laevis*)	Acute, static, 48-hr	Tetraniliprole	LC_{50}: >8.60 mg a.i./L	Moderately toxic	2732075

Organism	Exposure	Test Substance	Endpoint value	Degree of toxicity	PMRA#
Bluegill sunfish (*Lepomis macrochirus*)	Bio-concentration Factor (BCF)	Tetraniliprole	BCFs: < 2.0 L/Kg	Low potential for bioaccumulation	2732055
Rainbow trout (*Oncorhynchus mykiss*)	Acute, static, 96-hr	End-use product: Tetraniliprole FS 480 G	LC_{50}: > 96.0 mg formulation/L; > 38.8 mg a.i./L	Practically non-toxic	2733968
Rainbow trout (*Oncorhynchus mykiss*)	Acute, static, 96-hr	End-use product: Tetraniliprole SC 200	LC_{50}: > 566 mg formulation/L; 105 mg a.i./L	Practically non-toxic	2732271
Bluegill sunfish (*Lepomis macrochirus*)	Bio-concentration Factor (BCF)	TP: BCS-CQ63359 bioaccumulation	BCFs: 124 L/Kg low dose 183 L/Kg high dose	Low potential for bioaccumulation	2732056

TP: Transformation product

Table 19.9 Effects on marine fish and invertebrates

Organism	Exposure	Test Substance	Endpoint value	Degree of Toxicity	PMRA #
Eastern oyster (*Crassostrea virginica*)	Acute, flow-through, 96-hr	Tetraniliprole	IC_{50} 1.74 mg a.i./L NOEC 0.66 mg a.i./L	Moderately toxic	2732048
Mysid Shrimp (*Americamysis bahia*)	Acute, static, 96-hr	Tetraniliprole	LC_{50} 8.29 mg a.i./L NOEC 2.2 mg a.i./L	Moderately toxic	2732045
Mysid Shrimp (*Americamysis bahia*)	Chronic, flow-through, 28-day	Tetraniliprole	NOEC 0.58 mg a.i./L (based on reproduction)	No classification	2732049
Sheepshead minnow (*Cyrinodon variegatus*)	Acute, static, salt water, 96-hr	Tetraniliprole	LC_{50} >9.09 mg a.i./L NOEC ≥9.09 mg a.i./L	Moderately toxic	2732051
Sheepshead minnow (*Cyrinodon variegatus*)	Chronic early life stage, flow-through, salt water, 33-day	Tetraniliprole	NOEC 4.21 mg a.i./L LOEC >4.21 mg a.i./L	Moderately toxic	2732053

Table 19.10 Effects on marine and freshwater sediment dwelling organisms

Organism	Exposure	Test substance	Endpoint value	PMRA#
Marine amphipod (*Leptocheirus plumulosus*)	Acute, spiked sediment, 10-day	Tetraniliprole	Sediment LC_{50}: >728 µg a.i./kg NOAEL: 728 µg a.i./kg Pore Water LC_{50}: >553 µg ai/L NOAEL: 553 µg ai/L Overlying Water LC_{50}: >35.2 µg a.i./L NOAEL: 35.2 µg a.i./L	2732046, 2732047
Freshwater Amphipod (*Hyalella azteca*)	Acute, spiked sediment, 10-day	Tetraniliprole	Sediment LC_{50}: >391 µg a.i./kg NOEC: 391 µg a.i./kg Pore Water LC_{50}: >1170 µg a.i./L NOEC: 1170 µg a.i./L (survival and growth)	2732017, 2732018
Midge larvae *(Chironomus dilutus)*	Acute, spiked sediment, 10-day	Tetraniliprole	Sediment LC_{50}: 29.3 µg a.i./kg NOAEL: 11 µg a.i./kg Pore Water LC_{50}: 5.0 µg a.i./L NOAEL: 1.7 µg a.i./L	2732015, 2732016
Midge larvae *(Chironomus riparius)*	Acute, static, larvae 48 hr	End-use product: Tetraniliprole SC 200 G	EC_{50}: 0.873 mg a.i./; 4.69 mg formulation/L (immobility)	2732269, 2732270
Midge larvae *(Chironomus riparius)*	Chronic, spiked sediment, 28-day	Tetraniliprole	Sediment NOAEL: 5.81 µg a.i./kg Overlying Water NOAEL: 0.20 µg a.i./L Pore Water NOAEL: 0.466 µg ai/L (emergence and development)	2732022
Midge larvae *(Chironomus riparius)*	Chronic, spiked water, 28-day	Tetraniliprole	Overlying Water NOAEL: 0.23 µg a.i./L (emergence and development)	2732023
Midge larvae *(Chironomus riparius)*	Acute, static, larvae, 48-hr	Tetraniliprole	EC_{50}: 271 µg a.i./L (immobility)	2732024, 2732025

Organism	Exposure	Test substance	Endpoint value	PMRA#
Midge larvae *(Chironomus dilutus)*	Chronic (life cycle), spiked sediment, flow-through, 57-day	Tetraniliprole	Sediment NOAEL: 33.0 µg a.i.kg Pore Water LC_{50}: > 0.704 µg a.i./L NOAEL: 0.704 µg a.i./L (survival and growth)	2732032, 2732033, 2732034, 2732035, 2732036
Midge larvae *(Chironomus riparius)*	Acute, spiked, flow-through sediment, 10-day	TP: BCS-CQ63359	Sediment LC_{50}: >4,450 µg TP/kg NOAEL: 4,450 µg TP/kg Pore Water LC_{50} for: >22.9 µg TP/L NOAEL: 22.9 µg TP/L Overlying Water LC_{50}: >0.527 µg TP/L NOAEL: 0.527 µg TP/L (survival and growth)	2732037, 2732038
Midge larvae *(Chironomus riparius)*	Acute, static, limit test, 48-hr	TP: BCS-CU81056	EC_{50} >9.87 mg p.m./L NOAEL: 9.87 mg p.m./L (immobilisation)	2732026
Midge larvae *(Chironomus riparius)*	Acute, static, water only, 48-hr	TP: BCS-CR60014	EC_{50}: >9.9 mg p.m./L (immobilisation)	2732028
Midge larvae *(Chironomus riparius)*	Acute, static, limit test, water only, 48-hr	TP: BCS-CR74541	EC_{50}: >9.00 mg p.m./L (immobilisation)	2732029
Midge larvae *(Chironomus riparius)*	Acute, static, limit test, water only, 48-hr	TP: BCS-CQ63359	EC_{50}: 0.852 mg p.m./L (immobilisation)	2732030
Midge larvae *(Chironomus riparius)*	Acute, static, limit test, water only, 48-hr	TP: BCS-CY28900	EC_{50}: >1.10 mg p.m./L (immobilisation)	2732039
Midge larvae *(Chironomus riparius)*	Acute, static, limit test, water only, 48-hr	TP: BCS-CT30672	EC_{50}: >2.24 mg p.m./L (immobilisation)	2732040
Midge larvae *(Chironomus riparius*	Acute, static, limit test, water only, 48-hr	TP: BCS-CY28897	EC_{50}: >9.74 mg p.m./L (immobilisation)	2732041
Midge larvae *(Chironomus riparius*	Acute, static, limit test, water only, 48-hr	TP: BCS-CY28906	EC_{50}: > 2.62 mg p.m./L (immobilisation)	2732042
Midge larvae *(Chironomus riparius*	Acute, static, limit test, water only, 48-hr	TP: BCS-CT30673	EC_{50}: > 9.04 mg p.m./L (immobilisation)	2732043
Midge larvae *(Chironomus riparius*	Acute, static, limit test, water only, 48-hr	TP: BCS-CU81055	EC_{50}: > 10.6 mg p.m./L (immobilisation)	2732044

TP: Transformation product

Table 19.11 Effects on aquatic plants and algae

Organism	Exposure	Test substance	Endpoint value	PMRA#
Duckweed (*Lemna gibba*)	Acute, static renewal, 7-day	Tetraniliprole	IC_{50}:11.3 mg a.i./L NOAEC: 2.08 mg a.i./L (frond area)	2732074
Cyanobacteria (*Anabaena flos-aquae*)	Acute, static, 96-hr	Tetraniliprole	IC_{50}: >9.06 mg a.i./L NOEC: 9.06 mg a.i./L (yield, growth rate, area under the curve)	2732069
Green algae *(Pseudokirchneriella subcapitata)*	Chronic, multi-generational, 96-hr	End-use product: Tetraniliprole SC 200 G	IC_{50}: 58.46 mg a.i./L NOAEC: 3.24 mg a.i./L (area under the curve)	2732284
Saltwater Diatom (*Skeletonema costatum*)	Acute, static, 96-hr	Tetraniliprole	IC_{50}: 0.911 mg a.i./L NOAEC: 0.58 mg a.i./L (yield)	2732073
Freshwater Diatom (*Navicula pelliculosa*)	Acute, static, 96-hr	Tetraniliprole	IC_{50}: 3.37 mg a.i./L NOAEC: 2.42 mg a.i./L (yield)	2732065
Green Algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	TP: BCS-CT30673	IC_{50}: 12.5 mg p.m./L (area under the curve)	2732066
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	TP: BCS-CR60014	LC_{50}: >7.70 mg p.m./L NOEC: 7.70 mg p.m./L (yield, growth rate, area under the curve)	2732067
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	TP: BCS-CU81055	LC_{50}: >7.88 mg p.m./L NOEC: 7.88 mg p.m./L (yield, growth rate, area under the curve)	2732068
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	Tetraniliprole	IC_{50}: >2.31 mg a.i./L NOEC: 2.31 mg a.i/L (cell counts)	2732071
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	TP: BCS-CR74541	IC_{50} >8.61 mg p.m./L	2732070
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	TP: BCS-CU81056	IC_{50}: >7.11 mg p.m./L NOEC: 7.11 mg p.m./L (yield, growth rate, area under the curve)	2732072

Organism	Exposure	Test substance	Endpoint value	PMRA#
Green algae (*Pseudokirchneriella subcapitata*)	Acute, static, 72-hr	End-use product: Tetraniliprole FS 480 G	IC_{50}: 55.5 mg a.i./L; 137.3 mg formulation/L NOEC: 16.9 mg a.i./L; 41.9 mg formulation/L	2733970

Table 20 Screening Level Risk Assessment on Non-target Species

Risk Assessment on Non-Target Terrestrial Organisms

Foliar Application

Table 20.1 Screening Level Risk Assessment of Foliar Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Earthworms, Non-target Arthropods and Vascular Plants

Organism	Exposure	Endpoint value	EEC	RQ[2]	Level of Concern[3]
Invertebrates					
Earthworm	Acute	$LC_{50}/2^4$: >92.5 mg a.i./kg soil dw	0.087 mg a.i./kg soil[1]	0.0009	Not Exceeded
	Chronic	NOAEC: 182 mg a.i./kg soil dw	0.087 mg a.i./kg soil	0.0005	Not Exceeded
Non-target Arthropods	Acute,treated glass surface, parasitic wasp: *Aphidius rhopalosiphi*	$2xLR_{50}$: 0.627 g a.i./ha	195.022 g a.i./ha[5]	155.52	Exceeded
	Reproduction, treated glass surface, predatory foliar dwelling mite *Typhlodromus pyri*	>44 g a.i./ha	195.022 g a.i./ha	4.43	Exceeded
Vascular plants					
Vascular plant	Seedling emergence	EC_{25}: >201.6 g a.i./ha	195.022 g a.i./ha	0.97	At the level of concern
	Vegetative vigour	EC_{25}: >201.6 g a.i./ha	195.022 g a.i./ha	0.97	At the level of concern

[1] EEC = Estimated Environmental Concentration. The EEC for foliar applications in soil is 0.087 mg a.i./kg soil. It was calculated with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. Dissipation from soil was accounted for and concentrations were estimated for a soil depth of 15 cm.
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1 for most species; and 2 for glass plate studies using the standard beneficial arthropod test species, *Typhlodromus pyri* and *Aphidius rhopalosiphi*). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.
[4] For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints.
[5] EEC = Estimated Environmental Concentration. The EEC for foliar applications is 195.022 g a.i./ha. It was calculated with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications and accounting for dissipation from soil.

Table 20.2 Screening Level Risk Assessment of Foliar Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Birds and Mammals using Maximum Residues Expected Following Multiple Applications on Orchard fruits (EEC[1] = 3 × 60 g a.i./ha at 7-day intervals; assuming a foliar dissipation of 10 days).

	Endpoint value	Feeding guild (food item)[2]	On-field EDE[3]	On-field RQ[4]	Off-field RQ (74% drift)[5]	Level of Concern[6]
BIRDS						
Small Bird (0.02 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	9.74 mg a.i./kg bw	0.05	0.04	Not Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Insectivore	9.74 mg a.i./kg bw	0.23	0.17	Not Exceeded
Medium Sized Bird (0.1 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	7.60 mg a.i./kg bw	0.04	0.03	Not Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Insectivore	7.60 mg a.i./kg bw	0.18	0.13	Not Exceeded
Large Sized Bird (1 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	4.91 mg a.i./kg bw	0.02	0.02	Not Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Herbivore (short grass)	4.91 mg a.i./kg bw	0.11	0.08	Not Exceeded
MAMMALS						
Small Mammal (0.015 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	5.60 mg a.i./kg bw	0.03	0.02	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Insectivore	5.60 mg a.i./kg bw	0.03	0.02	Not Exceeded
Medium Sized Mammal (0.035 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	10.87 mg a.i./kg bw	0.05	0.04	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Herbivore (short grass)	10.87 mg a.i./kg bw	0.06	0.04	Not Exceeded
Large Sized Mammal (1 kg)						
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	5.81 mg a.i./kg bw	0.03	0.02	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Herbivore (short grass)	5.81 mg a.i./kg bw	0.03	0.02	Not Exceeded

[1] EEC = Estimated Environmental Concentration. At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

[2] Specialized feeding guilds are considered for each category of animal weights to help determine exposure (herbivore, frugivore, insectivore and granivore).

[3] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight 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

[4] RQ = Risk Quotient. The on field RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

[5] RQ = Risk Quotient. The off field RQ is calculated by dividing the EDE by the endpoint value and accounting for spray drift to non-target areas. The most conservative drift value of 74% for airblast application using early season fine droplets is used (RQ = (EDE/endpoint value)*74%)

[6] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.3 Screening Level Risk Assessment of Foliar Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Pollinators

Organism	Exposure	Endpoint value	Application rate (relevant use)	EEC[1]	RQ[2]	Level of Concern[3]
Honey bee, *Apis mellifera*	**Adult acute oral**					
	Acute oral, adults/technical grade active ingredient	72-h LD_{50} = 0.010 µg a.i./bee	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 2.9 µg a.i./bee	290	Exceeded
	Acute oral, adults/technical grade active ingredient	72-h LD_{50} = 0.010 µg a.i./bee	0.06 kg a.i./ha (orchard)	0.06 kg a.i./ha × 29 µg a.i./bee per kg/ha = 1.74 µg a.i./bee	174	Exceeded
	Acute oral, adults/transformation product	48-h LD_{50} >53.3 µg t.p./bee	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 29 µg t.p./bee per kg/ha = 2.9 µg t.p./bee	<0.05	Not exceeded
	Acute oral, adults/Tetraniliprole SC 200 G	96-h LD_{50} = 0.0479 µg a.i./bee	0.06 kg a.i./ha (orchard)	0.06 kg a.i./ha × 29 µg a.i./bee per kg/ha = 1.74 µg a.i./bee	36	Exceeded
	Adult acute contact					
	Acute contact, adults/technical grade active ingredient	96-h LD_{50} = 0.39 µg a.i./bee	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.24 µg a.i./bee	0.62	Exceeded
	Acute contact, adults/technical grade active ingredient	96-h LD_{50} = 0.39 µg a.i./bee	0.06 kg a.i./ha (orchard)	0.06 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.144 µg a.i./bee	0.37	Not exceeded
	Acute contact, adults/transformation product	48-h LD_{50} >100 µg t.p./bee	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 2.4 µg t.p./bee per kg/ha = 0.24 µg t.p./bee	<0.002	Not exceeded
	Acute contact, adults/Tetraniliprole SC 200 G	48-h LD_{50} = 0.406 µg a.i./bee	0.06 kg a.i./ha (orchard)	0.06 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.144 µg a.i./bee	0.35	Not exceeded
	Adult chronic oral					
	Chronic oral, adults/Tetraniliprole SC 200 G	10-d NOAEL = 0.00723 µg a.i./bee (mortality and food consumption)	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 29 µg a.i./bee per kg/ha = 2.9 µg a.i./bee	401	Exceeded
	Chronic oral, adults/Tetraniliprole SC 200 G	10-d NOAEL = 0.00723 µg a.i./bee (mortality and food consumption)	0.06 kg a.i./ha (orchard)	0.06 kg a.i./ha × 29 µg a.i./bee per kg/ha = 1.74 µg a.i./bee	240	Exceeded
	Larvae					
	Acute oral, larvae/technical grade active ingredient	LD_{50} = 0.013 µg a.i./larva	0.1 kg a.i./ha (turf)	0.1 kg a.i./ha × 12 µg a.i./larva per kg/ha = 1.2 µg a.i./larva	92	Exceeded
	Acute oral,	LD_{50} = 0.013 µg a.i./larva	0.06 (orchard)	0.06 kg a.i./ha × 12 µg	55	Exceeded

Organism	Exposure	Endpoint value	Application rate (relevant use)	EEC[1]	RQ[2]	Level of Concern[3]
	larvae/technical grade active ingredient			a.i./larva per kg/ha = 0.72 µg a.i./larva		
	Chronic oral, larvae/technical grade active ingredient	22-d NOAEL = 0.00088 µg a.i./larva	0.1 (turf)	0.1 kg a.i./ha × 12 µg a.i./larva per kg/ha = 1.2 µg a.i./larva	1363	Exceeded
	Chronic oral, larvae/technical grade active ingredient	22-d NOAEL = 0.00088 µg a.i./larva	0.06 (orchard)	0.06 kg a.i./ha × 12 µg a.i./larva per kg/ha = 0.72 µg a.i./larva	818	Exceeded

[1]EEC = Estimated Environmental Concentration. The EEC for foliar applications was calculated for turf using the maximum single application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha and for orchard fruit from the Tetraniliprole 200SC Insecticide: 60 g a.i./ha.
EEC = application rate (kg ai/ha) × adjustment factor (2.4 µg ai/bee per kg ai/ha for adult contact, and 29 µg ai/bee per kg ai/ha for adult oral and 12 µg a.i./larva per kg/ha for larvae)
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 0.4 for Acute exposure and 1.0 for Chronic). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.4 Further Characterization of the Risk of Foliar Applications of Tetraniliprole to Non-Target Pollinators: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Tetraniliprole (ppb)

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
TURF USE											
PMRA# 2732317 **PRE-BLOOM CLOVER** **End-use product:** Tetraniliprole SC 200 (end-use product; 18.20 or 18.60% a.i.) **Study summary:** Semi-field study; clover was mowed prior to application. **T1:** 100 g a.i./ha applied with irrigation immediately afterwards **T2:** 100 g a.i./ha applied	Tetraniliprole: (T1) 787 (T2) 947	Tetraniliprole: (T1) 3.4 (T2) 2.5	No (T1) RQ=0.1 (T2) RQ=0.08	**Yes** **(T1)** **RQ=0.80** **(T2)** **RQ=0.94**	No (T1) RQ=0.25 (T2) RQ=0.29	Tetraniliprole: (T1) 576 (T2) 645	Tetraniliprole: (T1) 1.9 (T2) 2	No (T1) RQ=0.08 (T2) RQ=0.08	No (T1) RQ=0.80 (T2) RQ=0.90	**Yes** **(T1)** **RQ =2.62** **(T2)** **RQ =2.91**	**CROP/USE:** TURF Pre-bloom **End-use product:** Tetraniliprole 43 SC Insecticide; Tetraniliprole 200SC Insecticide **Application:** 100 g a.i./ha × 2 applications **= RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
without irrigation immediately afterwards **Sampling:** Honey bees and bumble bees were used for sample collection of pollen and nectar from the clover.											
VEGETABLE CROPS											
PMRA# 2372299 **DURING BLOOM SOYBEAN** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.3% a.i.) **Study summary:** Semi-field study **T1:** 50 g a.i./ha during bloom at 10-20% bloom **T2:** 50 g a.i./ha during bloom 3-4 days after 1st application **Sampling:** Honey bees were used for nectar sample collection and hand-collection was used for flower samples.	Tetraniliprole: Flower: 5370 Pollen: Not applicable	Tetraniliprole: Nectar: 2.47	Flower: No RQ=0.09 Nectar only: No RQ=0.07	**Flower** **Yes** **RQ=5.19** Nectar only: No RQ=0.03	**Flower** **Yes** **RQ=1.5** Nectar only: No RQ=0.02	Tetraniliprole: Flower: 3890 Pollen: Not applicable	Tetraniliprole: Nectar: 1.2	Flower No RQ=0.07 Nectar only: No RQ=0.05	**Flower** **Yes** **RQ=5.2** Nectar only: No RQ=0.02	**Flower** **Yes** **RQ=16** Nectar only: No RQ=0.16	**CROP/USE:** SOYBEAN During bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 30 g a.i./ha × 2 applications **= RISK**
PMRA# 2732303 **PRE-BLOOM DURING BLOOM TOMATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.3% a.i.) **Study summary:** Semi-field study **Pre-bloom:** **T1:** 45 g a.i./ha when	Tetraniliprole: (T3) 14500 (T1) 12916	Not applicable	T3 No RQ=0.06 T1 No RQ=0.05	**T3** **Yes** **RQ=13.9** **T1** **Yes** **RQ=12.4**	**T3** **Yes** **RQ=4.0** **T1** **Yes** **RQ=3.58**	Tetraniliprole: (T3) 11700 (T1) 9250	Not applicable	T3 No RQ=0.07 T1 No RQ=0.05	**T3** **Yes** **RQ=15.5** **T1** **Yes** **RQ=12.3**	**T3** **Yes** **RQ=48** **T1** **Yes** **RQ=38**	**CROP/USE:** TOMATO Pre-bloom During bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 30 g a.i./ha × 4 applications **= RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
first flower open **During bloom:** **T3:** 45 g a.i./ha during bloom 5-6 days after 1st application **Sampling:** Pollen and flower samples were collected by hand.											
PMRA# 2732307 **PRE-BLOOM DURING BLOOM TOMATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.2% a.i.) **Study summary:** Semi-field study **T1:** 40 g a.i./ha 7 days before bloom **T2:** 60 g a.i./ha × 2 applications 9-10 days after transplanting and before bloom **Sampling:** Pollen was collected by bumble bees, and flowers were collected by hand.	Tetraniliprole: (T2) 40	Not applicable	No RQ=0.00	No RQ=0.04	No RQ=0.01	Tetraniliprole: (T2) 40	Not applicable	No RQ=0.00	No RQ=0.05	No RQ=0.16	**CROP/USE:** TOMATO Pre-bloom Tetraniliprole 200SC Insecticide **Application:** 30 g a.i./ha × 4 applications **= DURING BLOOM ACCEPTABLE RISK**
PMRA# 2732319 **PRE-BLOOM DURING BLOOM POTATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.20 or 18.60% a.i.) **Study summary:** Semi-field study **T2:** 30 g a.i./ha 30 days	Tetraniliprole: (T4) 3660 (T3) 102 (T2) 66.2	Not applicable	T4 No RQ=0.02 T3 No RQ=0.00	**T4** **Yes** **RQ=3.51** T3 No RQ=0.10	**T4** **Yes** **RQ=1.0** T3 No RQ=0.03	Tetraniliprole: (T4) 3660 (T3) 102 (T2) 66.2	Not applicable	T4 No RQ=0.02 T3 No RQ=0.00	**T4** **Yes** **RQ=4.5** T3 No RQ=0.14	**T4** **Yes** **RQ =13.8** T3 No RQ=0.42	**CROP/USE:** POTATO Pre-bloom During bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 30 g a.i./ha × 2 applications **= DURING**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	**Nectar Residue**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen Residue**	**Nectar Residue**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
before bloom + 30 g a.i./ha 10 days after 1st application **T3:** 30 g a.i./ha 30 days before bloom + 30 g a.i./ha 10 days after 1st application **T4:** 30 g a.i./ha at bloom + 30 g a.i./ha 10 days after 1st application **Sampling:** Pollen samples were collected with bumble bees and/or by hand.			T2 No RQ=0.00	T2 No RQ=0.06	T2 No RQ=0.02			T2 No RQ=0.00	T2 No RQ=0.09	T3 No RQ=0.27	**BLOOM RISK**
PMRA# 2732305 **PRE-BLOOM POTATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.5% a.i.) **Study summary:** Semi-field study **T1:** 8 g a.i./ha applied 13 days before bloom + 8 g a.i./ha applied 8 days after 1st application **Sampling:** Bumble bees were used to collect pollen, and hand-sampling was used to collect flowers.	Tetraniliprole: (T1) 18 Flower : (T1) 140	Not applicable	Using pollen only: No RQ=0.00 Using flower : No RQ=0.00	Using pollen only: No RQ=0.02 Using flower : No RQ=0.12	Using pollen only: No RQ=0.00 Using flower : No RQ=0.03	Tetraniliprole: (T1) 12.2 Flower: (T1) 126	Not applicable	Using pollen only: No RQ=0.00 Using flower: No RQ=0.00	Using pollen only: No RQ=0.02 Using flower: No RQ=0.17	Using pollen only: No RQ=0.05 Using flower: No RQ=0.52	**CROP/USE:** POTATO Pre-bloom During bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 30 g a.i./ha × 2 applications = **ACCEPTABLE RISK**
ORCHARD CROPS											
PMRA# 2732311 **POSTBLOOM ALMOND** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.3% a.i.)	Tetraniliprole: (T2) 454 (T1) 213	Tetraniliprole: (T2) 69.2 (T1) 7.68	**T2** **Yes** **RQ=2.02** T1 No RQ=0.23	**T2** **Yes** **RQ=1.40** T1 No RQ=0.31	**T2** **Yes** **RQ=0.76** T1 No RQ=0.13	Tetraniliprole: (T2) 207 (T1) 106	Tetraniliprole: (T2) 45.4 (T1) 6.7	**T2** **Yes** **RQ=1.83** T1 No RQ=0.27	**T2** **Yes** **RQ=1.15** T1 No RQ=0.27	**T2** **Yes** **RQ =7.04** **T1** **Yes** **RQ =1.35**	**CROP/USE:** TREE NUT Postbloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 60

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
Study summary: Semi-field study **T1:** 45 g a.i./ha applied postbloom + 45 g a.i./ha applied postbloom + 45 g a.i./ha applied postbloom + 45 g a.i./ha applied 10 days before pre-harvest **T2:** 45 g a.i./ha applied postbloom + 45 g a.i./ha applied 10 days before pre-harvest **Sampling:** Nectar and pollen samples were collected by hand the season following treatment.											g a.i./ha × 3 applications **= RISK**
PMRA# 2732313 **POSTBLOOM CHERRY** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.3% a.i.) **Study summary:** Semi-field study **T1:** 58 g a.i./ha applied postbloom + 58 g a.i./ha applied 7 days after 1st application + 58 g a.i./ha applied 6 days after 2nd application **Sampling:** Nectar and pollen samples (cherry flowers) were collected by hand the next year season after treatment.	Tetraniliprole: 10.8	Tetraniliprole: <0.3	No RQ=0.01	No RQ=0.01	No RQ=0.01	Tetraniliprole: 4.71	Tetraniliprole: <0. 3	No RQ=0.01	No RQ=0.01	No RQ=0.01	**CROP/USE:** STONE FRUIT Postbloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 60 g a.i./ha × 3 applications **= ACCEPTABLE RISK**
PMRA# 273228 **POSTBLOOM APPLE**	Tetraniliprole: 1	Tetraniliprole: 0.1	No RQ=0.00	No RQ=0.00	No RQ=0.00	Tetraniliprole: 1	Tetraniliprole: 0.1	No RQ=0.00	No RQ=0.00	No RQ=0.00	**CROP/USE:** POME FRUIT Postbloom **End-use**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
End-use product: Tetraniliprole SC 200 G (end-use product; 18.2%) **Study summary:** Semi-field study **T1:** 60 g a.i./ha applied postbloom at the start of ripening + 60 g a.i./ha applied postbloom + 60 g a.i./ha applied postbloom 7 days before harvest **Sampling:** Apple flowers (used for nectar and pollen samples) were collected by hand the spring following treatment.											**product:** Tetraniliprole 200SC Insecticide **Application:** 60 g a.i./ha × 3 applications **= ACCEPTABLE RISK**
RADIOACTIVE TRANSLOCATION STUDIES											
ORCHARD CROPS											
PMRA# 2732321 **POSTBLOOM APPLE** **End-use product:** [Phenyl-carbamoyl-^{14}C] tetraniliprole formulated as SC 200 (radiochemical purity >98%) **Study summary:** Study to determine translocation to petals and anthers with pollen/sepals from apple flowers. **T1:** 88 g a.i./ha applied after bloom at the start of fruit development + 86 g a.i./ha applied 33 days	Total radioactive residues: Petals: 2 µg a.i. equiv./kg sample Anthers with pollen/sepals: 6 µg a.i. equiv./kg sample	Total radioactive residues: Petals: 2 µg a.i. equiv./kg sample	No RQ=0.06	No RQ=0.03	No RQ=0.02	Total radioactive residues: Petals: 2 µg a.i. equiv./kg sample Anthers with pollen/sepals: 6 µg a.i. equiv./kg sample	Total radioactive residues: Petals: 2 µg a.i. equiv./kg sample	No RQ=0.08	No RQ=0.05	No RQ=0.30	**CROP/USE:** POME FRUIT Postbloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 60 g a.i./ha × 3 applications **= ACCEPTABLE RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	Pollen Residue	Nectar Residue	Nectar forager	Nurse bee	Bee larvae	
after fruit fall **Sampling:** Whole flowers were collected by hand one year after application.											
PMRA# 2732322 **POSTBLOOM APPLE** **End-use product:** [Pyrazole-carboxamide-^{14}C] tetraniliprole formulated as SC 200 (radiochemical purity >98%) **Study summary:** Study to determine translocation to petals, anthers with pollen, sepals, receptacles, and carpels from apple flowers. **T1:** total of 159.1 g a.i./ha applied: 1 application after bloom at the start of fruit development + 1 application after bloom 33 days after fruit fall **Sampling:** Whole flowers were collected by hand one year after application. ***Note:** appears actual rate was much higher than intended.	Total radioactive residues: Petals: 1 µg a.i. equiv./kg sample Anthers with pollen/sepals: 4 µg a.i. equiv./kg sample	Total radioactive residues: Petals: 1 µg a.i. equiv./kg sample	No RQ=0.03	No RQ=0.02	No RQ=0.01	Total radioactive residues: Petals: 1 µg a.i. equiv./kg sample Anthers with pollen/sepals: 4 µg a.i. equiv./kg sample	Total radioactive residues: Petals: 1 µg a.i. equiv./kg sample	No RQ=0.04	No RQ=0.02	No RQ=0.15	**CROP/USE:** POME FRUIT Postbloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 60 g a.i./ha × 3 applications = **ACCEPTABLE RISK**
PHACELIA											
PMRA# 2732324 **PRE-BLOOM PHACELIA**	Highest total radioactive residues: Pollen:	Highest total radioactive residues: Nectar:	Yes (RQ 0.92)	Yes (RQ 0.44)	No (RQ 0.29)	Highest total radioactive residues: Pollen:	Highest total radioactive residues: Nectar:	Yes (RQ 1.27)	No (RQ 0.61)	Yes (RQ 4.3)	**Not used in quantitative risk assessment**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ[1] exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ[2] exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen Residue	**Nectar Residue**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen Residue**	**Nectar Residue**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
End-use product: 1:1 ratio of [pyrazole-carboxamide-^{14}C] tetraniliprole : [phenyl-carbamoyl-^{14}C] tetraniliprole formulated as SC 200 (radiochemical purities >98%) **Study summary:** Semi-field study to determine translocation to nectar and pollen from Phacelia. **T1: :** total of 107.3 g a.i./ha applied: 1 application 15 days before bloom + 1 application 4 days before bloom **Sampling:** Nectar and pollen were collected by hand.	Maximum: 31.5 µg a.i. equiv./kg sample (4-10 days after last treatment)	Maximum: 0.8 µg a.i. equiv./kg sample (4-8 days after last treatment)				Maximum: 31.5 µg a.i. equiv./kg sample (4-10 days after last treatment)	Maximum: 0.8 µg a.i. equiv./kg sample (4-8 days after last treatment)				

Bold values in a grey cell indicate that acute Level of Concern (LOC) (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
1 Acute Risk Quotient (RQ) = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0×10^6] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0×10^6]
2 Chronic Risk Quotient (RQ) = Chronic estimated daily dose (EDD)/acute toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0×10^6] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total
Note, for tetraniliprole RA: adult acute oral **LD_{50} = 0.010 µg a.i./bee for technical grade active ingredient; chronic NOAEL: 0.00723 µg a.i./bee for SC 200 G EUP,** bee larvae acute **7-day LD_{50} = 0.013 µg a.i./larva/day for technical grade active ingredient and larva chronic NOAEL: 0.00088 µg a.i./larva/day**
Note: When flower residues were available, they were considered as pollen residues, not pollen and nectar combined.

Table 20.5 Further Characterization of the Risk of Foliar Applications of Tetraniliprole to Non-Target Arthropods: Using Results from Extended Laboratory Studies

Organism	Exposure	Endpoint value	EEC[1]	RQ[2]	Level of Concern[3]
EXTENDED LABORATORY STUDIES					
Parasitic wasps (*Aphidius rhopalosiphi*)	Extended laboratory test, barley seedlings, 11-day	Mortality 2 × LR_{50}: 2 × 0.7 g a.i./ha = 1.4 g a.i./ha	195.022 a.i. g /ha	139.30	Exceeded
		Reproduction 2 × ER_{50}: 0.4 × 2 g a.i./ha = 0.8 g a.i./ha	195.022 a.i. g /ha	243.78	Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC for foliar applications is 195.022 g a.i./ha. It was calculated with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications and accounting for dissipation from soil.

[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)

[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.6 Further Characterization of the Risk of Foliar Applications of Tetraniliprole to Non-Target Arthropods: Using Results from Semi-Field and Full-Field Studies

Organism	Exposure	Endpoint value	Conclusions	PMRA#
SEMI-FIELD STUDY				
Parasitic wasp (*Encarsia formosa*)	End-use product: Tetraniliprole (25 g/L) Application: Test: 60 g a.s./ha (2400 mL product/ha) to tomato in a greenhouse Toxic reference: lambda-cyhalothrin at 12.5 g a.s./ha (125 mL product/ha) Control: untreated Assessment: parasitization of aphids was measured for up to 16 DAA	NOEC: 60 g a.i./ha	A 50% effect in a semi-field test is considered to be acceptable for in-crop tests if recovery between seasons is seen and not impeded at the level of exposure. No harmful effects were seen for 16 days after a cumulative application of 60 g a.i./ha was made in this study. Therefore after biological examination of the data the NOEC is 60 g a.s./ha. This suggests that in cropping systems like those seen in a greenhouse where beneficial organisms are very important to pest management, there are risks to non-target arthropods at a rate of 60 g a.i./ha that will recover and are not expected to impact the population levels of these organisms.	2732265
ON-FIELD EXPOSURE FULL-FIELD STUDY				
Parasitic wasps (*Aphelinus mali*)	End-use products: Study 1 : Tetraniliprole (25 g/L) Study 2-5 : Tetraniliprole (200 g/L) Application to apple trees: Test: Study 1: 1 × 20 g a.s./ha/m canopy height Study 2-4: 2 × 20 g a.s./ha/m ch Study 5: 2 × 10 g a.s./ha/m ch Toxic reference: Study 1: clothianidin at 37.5 g a.s./ha/m ch Study 2-5: lambda-cyhalothrin at 12.5 g a.s./ha/m ch Control: untreated Assessment:	NOEC: >40 g a.i./ha	A 25% effect in a field test is considered to be acceptable if recovery between seasons is seen and not impeded at the level of exposure. Effects on parasitic wasps after one application of 20 g a.i./ha/m ch were classified as slightly harmful (25-50%) but then recovered to harmless levels (<25%) 14 days after application. In the most sensitive trial, after exposure to a total of 40 g a.i./ha/m ch (2 × 20 g a.i./ha/m ch), effects were also classified as slightly harmful (25-50%) but did not recover by 14 days after the second application was applied. Therefore, after biological examination of the data the endpoint from this on-field use study is NOEC > 40 g a.i./ha/m ch. This suggests that in crops that are highly attractive to beneficial organisms like tree fruit, there are risks to non-target arthropods at application rates of 40 g a.i./ha or higher.	2732264

Organism	Exposure	Endpoint value	Conclusions	PMRA#
	parasitization of aphids was measured for up to 56 days after application			
OFF-FIELD EXPOSURE FILL FIELD STUDY				
Non-target, surface- and plant-dwelling, arthropods of a grassland habitat (off-crop) in The Netherlands (2732261) or Southwestern France (2732262)	End-use products: Tetraniliprole SC 200 G Application: Test: 0.2, 0.4, 0.8, 1.6 and 4.0 g a.s./ha equivalent to typical drift values for various use pattern of the test item. Toxic reference: lambda-cyhalothrin 40 g a.s./ha (100 g/L) Control: tap water Assessment: arthropod counts from various sampling methods were taken before application, and 3 days and approximately 1, 2, 4 and 8 weeks after application; initial effects followed by full recovery within the test period of 8 weeks was deemed an ecologically acceptable effect	NOEAER[1] = 4 g a.i./ha	In off-field tests, long-term adverse effects on non-target arthropods populations were not seen after exposure to grassland meadows treated with 4 g a.i./ha. Statistically significant adverse effects were seen in certain taxa however, the effects were short-lived and recovered within two months after application. These effects were determined to not be adverse to the population levels in accordance with the guidance. Therefore the statistically derived endpoint of a No Observed Ecological Adverse Effect Rate (NOEAER) = 4 g a.i./ha, was used in the risk assessment.	2732261 2732262

[1] NOEAER = No observed ecological adverse effect rate

In-Furrow Application

Table 20.7 Screening Level Risk Assessment of In-furrow Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Earthworms and Non-Target Arthropods

Organism	Exposure	Endpoint value	EEC	RQ[2]	Level of Concern[3]
Invertebrates					
Earthworm	Acute	$LC_{50}/2^{4}$: >92.5 mg a.i./kg soil dw	0.067 mg a.i./kg soil[1]	0.0007	Not Exceeded
	Chronic	NOAEC: 182 mg a.i./kg soil dw	0.067 mg a.i./kg soil	0.0004	Not Exceeded
Collembolan species (*Folsomia candida)*	Reproduction, 28-day in artificial soil	NOEC: 58.34 mg a.i./kg soil dw	0.067 mg a.i./kg soil	0.001	Not Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC for in-furrow applications in soil is 0.067 mg a.i./kg soil. It was calculated with the maximum in-furrow application rate from Tetraniliprole 200SC Insecticide: 1 application at 150 g a.i./ha. The concentration was estimated for a soil depth of 15 cm.
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1 for most species). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.
[4] For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints.

Table 20.8 Screening Level Risk Assessment of In-furrow Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Pollinators

Organism	Exposure	Endpoint value	Application rate (relevant crops)	EEC[1]	RQ[2]	Level of Concern[3]
Honey bee, *Apis mellifera*	**Adult acute oral**					
	Acute oral, adults/technical grade active ingredient	72-h LD_{50} = 0.010 µg a.i./bee	0.150 kg a.i./ha	0.022 µg a.i./bee	2.2	Exceeded
	Acute oral, adults/transformation product	48-h LD_{50} >53.3 µg t.p./bee	0.150 kg a.i./ha	0.022µg a.i./bee	<0.0004	Not exceeded
	Acute oral, adults/Tetraniliprole SC 200 G	96-h LD_{50} = 0.0479 µg a.i./bee	0.150 kg a.i./ha	0.022 µg a.i./bee	0.46	Exceeded
	Adult chronic oral					
	Chronic oral, adults/Tetraniliprole SC 200 G	10-d NOAEL = 0.00723 µg a.i./bee (mortality and food consumption)	0.150 kg a.i./ha	0.022 µg a.i./bee	3.0	Exceeded
	Larvae					
	Acute oral, larvae/technical grade active ingredient	LD_{50} = 0.013 µg a.i./larva	0.150 kg a.i./ha	0.009 µg a.i./bee	0.69	Exceeded
	Chronic oral, larvae/technical grade active ingredient	22-d NOAEL = 0.00088 µg a.i./larva	0.150 kg a.i./ha	0.009 µg a.i./bee	11.3	Exceeded

[1] EEC: $(10\^{}(0.95*LogK_{ow}-2.05)+0.82)*(-0.0648*(LogK_{ow}\^{}2)+0.2431*LogK_{ow}+0.5822)*(1.5/(0.2+1.5*K_{oc}*0.01))*(0.5*Srate/1.12) \times$ consumption rate for adults and larvae as listed above.

Organism	Exposure	Endpoint value	Application rate (relevant crops)	EEC[1]	RQ[2]	Level of Concern[3]

- For the soil EEC calculation, a K_{oc} value of 228 L/kg was used, and a log K_{ow} of 2.6 (pH 7).

[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)

[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 0.4 for Acute exposure and 1.0 for Chronic). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.9 Further Characterization of the Risk of In-furrow Applications of Tetraniliprole to Non-Target Pollinators: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Tetraniliprole (ppb)

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	
VEGETABLE CROPS											
PMRA# 2732315 **PRE-BLOOM DURING PLANTING CORN** **End-use product:** Tetraniliprole 200SC (end-use product; 18.3% a.i.) **Study summary:** Semi-field study **T1:** 200 – 210 g a.i./ha applied in-furrow during planting **Sampling:** Samples of pollen were hand-collected during pollen shed period of the same growing season at 51-69 days after application	Tetraniliprole: 11.6	Not applicable	No (RQ <0.00)	No (RQ <0.01)	No (RQ <0.00)	Tetraniliprole: 8.68	Not applicable	No (RQ 0.00)	No (RQ 0.01)	No (RQ 0.04)	**Not used in quantitative risk assessment**
PMRA# 2732319 **PRE-BLOOM AT PLANTING POTATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.20 or 18.60% a.i.) **Study summary:** Semi-field study **T1:** 200 g a.i./ha applied at planting **Sampling:** Pollen	Tetraniliprole: (T1) 25.6	Not applicable	No RQ=0.00	No RQ=0.02	No RQ=0.01	Tetraniliprole: (T1) 25.6	Not applicable	No RQ=0.00	No RQ=0.03	No RQ=0.10	**CROP/USE:** TUBEROUS AND CORM Pre-bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 150 g a.i./ha **= ACCEPTABLE RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ_1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ_2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
samples were collected with bumble bees and/or by hand.											
PMRA# 2732305 **PRE-BLOOM AT PLANTING POTATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.5% a.i.) **Study summary**: Semi-field study **T2:** 200 g a.i./ha applied in-furrow at planting **Sampling:** Bumble bees were used to collect pollen, and hand-sampling was used to collect flowers.	Tetraniliprole: (T1) Pollen: Maximum: 18 µg/kg (T1) Flower: Maximum: 140 µg/kg	Not applicable	T1 No Pollen: RQ=0.00 No Flower: RQ=0.00	T1 No Pollen: RQ=0.02 No Flower: RQ=0.13	T1 No Pollen: RQ=0.00 No Flower: RQ=0.04	Tetraniliprole: (T1) Pollen: Max. ave.: 12.2 µg/kg (T1) Flower: Max. ave.: 126 µg/kg	Not applicable	T1 No Pollen: RQ=0.00 No Flower: RQ=0.00	T1 No Pollen: RQ=0.01 No Flower: RQ=0.17	T1 No Pollen: RQ=0.00 No Flower: RQ=0.52	**CROP/USE:** TUBEROUS AND CORM Pre-bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 150 g a.i./ha **= ACCEPTABLE RISK**
PMRA# 2732303 **PRE-BLOOM TOMATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.3% a.i.) **Study summary:** Semi-field study **T2:** 150 g a.i./ha applied as a soil drench before bloom at 1st to 3rd flower bud stage **Sampling:** Pollen and flower samples were collected by hand.	Tetraniliprole: (T2) 1120 Indiana 281 Florida 258 Georgia	Not applicable	T2 No Indiana RQ=0.00 No Florida RQ=0.00 No Georgia RQ=0.00	**T2** **Yes** **Indiana** **RQ=1.08** No Florida RQ=0.27 No Georgia RQ=0.25	T2 No Indiana RQ=0.31 No Florida RQ=0.08 No Georgia RQ=0.07	Tetraniliprole: (T2) 829 Indiana 229 Florida 108 Georgia	Not applicable	T2 No Indiana RQ=0.00 No Florida RQ=0.00 No Georgia RQ=0.00	**T2** **Yes** **Indiana** **RQ=1.10** No Florida RQ=0.30 No Georgia RQ=0.14	**T2** **Yes** **Indiana** **RQ=3.39** No Florida RQ=0.94 No Georgia RQ=0.44	**Not used in quantitative risk assessment**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
PMRA# 2732309 **AFTER TRANSPLANT TOMATO** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.2% a.i.) **Study summary:** Semi-field study **T1:** 60 g a.i./ha applied by soil drench 2-3 days after transplant **T2:** 60 g a.i/ha × 2 applied by soil drench 2-3 days after transplant **Sampling:** Pollen was collected by bumble bees and flowers were collected by hand.	Tetraniliprole: (T2) 13 (T2) Flower: 102	Not applicable	T2 No Pollen: RQ=0.00 No Flower: RQ=0.00	T2 No Pollen: RQ=0.01 No Flower: RQ=0.10	T2 No Pollen: RQ=0.00 No Flower: RQ=0.03	Tetraniliprole: (T2) 13 (T2) Flower: 102	Not applicable	T2 No Pollen: RQ=0.00 No Flower: RQ=0.00	T2 No Pollen: RQ=0.02 No Flower: RQ=0.14	T2 No Pollen: RQ=0.05 No Flower: RQ=0.42	**Not used in quantitative risk assessment**
CARRY OVER STUDY											
PMRA# 2732292 **CARRY OVER STUDY TREATED POTATO FOLLOWED BY BUCKWHEAT AND CANOLA** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.2% a.i.) **Study summary:** Semi-field study to determine residues in nectar and pollen from buckwheat and canola grown after treated potato. **T1:** Potatoes were	Tetraniliprole: Buckwheat: 1.3 Canola: 2.6	Tetraniliprole: Buckwheat: 1.7 Canola: <1	No RQ<0.08	No RQ<0.04	No RQ<0.02	Tetraniliprole: Buckwheat: 0.5 Canola: 1.1	Tetraniliprole: Buckwheat: <1 Canola: <1	No RQ<0.04	No RQ<0.02	No RQ<0.14	**CROP/USE:** TUBEROUS AND CORM Pre-bloom **End-use product:** Tetraniliprole 200SC Insecticide **Application:** 150 g a.i./ha **= ACCEPTABLE RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	
treated with one in-furrow application of 200 g a.i./ha during planting before bloom. Buckwheat or canola was planted 56- 60 days after potato planting and 74-79 days after potato planting, respectively. **Sampling:** Sample collection began once the plants bloomed. Honey bees were used to collect nectar and pollen samples.											
PMRA# 2732301 **CARRY OVER STUDY TREATED BARE SOIL FOLLOWED BY MAIZE, BUCKWHEAT AND MUSTARD** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.5% a.i.) **Study summary**: Semi-field study to determine residues in nectar, pollen, and guttation fluid from maize, buckwheat, and mustard following bare soil application. **T1:** Bare soil was treated with two applications (100 g a.i./ha then 50 g a.i./ha) five to six days before seeding with test crops **Sampling:** Nectar and	Tetraniliprole: Pollen - buckwheat: Maximum: 1.2 µg/kg	Tetraniliprole: Nectar – mustard: Maximum and max.avg.: <0.3 µg/kg	No Pollen + Nectar: RQ=0.01	No Pollen + Nectar: RQ=0.01	No Pollen + Nectar: RQ=0.00	Tetraniliprole: Pollen - buckwheat: Max. ave.: <1 µg/kg Maximum and max.avg.: <0.3 µg/kg)	Tetraniliprole: Nectar – mustard: Maximum and max.avg.: <0.3 µg/kg	No Pollen + Nectar: RQ=0.01	No Pollen + Nectar: RQ=0.01	No Pollen + Nectar: RQ=0.00	**Not used in quantitative risk assessment.**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ[1] exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ[2] exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
pollen were collected by honey bees in the buckwheat and mustard plots, while guttation fluid and pollen were collected by hand from the maize plot.											
RADIOACTIVE TRANSLOCATION STUDY											
PMRA# 2732325 **PRE-BLOOM TOMATO** **End-use product:** 1 ratio of [pyrazole-carboxamide-^{14}C] tetraniliprole : [phenyl-carbamoyl-^{14}C] tetraniliprole formulated as SC 200 (radiochemical purities >98%) **Study summary:** Study to determine translocation to pollen and flowers from tomato. **T1:** 149.7 g a.i./ha applied as a soil drench before bloom **Sampling:** Pollen and flowers were collected by hand during flowering.	Total radioactive residues: Pollen: 4.8 µg a.i. equiv./kg sample	Total radioactive residues: Flowers: 2.7 µg a.i. equiv./kg sample	No Using pollen and flowers for nectar RQ=0.08	No Using pollen and flowers for nectar RQ=0.04	No Using pollen and flowers for nectar RQ=0.03	Total radioactive residues: Pollen: 4.8 µg a.i. equiv./kg sample	Total radioactive residues: Flowers: 2.7 µg a.i. equiv./kg sample	No Using pollen and flowers for nectar RQ=0.11	No Using pollen and flowers for nectar RQ=0.06	No Using pollen and flowers for nectar RQ=0.39	**Not used in quantitative risk assessment**

Bold values indicate that acute LOC (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
1 Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 10^6] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0 × 10^6]
2 Chronic RQ = Chronic estimated daily dose (EDD)/acute toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 10^6] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ1 exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ2 exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	
Note, for tetraniliprole RA: adult acute oral **LD_{50} = 0.010 µg a.i./bee for technical grade active ingredient; chronic NOAEL: 0.00723 µg a.i./bee for SC 200 G EUP,** bee larvae acute **7-day LD_{50} = 0.013 µg a.i./larva/day for technical grade active ingredient and larva chronic NOAEL: 0.00088 µg a.i./larva/day**											

Seed Treatment Application

Table 20.10 Seeding parameters for Tetraniliprole 480 FS (corn seed treatment)

SEED	**CORN – field, popcorn and sweet**	
Label rate	0.25 mg a.i./seed	
Number of seeds per kg	Minimum = 2650	Maximum = 3300
EEC[1]	662.50 mg a.i./kg seed	825.00 mg a.i./kg seed
Seeding rate (kg seeds/ha)	21.00 kg seeds/ha	32.00 kg seeds/ha
Application rate per ha (g a.i./ha)	13.91 g a.i./ha	26.40 g a.i./ha

[1] EEC = Estimated Environmental Concentration. The EEC for seed treatment application is 662.50 – 825.00 mg a.i./kg seed depending on the number of seeds per kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*2650 seeds/kg = 662.50 mg a.i./kg seed and 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

Table 20.11 Screening Level Risk Assessment of Seed Treatment Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Earthworms and Non-Target Arthropods

Organism	**Exposure**	**Endpoint value**	**EEC**	**RQ[2]**	**Level of Concern[3]**
Invertebrates					
Earthworm	Acute	$LC_{50}/2^{4}$: >92.5 mg a.i./kg soil dw	0.012 mg a.i./kg soil[1]	0.0001	Not Exceeded
	Chronic	NOAEC: 182 mg a.i./kg soil dw	0.012 mg a.i./kg soil	0.00007	Not Exceeded
Collembolan species (*Folsomia candida)*	Reproduction, 28-day in artificial soil	NOEC: 58.34 mg a.i./kg soil dw	0.012 mg a.i./kg soil	0.0002	Not Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC for seed treatment applications in soil is 0.012 mg a.i./kg soil. It was calculated with the maximum seed treatment application rate from Tetraniliprole 480 FS: 1 application at 26.4 g a.i./ha on corn. The concentration was estimated for a soil depth of 15 cm.
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1 for most species). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.
[4] For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints.

Table 20.12 Screening Level Risk Assessment of Seed Treatment Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Birds and Mammals using Maximum Residues Expected Following Application on Corn Seed (EEC^1 = 0.25 mg a.i./seed*3300 seeds/kg = 825 mg a.i./kg seed)

	Endpoint value	Feeding guild (food item)[2]	EDE[3]	RQ[4]	Level of Concern[5]
BIRDS					
Small bird (0.02 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	209.50 mg a.i./kg bw	1.0	Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Insectivore	209.50 mg a.i./kg bw	4.9	Exceeded
Medium bird (0.10 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	164.57 mg a.i./kg bw	0.8	Not Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Insectivore	164.57 mg a.i./kg bw	3.8	Exceeded
Large bird (1.00 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	47.98 mg a.i./kg bw	0.2	Not Exceeded
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	Herbivore (short grass)	47.98 mg a.i./kg bw	1.1	Exceeded
MAMMALS					
Small mammals (0.015 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Insectivore	119.72 mg a.i./kg bw	0.6	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Insectivore	119.72 mg a.i./kg bw	0.6	Not Exceeded
Medium mammals (0.035 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	102.96 mg a.i./kg bw	0.5	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Herbivore (short grass)	102.96 mg a.i./kg bw	0.5	Not Exceeded
Large mammals (1.00 kg)					
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	Herbivore (short grass)	56.69 mg a.i./kg bw	0.3	Not Exceeded
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	Herbivore (short grass)	56.69 mg a.i./kg bw	0.3	Not Exceeded

1 EEC = Estimated Environmental Concentration. The EEC for maximum seed treatment application is 825.00 mg a.i./kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

2 Specialized feeding guilds are considered for each category of animal weights to help determine exposure (herbivore, frugivore, insectivore and granivore).

3 EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the “passerine” equation was used; for generic birds with body weight 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

4 RQ = Risk Quotient. The RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

[5] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.13 Screening Level Risk Assessment of Seed Treatment Applications of Tetraniliprole for Non-Target Terrestrial Organisms: Pollinators

Organism	Exposure	Endpoint value	Application rate (relevant crops)	EEC[1]	RQ[2]	Level of Concern[3]
Honey bee, *Apis mellifera*	**Adult acute oral**					
	Acute oral, adults/technical grade active ingredientI	72-h LD_{50} = 0.010 µg a.i./bee	n/a	1 µg a.i./bee × 0.292 g/day = 0.29 µg a.i./bee	29	Exceeded
	Acute oral, adults/transformation product	48-h LD_{50} >53.3 µg t.p./bee	n/a	1 µg a.i./bee × 0.292 g/day = 0.29 µg a.i./bee	<0.005	Not exceeded
	Acute oral, adults/Tetraniliprole FS 480 G	96-h LD_{50} = 0.045 µg a.i./bee	n/a	1 µg a.i./bee × 0.292 g/day = 0.29 µg a.i./bee	6.4	Exceeded
	Adult chronic oral					
	Chronic oral, adults/Tetraniliprole SC 200 G	10-d NOAEL = 0.00723 µg a.i./bee (mortality and food consumption)	n/a	1 µg a.i./bee × 0.292 g/day = 0.29 µg a.i./bee	40	Exceeded
	Larvae					
	Acute oral, larvae/technical grade active ingredient	LD_{50} = 0.013 µg a.i./larva	n/a	1 µg a.i./bee × 0.124 g/day = 0.12 µg a.i./bee a.i./bee	9.2	Exceeded
	Chronic oral, larvae/technical grade active ingredient	22-d NOAEL = 0.00088 µg a.i./larva	n/a	1 µg a.i./bee × 0.124 g/day = 0.12 µg a.i./bee	136	Exceeded

[1] EEC:
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 0.4 for Acute exposure and 1.0 for Chronic). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.14 Expanded Risk Assessment for Birds and Mammals Exposed to Treated Seeds (corn seeds) at 825 mg a.i./ kg seeds (EEC[1] = 0.25 mg a.i./seed*3300 seeds/kg = 825 mg a.i./kg seed)

	Endpoint value	EDE[2] (mg ai/kg bw/day)	RQ[3]	Number of seeds needed to reach endpoint[4]		Area required (m^2)[5]			
						No Drilling		Precision drilling	
				min	max	min	max	min	max
BIRDS									
Small bird (0.02 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	209.50 mg a.i./kg bw	1.0	16	16	1.5	2.9	303	575
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	209.50 mg a.i./kg bw	4.9	3.4	3.4	0.3	0.6	65	123
Medium bird (0.10 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	164.57 mg a.i./kg bw	0.8	80	80	7.6	14	1515	2875
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	164.57 mg a.i./kg bw	3.8	17	17	1.6	3.1	325	617

	Endpoint value	EDE[2] (mg ai/kg bw/day)	RQ[3]	Number of seeds needed to reach endpoint[4]		Area required (m^2)[5]			
						No Drilling		Precision drilling	
				min	max	min	max	min	max
Large bird (1.00 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	47.98 mg a.i./kg bw	0.2	800	800	76	144	15152	28751
Reproduction (NOEL)	42.9 mg a.i./kg bw/day	47.98 mg a.i./kg bw	1.1	172	172	16	31	3250	6167
MAMMALS									
Small mammals (0.015 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	119.72 mg a.i./kg bw	0.6	12	12	1.1	2.1	227	431
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	119.72 mg a.i./kg bw	0.6	12	12	1.1	2.1	223	423
Medium mammals (0.035 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	102.96 mg a.i./kg bw	0.5	28	28	2.7	5.0	530	1006
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	102.96 mg a.i./kg bw	0.5	27	27	2.6	4.9	520	986
Large mammals (1.00 kg)									
Acute (1/10 LD_{50})	200 mg a.i./kg bw/day	56.69 mg a.i./kg bw	0.3	800	800	76	144	15152	28751
Reproduction (NOEL)	196.00 mg a.i./kg bw/day	56.69 mg a.i./kg bw	0.3	784	784	74	141	14848	28176

[1] EEC = Estimated Environmental Concentration. The EEC for maximum seed treatment application is 825.00 mg a.i./kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

[2] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight 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

[3] RQ = Risk Quotient. The RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

[4] 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

[5] 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

Table 20.15 Further Characterization of the Risk from Tetraniliprole Seed Treatment Applications to Bird Reproduction using Maximum Residues Expected Following Application on Corn Seed (EEC[1] = 0.25 mg a.i./seed*3300 seeds/kg = 825 mg a.i./kg seed) and using a Higher Reproductive Endpoint Value (NOAEC = 78 mg a.i./kg bw/day)

	Endpoint value	Feeding guild (food item)[2]	EDE[3]	RQ[4]	Level of Concern[5]
BIRDS					
Small bird (0.02 kg)					
Reproduction (NOAEC)	78 mg a.i./kg bw/day	Insectivore	209.50 mg a.i./kg bw	2.7	Exceeded
Medium bird (0.10 kg)					
Reproduction (NOAEC)	78 mg a.i./kg bw/day	Insectivore	164.565 mg a.i./kg bw	2.1	Exceeded
Large bird (1.00 kg)					
Reproduction (NOAEC)	78 mg a.i./kg bw/day	Herbivore (short grass)	47.98 mg a.i./kg bw	0.6	Not Exceeded

1 EEC = Estimated Environmental Concentration. The EEC for maximum seed treatment application is 825.00 mg a.i./kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

2 Specialized feeding guilds are considered for each category of animal weights to help determine exposure (herbivore, frugivore, insectivore and granivore).

3 EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight 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

4 RQ = Risk Quotient. The RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

5 LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.16 Further Characterization of the Risk from Tetraniliprole Seed Treatment Applications to Bird Reproduction using Maximum Residues Expected Following Application on Corn Seed (EEC[1] = 0.25 mg a.i./seed*3300 seeds/kg = 825 mg a.i./kg seed) and using a Higher Reproductive Endpoint Value (LOAEL = 129.5 mg a.i./kg bw/day)

	Endpoint value	Feeding guild (food item)[2]	EDE[3]	RQ[4]	Level of Concern[5]
BIRDS					
Small bird (0.02 kg)					
Reproduction (NOAEC)	129.5 mg a.i./kg bw/day	Insectivore	209.50 mg a.i./kg bw	1.6	Exceeded
Medium bird (0.10 kg)					
Reproduction (NOAEC)	129.5 mg a.i./kg bw/day	Insectivore	164.565 mg a.i./kg bw	1.3	Exceeded
Large bird (1.00 kg)					
Reproduction (NOAEC)	129.5 mg a.i./kg bw/day	Herbivore (short grass)	47.98 mg a.i./kg bw	0.4	Not Exceeded

1 EEC = Estimated Environmental Concentration. The EEC for maximum seed treatment application is 825.00 mg a.i./kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

2 Specialized feeding guilds are considered for each category of animal weights to help determine exposure (herbivore, frugivore, insectivore and granivore).

3 EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the “passerine” equation was used; for generic birds with body weight greater than 200 g, the “all birds” equation was used:
Passerine Equation (body weight < or = 200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$.
For mammals, the “all mammals” equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$
BW: Generic Body Weight

4 RQ = Risk Quotient. The RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

5 LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.17 Expanded Risk Assessment for Birds Exposed to Treated Seeds (corn seeds) During Reproduction at 825 mg a.i./ kg seeds (EEC[1] = 0.25 mg a.i./seed*3300 seeds/kg = 825 mg a.i./kg seed) and using a Higher Reproductive Endpoint Value (LOAEL = 129.5 mg a.i./kg bw/day)

	Endpoint value	EDE[2] (mg ai/kg bw/day)	RQ[3]	Number of seeds needed to reach endpoint[4]		Area required (m²)[5]			
						No Drilling		Precision drilling	
				min	max	min	max	min	max
BIRDS									
Small bird (0.02 kg)									
Reproduction (NOEL)	129.5 mg a.i./kg bw/day	209.50 mg a.i./kg bw	1.6	10	10	1.0	1.9	196	372
Medium bird (0.10 kg)									
Reproduction (NOEL)	129.5 mg a.i./kg bw/day	164.57 mg a.i./kg bw	1.3	52	52	4.9	9.3	981	1862
Large bird (1.00 kg)									
Reproduction (NOEL)	129.5 mg a.i./kg bw/day	47.98 mg a.i./kg bw	0.4	518	518	49	93	9811	18616

1 EEC = Estimated Environmental Concentration. The EEC for maximum seed treatment application is 825.00 mg a.i./kg. It was calculated by multiplying proposed label rate on corn by the number range of seeds per kg: 0.25 mg a.i./seed*3300 seeds/kg = 825.00 mg a.i./kg seed

2 EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the “passerine” equation was used; for generic birds with body weight greater than 200 g, the “all birds” equation was used:
Passerine Equation (body weight < or = 200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$.
For mammals, the “all mammals” equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$
BW: Generic Body Weight

3 RQ = Risk Quotient. The RQ is calculated by dividing the EDE by the endpoint value (RQ = EDE/endpoint value)

4 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

5 Area required to reach endpoint (in m²):
- o Number of seeds needed to reach endpoint ÷ seeding rate (kg seeds/ha) ÷ 10000 m²/ha × # seeds/kg

Table 20.18 Further Characterization of the Risk of Seed Treatment Applications of Tetraniliprole to Non-Target Pollinators: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Tetraniliprole (ppb) and the Transformation Product (BCS-CQ63359)

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ[1] exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ[2] exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	
BARE SOIL TREATED STUDIES											
PMRA# 2732301 **PRE-PLANT RESIDUES IN MAIZE, BUCKWHEAT AND MUSTARD AFTER BARE SOIL WAS TREATED** **End-use product:** Tetraniliprole SC 200 G (end-use product; 18.5% a.i.) **Study summary:** Semi-field study to determine residues in nectar, pollen, and guttation fluid from maize, buckwheat, and mustard following bare soil application. **T1:** Bare soil was treated with two applications (100 g a.i./ha then 50 g a.i./ha) five to six days before seeding with test crops at sites in France. **Sampling:** Nectar and pollen were collected by honey bees in the buckwheat and mustard plots, while guttation fluid and pollen were collected by hand from the maize plot.	Tetraniliprole: buckwheat: 1.2	Tetraniliprole: mustard: <0.3	No (RQ 0.01)	No (RQ 0.01)	No (RQ 0.01)	Tetraniliprole: buckwheat: <1	Tetraniliprole: mustard: <0.3	No (RQ 0.04)	No (RQ 0.02)	No (RQ 0.07)	**CROP/USE:** 1. CORN **End-use product:** Tetraniliprole 480 FS **Application:** 0.25 mg a.i./kernel **CROP/USE:** 2. SOYBEAN **End-use product:** Tetraniliprole 480 FS **Application:** 0.0675 mg a.i./kernel **= ACCEPTABLE RISK**

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ[1] exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ[2] exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bee**	**Bee larvae**	
***NOTE:** Residues in soil where mustard was planted: Maximum = 52 ppb Max.avg. = 45 ppb Residues in guttation fluid of maize: Maximum and Max.avg.= <0.3 ppb											
RADIOACTIVE TRANSLOCATION STUDIES											
PMRA# 2732323 **SEED TREATED MAIZE** **End-use product:** [Pyrazole-carboxamide-^{14}C] tetraniliprole formulated as FS380P (radiochemical purity >98%) **Study summary:** Semi-field study to determine translocation to pollen and anthers from maize. **T1:** Maize seeds were individually treated during sowing at a total application rate of 150.1 g a.i./ha (based on 80,000 seeds/ha). **Sampling:** Pollen and anthers were collected by hand during the flowering period.	Total radioactive residues: Pollen: 3 µg a.i. equiv./kg sample	Not applicable	No (RQ 0.00)	No (RQ 0.00)	No (RQ 0.00)	Total radioactive residues: Pollen: 3 µg a.i. equiv./kg sample	Not applicable	No (RQ 0.00)	No (RQ 0.00)	No (RQ 0.00)	**CROP/USE:** 1. CORN **End-use product:** Tetraniliprole 480 FS **Application:** 0.25 mg a.i./kernel **= ACCEPTABLE RISK** ***NOTE:** Because the seed treatment formulation was not pre-applied to the seed and allowed to dry prior to planting, there is some uncertainty regarding the amount of formulation that remained on the seed. Therefore, there is no g ai/seed to compare with proposed rate.

Bold values indicate that acute LOC (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
1 Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 10^6] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0 × 10^6]
2 Chronic RQ = Chronic estimated daily dose (EDD)/acute toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 10^6] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total

PMRA#, Sampled Crop and Study Details	Maximum residue value in parts per billion (ppb)		Did the Acute RQ[1] exceed the Level of Concern (LOC=0.4)? (RQ)			Mean residue value in ppb		Did the Chronic RQ[2] exceed the Level of Concern (LOC=1.0)? (RQ)			Conclusion: Study is Used in the Following Risk Assessment
	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bee	Bee larvae	
Note, for tetraniliprole RA: adult acute oral **LD_{50} = 0.010 µg a.i./bee for technical grade active ingredient; chronic NOAEL: 0.00723 µg a.i./bee for SC 200 G EUP,** bee larvae acute **7-day LD_{50} = 0.013 µg a.i./larva/day for technical grade active ingredient and larva chronic NOAEL: 0.00088 µg a.i./larva/day**											

Risk Assessment on Non-Target Aquatic Organisms

Screening Level

Table 20.19 Screening Level Risk Assessment of Tetraniliprole for Freshwater Organisms

Organism	Exposure	Endpoint value	EEC	RQ[5]	Level of Concern[6]
Fathead minnow (*Pimephales promelas*)	Acute, static, 96-hr	LC_{50} (1/10)[1]: >1.09 mg a.i./L	0.025 mg a.i./L[2]	0.02	Not exceeded
Rainbow trout (*Oncorhynchus mykiss*)	Acute, static, 96-hr	LC_{50}(1/10): >1.09 mg a.i./L	0.025 mg a.i./L	0.02	Not exceeded
Fathead minnow (*Pimephales promelas*)	Chronic, early life stage, flow- through, 33-day	NOEC: 0.646 mg a.i./L	0.025 mg a.i./L[3]	0.04	Not exceeded
Clawed Frog (*Xenopus laevis*)	Acute, static, 48-hr	LC_{50}(1/10): >0.86 mg a.i./L	0.132 mg a.i./L[4]	0.15	Not exceeded
Amphibians	Chronic, early life stage, flow- through, 33-day	NOEC: 0.646 mg a.i./L	0.132 mg a.i./L	0.20	Not exceeded
Waterflea (*Daphnia magna*)	Acute, static, 48-hr	LC_{50}/2: >0.015 mg a.i./L	0.025 mg a.i./L	1.67	Exceeded
Waterflea (*Daphnia magna*)	Chronic, static- renewal, 21-day	NOEC: 0.013 mg a.i./L	0.025 mg a.i./L	1.92	Exceeded
Midge *(Chironomus riparius)*	Acute, 48-hr	EC_{50}/2: 0.437 mg a.i./L water	0.025 mg a.i./L	0.06	Not exceeded
	Chronic, 57-day	NOEC: 0.704 µg a.i./L pore water	0.025 mg a.i./L	35.51	Exceeded
	Chronic, 28-day	NOEC: 0.23 µg a.i./L overlying water	0.025 mg a.i./L	108.69	Exceeded

[1] For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for aquatic organisms when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints.
[2] EEC = Estimated Environmental Concentration. The EEC in an 80 cm water depth is 0.025 mg a.i./L. It was calculated by assuming a direct foliar overspray to water with the

maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. Dissipation from water was accounted for.
[3] The fathead minnow chronic NOEC was used for a chronic amphibian endpoint value since no chronic data were submitted for amphibians.
[4] EEC = Estimated Environmental Concentration. The EEC in a 15 cm water depth is 0.132 mg a.i./L. It was calculated by assuming a direct foliar overspray to water with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. Dissipation from water was accounted for.
[5] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[6] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.20 Screening Level Risk Assessment of Tetraniliprole for Marine Organisms

Organism	Exposure	Endpoint value	EEC[1]	RQ[2]	Level of Concern[3]
Eastern oyster (*Crassostrea virginica*)	Acute, flow- through, 96-hr	EC_{50}/2: 0.87 mg a.i./L	0.025 mg a.i./L	0.029	Not Exceeded
Mysid Shrimp (*Americamysis bahia*)	Chronic, flow- through, 28-day	NOEC: 0.58 mg a.i./L	0.025 mg a.i./L	0.043	Not Exceeded
Sheepshead minnow (*Cyrinodon variegatus*)	Acute, static, 96-hr	LC_{50} (1/10): >4.55 mg a.i./L	0.025 mg a.i./L	0.005	Not Exceeded
Sheepshead minnow (*Cyrinodon variegatus*)	Chronic early life stage, flow-through, 33-day	NOEC: ≥4.21 mg a.i./L	0.025 mg a.i./L	0.006	Not Exceeded
Marine Diatom (*Skeletonema costatum*)	Chronic, static, 96-hr	EC_{50}: 0.46 mg a.i./L	0.025 mg a.i./L	0.054	Not Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC in an 80 cm water depth is 0.025 mg a.i./L. It was calculated by assuming a direct foliar overspray to water with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. Dissipation from water was accounted for.
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 20.21: Screening Level Risk Assessment of Tetraniliprole for Freshwater Plants and Algae

Organism	Exposure	Endpoint value	EEC[1]	RQ[2]	Level of Concern[3]
Duckweed (*Lemna gibba*)	Acute, static, 7-day	EC_{50}/2: >5.65 mg a.i./L	0.025 mg a.i./L	0.004	Not Exceeded
Green Alga (*Pseudokirchneriella subcapitata*)	Acute, static, 96-hr	EC_{50}/2: >29.23 mg a.i./L	0.025 mg a.i./L	<0.001	Not Exceeded

Freshwater Diatom (*Navicula pelliculosa*)	Acute, static, 96-hr	EC_{50}/2: >1.69 mg a.i./L	0.025 mg a.i./L	0.015	Not Exceeded
Cyanobacteria (*Anabaena flos-aquae*)	Acute, static, 96 hr	EC_{50}/2: >4.53 mg a.i./L	0.025 mg a.i./L	0.006	Not Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC in an 80 cm water depth is 0.025 mg a.i./L. It was calculated by assuming a direct foliar overspray to water with the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha at an interval of 28 days between applications. Dissipation from water was accounted for.
[2] RQ = Risk Quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value)
[3] LOC = Level of Concern. The RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Further Characterization of the Risk

Table 20.22 Further Characterization of the Risk using Modelling EECs for Tetraniliprole

Water depth	Use	EEC Water column (mg a.i./L)			EEC Pore water (mg a.i./L)	
		Peak	**4 day**	**21 day**	**Peak**	**21 day**
80 cm	CG 5-13: Brassica vegetables 4x45 g a.i./ha	**0.0098**[1]	0.0094	**0.0087**[2]	**0.0038**[3]	**0.0038**
80 cm	Turf 2x100 g a.i./ha	0.0086	0.0083	0.0074	0.0034	0.0034

[1] EEC = Estimated Environmental Concentration. The peak EEC in an 80 cm water depth is 0.0098 mg a.i./L. This EEC was based on modelling data and used in the acute pelagic invertebrate (*Daphnia* sp.) risk assessment.
[2] EEC = Estimated Environmental Concentration. The 21-day EEC in an 80 cm water depth is 0.0087 mg a.i./L. This EEC was based on modelling data and used in the chronic pelagic invertebrate (*Daphnia* sp.) and benthic midge *(Chironomus riparius)* risk assessment.
[3] EEC = Estimated Environmental Concentration. The peak and 21-day EEC values in an 80 cm water depth are both 0.0038 mg a.i./L. These EEC's were based on modelling data and used in the chronic benthic invertebrate (*Chironomus* sp.) risk assessment.

Table 20.23 Further Characterization of the Risk Assessment for Pelagic Invertebrate (*Daphnia* sp.) and Benthic Invertebrate (*Chironomus* sp.) with Surface Runoff EECs

Organism	Exposure	Endpoint value	EEC	RQ	Level of Concern
Waterflea (*Daphnia magna*)	Acute, static, 48-hr	LC_{50}/2: >0.015 mg a.i./L	0.0098 mg a.i./L[1]	0.65	Not Exceeded
Waterflea (*Daphnia magna*)	Chronic, static- renewal, 21-day	NOEC: 0.013 mg a.i./L	0.0087 mg a.i./L[2]	0.67	Not Exceeded
Midge larvae (*Chironomus riparius*)	Chronic, 28-day, spiked sediment	NOEC: 0.0005 mg a.i./L pore water	0.0038 mg a.i./L[3]	7.6	Exceeded
	Chronic, 28-day, spiked water	NOAEC: 0.00023 mg a.i./L overlying water	0.0087 mg a.i./L[4]	37.8	Exceeded

[1] EEC = Estimated Environmental Concentration. The peak EEC in an 80 cm water depth is 0.0098 mg a.i./L. This EEC was based on modelling data and used in the acute pelagic invertebrate (*Daphnia* sp.) risk assessment.
[2] EEC = Estimated Environmental Concentration. The 21-day EEC in an 80 cm water depth is 0.0087 mg a.i./L. This EEC was based on modelling data and used in the chronic pelagic invertebrate (*Daphnia* sp.) risk assessment.
[3] EEC = Estimated Environmental Concentration. The peak and 21-day EEC pore water values in an 80 cm water depth are both 0.0038 mg a.i./L. These EEC's were based on modelling data and used in the chronic benthic invertebrate (*Chironomus* sp.) risk assessment.
[4]EEC = Estimated Environmental Concentration. The 21-day EEC over-lying water value in an 80 cm water depth is 0.0087 mg a.i./L. These EEC's were based on modelling data and used in the chronic benthic invertebrate (*Chironomus* sp.) risk assessment.

Table 20.24 Further Characterization of the Risk Assessment for Pelagic Invertebrate (*Daphnia* sp.) and Benthic Invertebrate (*Chironomus* sp.) with Drift EECs

Organism	Exposure	Endpoint value	Spray Drift EEC	RQ[5]	Level of Concern[6]
Waterflea (*Daphnia magna*)	Acute, static, 48-hr	LC_{50}/2: >0.015 mg a.i./L	Ground boom (11% drift): 0.003 mg a.i./L[1]	0.20	Not Exceeded
			Aerial (26% drift): 0.002 mg a.i./L[2]	0.13	Not Exceeded
			Airblast early season (74% drift): 0.017 mg a.i./L[3]	1.13	Exceeded
			Airblast late season (59% drift): 0.013 mg a.i./L[4]	0.87	Not Exceeded
Waterflea (*Daphnia magna*)	Chronic, static-renewal, 21-day	NOEC: 0.013 mg a.i./L	Ground boom (11% drift): 0.003 mg a.i./L	0.23	Not Exceeded
			Aerial (26% drift): 0.002 mg a.i./L	0.15	Not Exceeded
			Airblast early season (74% drift): 0.017 mg a.i./L	1.31	Exceeded

			Airblast late season (59% drift): 0.013 mg a.i./L	1.0	Exceeded
Midge larvae *(Chironomus riparius)*	Chronic, 28-day	NOAEC: 0.00023 mg a.i./L overlying water	Ground boom (11% drift): 0.003 mg a.i./L	13.04	Exceeded
			Aerial (26% drift): 0.002 mg a.i./L	8.70	Exceeded
			Airblast early season (74% drift): 0.017 mg a.i./L	73.91	Exceeded
			Airblast late season (59% drift): 0.013 mg a.i./L	56.52	Exceeded

[1] EEC = Estimated Environmental Concentration. The EEC for ground boom drift (11%) to a body of water at an 80 cm water depth is 0.003 mg a.i./L. This EEC was based on the maximum cumulative foliar application from the Tetraniliprole 43 SC Turf Insecticide and the Tetraniliprole 200SC Turf Insecticide: 1 application at 100 g a.i./ha followed by 1 application at 100 g a.i./ha = 200 g a.i./ha.
[2] EEC = Estimated Environmental Concentration. The EEC for aerial drift (26%) to a body of water at an 80 cm water depth is 0.002 mg a.i./L. This EEC was based on the maximum cumulative aerial application from the Tetraniliprole 200SC Insecticide: 1 application at 30 g a.i./ha followed by 1 application at 30 g a.i./ha = 60 g a.i./ha.
[3] EEC = Estimated Environmental Concentration. The EEC for airblast early season drift (74%) to a body of water at an 80 cm water depth is 0.0017 mg a.i./L. This EEC was based on the maximum cumulative foliar application from the Tetraniliprole 200SC Insecticide: 1 application at 60 g a.i./ha + 1 application at 60 g a.i./ha + 1 application at 60 g a.i./ha = 180 g a.i./ha.
[4] EEC = Estimated Environmental Concentration. The EEC for airblast early season drift (59%) to a body of water at an 80 cm water depth is 0.013 mg a.i./L. This EEC was based on the maximum cumulative foliar application from the Tetraniliprole 200SC Insecticide: 1 application at 60 g a.i./ha + 1 application at 60 g a.i./ha + 1 application at 60 g a.i./ha = 180 g a.i./ha.

Table 20.25 Toxic Substances Management Policy considerations: comparison to TSMP Track 1 Criteria*

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Tetraniliprole values
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	25-380 days (laboratory) 39-359 days (Canadian relevant US bareground plots); 141-1000 days (Canadian bareground plots)
	Water	Half-life ≥ 182 days	Half-life: 1.33 days
	Sediment	Half-life ≥ 365 days	Total system half-life: 11 to 925 days
	Air	Half-life ≥ 2 days or evidence of long range transport	0.27-0.40 days
Bioaccumulation[4]	Log $K_{ow} \geq 5$		pH 4 and 7: 2.6 pH 9: 1.9
	BCF ≥ 5000		124-203
	BAF ≥ 5000		
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet all TSMP Track 1 criteria.

[1]All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).

[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

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

* Based on the properties of the parent and information in Table 6-1, the transformation products are unlikely to meet all of the TSMP Track 1 criteria.

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

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

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

Currently, there are no Codex MRLs[9] listed for tetraniliprole in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Table 1 compares the MRLs proposed for tetraniliprole in Canada with corresponding American tolerances.

Table 1 Comparison of Canadian MRLs and American Tolerances

Commodity	Recommended Canadian MRL (ppm)	Recommended U.S. Tolerances (ppm)
Leafy vegetables (Crop Group 4-13)	20	20
Citrus oil	7.0	7.0
Brassica head and stem vegetable group (Crop Group 5-13)	1.5	1.5
Lemons/limes (Revised) Crop Subgroup 10B	1.5	1.5
Small fruits vine climbing, except fuzzy kiwifruit (Crop Subgroup 13-07F)	1.5	1.5
Tomato paste	1.5	1.5
Oranges (Revised) Crop Subgroup 10A	1.0	1.0
Stone fruits (Crop Group 12-09)	1.0	1.0
Grapefruits (Revised) Crop Subgroup 10C	0.9	0.9
Pome fruits (Crop Group 11-09)	0.5	0.5
Fruiting vegetables (Crop Group 8-09)	0.4	0.4
Cottonseeds (Revised) (Crop Subgroup 20C)	0.4	0.4
Meat byproducts of cattle, goats, horses, and sheep	0.3	0.3
Dry soybeans	0.2	0.2
Milk	0.05	0.05

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

Commodity	Recommended Canadian MRL (ppm)	Recommended U.S. Tolerances (ppm)
Fat of cattle, goats, horses, and sheep	0.04	0.04
Tree nuts (Crop Group 14-11)	0.03	0.03
Meat of cattle, goats, horses and sheep	0.02	0.02
Tuberous and corm vegetables (Crop Subgroup 1C)	0.015	0.015
Eggs, fat, meat, and meat by-products of poultry	0.01	Not required[1]
Fat, meat, meat by-products of hogs	0.01	Not required[1]
Field corn, popcorn grain, sweet corn kernels plus cob with husks removed	0.01	0.01

[1] as per Category 3 of 40 CFR 180.6 (a) for livestock

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices, and legislative framework.

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

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2731792	2016, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3 CBI
2731793	2016, Discussion Of Formation Of Impurities, DACO: 2.11.4 CBI
2731794	2016, Establishing Certified Limits, DACO: 2.12.1 CBI
2731795	2016, Establishing Certified Limits, DACO: 2.12.1 CBI
2731796	2013, Methodology/Validation, DACO: 2.13.1 CBI
2731797	2013, Methodology/Validation, DACO: 2.13.1 CBI
2731798	2016, Methodology/Validation, DACO: 2.13.1 CBI
2731799	2016, Methodology/Validation, DACO: 2.13.1 CBI
2731800	2016, Methodology/Validation, DACO: 2.13.1 CBI
2731801	2016, Methodology/Validation, DACO: 2.13.1 CBI
2731802	2016, Methodology/Validation, DACO: 2.13.1 CBI
2731803	2016, Confirmation Of Identity, DACO: 2.13.2,2.13.3 CBI
2731804	2016, Confirmation Of Identity, DACO: 2.13.2,2.13.3 CBI
2731805	2016, Confirmation Of Identity, DACO: 2.13.2,2.13.3 CBI
2731806	2013, UV/Visible Absorption Spectra, DACO: 2.13.2,2.14.12 CBI
2731807	2015, Odour, DACO: 2.14.1,2.14.2,2.14.3 CBI
2731808	2013, Dissociation Constant, DACO: 2.14.10 CBI
2731809	2013, Octanol/Water Partition Coefficient, DACO: 2.14.11 CBI
2731810	2013, Stability (Temperature, Metals), DACO: 2.14.13 CBI
2731811	2016, Storage Stability Data, DACO: 2.14.14 CBI
2731812	2015, (PH), DACO: 2.14.15,830.7000 CBI
2731813	2016, Melting Point/Melting Range, DACO: 2.14.4,2.14.5 CBI
2731814	2013, Density Or Specific Gravity, DACO: 2.14.6 CBI
2731815	2013, Water Solubility (Mg/L), DACO: 2.14.7 CBI
2731816	2014, Solvent Solubility (Mg/L), DACO: 2.14.8 CBI
2731817	2013, Vapour Pressure, DACO: 2.14.9 CBI
2731818	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731819	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731820	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731821	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731822	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731823	2016, Other Studies/Data/Reports, DACO: 2.16 CBI
2731824	2013, Other Studies/Data/Reports, DACO: 2.16 CBI
2785899	2017, Methodology/Validation, DACO: 2.13.1 CBI

2785900	2017, Methodology/Validation, DACO: 2.13.1 CBI
2785901	2016, Methodology/Validation, DACO: 2.13.1 CBI
2785902	2016, Methodology/Validation, DACO: 2.13.1 CBI
2849545	2018, Confirmation Of Identity, DACO: 2.13.2 CBI
2872828	2018, Detailed Production Process Description, DACO: 2.11.3,2.11.4,2.13.3 CBI
2731911	2016, Independent Laboratory Validation of analytical method 01373 for the determination of BCS-CL73507 and the metabolites BCS-CQ63359, BCS-CR60014, BCS-CR74541, BCS-CU81055, BCS-CT30673 and BCS-CU81056 in soil and sediment by HPLC-MS/MS, DACO: 8.2.2.1
2731912	2014, Analytical method 01373 for the determination of BCS-CL73507 and the metabolites BCS-CQ63359, BCS-CR60014, BCS-CR74541, BCS-CU81055, BCS-CT30673 and BCS-CU81056 in soil and sediment by HPLC-MS/MS, DACO: 8.2.2.1
2731914	2015, Analytical method 01450 for the determination of BCS-CL73507 in soil by HPLC-MS/MS, DACO: 8.2.2.1
2731915	2016, Independent laboratory validation (ILV) of Bayer method FV-004-W16-01 for the determination of residues of tetraniliprole (BCS-CL73507) and its metabolites BCS-CQ63359, BCS-CU81055, BCS-CR74541, BCS-CR60014, BCS-CU81056, BCS-CT30673, BCSCY28900, BCS-CY-28897 and BCS-CY28906 in water using LC-MS/MS, DACO: 8.2.2.3
2731916	2016, An analytical method for the determination of residues of tetraniliprole (BCS-CL73507) and its metabolites BCS-CQ63359, BCS-CU81055, BCS-CR74541, BCS-CR60014, BCS-CU81056, BCS-CT30673, BCS-CY28900, BCS-CY28897 and BCS-CY28906 in water using LC/MS/MS, DACO: 8.2.2.3
2731917	2016, In house laboratory validation of analytical method for the determination of tetraniliprole (BCS-CL73507) and its metabolites: BCS-CQ63359, BCS-CU81055, BCS-CR74541, BCS-CR60014, BCS-CU81056, BCS-CT30673, BCS-CY28900, BCS-CY28897 and BCS-CY28906 in water by LC/MS/MS, DACO: 8.2.2.3
2732130	2016, Description Of Starting Materials, DACO: 3.2.1 CBI
2732131	2016, Description Of The Formulation Process, DACO: 3.2.2 CBI
2732132	2016, Discussion Of The Formation Of Impurities Of Toxicologal Concern, DACO: 3.2.3 CBI
2732133	2016, Establishing Certified Limits, DACO: 3.3.1 CBI
2732134	2012, Enforcement Analytical Method, DACO: 3.4.1 CBI
2732135	2017, Enforcement Analytical Method, DACO: 3.4.1 CBI
2732136	2015, PH, DACO: 3.5.1,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.9 CBI
2732137	2015, Storage Stability Data, DACO: 3.5.10 CBI
2732138	2016, Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
2732140	2015, Corrosion Characteristics, DACO: 3.5.10,3.5.14,3.5.5 CBI
2732141	2014, Explodability, DACO: 3.5.11,3.5.12,3.5.8 CBI
2732142	2016, Miscibility, DACO: 3.5.13,3.5.15,3.5.8 CBI
2733931	2016, Description Of Starting Materials, DACO: 3.2.1 CBI

2733932	2016, Description Of The Formulation Process, DACO: 3.2.2 CBI
2733933	2016, Discussion Of The Formation Of Impurities Of Toxicologal Concern, DACO: 3.2.3 CBI
2733934	2016, Establishing Certified Limits, DACO: 3.3.1 CBI
2733935	2012, Analytical method - Determination of BCS-CL73507 in formulations - Assay HPLC, external standard, DACO: 3.4.1
2733936	2016, Validation of Analytical Method AM018512MF1 - Determination of tetraniliprole in the formulation tetraniliprole FS 480 (480 g/L) - Final Report -, DACO: 3.4.1
2733937	2016, Physical, chemical and technical properties of tetraniliprole FS 480 (480 g/L), DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
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2733940	2016, Storage stability at elevated temperature and corrosion characteristics of tetraniliprole FS 480 (480 g/L) - Packaging material: HDPE - Final report (14 days), DACO: 3.5.10,3.5.14,3.5.4,3.5.5
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2735039	2016, Description Of The Formulation Process, DACO: 3.2.2 CBI
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4.0 Value

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