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Evaluation Report

Chlorantraniliprole

(publié aussi en français)

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Overview

Registration Decision for Chlorantraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, has granted conditional registration for the sale and use of Rynaxypr Technical Insecticide, Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide containing the technical grade active ingredient chlorantraniliprole to control a variety of insect pests in several agricultural crops and turf.

Current scientific data from the applicant and scientific reports were evaluated to determine if, under the proposed conditions of use, the products have value and do not pose an unacceptable risk to human health or the environment.

This report summarizes the information that was evaluated and provides the results of the evaluation as well as the reasons for the registration decision, with an outline of additional scientific information required from the applicant. It also describes the conditions of registration that the applicant must meet to ensure that the health and environmental risks as well as the value of these pest control products are acceptable for their intended uses.

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 Rynaxypr Technical Insecticide, Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to 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 population groups

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."

(e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Chlorantraniliprole?

Chlorantraniliprole is an agricultural insecticide to be applied as a foliar application to control a variety of insect pests in several agricultural crops and turf. Chlorantraniliprole has a mode of action that is new to Canada. It kills insects by overstimulating their muscles.

Health Considerations

Can Approved Uses of Chlorantraniliprole Affect Human Health?

Chlorantraniliprole is unlikely to affect your health when used according to label directions.

Exposure to chlorantraniliprole may occur through diet (food and water), when handling and applying the product, or through contact with residues on turf. 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. 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 using chlorantraniliprole products according to label directions.

The technical grade active ingredient chlorantraniliprole and its end-use products DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide are of low acute toxicity to animals after a single dose, are non-irritating to the skin and eyes, and do not cause an allergic skin reaction.

Chlorantraniliprole did not cause cancer in animals and does not damage genetic material such as DNA. There was no indication that chlorantraniliprole affects the immune or endocrine system, and there was no evidence that it causes damage to the nervous system in rats. When chlorantraniliprole was given to pregnant animals, there was no evidence that it affects the developing fetus.

The first signs of toxicity in animals given daily doses of chlorantraniliprole over longer periods of time were adaptive effects on the liver. At high doses, however, male mice did show signs of liver effects that were considered adverse. In some studies, the adrenal gland of male rats changed in appearance due to a slight increase in the amount of lipid

droplets following exposure to chlorantraniliprole. However, this was not considered toxicologically significant.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that children 1 to 2 years old, the population group that would ingest the most chlorantraniliprole relative to body weight, are expected to be exposed to $\leq 1.3\%$ of the acceptable daily intake. Based on these estimates, the chronic dietary risk from chlorantraniliprole is not of concern for all segments of the population. Chlorantraniliprole is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of chlorantraniliprole 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* (PCPA). Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using chlorantraniliprole on apple, pear, peach, plum, sweet and sour cherries, grapes, broccoli/cauliflower, cabbage, mustard greens, cucumber, cantaloupe/muskmelon, summer squash, tomato, bell and non-bell peppers, head/leaf lettuce, celery, spinach, potato and cotton were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide is used according to the proposed label directions.

Individuals entering recreational areas such as golf courses and parks, or home and residential lawns treated with Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide, can come in contact with foliar residues of chlorantraniliprole. However, subsequent risk to these individuals is considered negligible.

Occupational Risks From Handling Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide

Occupational risks are not of concern when Altacor 35 WG Insecticide, Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide is used according to the proposed label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Altacor 35 WG Insecticide, Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide, as well as field workers re-entering freshly treated fields, can come in direct contact with chlorantraniliprole on the skin or through inhalation of spray mists. Therefore, the labels will specify that anyone mixing, loading or applying Altacor 35 WG Insecticide, Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide must wear a long-sleeved shirt, long pants and chemical-resistant gloves. Taking into consideration these label requirements, risk to farmers, applicators or field workers is not a concern.

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

Environmental Considerations

What Happens When Chlorantraniliprole Is Introduced Into the Environment?

Chlorantraniliprole enters the environment when used as an insecticide on turf, pome fruit, grapes, stone fruit, potatoes, fruiting vegetables, *Brassica* vegetables and leafy vegetables. Chlorantraniliprole is persistent and mobile in soil and moderately persistent in water. The major breakdown product is 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3,8 dimethyl-4(3H)-quinazolinone (IN-EQW78). IN-EQW78 is more persistent than chlorantraniliprole in soil and water. Chlorantraniliprole is expected to leach through the soil profile beyond 60 cm; therefore, it is expected to reach groundwater. In surface waters, chlorantraniliprole will partition to sediment and may be expected to accumulate in aquatic systems. A Canadian field dissipation study in Prince Edward Island demonstrated that up to approximately 48% of applied chlorantraniliprole is expected to carry over to the following growing season. Chlorantraniliprole residues are not expected in the air because of chlorantraniliprole's low volatility.

Chlorantraniliprole and its major breakdown product present a low risk to wild mammals, birds, earthworms, terrestrial plants, bees, fish, algae and aquatic plants. However, given that chlorantraniliprole is an insecticide, it is expected to adversely affect some non-target terrestrial arthropods and aquatic invertebrates in adjacent areas. Buffer zones of one to 15 metres (depending on application equipment and rates) are required to protect nearby non-target aquatic organisms from the effects of spray drift. Moreover, environmental hazard label statements are required to advise users that the product is toxic to non-target arthropods and that it has the potential to contaminate groundwater and carry over to the next growing season.

Value Considerations

What Is the Value of Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 Insecticide?

Sufficient efficacy data were provided to support Altacor 35 WG Insecticide for the control of a variety of insect pests in pome fruits, stone fruits and grapes. The lowest effective rate for pests has been established and is supported by efficacy data. Coragen 200 SC Insecticide controls many insect pests in potatoes, fruiting vegetables, *Brassica* vegetables, leafy vegetables and in turf. The lowest effective rate for the pests on the Coragen 200 SC Insecticide label has been established. The control of several insect pests in turf and the lowest effective rates can also be supported on the DPX-E2Y45 20 SC Insecticide label.

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 Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

As users may come into direct contact with chlorantraniliprole on the skin or through inhalation of spray mists, anyone mixing, loading or applying Altacor 35 WG Insecticide, Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide must wear a long-sleeved shirt, long pants and chemical-resistant gloves.

Because individuals can come into contact with treated foliage when re-entering treated residential areas, re-entry into treated areas is restricted for 12 hours after application.

- **Environment**

Because there are concerns related to carryover, runoff, leaching and risk to non-target arthropods, environmental hazard and precautionary label statements are required for DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide. To protect aquatic organisms, buffer zones of one to 10 metres are required for ground applications and buffer zones of one to 15 metres are required for aerial applications.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report and in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information by 30 September 2009.

- **Value**

Confirmatory efficacy data are required to support peach twig borer on stone fruits.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted³, the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation

Chlorantraniliprole

1.0 The Active Ingredient, Its Properties and Uses

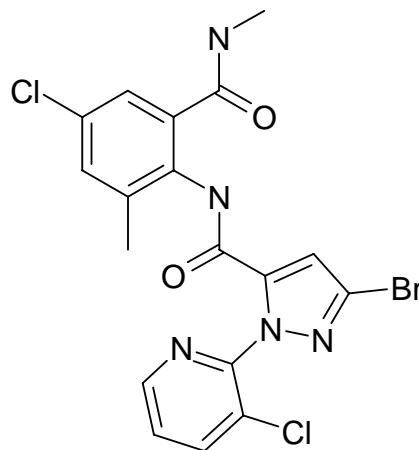
1.1 Identity of the Active Ingredient

Active substance	Chlorantraniliprole
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-Bromo- <i>N</i> -[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1 <i>H</i> -pyrazole-5-carboxamide
2. Chemical Abstracts Service (CAS)	3-Bromo- <i>N</i> -[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 <i>H</i> -pyrazole-5-carboxamide
CAS number	500008-45-7

Molecular formula C₁₈H₁₄BrCl₂N₅O₂

Molecular weight 483.15 g/mole

Structural formula



Purity of the active ingredient 95.3% (93–100%)

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

Technical Product—Chlorantraniliprole Technical

Property	Result																				
Colour and physical state	Fine brown powder																				
Odour	No odour																				
Melting range	200–202°C																				
Boiling point or range	Not applicable																				
Density	1.5189 g/mL																				
Vapour pressure at 20°C	6.3×10^{-12} Pa (estimated)																				
Henry's law constant at 20°C	3.1×10^{-9} Pa·m ³ /mole																				
Ultraviolet (UV)–visible spectrum	<table> <thead> <tr> <th>pH</th> <th>λ max (nm)</th> </tr> </thead> <tbody> <tr> <td>neutral</td> <td>290</td> </tr> <tr> <td>acidic</td> <td>290</td> </tr> <tr> <td>basic</td> <td>320</td> </tr> </tbody> </table>	pH	λ max (nm)	neutral	290	acidic	290	basic	320												
pH	λ max (nm)																				
neutral	290																				
acidic	290																				
basic	320																				
Solubility in water at 20°C	<table> <thead> <tr> <th>pH</th> <th>Solubility (mg/L)</th> </tr> </thead> <tbody> <tr> <td>Deionized water</td> <td>1.023</td> </tr> <tr> <td>4</td> <td>0.972</td> </tr> <tr> <td>7</td> <td>0.880</td> </tr> <tr> <td>9</td> <td>0.971</td> </tr> </tbody> </table>	pH	Solubility (mg/L)	Deionized water	1.023	4	0.972	7	0.880	9	0.971										
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9	0.971																				
Solubility in organic solvents at 20°C	<table> <thead> <tr> <th>Solvent</th> <th>Solubility (mg/mL)</th> </tr> </thead> <tbody> <tr> <td>Acetone</td> <td>3.4</td> </tr> <tr> <td>Acetonitrile</td> <td>0.71</td> </tr> <tr> <td>Ethyl acetate</td> <td>1.1</td> </tr> <tr> <td>Dichloromethane</td> <td>2.5</td> </tr> <tr> <td>Dimethylformamide</td> <td>124</td> </tr> <tr> <td><i>n</i>-Octanol</td> <td>0.39</td> </tr> <tr> <td>Methanol</td> <td>1.7</td> </tr> <tr> <td><i>o</i>-Xylene</td> <td>0.16</td> </tr> <tr> <td><i>n</i>-Hexane</td> <td><0.1 µg/mL</td> </tr> </tbody> </table>	Solvent	Solubility (mg/mL)	Acetone	3.4	Acetonitrile	0.71	Ethyl acetate	1.1	Dichloromethane	2.5	Dimethylformamide	124	<i>n</i> -Octanol	0.39	Methanol	1.7	<i>o</i> -Xylene	0.16	<i>n</i> -Hexane	<0.1 µg/mL
Solvent	Solubility (mg/mL)																				
Acetone	3.4																				
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<i>n</i> -Octanol–water partition coefficient (K_{ow})	<table> <thead> <tr> <th>pH</th> <th>log K_{ow}</th> </tr> </thead> <tbody> <tr> <td>Distilled water</td> <td>2.76</td> </tr> <tr> <td>4</td> <td>2.77</td> </tr> <tr> <td>7</td> <td>2.86</td> </tr> <tr> <td>9</td> <td>2.80</td> </tr> </tbody> </table>	pH	log K_{ow}	Distilled water	2.76	4	2.77	7	2.86	9	2.80										
pH	log K_{ow}																				
Distilled water	2.76																				
4	2.77																				
7	2.86																				
9	2.80																				
Dissociation constant (pK_a)	10.88																				

Property	Result
Stability (temperature, metal)	The test substance was determined to be stable at normal and elevated (54°C) temperatures, stable when in contact with the metals iron and aluminum, and stable when in contact with the metal ions from iron (II) acetate and aluminum acetate solutions.

End-Use Product—DPX-E2Y45 20 SC/Coragen 200 SC Insecticide

Property	Result
Colour	White
Odour	Slight alcohol odour
Physical state	Slightly viscous liquid
Formulation type	Suspension concentrate
Guarantee	200 g/L (188–212 g/L)
Container material and description	High density polyethylene (HDPE) or polyethylene terephthalate (PET)
Density	1.094 g/mL
pH of 1% dispersion in water	7.8
Oxidizing or reducing action	The test substance was not found to be an oxidizer or reducer
Storage stability	Stable after accelerated storage at 54°C after 2 weeks. A one-year stability study is in progress and the report is expected to be available in August 2008.
Explodability	The product is not explosive.

End-Use Product—Altacor 35 WG Insecticide

Property	Result
Colour	Light brown
Odour	Faint semi-sweet odour
Physical state	Solid
Formulation type	Wettable granules (WG)
Guarantee	35% (limits: 33.25–36.75%)
Container material and description	Plastic
Density	0.782 g/mL
pH of 1% dispersion in water	9.4
Oxidizing or reducing action	The test substance was not found to be an oxidizer or reducer
Storage stability	Stable after accelerated storage at 54°C for 2 weeks. A one-year stability study is in progress and the report is expected to be available in August 2008.
Explosibility	The product is not explosive.

1.3 Directions for Use

Chlorantraniliprole is an agricultural insecticide to be used as a foliar application to control a variety of insect pests in several agricultural crops. Altacor 35 WG Insecticide is approved for use on pome fruits, stone fruits and grapes at 145 to 285 g formulated product/ha, to be applied with a minimum spray volume of 450 L/ha and a maximum of three applications per season. Coragen 200 SC Insecticide is approved for use on potatoes, *Brassica*, leafy vegetables and fruiting vegetables at 250 to 375 mL finished product/ha, to be applied in minimum spray volumes of 100 L/ha (50 L/ha by air on potatoes only) and a maximum of four applications per season. DPX-E2Y45 20 SC Insecticide is approved for use on turf at 145 to 1125 g finished product/ha, to be applied in spray volumes of 200 to 1400 L finished product/ha and a maximum of one application per season.

1.4 Mode of Action

Chlorantraniliprole is an anthranilic diamide insecticide with a novel mode of action. Chlorantraniliprole induces the activation of insect ryanodine receptors. This activation stimulates uncontrolled release of calcium from the internal stores of smooth and striated muscle, causing impaired muscle regulation, paralysis and ultimately insect death. Chlorantraniliprole belongs to the “ryanodine receptor modulators,” namely “Group 28 Insecticide” according to IRAC International Mode of Action classification. The mode of action of E2Y45 is currently only shared with one other commercial insecticide active substance, flubendiamide.

Flubendiamide is not currently approved for use in Canada and is structurally different from chlorantraniliprole.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

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

2.3 Methods for Residue Analysis

High performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data gathering and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media. Acceptable extraction efficiencies were obtained when lettuce and apple samples collected from the metabolism studies were analyzed with the enforcement method. The proposed enforcement methods were successfully validated by independent laboratories. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicological Summary

The PMRA conducted a detailed review of the toxicological database for chlorantraniliprole. The database is complete, consisting of a full array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies currently required for health hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to characterize the toxicity of this pest control product.

Chlorantraniliprole is an anthranilic diamide insecticide that operates via a unique mode of action. Chlorantraniliprole binds and activates ryanodine receptors located in the sarcoendoplasmic reticulum to release stored intracellular calcium in the cell's cytoplasm. Sustained exposure to chlorantraniliprole leads to impaired regulation of the muscle excitation, contraction and relaxation cycle. This leads to complete muscle contraction, paralysis and ensuing death of the insect (Cordova et al. 2006). Comparative studies with mammalian cell

lines that endogenously express ryanodine receptors demonstrate that chlorantraniliprole exhibits a greater than 350-fold differential selectivity for insect receptors relative to mammalian receptors (Cordova et al. 2007). Differences in specificity and potency of effects distinguish the mammalian ryanodine receptor response from that of the insect and these differences appear to be the major contributing factor in the low mammalian toxicity exhibited for chlorantraniliprole.

Chlorantraniliprole was of low acute toxicity by the oral, dermal and inhalation routes in Sprague-Dawley rats. It was non-irritating when applied to the skin and minimally irritating when instilled into the eyes of New Zealand white rabbits. Results of skin sensitization testing were negative for both the local lymph node assay (LLNA) method using CBA/JHsd mice and the Magnusson-Kligman Maximization method using Dunkin-Hartley guinea pigs.

The end-use products, DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide, and Coragen 200 SC Insecticide, were of low acute toxicity by the oral, dermal and inhalation routes in Sprague-Dawley rats. They were non-irritating when applied to the skin or instilled into the eyes of New Zealand white rabbits. Results of skin sensitization testing in CBA/JHsd mice using the LLNA method were negative.

An extensive toxicokinetic assessment was carried out in the rat. In addition, analysis of plasma for parent and primary metabolites was conducted during the 90-day dietary administration studies in rats, mice and dogs and the rat 14-day oral gavage study.

In the rat, the absorption of chlorantraniliprole was rapid with peak concentrations occurring at 5 to 12 hours after low or high dose administration. Absorption at the low dose was determined to be 72.9 to 85.2% compared with 11.8 to 13.3% at the high dose using bile-duct cannulated rats. The plasma elimination half-lives ranged from 38 to 43 hours in males and 78 to 82 hours in females. Tissue distribution of the absorbed dose was extensive, with low retention in tissues indicating low potential for accumulation. The tissue residues were higher in female than in male rats, which is consistent with female rats having a longer elimination half-life and higher area under the curve in plasma. Excretion was substantially complete by 48 to 72 hours after dosing. Fecal excretion was the primary route of elimination followed by urinary excretion. There was no significant excretion occurring by exhalation. Most of the administered dose (88–97%) was eliminated in the excreta.

Metabolism of the absorbed dose was extensive and involved sex differences primarily in initial tolyl methyl and *N*-methyl carbon hydroxylation. Further metabolism of the hydroxylated metabolites included *N*-demethylation, nitrogen-to-carbon cyclization with loss of a water molecule resulting in the formation of the pyrimidone ring, oxidation of alcohols to carboxylic acids, amide bridge cleavage, amine hydrolysis and *O*-glucuronidation.

Possible species differences in the formation of primary metabolites among rats, mice and dogs were noted. The concentration of chlorantraniliprole in plasma was highest in the dog, followed by the rat and then the mouse. The primary methylphenyl ring hydroxylated metabolite (IN-HXH44) was quantified only in dog plasma, while the *N*-methyl hydroxylated metabolite (IN-H2H2O) was quantified only in rat plasma. The metabolite IN-GAZ70 (the cyclization

product of IN-H2H2O with loss of a water molecule or the N-demethylation product of IN-EQW78) was quantified only in mouse and rat plasma, with mouse plasma containing higher concentrations of IN-GAZ70 than rat plasma. In all three species, the relatively constant analyte concentrations at the higher dose levels suggested decreased absorption with increasing dose, confirming the results from previous rat metabolism studies. A significant sex difference was observed in rats, with female rats showing higher concentrations of the parent compound IN-H2H2O and IN-GAZ70 than male rats. No sex difference was noted in the dog or mouse.

In short- and long-term toxicity studies for all species, a consistent observation was an effect on the liver consisting of increased absolute and relative liver weight and hepatocellular hypertrophy. These liver changes were considered to be a non-adverse pharmacological response due to liver metabolism, coupled with induction of cytochrome P450 liver enzymes. In the short-term studies, there was a transient decrease in body-weight gain and food efficiency, which occurred at relatively high doses in both the rat 28-day dermal study and the mouse 28-day feeding study. These effects were not repeated in longer-term feeding studies in the mouse because the doses used in the 28-day study were substantially higher than those employed in the 90-day and 18-month studies. In the 18-month carcinogenicity study in mice, eosinophilic foci of cellular alteration in the liver of males at 935 mg/kg bw/day were test-substance related and considered adverse.

There was no evidence of carcinogenic potential of chlorantraniliprole in the mouse or the rat. The dose levels chosen for these studies were close to or exceeded the limit dose (1000 mg/kg bw/day). Chlorantraniliprole was determined to be non-genotoxic in both the in vitro and in vivo mutagenicity studies.

There was no evidence of increased susceptibility of the young following in utero or early life exposure to chlorantraniliprole. In the rat and rabbit developmental toxicity studies, there were no treatment-related effects on any maternal or fetal parameters up to the limit dose. In a two-generation reproductive toxicity study, a transient reduction in pup body weight was noted during the latter half of lactation in the high dose first filial [F₁] generation pups. After weaning, the body-weight gains in the F₁ offspring were similar to those of the control group, and by Day 35, postweaning body weights in these animals were comparable to the controls. No toxicologically significant treatment-related effects were observed in the parental animals at this dose level. The body weight effects in the F₁ offspring occurred at a dose in excess of the limit dose (1199/1594 mg/kg bw/day in parental [P] generation males/females), and were not repeated in the second generation when doses to the F₁ parents (1926/2178 mg/kg bw/day in males/females) were even higher than those provided to the P generation parents. For this reason, there is a low level of concern for the body weight findings in pups at maternally non-toxic doses.

A consistent, treatment-related observation in the rat repeated dose toxicology studies was an increased degree of microvesiculation in the cells of the *zona fasciculata* of the adrenal cortex. This finding was consistently observed in male rats after dermal and dietary administration of chlorantraniliprole, but was not observed in mice or dogs. The only occurrence of this finding in female rats was in F₁ parental females in the multigeneration reproduction study at a very high

dose (2178 mg/kg bw/day). The microvesiculation in affected groups was graded as mild and was not associated with changes in gross appearance, adrenal cortical cytotoxicity, hypertrophy or atrophy. No effect on cortical cell function was associated with the microvesiculation changes as demonstrated by studies evaluating corticosterone concentrations in serum (basal conditions) and urine (stimulated conditions). In addition, no treatment-related neoplastic changes were observed in the adrenal cortex of rats following chronic dietary administration of chlorantraniliprole. The adrenal cortex normally has a microvesiculation appearance under light microscope resulting from the storage of lipid to be used as precursors for steroid hormone synthesis. Rats exposed to chlorantraniliprole showed a slight increase in lipid storage in the adrenal cortex. Although clearly treatment-related, the slight microvesiculation of the adrenal cortex noted following exposure to chlorantraniliprole is not considered to be toxicologically significant.

Immunotoxicity tests conducted in the rat and mouse did not reveal any effects on thymus or spleen weights or on the antibody response to sheep red blood cells from exposure to chlorantraniliprole. In addition, no indication of potential for adverse effects on the immune system was noted in longer-term studies in rats, mice or dogs. Based on these results, chlorantraniliprole does not pose an immunotoxic hazard.

No evidence of neurotoxicity was observed in either the acute or subchronic neurotoxicity studies in rats. There was no treatment-related effect on systemic toxicity or neurotoxicity. Neurological assessments conducted in the 18-month oncogenicity study in mice did not indicate potential neurotoxicity. Furthermore, no treatment-related clinical signs indicative of neurotoxicity were observed in short- and long-term exposure studies in rats, mice or dogs. Therefore, it was concluded that chlorantraniliprole is not a neurotoxicant.

During development of the product, a modification was made to the manufacturing process of chlorantraniliprole. The mammalian toxicology database reflects the initial manufacturing process. To address potential differences in the toxicology profile as a result of differences in impurities between the new and previous processes, several acute and genotoxicity tests were submitted with sample DPX-E2Y45-282, a sample that simulated the new process.

Structural activity relationship analyses were also conducted on four impurities using DEREK. DEREK is a computer program that performs a structural activity analysis by comparing the query structure to a knowledge base of toxicophores (fragments of structures with biological activity) for which there is toxicological information. The four impurities selected for DEREK analyses included IN-KVW95, IN-E8S90, IN-LEU00 and IN-G2S78. These substances were selected based on their presence at >1 g/kg (0.1%) in test sample DPX-E2Y45-282 and after eliminating other impurities based on structural similarity to the parent compound, low potential for absorption, and whether they were already included in the rat metabolism cascade or present in previous test samples used in the animal toxicity studies. DEREK was used to assess several endpoints including the following: carcinogenicity, genotoxicity (which includes bacterial mutagenicity and chromosome aberrations among other endpoints), developmental toxicity and teratogenicity, oral toxicity, skin and eye irritation and skin sensitization. For two substances,

IN-G2S78 and IN-E8S90, for which actual acute toxicity and bacterial mutagenicity studies were provided, DEREK was not used to predict those endpoints.

These toxicity study results and those of the DEREK analyses of toxicological predictions showed low potential for acute toxicity and genotoxicity, similar to the parent compound and across the two manufacturing processes, with the exception of the results for IN-G2S78. Although the results show that this impurity is of high acute oral toxicity, it is present in the DPX-E2Y45-282 test sample (itself of low acute oral toxicity) at approximately 60% of the proposed specification. DEREK analysis of IN-G2S78 did not provide any structural alerts beyond the aromatic amine alert for carcinogenicity, which was concluded to be a low possibility based on the empirical data showing no mutagenic potential and no mutagenic or carcinogenic potential of the parent compound. In addition, due to steric hindrance, hydroxylation resulting in a hydroxylamino group, which may be activated to bind with DNA, may not occur or may occur very slowly. Therefore, the expected toxicity concern for IN-G2S78 is low. In conclusion, the data provided for sample DPX-E2Y45-282 was considered adequate, from a toxicology perspective, to bridge the change in manufacturing process for chlorantraniliprole.

Results of the acute and chronic tests conducted on laboratory animals with chlorantraniliprole, its impurities, metabolites, associated end-use products as well as the toxicological endpoints selected for human health risk assessment are summarized in Appendix I, Tables 2, 3 and 4.

Pest Control Products Act Hazard Characterization

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

With respect to the completeness of the toxicity database, extensive data were available for chlorantraniliprole, including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, the toxicology profile revealed chlorantraniliprole to be of relatively low toxicity in all studies. The developmental toxicity studies did not indicate increased susceptibility of fetuses to in utero exposure relative to the adult. In the reproductive toxicity study, decreased pup body weights were observed at dose levels that did not elicit any toxicity in the adults. Concern for these findings was offset by the fact that they occurred at a dose much higher than the limit dose of testing and that pups subsequently regained the body weight after weaning. There was no indication in the toxicology database that chlorantraniliprole had neurotoxic potential.

Overall, there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children. For these reasons, the 10-fold PCPA factor was reduced to one-fold for risk assessment purposes.

3.2 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) is 1.58 mg/kg bw/day, calculated using the NOAEL of 158 mg/kg bw/day from the 18-month feeding study in male mice. Eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight were observed at the next highest dose (935 mg/kg bw/day). The standard uncertainty factor (UF) of 100 is applied to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). As indicated under PCPA Hazard Characterization above, the PCPA factor for chlorantraniliprole was reduced to one-fold.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{UF}} = \frac{158 \text{ mg/kg bw/day}}{100} = 1.58 \text{ mg/kg bw/day}$$

3.3 Acute Reference Dose (ARfD)

An acute reference dose was not determined because an endpoint of concern attributable to a single exposure was not identified in the oral toxicity studies.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoint Selection: Occupational and Bystander Risk Assessment

Farmers, custom applicators, lawn care operators and golf course and sod farm workers have potential for exposure during application of products containing chlorantraniliprole over a short- to intermediate-term duration via the dermal and inhalation routes. Following application, agricultural, golf course and sod farm workers as well as adults and children in residential and recreational settings have potential for short- to intermediate-term exposure to chlorantraniliprole residues via the dermal and oral routes when entering treated areas.

Incidental Oral Exposure (short- to intermediate-term)

Although reduced body-weight gain and food efficiency were noted in males in the 28-day dietary study in the mouse, these effects occurred at an excessively high dose (1443 mg/kg bw/day) and were not reproduced in the 90-day dietary study in the mouse, in which the dose to the male mice was somewhat lower (1144 mg/kg bw/day). As there was no identified hazard of concern attributable to short- to intermediate-term oral exposure to chlorantraniliprole, the selection of an oral short- to intermediate-term toxicological endpoint is not required.

Dermal Exposure (short- to intermediate-term)

In a 28-day rat dermal toxicity study, a NOAEL of 300 mg/kg bw/day was established on the basis of effects at the highest dose tested (1000 mg/kg bw/day), which included reductions in body-weight gain and food efficiency in males and females. However, the overall concern for these effects, and thus for toxicity via the dermal route, is low. No significant treatment-related

changes in absolute body weight were noted in the dermal study. Similar effects on body-weight gain and food efficiency were not noted in oral dosing studies of similar or longer duration, often up to doses exceeding the limit dose. In comparison, an increased incidence of adrenal microvesiculation was noted in male rats in the 28-day dermal study at 1000 mg/kg bw/day, at 584 mg/kg bw/day in the 28-day dietary study, and at 1188 mg/kg bw/day in the 90-day dietary study. This lesion was graded “minimal” in the dermal study but was more severe (graded mild) in some rats in the 28- and 90-day dietary studies. Even though the systemic reaction following exposure to chlorantraniliprole was more severe following oral dosing than dermal dosing, effects on body-weight gain and food efficiency were not noted in these dietary studies. The reduction in body-weight gain and food efficiency occurred at the limit dose in the dermal study. Therefore, the decreases in body-weight gain and food efficiency in isolation, with no other toxicity or change in absolute body weight in this study, and the absence of similar effects in longer-term oral dietary studies led to the conclusion that selection of an endpoint for short- to intermediate-term risk assessment was not warranted.

Inhalation Exposure (short- to intermediate-term)

A repeated-exposure inhalation study with chlorantraniliprole was not provided. However, this study was not required on the basis of low toxicity and lack of irritation in the acute inhalation study, and low volatility (vapour pressure 2.1×10^{-11} Pa) and overall low systemic toxicity in the oral toxicity studies. For these reasons, establishment of an endpoint for short- to intermediate-term inhalation exposure was not required.

Dermal Absorption

One in vivo dermal penetration study was conducted for each of the two formulations (WG and SC). Three groups of four male rats were administered nominal doses of DPX-E2Y45 (chlorantraniliprole) as the 35 WG formulation. The test substance was applied as the undiluted concentrate at 350 g DPX-E2Y45/kg and as a 0.75 g DPX-E2Y45/L aqueous dilution. The target dose level per unit area of skin was $1750 \mu\text{g}/\text{cm}^2$ and $7.5 \mu\text{g}/\text{cm}^2$ for the undiluted and aqueous dilutions, respectively. Total recovery ranged from 97.8 to 98.2%. Total amounts of radioactivity in samples were reported as a percentage of the total dose. All rats were washed after six hours of exposure and groups were sacrificed at 6, 24, and 504 hours postdosing (0, 18 and 498 h postexposure). Evidence from both dose levels indicates that a portion of the dose found in the tape strips (representing the stratum corneum) becomes systematically absorbed over time. Therefore, the skin-bound residues should be included in the estimate of absorbable dose.

Similarly, three groups of four male rats were administered doses of DPX-E2Y45 (chlorantraniliprole) as the 200 SC formulation. The target doses were $2000 \mu\text{g}/\text{cm}^2$ and $7.5 \mu\text{g}/\text{cm}^2$ for the undiluted and aqueous dilutions, respectively. Again, total recovery was high at 94.6 to 99.5%. As before, results provide sufficient evidence to support the inclusion of tape strips in the estimate of total dose absorbable.

Both studies indicate similar absorbable dose estimates ranging from approximately 1.7 to 7.5%. The highest estimate of total absorbable dose including the tape strips ($7.5\% \pm 3.02$) occurred in the 24-hour postdose group of the rats dosed with the 200 SC formulation. A maximum apparent absorption (systemic absorption and skin-bound residues combined) value of 7.5% is considered

appropriate for use in a dermal exposure assessment for Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide.

3.4.2 Occupational Exposure and Risk

Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide

Dermal and inhalation exposure to chlorantraniliprole is possible for chemical handlers mixing/loading and applying Coragen 200 SC Insecticide, DPX-E2Y45 20 SC Insecticide or Altacor 35 WG Insecticide. Workers re-entering treated areas are potentially exposed mainly via the dermal route. Furthermore, there is potential for oral exposure for individuals (including toddlers) entering treated residential turf areas. All expected exposure scenarios are considered short- to intermediate-term in duration.

The toxicology assessment suggests no hazard of concern attributable to short- to intermediate-term oral, dermal or inhalation exposure. As such, a quantitative risk assessment is not required for the proposed uses of chlorantraniliprole.

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

As no hazards of concern were identified via the oral, inhalation and dermal routes of exposure, no quantitative risk assessment was required

3.4.2.2 Postapplication Worker Exposure and Risk

Given no hazards of concern were identified via the oral, inhalation and dermal routes of exposure, no quantitative risk assessment was required. However, chemical-specific data describing the foliar dissipation of chlorantraniliprole on tomatoes, cabbage and apples were submitted and reviewed. Dermal exposure to workers entering treated areas is generally estimated by coupling dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients. The supporting DFR studies were conducted in the United States and do not entirely reflect the Canadian use pattern.

Three DFR studies were conducted by the applicant on tomatoes, cabbage and apples. The apple DFR study was intended to represent the orchard fruits proposed on the label. However, this study does not accurately reflect the Canadian use pattern on orchard fruits. The tomato study represents fruiting and leafy green vegetables, whereas the cabbage study represents *Brassica* leafy vegetables. This grouping is based on the similarity of the rates applied, the method of application, as well as the description of the leaf texture.

Dissipation kinetics were determined for each location across all three crops. One site in the apple study experienced unusually high rain events during the study, which resulted in a significantly higher dissipation rate with a half-life of five days. All other locations had relatively slow dissipation rates with half-lives ranging from 13 to 31 days. Data from several study locations did not follow a pseudo first-order regression model and should therefore not be used to conduct a restricted entry analysis.

Peak DFR values from those data that did follow the first-order kinetics are 0.135 µg/cm² for cabbage and 0.155 µg/cm² for tomato, when chlorantraniliprole is applied as Coragen 200 SC Insecticide according to label directions. The peak DFR value of chlorantraniliprole when applied to apples, as directed on the Canadian Altacor 35 WG Insecticide label, cannot be determined from the study. This is due to differences in the number of applications, the application rate and the climatic conditions of the study compared to the Canadian use pattern. Evidence at all locations indicates a reduced dissipation rate. Thus, a dissipation rate of 5% per day is considered more appropriate than the generally assumed 10% per day.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Although applied in residential areas, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide are commercial products. Therefore, no residential handler risk assessment is required.

3.4.3.2 Postapplication Exposure and Risk

Individuals (adults, youth and toddlers) re-entering treated residential or recreational areas, such as lawns or golf courses, can come in contact with chlorantraniliprole residues. Since no oral, dermal or inhalation toxicology hazards were identified, risks are considered acceptable for all groups described.

3.4.3.3 Bystander Exposure and Risk

As no oral, dermal or inhalation toxicology hazards were identified, bystander risks are considered acceptable.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products is chlorantraniliprole. The residue definition for enforcement in animal commodities is chlorantraniliprole. The residue definitions for risk assessment are the following: in animal tissues, chlorantraniliprole; in milk, chlorantraniliprole and metabolites IN-HXH44 and IN-9T00; and in eggs, chlorantraniliprole and metabolites IN-H2H20, IN-GAZ70 and IN-K7H29. The HPLC-MS/MS enforcement analytical methods were valid for the quantification of chlorantraniliprole residues in various plant and livestock matrices. The residues of chlorantraniliprole are stable when stored in a freezer at -20°C for 24 months in five diverse crops, including fruits, a fruiting vegetable, a root crop, a non-oily grain and an oilseed. This indicates that residues of chlorantraniliprole are stable in all crops. The residues of chlorantraniliprole are stable when stored in a freezer at -20°C for 12 months in representative processed crop fractions, including raisins, ketchup, apple juice, cottonseed meal and cottonseed

oil. Therefore, residues of chlorantraniliprole are stable in all processed crop fractions. The residues of chlorantraniliprole are stable when stored in a freezer at -20°C for six months in milk and three months in liver, kidney, muscle and fat. Raw agricultural commodities were processed. The only processed food commodities where chlorantraniliprole residues concentrated are raisins (4.2 \times), red wine (1.2 \times), tomato paste (1.5 \times), tomato puree (1.5 \times) and plums (1.9 \times). Supervised residue trials conducted throughout Canada and the United States using end-use products containing chlorantraniliprole at the approved rates in apple, pear, peach, plum, sweet and sour cherries, grapes, broccoli/cauliflower, cabbage, mustard greens, cucumber, cantaloupe/muskmelon, summer squash, tomato, bell and non-bell peppers, head/leaf lettuce, celery, spinach, potato and cotton are sufficient to support the proposed MRLs.

3.5.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCIDTM, Version 2.0), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994-1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic analysis: MRLs for all crops and all animal commodities were used (except poultry and hog matrices). For the basic chronic analysis, MRLs for all crops and animal commodities, except poultry and hog matrices, were used. As no MRLs are recommended for hog and poultry matrices, the method limit of quantitation (LOQ) of 0.1 ppm for each analyte of the residue definition for risk assessment was used. The basic chronic dietary exposure from all supported chlorantraniliprole food uses only for the total population is 0.5% of the acceptable daily intake (ADI). The PMRA estimates that aggregate chronic dietary exposure to chlorantraniliprole from food and water is 0.6% of the ADI for the total population. The highest exposure and risk estimate is for children 1 to 2 years old at 1.3% (0.019911 mg/kg bw/day) of the ADI. Aggregate exposure from food and water is considered acceptable.

3.5.2.2 Acute Dietary Exposure Results and Characterization

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

3.5.3 Aggregate Exposure and Risk

The aggregate risk for chlorantraniliprole consists of exposure from food and drinking water sources only. Aggregate risks were calculated based on chronic endpoints. There was no acute endpoint identified for the general population, including infants and children.

3.5.4 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

MRLs (ppm)	Foods
13	Leafy vegetables (Crop Group 4)
11	Leafy <i>Brassica</i> greens (Crop Subgroup 5B)
4	Head and stem <i>Brassica</i> vegetables (Crop Subgroup 5A)
2.5	Raisins
1.2	Small fruit vine climbing (Crop Subgroup 13-07F)
1	Stone fruits (Crop Group 12)
0.7	Fruiting vegetables (Crop Group 8)
0.3	Cottonseed; pome fruits (Crop Group 11)
0.25	Cucurbit vegetables (Crop Group 9)
0.01	Fat, meat and meat by-products of cattle, goat, horses and sheep; milk; potato

For 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 estimates are summarized in Appendix I, Tables 1, 5 and 6.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Chlorantraniliprole enters the terrestrial environment when it is used as an insecticide on turf and a variety of crops. Chlorantraniliprole will not phototransform on soil surfaces. It undergoes hydrolysis in alkaline environments. It is persistent and mobile in terrestrial environments. Under field conditions relevant to Canada, the DT₅₀ (time estimated for test chemical to dissipate to half of the initial applied amount based on non-linear regression fit) is estimated to be 399 days. The major transformation product is 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3, 8 dimethyl-4(3H)-quinazolinone (IN-EQW78). IN-EQW78 is also very persistent, and the laboratory half-life (time required for test chemical to decrease to half of the initial applied amount based on single first-order linear fit) ranges from 646 to 785 days. Field data indicate that chlorantraniliprole is expected to leach through the soil profile beyond 60 cm and may therefore be expected to enter groundwater. As indicated by its *K*_{oc} values, chlorantraniliprole adsorbs to soil particles. The major routes of dissipation are identified as leaching and runoff.

Chlorantraniliprole could reach aquatic habitat through spray drift or runoff. It has low solubility in water at environmentally relevant pHs. Chlorantraniliprole partitions into sediment and gradually transforms into IN-EQW78 in the water column and sediment. Chlorantraniliprole is considered to be moderately persistent in aerobic water-sediment systems, with half-lives ranging from 125 to 231 days. It is slightly persistent in anaerobic water-sediment systems with a DT₅₀ of 42 days. Chlorantraniliprole undergoes hydrolysis under alkaline conditions; however, hydrolysis is not expected to be an important route of dissipation in colder water systems because the rate is temperature dependent. The major transformation product, IN-EQW78, is expected to be persistent with half-lives of 680 and 701 days in aerobic and anaerobic water-sediment systems, respectively.

The low vapour pressure and Henry's law constant indicate that chlorantraniliprole is non-volatile in the environment. Therefore, chlorantraniliprole residues are not expected in the atmosphere, and long-range transport is not expected.

Data on the fate and behaviour of chlorantraniliprole and its transformation products are summarized in Appendix I, Table 7. The transformation pathway for chlorantraniliprole is summarized in Appendix I, Figure 2.

4.2 Effects on Non-Target Species

The toxicity of chlorantraniliprole, DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide and transformation products to terrestrial and aquatic organisms is summarized in Appendix I, Table 8. To estimate the risk of potential adverse effects on non-target species, a risk quotient method is used. The risk quotient (RQ) is calculated by dividing the exposure estimate by a value representing a toxicity endpoint. A screening level risk assessment is initially performed using the expected environmental concentrations (EECs) for a worst-case scenario (e.g. direct overspray of a body of water) and the most sensitive toxicity endpoint. Low risk is predicted if the risk quotient is less than the trigger value of one. In these cases, no further assessment is done. For those groups of organisms for which the RQ is greater than one, a refined assessment is undertaken. A refined assessment takes into consideration more realistic exposure scenarios (e.g. drift to non-target habitats and runoff to water bodies) and may consider different toxicity endpoints.

4.2.1 Effects on Terrestrial Organisms

Risk of chlorantraniliprole to terrestrial organisms was based upon evaluation of toxicity data for two mammals and two bird species (acute gavage, short- and long-term dietary exposure); one bee species and five non-target arthropods; one earthworm species (acute or chronic exposure); and 10 crop species (short-term exposure) (Appendix I, Table 9). Risk of IN-EQW78 to terrestrial organisms was based on toxicity data available for the earthworm, bobwhite quail and rat. Risk of other transformation products of chlorantraniliprole, IN-ECD73, IN-GAZ70, IN-F6L99, to soil-dwelling invertebrates was based on toxicity data available for the earthworm. Risk of IN-ECD73, IN-F6L99 and IN-LBA24 to small mammals was based on toxicity data available for the mouse.

Chlorantraniliprole did not cause mortality to birds and small mammals in acute studies at the highest dose tested. Sublethal effects were not observed in bobwhite exposed to the DPX-E2Y45 20 SC formulation up to 430 mg a.i./kg body weight. No transient signs of toxicity were observed in birds exposed to the Altacor 35 WG formulation up to 486 g a.i./kg body weight. No observable reproductive effects were found in the bobwhite quail (e.g. reduced eggshell thickness or increased percent cracked eggs) at concentrations up to 120 mg a.i./kg diet, or in the mallard duck (reduction in live three-week-old embryos) at concentrations up to 500 mg a.i./kg diet. Chlorantraniliprole was not found to adversely affect rats or mice. It did not exert any effects on the reproduction of rats at 20 000 mg a.i./kg dw). IN-EQW78, IN-ECD73, IN-F6L99 and IN-LBA24 of chlorantraniliprole were not found to be more toxic than chlorantraniliprole to small mammals. The screening level risk quotients for birds and small mammals did not exceed the level of concern (Appendix I, Table 9).

Chlorantraniliprole and transformation products IN-EQW78, IN-ECD73 and IN-GAZ70 were not acutely toxic to earthworms. However, transformation product IN-F6L99 and the two formulations of chlorantraniliprole are more toxic to the earthworm than chlorantraniliprole. They exerted toxic effects on earthworms at concentrations higher than 250 mg/kg dw soil. In several chronic studies, reproduction of earthworms exposed to Altacor 35 WG formulation, IN-EQW78, IN-ECD73 and IN-GAZ70 was assessed. No significant effects on mortality, weight change or reproduction was observed at any treatment level. The screening level risk quotients for earthworms did not exceed the level of concern (Appendix I, Table 9).

Honeybees were not adversely affected by acute contact or oral exposure to chlorantraniliprole, DPX-E2Y45 20 SC Insecticide or Altacor 35 WG Insecticide under laboratory conditions. Chlorantraniliprole did not exert any toxic effect on bees at concentrations up to 0.0274 µg a.i./bee and 0.125 µg a.i./bee for acute oral and contact exposure, respectively. The 48-hour LD₅₀s were higher than the highest doses tested. The screening level risk quotients for bees did not exceed the level of concern (Appendix I, Table 9).

In other laboratory studies with other non-target arthropods, chlorantraniliprole was found to be acutely toxic to three of the five species tested (ladybird beetle, hoverfly and *Orius laevigatus*). The screening level risk quotients exceeded the level of concern for these three species exposed to food contaminated with chlorantraniliprole (Appendix I, Table 9). Appropriate label statements are required on the end-use product labels to identify the potential risk to some beneficial arthropods.

For terrestrial plants, seedling emergence and vegetative vigour of 10 species of plants were not reduced by more than 25% when exposed to DPX-E2Y45 20 SC Insecticide at 237 g a.i./ha, which is higher than the maximum seasonal rate approved by the PMRA. The screening level risk quotients for terrestrial plants did not exceed the level of concern (Appendix I, Table 9).

4.2.2 Effects on Aquatic Organisms

Risk of chlorantraniliprole to aquatic organisms was based on an evaluation of toxicity data for 15 freshwater species (nine invertebrates, two fish, three algae and one vascular plant) and four

marine/estuarine species (two invertebrates, one fish and one alga). The risk of five transformation products (IN-EQW78, IN-ECD73, IN-GAZ70, IN-F6L99 and IN-F9N04) to aquatic organisms was based on the toxicity data available for one freshwater invertebrate species.

In the freshwater environment, chlorantraniliprole was not acutely toxic to fish, algae or vascular plants; no observed effect concentrations (NOECs) were all greater than the solubility limit of chlorantraniliprole. DPX-E2Y 20 SC was slightly toxic to rainbow trout (96-h NOEC <2.16 mg a.i./L). The screening level risk quotients for fish and aquatic vegetation did not exceed the level of concern (Appendix I, Table 9). Chlorantraniliprole exhibited acute and chronic toxicity to freshwater invertebrates at concentrations lower than the solubility limit of chlorantraniliprole. The median lethal concentrations (LC₅₀s) ranged from 0.00302 mg a.i./L (*D. magna*) to >1.49 mg a.i./L (*L. variegatus*). The screening level risk quotients for freshwater invertebrates exceeded the level of concern (Appendix I, Table 9). Based on acute toxicity studies with *Daphnia magna*, IN-EQW78, IN-ECD73, IN-GAZ70, IN-F6L99 and IN-F9N04 were less toxic than chlorantraniliprole. Therefore, risk assessments were not conducted for any of these transformation products.

In the marine environment, chlorantraniliprole was acutely toxic to invertebrates with lethal concentrations 50% (LC₅₀s) (or effective concentrations on 50% of the population [EC₅₀s]) ranging from 0.0399 mg a.i./L to 1.15 mg a.i./L. However, it was not acutely toxic to fish or marine algae since NOECs for these species were greater than the solubility limit of chlorantraniliprole. The screening level risk quotients for marine fish and algae did not exceed the level of concern. The screening level risk quotients for the Eastern oyster exceeded the level of concern but not for the mysid (Appendix I, Table 9).

To assess the risk to amphibians for acute and chronic exposure, the toxicity values for the most sensitive fish species were used as surrogate data along with the EEC in a 15 cm deep body of water. The screening level risk quotients exceeded the level of concern for amphibians (Appendix I, Table 9).

A refined assessment considered that the most likely routes of entry of chlorantraniliprole into water would be through drift and runoff (Appendix I, Table 10). For drift, the screening level assumes 100% drift to a water body. The actual maximum drift deposition expected for field boom sprayers, airblast sprayers and aerial application at one metre downwind of a sensitive habitat is 11%, 74% (early application) and 26%, respectively. Based on the EECs corrected for maximum drift from field boom sprayers, the level of concern was not exceeded for all aquatic invertebrates, except for the chronic effect of chlorantraniliprole on *D. magna* and *Chironomus riparius*. Based on the EECs corrected for maximum drift from airblast sprayers, the level of concern was still exceeded for all aquatic invertebrates. Based on the EECs corrected for maximum drift from aerial application, the level of concern was not exceeded for all freshwater invertebrates, except for the acute effect of DPX-E2Y45 20 SC Insecticide and chronic effect of chlorantraniliprole on *D. magna* and *C. riparius*. The level of concern was also not exceeded for marine invertebrates. Therefore, buffer zones of one metre are required to mitigate the risk to aquatic invertebrates when field boom sprayers are used. Buffer zones ranging from one to

10 metres are required to mitigate the risk to aquatic invertebrates and amphibians when airblast sprayers are used. Buffer zones ranging from one to 15 metres are required to mitigate the risk to aquatic invertebrates and amphibians when aerial application is used. Buffer zones have been calculated and added to the product label under the **DIRECTIONS FOR USE**.

The runoff assessment initially involved determining the geographic areas where the major crops are grown. Then the scenario that generated the highest expected chlorantraniliprole concentration for either freshwater or estuarine/marine habitats was chosen (based on potatoes grown in Prince Edward Island and turf), assuming no drift. The calculated risk quotients for turf did not exceed the level of concern. Therefore, no mitigation is needed. The calculated risk quotients for the potato exceeded the level of concern for *D. magna*, mayfly, caddisfly and *C. riparius*. Statements providing instructions to minimize runoff and a statement indicating the toxicity of this pesticide to aquatic organisms have been added to the product label.

5.0 Value

E2Y45 is the generic term that will be used throughout this section to describe the three chlorantraniliprole formulations: Altacor 35 WG Insecticide, Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide.

5.1 Effectiveness Against Pests

5.1.1 Control of Codling Moth (*Cydia pomonella*) in Pome Fruits

Data from eight field trials were provided to demonstrate the efficacy of E2Y45 against codling moth (CM). Trials were conducted in Canada (four in Ontario, two in Nova Scotia) and the United States (one in New York, one in Michigan). Pest pressure levels varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 50 g a.i./ha. Acceptable control was demonstrated at the proposed rates. The rate range of 50 to 75 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every 10 days, is acceptable.

5.1.2 Control of Oriental Fruit Moth (*Grapholita molesta*) in Pome Fruits

Data from three field trials were provided to demonstrate the efficacy of E2Y45 against oriental fruit moth (OFM). Trials were conducted in Canada (one in Ontario) and the United States (one in New York, one in Michigan). Pest pressure levels varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 50 g a.i./ha. The rate range of 50 to 75 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every 10 days, is acceptable. In pome fruit orchards where OFM and CM occur together, growers will often manage these pests together.

5.1.3 Control of Spotted Tentiform Leafminer (*Phyllonorycter blancardella*) and Western Tentiform Leafminer (*P. elmaella*) in Pome Fruits

Data from six field trials were provided to evaluate the efficacy of E2Y45 against spotted tentiform leafminer (STLM). Trials were conducted in Canada (five in Ontario, one in Nova Scotia). Pest pressure varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 50 g a.i./ha. Acceptable control was demonstrated at the proposed rates. The rate range of 50 to 75 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every 10 days, is acceptable. Results from STLM can be extrapolated to Western tentiform leafminer because of their similar life cycles and the similar feeding damage to apple trees.

5.1.4 Control of Oblique-Banded Leafroller (*Choristoneura rosaceana*) and Three-Lined Leafroller (*Pandemis limitata*) in Pome Fruits

A total of 18 field trials were provided to demonstrate the efficacy of E2Y45 against oblique-banded leafroller (OBLR). Trials were conducted in Canada (seven in Ontario, two in Nova Scotia) and in the United States (one in New York, six in Oregon, two in Michigan). As three trials had insufficient and uneven pest pressure or applications were not timed for the OBLR, they are not considered in the following discussion. Pest pressure levels varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 50 g a.i./ha. Acceptable control was achieved across a range of rates. The rate range of 50 to 100 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every 10 days, is acceptable. Submitted data can also be used to support the control claim for the three-lined leafroller at 50 to 100 g a.i./ha based on the similarity of life cycle, behaviour and feeding damage with the OBLR.

5.1.5 Control of Oriental Fruit Moth (*Grapholita molesta*) in Stone Fruits

A total of six field trials were provided, which demonstrate the efficacy of E2Y45 against oriental fruit moth. Trials were conducted in Canada (five in Ontario) and the United States (one in Michigan). Pest pressure levels varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 75 g a.i./ha. Acceptable control was demonstrated at the proposed rates. The rate range of 75 to 100 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every seven days, is acceptable.

5.1.6 Control of Peach Twig Borer (*Anarsia lineatella*) in Stone Fruits

A single trial was provided to support the claim for the control of peach twig borer in stone fruit crops. The trial was conducted in Canada (British Columbia). Based on the similarity of life cycle, behaviour and feeding damage with CM and OFM, the rate range of 75 to 100 g a.i./ha can be supported, provided that confirmatory efficacy data are generated.

5.1.7 Control of Oblique-Banded Leafroller (*Choristoneura rosaceana*) and Three-Lined Leafroller (*Pandemis limitata*) in Stone fruits

Efficacy data from one trial were provided demonstrating the efficacy of E2Y45 against OBLR in stone fruits. The trial was conducted in Oregon. The efficacy data generated on apples may be used to support a label claim for OBLR on the stone fruit crop group based on the pest biology, type of damage, crop morphology and application methods, which are similar. The three-lined leafroller claim can similarly be supported. Therefore, control of OBLR and three-lined leafroller at rates of 50 to 100 g a.i./ha, with the higher rate to be applied under high pest pressure, can be supported. A maximum of three applications per season, not more than once every seven days, is acceptable.

5.1.8 Control of Grape Berry Moth (*Endopiza viteana*) in Grapes

Data from eight field trials were provided to demonstrate the efficacy of E2Y45 against grape berry moth (GBM). Trials were conducted in Canada (three in Ontario) and the United States (three in New York, one in Pennsylvania, one in Michigan). Pest pressure levels varied from low to high in the submitted trials with the lowest effective rate being demonstrated at 50 g a.i./ha. Acceptable control was achieved across a range of rates. The rate range of 50 to 100 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of three applications per season, not more than once every seven days, is acceptable.

5.1.9 Control of Climbing Cutworm (*Heliothis punctigera*) in Grapes

Data from one trial were provided to demonstrate the efficacy of E2Y45 against climbing cutworms. The trial was conducted in a mature planting (approximately 20 years old) of Gewürztraminer grapes in Canada (British Columbia). E2Y45 applied directly to the grapevine at early bud development significantly reduced bud damage by climbing cutworms. The lowest effect rate was demonstrated to be 75 g a.i./ha. Therefore, the proposed rate range of 75 to 100 g a.i./ha, with the higher rate to be applied at high pest pressure, is acceptable. A maximum of three applications per season, not more than once every seven days, is acceptable.

5.1.10 Control of Colorado Potato Beetle (*Leptinotarsa decemlineata*) in Potatoes

A total of 13 field trials were provided to demonstrate the efficacy of E2Y45 against Colorado potato beetle (CPB). Trials were conducted in Canada (five in Ontario, two in Prince Edward Island, one in New Brunswick, two in Manitoba, one in Alberta) and the United States (one in Wisconsin, one in New York). Pest pressure levels varied from low to high in the submitted trials, with the lowest effective rate being demonstrated at 50 g a.i./ha. The rate range of 50 to 75 g a.i./ha, with the higher rate to be applied at high pest pressure, is acceptable. A maximum of four applications per season, not more than once every five days, by either ground or aerial application is acceptable.

5.1.11 Control of European Corn Borer (*Ostrinia nubilalis*) in Potatoes

A total of six field trials were provided to demonstrate the efficacy of E2Y45 against European corn borer (ECB). Trials were conducted in Canada (Prince Edward Island). E2Y45 formulated as both 35 WG and 20 SC were both used throughout the efficacy trials. Pest pressure levels varied from low to high in the submitted trials, with the lowest effective rate being demonstrated at 50 g a.i./ha. The rate range of 50 to 75 g a.i./ha, with the higher rate to be applied under high pest pressure, is acceptable. A maximum of four applications per season, not more than once every five days, by either ground or aerial application is acceptable.

5.1.12 Control of Colorado Potato Beetle (*Leptinotarsa decemlineata*) in Fruiting Vegetables

A total of three field trials on tomatoes were provided to demonstrate the efficacy of E2Y45 against CPB. All trials were conducted in Ontario. The efficacy data provided for the control of CPB on potatoes can be extrapolated to fruiting vegetables based on the bridging trials submitted. Therefore, control of CPB at rates of 50 to 75 g a.i./ha, with the higher rate to be applied at high pest pressure, can be supported. A maximum of four applications per season, not more than once every five days, is acceptable.

5.1.13 Control of Imported Cabbageworm (*Pieris rapae*) in Brassica

A total of 12 field trials were provided to demonstrate the efficacy of E2Y45 against imported cabbageworm. The trials were conducted in Canada (nine in Ontario) and the United States (three in Ohio). Application of E2Y45 at 50 g a.i./ha with the addition of Hasten adjuvant provided a consistently high level of control of imported cabbageworm larvae. Treatments below this rate were not as consistent, showing some failures. Therefore, the rate of 50 g a.i./ha with a modified seed oil adjuvant such as Hasten or MSO is acceptable. A maximum of four applications per season, not more than once every three days, is acceptable.

5.1.14 Control of Diamondback Moth (*Plutella xylostella*) in Brassica

A total of 12 field trials were provided to demonstrate the efficacy of E2Y45 against diamondback moth. The trials were conducted in Canada (eight in Ontario) and the United States (two in Ohio, two in Wisconsin). Application of E2Y45 at 50 g a.i./ha with the addition of Hasten or MSO adjuvants provided a consistently high level of control of diamondback moth larvae. Therefore, the rate of 50 g a.i./ha with a modified seed oil adjuvant such as Hasten or MSO is acceptable. A maximum of four applications per season, not more than once every three days, is acceptable.

5.1.15 Control of Cabbage Looper (*Trichoplusia ni*) in Brassica

A total of 12 field trials were provided to demonstrate the efficacy of E2Y45 against cabbage looper. The trials were conducted in Canada (eight in Ontario) and the United States (two in Ohio, two in Wisconsin). Application of E2Y45 at 50 g a.i./ha with the addition of Hasten or

MSO adjuvants provided a consistently high level of control of cabbage looper larvae. Therefore, the rate of 50 g a.i./ha with a modified seed oil adjuvant such as Hasten or MSO is acceptable. A maximum of four applications per season, not more than once every three days, is acceptable.

Extrapolation from the control of cabbage looper larvae on *Brassica* can be made to cabbage looper larvae on leafy vegetables based on the similarity of crop structure and management techniques. The addition of a modified seed oil adjuvant is not required on leafy vegetables due to the lack of waxy cuticle found on *Brassica*. Therefore, the rate of 50 g a.i./ha is acceptable. A maximum of four applications per season, not more than once every three days, is acceptable.

5.1.16 Control of European Chafer (*Rhizotrogus majalis*) in Turf

Efficacy data from seven trials were provided to demonstrate the efficacy of E2Y45 against European chafer. The trials were conducted in Canada (five in Ontario) and the United States (two in New Hampshire). Application of E2Y45 at rates of 112 to 176 g a.i./ha provided adequate control of European chafer with the lowest effective rate being demonstrated at 112 g a.i./ha. Therefore, the rate range of 112 to 176 g a.i./ha for control of European chafer larvae is acceptable with a maximum of one application per season.

5.1.17 Control of Japanese Beetle (*Popillia japonica*) in Turf

Efficacy data from four trials were provided to demonstrate the efficacy of E2Y45 against Japanese beetle larvae. The trials were conducted in the United States (two in Wisconsin, one in Pennsylvania, one in Ohio). Treatments were applied in the spring (three trials) and in the summer (one trial). Application of E2Y45 at rates of 112 to 176 g a.i./ha provided adequate control of Japanese beetle larvae, with the lowest effective rate being demonstrated at 112 g a.i./ha. Therefore, the rate range of 112 to 176 g a.i./ha for control of Japanese beetle larvae is acceptable with a maximum of one application per season.

5.1.18 Control of Black Cutworm (*Agrotis ipsilon*) in Turf

Efficacy data from three trials were provided demonstrating the efficacy of E2Y45 against black cutworm. The trials were conducted in the United States (two in Pennsylvania, one in Indiana). Treatments were applied in the spring (one trial) and the summer (two trials). Application of E2Y45 at rates of 29 to 58 g a.i./ha provided adequate control of black cutworm. Therefore, the rate range of 29 to 58 g a.i./ha to control black cutworm is acceptable with a maximum of one application per season.

5.1.19 Control of Annual Bluegrass Weevil (*Listroderes* sp.) in Turf

Efficacy data from three trials were provided demonstrating the efficacy of DPX-E2Y45 against annual bluegrass weevil. Trials were conducted in the United States (two in New Hampshire, one in Pennsylvania). Treatments were applied in the spring. Application of E2Y45 at rates of 176 to 225 g a.i./ha provided adequate control of annual bluegrass weevil, with the lowest effective rate

being demonstrated at 176 g a.i./ha. Therefore, the rate range of 176 to 225 g a.i./ha for the control of annual bluegrass weevil is acceptable, with a maximum of one application per season.

5.1.20 Acceptable Efficacy Claims

Efficacy data support the use of Altacor 35 WG Insecticide for control of a variety of insect pests in pome fruits, stone fruits and grapes. The lowest effective rate for the pests has been established and is supported by provided efficacy data (Appendix I, Table 12.1). Coragen 200 SC Insecticide controls many insect pests in potatoes, fruiting vegetables, *Brassica* vegetables, leafy vegetables and turf. The lowest effective rate for the pests on the Coragen 200 SC label has been established (see Appendix I, Table 12.2). The control of several insect pests in turf and the lowest effective rates can also be supported on the DPX-E2Y45 Insecticide label (see Appendix I, Table 12.3).

5.2 Phytotoxicity to Host Plants

No phytotoxic effects were noted in any of the submitted trials.

5.3 Economics

No economic analysis was conducted for this product evaluation.

5.4 Sustainability

5.4.1 Survey of Alternatives

The availability of alternative insecticides varies depending on the pest and crop. Most insecticide products are registered for use on pome fruits and potatoes while fewer are registered for use on *Brassica* and turf (Appendix I, Table 11). Some of the currently available alternatives are older classes of chemistry (carbamates and organophosphates), which are currently undergoing re-evaluation. Other alternatives include synthetic pyrethroids, neonicotinoids, growth regulators, microbials, mineral oil and kaolin clay.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

E2Y45 offers broad-spectrum insect control. It is also compatible with current management practices and conventional crop production systems. Growers are familiar with the monitoring techniques to determine if and when applications are needed.

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

The registrant has indicated that with the unique mode of action, target site cross-resistance is not expected to be present in field populations of target pest insects. Also, in the extensive

baseline susceptibility bioassays with E2Y45 against key target species on a global basis, no insect population has been identified as resistant or cross-resistant.

Given the history of resistance associated with some of the pests, the applicant's management strategy is to limit the number of applications of the end-use products to one per year for turf, three per year for grapes and stone fruits, and four per year for pome fruits, potatoes, fruiting vegetables, *Brassica* vegetables and leafy vegetables. The applicant also plans to advise users that programs for control of these pests should include alternation with products that have a different mode of action. As part of this strategy, the labels also recommend the monitoring of insect populations and the application of the end-use products at economic pest threshold levels.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, chlorantraniliprole was assessed in accordance with PMRA Regulatory Directive [DIR99-03](#), *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of chlorantraniliprole were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products, DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide. The PMRA has reached the following conclusions:

- Chlorantraniliprole does not meet TSMP Track 1 criteria because it is not bioaccumulative. The *n*-octanol–water partition coefficient ($\log K_{ow}$) is 2.76 to 2.86, which is below the TSMP Track 1 cut-off criterion of 5.0. The result of the bioconcentration study demonstrates little bioconcentration of chlorantraniliprole because the bioconcentration factor in whole fish was 13.
- Chlorantraniliprole does not form any major transformation products in the environment that meet the TSMP Track 1 criteria based on the studies submitted by the applicant. IN-EQW78 meets the criteria for persistence. Its toxicity can only be partially evaluated because the only organisms tested with these compounds were the rat, earthworm, mouse and *D. magna*. The assessment conducted for these organisms indicated that they are not at risk. No bioaccumulation information is available for IN-EQW78.

- Chlorantraniliprole (technical grade) does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.
- The formulated products, DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide, do not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

Therefore, the use of chlorantraniliprole is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

The toxicology database for chlorantraniliprole is adequate to define the majority of toxic effects that may result from human exposure to chlorantraniliprole. In subchronic and chronic studies with laboratory animals, effects were limited to reduced body-weight gain and food efficiency in rats and mice and liver toxicity in mice at doses exceeding the limit dose for toxicological testing. There was no evidence of carcinogenicity, immunotoxicity, neurotoxicity, or reproductive or developmental toxicity.

Mixers, loaders, applicators and workers entering treated fields and turf are not expected to be exposed to levels of chlorantraniliprole that will result in unacceptable risk when Altacor 35 WG Insecticide, Coragen 200 SC Insecticide or DPX-E2Y45 20 SC Insecticide is used according to label directions. The recommended personal protective equipment on the product label is adequate to protect chemical handlers.

The nature of the residues in plants (apple, tomato, lettuce, rice and cotton) and animals (hen and goat) is adequately understood. The residue definition for enforcement purposes is chlorantraniliprole. The use of chlorantraniliprole on crops listed on the labels and the import of chlorantraniliprole-treated commodities does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs to protect human health. The PMRA recommends that the following MRLs be specified for residues of chlorantraniliprole.

MRLs (ppm)	Foods
13	Leafy vegetables (Crop Group 4)
11	Leafy <i>Brassica</i> greens (Crop Subgroup 5B)
4	Head and stem <i>Brassica</i> vegetables (Crop Subgroup 5A)
2.5	Raisins
1.2	Small fruit vine climbing (Crop Subgroup 13-07F)
1	Stone fruits (Crop Group 12)
0.7	Fruiting vegetables (Crop Group 8)
0.3	Cottonseed; pome fruits (Crop Group 11)
0.25	Cucurbit vegetables (Crop Group 9)
0.01	Fat, meat and meat by-products of cattle, goat, horses and sheep; milk; potato

7.2 Environmental Risk

The use of DPX-E2Y45 20 SC Insecticide, Altacor 35 WG Insecticide and Coragen 200 SC Insecticide present a low risk to wild mammals, birds, earthworms, bees, terrestrial plants, fish, algae and aquatic plants. However, given that chlorantraniliprole is an insecticide, it poses a risk to beneficial arthropods other than bees. It is also expected to adversely affect freshwater and marine invertebrates and amphibians. Precautionary label statements appear on the product labels to identify and mitigate this risk. Buffer zones of 1 to 15 metres are required to protect sensitive non-target aquatic organisms.

7.3 Value

Sufficient efficacy data were provided to support Altacor 35 WG Insecticide for the control of a variety of insect pests in pome fruits, stone fruits and grapes. The lowest effective rate for pests has been established and is supported by efficacy data. However, confirmatory efficacy data are required to support peach twig borer on stone fruits. Coragen 200 SC Insecticide controls many insect pests in potatoes, fruiting vegetables, *Brassica* vegetables, leafy vegetables and in turf. The lowest effective rate for the pests on the Coragen 200 SC label has been established. The control of several insect pests in turf and the lowest effective rates can also be supported on the DPX-E2Y45 20 SC Insecticide label.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of the technical grade active ingredient Rynaxypr Technical Insecticide and the end-use products Altacor 35 WG Insecticide,

Coragen 200 SC Insecticide and DPX-E2Y45 20 SC Insecticide to control a variety of insect pests in several agricultural crops and turf.

An evaluation of current scientific data from the applicant and scientific reports has resulted in the determination that, under the approved conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been determined to be acceptable when all risk-reduction measures are followed, as a condition of these registrations, additional scientific information is being requested from the applicant as a result of this evaluation to ensure that chlorantraniliprole will control peach twig borer in stone fruits. For more details, refer to the Section 12 Notice associated with these conditional registrations. The applicant will be required to submit this information by 30 September 2009.

NOTE: The PMRA will publish a consultation document when a proposed decision is made on applications to convert these conditional registrations or on applications to renew the conditional registrations, whichever occurs first.

Value

Confirmatory efficacy data are required to support peach twig borer on stone fruits.

List of Abbreviations

µg	microgram(s)
µL	microlitre(s)
a.i.	active ingredient
AD	administered dose
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	BASF, Bayer, Ciba-Geigy and Hoechst
bw	body weight
BWI	body weight per individual
ca	circa (approximately)
CAS	Chemical Abstracts Service
cm	centimetre(s)
d	day(s)
DALA	day(s) after last application
DAT	day(s) after treatment
DFR	dislodgeable foliar residues
DNA	deoxyribonucleic acid
DT ₅₀	dissipation time 50% (the dose required to observe a 50% decline in the test population)
dw	dry weight
EC ₂₅	effective concentration on 25% of the population
EC ₅₀	effective concentration on 50% of the population
EEC	expected environmental concentration
F	female(s)
F ₁	first filial generation
FC	food consumption
FDA	<i>Food and Drugs Act</i>
g	gram(s)
GC-ECD	gas chromatography with electron capture detector
GIT	gastrointestinal tract
h	hours(s)
ha	hectare(s)
HAFT	highest average field trial
HDT	highest dose tested
HPLC	high performance liquid chromatography
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ind	individual
kg	kilogram(s)
km	kilometre(s)
K _{oc}	adsorption quotient normalized to organic carbon
K _{ow}	<i>n</i> -octanol–water partition coefficient
L	litre(s)

LC ₅₀	lethal concentration 50%
LC-MS	liquid chromatography with mass spectrometry
LD	lactation day
LD ₅₀	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOQ	limit of quantitation
LR ₅₀	lethal rate 50%
M	male(s)
m/z	mass-to-charge ratio of an ion
mg	milligram(s)
mL	millilitre(s)
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NAFTA	North American Free Trade Agreement
ND	not detected
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
P	parental generation
Pa	Pascal
PBI	plantback interval
PCPA	<i>Pest Control Products Act</i>
PHI	preharvest interval
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RD	residue definition
RQ	risk quotient
SC	soluble concentrate
SF	safety factor
t _{1/2}	half-life
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
US	United States
USEPA	United States Environmental Protection Agency
v/v	volume per volume dilution
WG	wettable granular
w/v	weight by volume concentration
w/w	weight by weight concentration

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Plant	DuPont-13291	Chlorantraniliprole	GC-ECD (gas chromatography with electron capture detector)	0.01 ppm	1365371
	DuPont-11374	Chlorantraniliprole	HPLC-MS/MS (high performance liquid chromatography with tandem mass spectrometry detection)	0.01 ppm	1332075
	DuPont-13294, Revision 1 Enforcement Method	Chlorantraniliprole	HPLC-MS/MS	0.01 ppm	1332078
	DuPont-14314	Chlorantraniliprole IN-EQW78 IN-ECD73 IN-F6L99	HPLC-MS/MS	0.01 ppm (processed commodities)	1332077
	DuPont-14314, Supplement No. 1	Chlorantraniliprole IN-EQW78 IN-ECD73 IN-F6L99	HPLC-MS/MS	0.01 ppm (oil processed commodities)	1365379
Animal	DuPont-11376	Chlorantraniliprole IN-EQW78 IN-K9T00 IN-HXH44 IN-GAZ70	HPLC-MS/MS	0.01 ppm	1332076
	DuPont-18100, Amendment 1 (Validation of DuPont-11376)	Chlorantraniliprole IN-EQW78 IN-K9T00 IN-HXH44 IN-GAZ70	HPLC-MS/MS	0.01 ppm	1365384
	DuPont-20978 (parent only summary of DuPont-11376) Enforcement Method	Chlorantraniliprole	HPLC-MS/MS	0.01 ppm	1365388
	DuPont-19533	Chlorantraniliprole	GC-ECD	0.01 ppm	1365387

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil	DuPont-10814 14819 14942	Chlorantraniliprole	LC/MS-MS 483–285 m/z	0.5 ppb (LC/MS-MS)	1332527 1332528 1365403
	DuPont-10814 14819		Metabolites	LC/MS-MS	10 ppb (GC-ECD) 1365405
Sediment	DuPont-18017	Chlorantraniliprole	LC/MS-MS 483–285 m/z	1.0 ppb	1365409
		Metabolites	LC/MS-MS		
Water	DuPont-16058 16708 14940	Chlorantraniliprole	LC/MS-MS 484–285.5 m/z	0.1 ppb (LC/MS-MS)	1365406 1364507 1365408
	DuPont-16058 16708		Metabolite	LC/MS-MS	10 ppb (GC-ECD) 0.1 ppb

Table 2 Acute Toxicity of Chlorantraniliprole (DPX-E2Y45), Its Associated End-Use Products (DPX-E2Y45 20 SC Insecticide, Coragen 200 SC Insecticide and Altacor 35 WG Insecticide) and Selected Impurities and Metabolites

Study Type	Species	Result	Comment	Reference
Acute Toxicity of Chlorantraniliprole				
Oral	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1332480
Dermal	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1332481
Inhalation	Rat	LC ₅₀ > 5.1 mg/L	Low toxicity	1332482
Skin irritation	Rabbit	MAS ^a = 0.0	Non-irritating	1332484
Eye irritation	Rabbit	MAS = 2.7	Minimally irritating	1332483
Skin sensitization (LLNA)	Mouse	Negative	Non-sensitizing	1332485
Skin sensitization (maximization)	Guinea pig	Negative	Non-sensitizing	1365431
Acute Toxicity of Chlorantraniliprole: DPX-E2Y45-282				

Study Type	Species	Result	Comment	Reference
Oral	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1365424
Skin irritation	Rabbit	MAS = 0.0	Non-irritating	1365428
Eye irritation	Rabbit	MAS = 0.0	Non-irritating	1365430
Acute Toxicity of End-Use Products: DPX-E2Y45 SC Insecticide and Coragen 200 SC Insecticide				
Oral	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1366024
Dermal	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1366025
Inhalation	Rat	LC ₅₀ > 2.0 mg/L	Low toxicity	1366027
Skin irritation	Rabbit	MAS = 0.0	Non-irritating	1366028
Eye irritation	Rabbit	MAS = 0.2	Minimally irritating	1366029
Skin sensitization (LLNA)	Mouse	Negative	Non-sensitizing	1366030
Acute Toxicity of End-Use Product: Altacor 35 WG Insecticide				
Oral	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1332062
Dermal	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1332063
Inhalation	Rat	LC ₅₀ > 6.2 mg/L	Low toxicity	1332065
Skin irritation	Rabbit	MAS = 0.0	Non-irritating	1332068
Eye irritation	Rabbit	MAS = 0.4	Minimally irritating	1332066
Skin sensitization (LLNA)	Mouse	Negative	Non-sensitizing	1332069
Acute Toxicity of Impurities/Metabolites				
Oral: IN-EQW78	Rat	LD ₅₀ > 2000 mg/kg bw	Low toxicity	1365505
Oral: IN-LBA24	Mouse	LD ₅₀ > 2000 mg/kg bw	Low toxicity	1365507
Oral: IN-ECD73	Mouse	LD ₅₀ > 2000 mg/kg bw	Low toxicity	1365509
Oral: IN-F6L99	Mouse	LD ₅₀ > 2000 mg/kg bw	Low toxicity	1365510
Oral: IN-G2S78	Rat	LD ₅₀ = 323.5 mg/kg bw	High toxicity	1444485
Dermal: IN-G2S78	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1444480
Inhalation: IN-G2S78	Rat	LC ₅₀ > 2.1 mg/L	Low toxicity	1444487
Skin irritation: IN-G2S78	Rabbit	MAS = 0.0	Non-irritating	1444478

Study Type	Species	Result	Comment	Reference
Eye irritation: IN-G2S78	Rabbit	MAS = 0.0	Non-irritating	1444483
Skin sensitization (LLNA): IN-G2S78	Mouse	Negative	Non-sensitizing	1444491
Oral: IN-E8S90	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1444473
Dermal: IN-E8S90	Rat	LD ₅₀ > 5000 mg/kg bw	Low toxicity	1444468
Skin irritation: IN-E8S90	Rabbit	MAS = 0.0	Non-irritating	1444466
Eye irritation: IN-E8S90	Rabbit	MAS = 0.4	Minimally irritating	1444470
Skin sensitization (LLNA): IN-E8S90	Mouse	Negative	Non-sensitizing	1444476

^a MAS = maximum average score for 24, 48 and 72 hours

Table 3 Toxicity Profile of Chlorantraniliprole

Study Type	Species	Results ^a	Reference
28-day dermal	Rat	<p>NOAEL: 300 mg/kg bw/day LOAEL: 1000 mg/kg bw/day, based on reduced body weight-gain and food efficiency.</p> <p>Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in males at 100 mg/kg bw/day and higher.</p>	1332499
14-day gavage	Rat	<p>NOAEL: 1000 mg/kg bw/day (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	1365422
28-day dietary	Rat	<p>NOAEL: 584/675 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p> <p>Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in males at 584 mg/kg bw/day (HDT).</p> <p>There was no effect on thyroid hormone levels.</p>	1365437 1365438

Study Type	Species	Results ^a	Reference
90-day dietary	Rat	<p>NOAEL: 1188/1526 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p> <p>Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in males at 1188 mg/kg bw/day (HDT).</p>	1332490 1332491 1332489 1365442
28-day dietary	Mouse	<p>NOAEL (M): 538 mg/kg bw/day LOAEL (M): 1443 mg/kg bw/day, based on reduced body-weight gain and food efficiency. NOAEL (F): 1524 mg/kg bw/day (HDT) LOAEL (F): not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	1365435
90-day dietary	Mouse	<p>NOAEL: 1135/1539 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	1332486 1332487 1332488
28-day capsule	Dog	<p>A NOAEL and LOAEL were not established as this was a dose range-finding study and was considered supplemental.</p> <p>Effects at 300 and 1000 mg/kg bw/day included induction of hepatic cytochrome P450 enzymes.</p>	1365433 1365434
28-day dietary	Dog	<p>A NOAEL and LOAEL were not established as this was a dose range-finding study and was considered supplemental.</p> <p>Concentration of chlorantraniliprole in the diet up to 40 000 ppm had no adverse effect on palatability or any evaluated toxicology parameters.</p>	1365436
90-day dietary	Dog	<p>NOAEL: 1162/1220 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	1332493 1332495 1332496 1459459
12-month dietary	Dog	<p>NOAEL: 1164/1233 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	1365450 1365451 1365452 1365453 1365454

Study Type	Species	Results ^a	Reference
Carcinogenicity (2-year dietary)	Rat	<p>NOAEL: 805/1076 mg/kg bw/day in M/F (HDT) LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p> <p>Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in males at 39 mg/kg bw/day and higher.</p> <p>There was no effect on basal urinary corticosterone levels. No changes to adrenal cortical cell organelles were apparent by electron microscopy.</p>	<p>1365462 1365463 1365464 1365465 1365466 1365467 1365468 1365469 1365470</p>
Carcinogenicity (18-month dietary)	Mouse	<p>NOAEL (M): 158 mg/kg bw/day NOAEL (F): 1155 mg/kg bw/day (HDT)</p> <p>LOAEL (M): 935 mg/kg bw/day, based on an increased incidence of eosinophilic foci of cellular alteration in the liver and hepatocellular hypertrophy. LOAEL (F): not established as no toxicologically significant effects were noted up to the highest dose tested.</p>	<p>1365471 1365472 1365473 1365474 1365475 1365476 1365477 1365478 1365479</p>
Two-generation reproduction	Rat	<p>Parental systemic NOAEL: 1199/1594 mg/kg bw/day in P generation M/F (HDT) Parental systemic LOAEL: not established as no toxicologically significant effects were noted up to the highest dose tested.</p> <p>Offspring systemic NOAEL: 238/318 mg/kg bw/day in P generation M/F Offspring systemic LOAEL: 1199/1954 mg/kg bw/day in P generation M/F, based on reduced body weights in F₁ offspring on LD 14 and 21.</p> <p>Reproductive NOAEL: 1199/1594 mg/kg bw/day in P generation M/F (HDT) Reproductive LOAEL: not established as no reproductive effects were noted up to the highest dose tested.</p> <p>Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in F₁ males at 18 mg/kg bw/day and higher, in P males at 60 mg/kg bw/day and higher, and in F₁ females at 2178 mg/kg bw/day (HDT).</p> <p>No changes to adrenal cortical cell organelles were apparent by electron microscopy.</p>	<p>1365481 1365485 1365487 1365489 1365491 1365493 1365495 1365498 1365500 1365483</p>

Study Type	Species	Results ^a	Reference
Developmental toxicity	Rat	Maternal NOAEL: 1000 mg/kg bw/day (HDT) Maternal LOAEL: not established as no treatment-related effects were noted up to the highest dose tested. Developmental NOAEL: 1000 mg/kg bw/day (HDT) Developmental LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1332511
Developmental toxicity	Rabbit	Maternal NOAEL: 1000 mg/kg bw/day (HDT) Maternal LOAEL: not established as no treatment-related effects were noted up to the highest dose tested. Developmental NOAEL: 1000 mg/kg bw/day (HDT) Developmental LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1332512
Acute neurotoxicity	Rat	NOAEL: 2000 mg/kg bw (HDT) LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1365503
Subchronic neurotoxicity	Rat	NOAEL: 1313/1586 mg/kg bw/day in M/F (HDT) LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1365504
Immunotoxicity	Rat	NOAEL: 1494/1601 mg/kg bw/day in M/F (HDT). LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1365416
Immunotoxicity	Mouse	NOAEL: 1144/1566 mg/kg bw/day in M/F (HDT) LOAEL: not established as no treatment-related effects were noted up to the highest dose tested.	1459460
28-day dermal (mechanistic study in male rats)	Rat	A NOAEL and LOAEL were not established as this was a non-guideline study and was considered supplemental. Increased microvesiculation in the <i>zona fasciculata</i> of the adrenal cortex was noted in males at 1000 mg/kg bw/day, the only dose tested. There was no effect on ACTH-stimulated serum corticosterone levels.	1332498
Reverse gene mutation assay	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1332513
Reverse gene mutation assay: Lot 282	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1365457

Study Type	Species	Results ^a	Reference
In vitro forward gene mutation	Chinese hamster ovary cells	Negative	1332515
In vitro mammalian chromosomal aberration	Human peripheral blood lymphocytes	Negative	1332516
In vitro mammalian chromosomal aberration: Lot 282	Human peripheral blood lymphocytes	Negative	1365459
In vivo mammalian cytogenetics	Mouse micronucleus assay	Negative	1332517
Reverse gene mutation assay: IN-EQW78	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1365508
Reverse gene mutation assay: IN-LBA24	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1365506
Reverse gene mutation assay: IN-ECD73	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1365511
Reverse gene mutation assay: IN-F6L99	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1365512
Reverse gene mutation assay: IN-E8S90	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1444475
Reverse gene mutation assay: IN-G2S78	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative	1444488
Structure activity relationship (DEREK): IN-KVW95	N/A	DEREK analysis identified an aromatic amine alert: carcinogenicity in humans or mammals is plausible. Molecule largely composed of parent compound; based on this similarity to the parent and the lack of genotoxicity and carcinogenicity of the parent, the carcinogenicity of this compound would likely be negative.	1444499
Structure activity relationship (DEREK): IN-E8S90	N/A	No relevant structural alerts	1444493

Study Type	Species	Results ^a	Reference
Structure activity relationship (DEREK): IN-LEU00	N/A	No relevant structural alerts	1444501
Structure activity relationship (DEREK): IN-G2S78	N/A	DEREK analysis identified an aromatic amide alert: carcinogenicity in humans or mammals is plausible. The alert is based on the proposition that aromatic amides can be hydroxylated resulting in a hydroxylamino group, which may be further activated to bind with DNA. However, the amide group in IN-G2S78 results in significant steric hindrance such that hydroxylation of the amine either does not occur or occurs very slowly.	1444495
Metabolism	Rat	<p>Absorption Absorption from the gastrointestinal tract was approximately 73–85% at the low dose and 12–13% at the high dose. Absorption was rapid with a maximum plasma concentration at 5–12 hours.</p> <p>Distribution Tissue burdens were minimal with the gastrointestinal tract exhibiting the highest concentration. Females showed higher tissue retentions than males. The low tissue burdens indicated low potential for accumulation.</p> <p>Excretion Fecal excretion was the primary route of elimination, and was greater at the low dose compared to the high dose. Urinary excretion was higher in males compared to females. The majority of chlorantraniliprole is eliminated within 48–72 hours. Excretion via expired air was negligible (<0.1).</p> <p>Metabolism Unmetabolized chlorantraniliprole was present in excreta at 5–7% at the low dose and 79–86% at the high dose. Significant sex differences were noted in the metabolic profile. The primary metabolite in females was IN-H2H20 (resulting from N-methyl carbon hydroxylation), while the primary metabolite in males was IN-HXH44 (resulting from methylphenyl monohydroxylation). The metabolite IN-KAA24 (a carboxylic acid metabolite of IN-HXH44) was found only in males.</p>	1332518 1365415

^a Effects observed in males as well as females unless otherwise reported

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

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	UF/SF or Target MOE	Reference
Acute dietary	Not required as no endpoint of concern attributable to a single dose was identified.				
Chronic dietary, all populations	NOAEL = 158	18-month dietary study in the mouse	Increased liver weight, hepatocellular hypertrophy and increased incidence of eosinophilic foci cellular alteration in the liver.	100	1365471 to 1365479
ADI = 1.58 mg/kg bw/day					
Short- and intermediate-term dermal and inhalation	Not required as no endpoint of concern following short- to intermediate-term exposure was identified.				

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN APPLE		PMRA #1332524
Radiolabel Position	[Benzamide Carbonyl- ¹⁴ C]	[Pyrazole Carbonyl- ¹⁴ C]
Test site	Temperature-controlled glasshouses in Scotland.	
Treatment	Three 100 g a.i./ha foliar overhead applications per radiolabelled form: (1) when fruit had reached 10% of final size (early fruiting stage; BBCH 71); (2) when fruit had reached 50% of final size (mid-fruit size; BBCH 75); and (3) at 30 days prior to maturity.	
Total rate	300 g a.i./ha	300 g a.i./ha
End-use product	Formulated as a soluble concentrate (SC formulation)	
Preharvest interval	Immature apple leaves and fruit samples were taken immediately after the first application, before and after the second and third (final) applications and 15 days after the third application. The final (maturity) harvest was taken 30 days after the last application (PHI of 15 and 30 days).	
<p>For both labels, the majority of the total radioactive residues (TRRs) were in the surface wash. TRRs were determined by summing the radioactivity in the surface washes, pulverized tissue extracts and unextracted residues. The TRRs in apple leaves ranged from 2.603 to 14.733 ppm and from 3.723 to 9.729 ppm for the BC-labelled and PC-labelled chlorantraniliprole, respectively. The TRRs in apple fruits ranged from 0.088 to 0.672 ppm and from 0.032 to 0.626 ppm for the BC-labelled and PC-labelled chlorantraniliprole, respectively. Residues were extractable with acetonitrile and acetonitrile/water (1:1, v/v).</p> <p>Chlorantraniliprole was not metabolized in apple to any significant extent and dissipated mainly due to growth dilution. No metabolites were formed in any significant amount (<1.7% of the TRRs, <0.004 ppm). The metabolism of chlorantraniliprole in apples is well understood.</p>		

Metabolites Identified	Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position	[BC- ¹⁴ C]	[PC- ¹⁴ C]	[BC- ¹⁴ C]	[PC- ¹⁴ C]
Apple leaves	Chlorantraniliprole	Chlorantraniliprole	None	None
Apple fruits	Chlorantraniliprole	Chlorantraniliprole	None	None
NATURE OF THE RESIDUE IN TOMATO			PMRA #1332523	
Radiolabel Position	Mixture of [Benzamide Carbonyl- ¹⁴ C] and [Pyrazole Carbonyl- ¹⁴ C] in a 1:1 Ratio			
Test site	Glasshouses in Scotland.			
Treatment	Three 100 g a.i./ha foliar over-the-top applications of the two radiolabelled forms combined in a 1:1 ratio. The first application was made to <i>ca.</i> 9-week-old tomato plants with subsequent applications approximately 25 days apart.			
Total rate	300 g a.i./ha			
End-use product	Formulated as a soluble concentrate (SC formulation)			
Preharvest interval	Immature treated tomato leaf and fruit samples were taken immediately after the first application, before and after the second and third (final) applications, and 7 days after the third application. Final (maturity) harvest was 15 days after the last application (PHI of 7 and 15 days).			
<p>For both labels, the majority of the total radioactive residues (TRRs) were in the surface wash. TRRs were determined by summing the radioactivity in the surface washes, pulverized tissue extracts and unextracted residues. The TRRs in tomato leaves ranged from 0.926 to 2.451 ppm. The TRRs in tomato fruits ranged from 0.001 to 0.073 ppm. Residues were extractable with acetonitrile and acetonitrile/water (1:1, v/v).</p> <p>Chlorantraniliprole was not metabolized in either tomato leaves or fruits. No metabolites were formed in any significant amounts (<1.9% of the TRRs, <0.008 ppm). The metabolism of chlorantraniliprole in tomatoes is well understood.</p>				
Metabolites Identified	Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position	[BC- ¹⁴ C]:[PC- ¹⁴ C]		[BC- ¹⁴ C]:[PC- ¹⁴ C]	
Tomato leaves	Chlorantraniliprole		None	
Tomato fruits	Chlorantraniliprole		None	
NATURE OF THE RESIDUE IN LETTUCE			PMRA #1332525	
Radiolabel Position	Mixture of [Benzamide Carbonyl- ¹⁴ C] and [Pyrazole Carbonyl- ¹⁴ C] in a 1:1 Ratio			
Test site	Outside plots in Scotland.			
Treatment	Three 100 g a.i./ha foliar over-the-top applications of the two radiolabelled forms combined in a 1:1 ratio. The first application was made to 4- to 5-week-old lettuce plants (3 leaves unfolded; BBCH 13), subsequent applications (both at BBCH 19) were approximately 10 days apart.			
Total rate	300 g a.i./ha			

End-use product	Formulated as a soluble concentrate (SC formulation)	
Preharvest interval	Immature treated lettuce foliage samples (whole plants) were taken immediately after the first application, before and after the second and third (final) applications, and 7 days after the third application. Final (maturity) harvest was 15 days after the last application (PHI of 7 and 15 days).	
<p>For both labels, the majority of the total radioactive residues (TRRs) were in the surface wash. TRRs were determined by summing the radioactivity in the surface washes, pulverized tissue extracts and unextracted residues. The TRRs in lettuce leaves ranged from 0.088 to 2.860 ppm. Residues were extractable with acetonitrile and acetonitrile/water (1:1, v/v).</p> <p>Chlorantraniliprole was not metabolized in lettuce to any significant extent and dissipated mainly due to growth dilution. No metabolites were formed in any significant amounts (<1.7% of the TRRs, <0.004 ppm). The metabolism of chlorantraniliprole in lettuce is well understood.</p>		
Metabolites Identified	Major Metabolites (>10% TRRs)	Minor Metabolites (<10% TRRs)
Radiolabel Position	[BC-¹⁴C]:[PC-¹⁴C]	[BC-¹⁴C]:[PC-¹⁴C]
Lettuce	Chlorantraniliprole	None
NATURE OF THE RESIDUE IN RICE		PMRA #1365521
Radiolabel Position	Mixture of [Benzamide Carbonyl-¹⁴C] and [Pyrazole Carbonyl-¹⁴C] in a 1:1 Ratio	
Test site	In containers kept outdoors in a protective enclosure constructed of wire mesh and netting in Spain.	
Treatment	One soil drench application (applied evenly to the soil surface) around rice seedlings (16 days old; BBCH 11 to 12; 1–2 leaves unfolded) of a simulated 20 SC formulation containing the two radiolabelled forms combined in a 1:1 ratio. The soil was flooded (3 cm depth) two days after treatment until four days prior to crop maturity (BBCH 87; grain at hard dough) to allow the crop to dry.	
Total rate	300 g a.i./ha	
End-use product	20 SC formulation	
Preharvest interval	<p>Immature whole rice plants (separated into leaf, sheath and root fractions) were sampled at 14, 28 and 56 days after treatment (DAT). Whole rice plants were also collected at crop maturity (132 DAT) and were separated into leaf, sheath, hulls and grain (with bran).</p> <p>Soil, water and sediment samples were collected for analysis on the day of application (soil) and at 14, 28, 56 and 128 DAT (water and sediment).</p>	
<p>Rice plants: TRRs, expressed as chlorantraniliprole equivalents on a fresh weight basis in samples taken 14 DAT, were 0.338, 0.174 and 0.065 ppm, respectively, for leaves, sheaths and roots. At 56 DAT, TRRs in leaves, sheaths and roots were 1.269, 0.081 and 0.207 ppm, respectively. Corresponding values at maturity were 4.056, 0.133 and 0.279 ppm. TRRs in hulls and grain were 0.174 and 0.155 ppm, respectively.</p> <p>The TRRs in immature foliage and straw were calculated as a sum of the total radioactivity determined in the leaf blades and sheaths with respect to the combined weight of these tissues. The TRRs in immature foliage at 14 DAT and 56 DAT were 0.219 and 0.399 ppm, respectively. TRR in straw at final harvest was 0.903 ppm.</p> <p>Soil, water and sediment: The TRR in soil sampled on the day of application (0 DAT) was 0.404 ppm. The TRR declined after flooding (2 DAT) and concentrations of 0.208, 0.154 and 0.040 ppm were measured in sediment at 14, 56 and 128 DAT, respectively. The unextracted residues increased with time, accounted for <1.0, 3.3, 6.9 and 16.0% TRRs at 0, 14, 56 and 128 DAT, respectively. Surface water at 14, 28, 56 and 128 DAT contained 0.053, 0.084, 0.004 and 0.004 ppm chlorantraniliprole equivalents, respectively.</p>		

Chlorantraniliprole was the major component in all matrices at all sampling intervals. No major metabolites were detected in any tissue at any sampling time. Numerous minor metabolites were observed in each of the various tissues sampled; none exceeded 6% of the TRRs at harvest.

Metabolism of Chlorantraniliprole in Rice

The metabolism of chlorantraniliprole in rice grown under flooded conditions was complex with the formation of many metabolites present at low levels in the different plant and soil matrices. This complex metabolic pathway in rice is attributed to the uptake of the sediment/soil degradates during the maturation of the rice plant. Chlorantraniliprole is either metabolized in the sediment and taken up by the root, or in part metabolized in the rice plants. The proposed metabolic pathways for chlorantraniliprole in rice are presented in Figure 1. Although numerous metabolites were observed at low levels in the rice matrices, the major residue in all the rice fractions was chlorantraniliprole.

Sediment: Chlorantraniliprole was the primary residue. Low levels of IN-EQW78, IN-GAZ70, IN-F9N04 and IN-F6L99 were detected in the majority of the samples and IN-DBC80, IN-E5F18, IN-HXH44 and IN-H2H20 in some samples. Cyclization with loss of a water molecule from chlorantraniliprole resulted in the quinazolinone derivative, IN-EQW78. Hydroxylation of the N-methyl group of chlorantraniliprole led to IN-H2H20. Condensation with loss of -CH₂OH from the amide nitrogen of IN-H2H20 gave IN-GAZ70. The direct loss of -CH₂OH from IN-H2H20 resulted in IN-F9N04. Small amounts of IN-F6L99, IN-E5F18 and IN-DBC80 were detected, indicating limited amide hydrolysis of the carboxamide linkage between the phenyl and heterocycle rings accompanied by cleavage of the pyrazole and pyridine rings.

Rice plants: Chlorantraniliprole was the primary residue in all plant parts at all sampling intervals. There were no major metabolites in rice leaves, straw, hulls, or grain at any sampling interval. There was evidence of the formation of many minor metabolites.

Chlorantraniliprole was metabolized in rice primarily through three pathways:

- (1) hydroxylation of the N-methyl group to IN-H2H20 or hydroxylation of the methyl-phenyl carbon to yield IN-HXH44;
- (2) condensation with the loss of water from chlorantraniliprole to yield a quinazolinone derivative, IN-EQW78; and similar condensation of IN-H2H20 with an additional loss of -CH₂OH giving rise to IN-GAZ70; and
- (3) further metabolism such as N-demethylation of the hydroxymethylamide group in IN-H2H20 to IN-F9N04. The amidic bridge cleavage between the phenyl and heterocyclic rings was a minor pathway yielding IN-L8F56 and IN-DBC80, with further metabolism forming small amounts of IN-F6L99.

The metabolism of chlorantraniliprole in rice is well understood.

Metabolites Identified	Major Metabolites (>10% TRRs)	Minor Metabolites (<10% TRRs)	
Radiolabel Position	[BC- ¹⁴ C]:[PC- ¹⁴ C]	[BC- ¹⁴ C]:[PC- ¹⁴ C]	
14 DAT leaves	Chlorantraniliprole	IN-HXH44 IN-DBC80 IN-F6L99	IN-HXH40 IN-L8F56 IN-EQW78
56 DAT leaves	Chlorantraniliprole	IN-HXH40 IN-F9N04 IN-H2H20 IN-F6L99 IN-EQW78	IN-GAZ70 IN-K7H29 IN-KAA24 IN-K9T00
Mature leaves (132 DAT)	Chlorantraniliprole	IN-HXH40 IN-F9N04 IN-H2H20 IN-F6L99 IN-DBC80 IN-E5F18	IN-KAA24 IN-EQW78 IN-GAZ70 IN-HXH44 IN-L8F56
14 DAT sheaths	Chlorantraniliprole	IN-F6L99/IN-EVK64 IN-K9X71/IN-F6L99 IN-HXH40	IN-GAZ70 IN-EQW78 IN-DBC80

56 DAT sheaths	Chlorantraniliprole	IN-F6L99 IN-L8F56 IN-K9T00/IN-HXH40	IN-F9N04 IN-EQW78 IN-GAZ70
Mature sheaths (132 DAT)	Chlorantraniliprole	IN-F6L99 IN-HXH40/IN-DBC80	IN-KAA24 IN-EQW78
Mature grain with bran (132 DAT)	Chlorantraniliprole	IN-F6L99 IN-L8F56	IN-KAA24 IN-EQW78
Mature straw (132 DAT)	Chlorantraniliprole	IN-HXH40 IN-F9N04 IN-H2H20 IN-KAA24 IN-DBC80 IN-L8F56	IN-GAZ70 IN-EQW78 IN-F6L99 IN-HXH44 IN-E5F18
Mature hulls (132 DAT)	Chlorantraniliprole	IN-HXH40	IN-DBC80
0 DAT soil	Chlorantraniliprole	IN-F6L99 IN-EQW78	IN-GAZ70
14 DAT sediment	Chlorantraniliprole	IN-F6L99 IN-F9N04	IN-GAZ70 IN-EQW78
56 DAT sediment	Chlorantraniliprole	IN-DBC80 IN-HXH44 IN-H2H20	IN-GAZ70 IN-EQW78 IN-F9N04
128 DAT sediment	Chlorantraniliprole	IN-E5F18 IN-F9N04	IN-EQW78 IN-GAZ70
NATURE OF THE RESIDUE IN COTTON		PMRA #1365520	
Radiolabel Position	[Benzamide Carbonyl-¹⁴C] and/or [Pyrazole Carbonyl-¹⁴C]		
Test site	Field and greenhouse in Delaware.		
Treatment, rate and end-use product	<p>(1) Excised plant study: 18-day-old cotton seedlings were incubated for 4 days in uptake solution (~50 ppm) containing either [BC-¹⁴C] or [PC-¹⁴C] chlorantraniliprole.</p> <p>(2) Surfactant treatment study: 41-day-old cotton plants were treated with a single foliar (over the top) application at 150 g a.i./ha with a primarily aqueous solution of either [BC-¹⁴C] or [PC-¹⁴C] chlorantraniliprole containing a non-ionic surfactant (0.5% Agridex).</p> <p>(3) 20 SC formulation study: 57-day-old cotton plants were treated with a single foliar application at 150 g a.i./ha of a simulated 20 SC formulation (primarily aqueous solution containing inert ingredients) of [BC-¹⁴C] chlorantraniliprole.</p>		
Preharvest interval	Surfactant treatment study:	Immature samples were taken 8 (foliage), 15 (foliage), 22 (foliage) and 86 (foliage, hulls, undelinted seed) days after treatment. Mature samples were taken 126 days after treatment (foliage with hulls, lint, undelinted seed).	
	20 SC formulation study:	Plants were not grown to maturity. Immature foliage samples were collected 8, 21 and 48 days after treatment.	

TRRs in excised plants were 84.44 ppm (BC label) and 39.34 ppm (PC label). TRR levels in plants treated with solutions containing surfactant declined from 2.20 to 0.06 ppm (BC label) and from 1.80 to 0.06 ppm (PC label) in cotton foliage. TRRs in immature cotton undelinted seeds (Day 86) were 0.01 ppm and in mature cottonseed and lint (Day 126) were <0.01 ppm. TRR levels in immature foliage from plants treated with the 20 SC formulation were 0.66 ppm (Day 8), 3.68 ppm (Day 22) and 1.45 ppm (Day 48).

Residues were extractable with acetonitrile/water. Chlorantraniliprole was the only quantifiable residue in cotton samples (foliage, hulls and seed) at all sampling intervals regardless of the treatment regimen. Minor components present in immature cotton foliage included IN-EQW78 and IN-GAZ70 ($\leq 2\%$ of the TRRs; ≤ 0.02 ppm) and polar metabolites ($\leq 12\%$ of the TRRs; ≤ 0.05 ppm).

Chlorantraniliprole was not metabolized to an appreciable extent in cotton foliage, hulls or undelinted seed. Therefore, a metabolic pathway was not proposed. There was no apparent transfer of residues to the cottonseed. Metabolism of chlorantraniliprole in the cotton plant was not significant. The metabolism of chlorantraniliprole in cotton is well understood.

Metabolites Identified		Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position		[BC- ¹⁴ C]	[PC- ¹⁴ C]	[BC- ¹⁴ C]	[PC- ¹⁴ C]
Cotton samples (foliage, hulls and seed) at all sampling intervals regardless of the treatment regimen		Chlorantraniliprole	Chlorantraniliprole	Foliage only IN-EQW78 IN-GAZ70	Foliage only IN-EQW78 IN-GAZ70
CONFINED ROTATIONAL CROP STUDY USING RED BEET, LETTUCE AND SPRING WHEAT				PMRA #1332083	
Radiolabel Position		[Benzamide Carbonyl- ¹⁴ C]		[Pyrazole Carbonyl- ¹⁴ C]	
Test site		Temperature-controlled glasshouses in Scotland.			
Application rate and timing		Crops were planted at 30 days after a 300 g a.i./ha treatment to soil with [benzamide carbonyl- ¹⁴ C]		Crops were planted 0, 30, 120 and 365 days after a 300 g a.i./ha treatment to soil with [pyrazole carbonyl- ¹⁴ C]. Spring wheat was also sown at 0 and 365 days after soil treatment with [PC- ¹⁴ C] at an elevated rate of 900 g a.i./ha as an aid to metabolite and soil degradate identification.	
Metabolites Identified		Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
MATRIX	Plantback Interval (days)	[BC- ¹⁴ C]	[PC- ¹⁴ C]	[BC- ¹⁴ C]	[PC- ¹⁴ C]
Soil (0–15 cm)	0	—	Chlorantraniliprole	—	IN-F6L99
	30	—	Chlorantraniliprole	—	IN-F9N04
	108	—	Chlorantraniliprole	—	IN-F9N04 IN-EQW78
	165	—	Chlorantraniliprole	—	IN-F9N04
	120	—	Chlorantraniliprole	—	IN-F9N04 IN-EQW78

	249	—	Chlorantraniliprole IN-EQW78	—	IN-F9N04
	365	—	Chlorantraniliprole	—	IN-F9N04 IN-EQW78
	479	—	Chlorantraniliprole	—	IN-F9N04 IN-EQW78 IN-F6L99 IN-HXH40 IN-KAA24 IN-LEM10 IN-GAZ70
Wheat forage	0	—	Chlorantraniliprole	—	None
	30	Chlorantraniliprole	Chlorantraniliprole	IN-F9N04 IN-EQW78 IN-L8F56 IN-HXH44 IN-KAA24 IN-K7H29 IN-GAZ70	IN-F9N04 IN-EQW78 IN-HXH40/IN-HXH44 IN-KAA24 IN-K7H29 IN-GAZ70
	120	—	Chlorantraniliprole	—	IN-F6L99 IN-KAA24 IN-HXH40 IN-HXH44 IN-F9N04 IN-EQW78 IN-GAZ70
	365	—	Chlorantraniliprole	—	IN-F9N04 IN-EQW78 IN-GAZ70 IN-KAA24 IN-HXH44 IN-F9N04
Wheat hay	0	—	Chlorantraniliprole	—	IN-HXH40 IN-HXH44 IN-F9N04 IN-EQW78 IN-GAZ70 IN-K7H29
	30	Chlorantraniliprole	Chlorantraniliprole	IN-HXH44 IN-F9N04 IN-EQW78 IN-GAZ70 IN-H2H20 IN-L8F56	IN-HXH44 IN-F9N04 IN-EQW78 IN-GAZ70 IN-H2H20 IN-F6L99
	120	—	Chlorantraniliprole	—	IN-HXH44 IN-F9N04 IN-EQW78 IN-GAZ70 IN-HXH40 IN-F6L99 IN-KAA24

	365	—	Chlorantraniliprole	—	IN-F9N04 N-F6L99
Wheat straw	0	—	Chlorantraniliprole	—	IN-HXH44 IN-KAA24 IN-H2H20 IN-EQW78 IN-GAZ70 IN-K7H29
	30	Chlorantraniliprole	Chlorantraniliprole	IN-HXH40 IN-HXH44 IN-KAA24 IN-H2H20 IN-EQW78 IN-GAZ70 IN-K7H29 IN-F9N04	IN-F6L99 IN-HXH40/IN-HXH44 IN-H2H20 IN-EQW78 IN-GAZ70 IN-F9N04
	120	—	Chlorantraniliprole	—	IN-F6L99 IN-HXH44 IN-KAA24 IN-EQW78 IN-GAZ70 IN-K7H29 IN-F9N04
	365	—	Chlorantraniliprole	—	IN-F6L99 IN-HXH44 IN-EQW78 IN-K7H29 IN-F9N04
	120	—	Chlorantraniliprole	—	None
Wheat grain	120	—	Chlorantraniliprole	—	None
Red beet foliage (TRRs in red beet root were <0.01 ppm, warranting no characterization)	0	—	None	—	Chlorantraniliprole IN-H2H20 IN-F9N04 IN-EVK64 IN-HXH44
	30	Chlorantraniliprole IN-K9X71	None	IN-HXH40 IN-HXH44 IN-KAA24 IN-K7H29 IN-F9N04 IN-GAZ70	Chlorantraniliprole IN-EVK64 IN-HXH40 IN-HXH44 IN-KAA24 IN-F9N04
	120	—	None	—	IN-HXH40 IN-F9N04

	365	—	None	—	Chlorantraniliprole IN-F6L99/IN-EVK64 IN-HXH40 IN-HXH44 IN-KAA24 IN-F9N04 IN-H2H20 IN-LEM10 IN-GAZ70
Lettuce	0	—	Chlorantraniliprole	—	IN-GAZ70
	30	Chlorantraniliprole	Chlorantraniliprole	IN-GAZ70	IN-GAZ70 IN-F9N04 IN-F6L99
	120	—	Chlorantraniliprole	—	IN-GAZ70 IN-F9N04
	365	—	Chlorantraniliprole	—	IN-GAZ70 IN-F9N04
CONFINED ROTATIONAL CROP STUDY USING RADISH, SOYBEANS AND WHEAT				PMRA #1365573	
Radiolabel Position		[Benzamide Carbonyl-¹⁴C]		[Pyrazole Carbonyl-¹⁴C]	
Test site		Soil aging was conducted in the greenhouse for 1 week (due to rain) and in the field (3 weeks) in Delaware. Crops were grown to maturity in the greenhouse.			
Application rate and timing		Seeds of each crop were sown into a sandy loam soil 30 days after a single 150 g a.i./ha treatment to soil with a primarily aqueous solution of [PC- ¹⁴ C] or [BC- ¹⁴ C] containing 0.5% Agridex surfactant.			
Metabolites Identified		Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
MATRIX	Plantback Interval (days)	[BC-¹⁴C]	[PC-¹⁴C]	[BC-¹⁴C]	[PC-¹⁴C]
Radish foliage	30	—	Chlorantraniliprole	—	IN-EQW78 IN-F9N04
Radish root	30	—	Chlorantraniliprole	—	IN-EQW78 IN-F9N04
Wheat straw	30	Chlorantraniliprole	—	IN-EQW78 IN-F9N04 IN-GAZ70	—
Wheat chaff	30	Chlorantraniliprole	—	IN-EQW78	—
Wheat grain	30	Chlorantraniliprole	—	None	—
Soybean foliage	30	Chlorantraniliprole	Chlorantraniliprole	IN-EQW78 IN-F9N04 IN-GAZ70	IN-EQW78 IN-F9N04 IN-GAZ70

Chlorantraniliprole was the only significant radiolabelled component found in soil samples. Other soil components (e.g. IN-F9N04 and IN-EQW78) were present at trace levels. Chlorantraniliprole was also the only predominant residue in both food and feed items from rotated crops (wheat, beet, radish, lettuce and soybeans) at a 30-day PBI when soil was treated at 150 g a.i./ha.

The uptake, translocation and metabolic fate of chlorantraniliprole were investigated in rotational crops and are considered to be well understood.

The metabolic pathways of chlorantraniliprole in rotational crops (secondary) proceeded via similar processes as that in the primary crops.

The results from the confined accumulation studies **triggered** the need for field accumulation studies.

The residue definition (RD) in rotational crops (secondary crops) is chlorantraniliprole.

NATURE OF THE RESIDUE IN LAYING HEN

PMRA #1365522

Five laying hens (ISA brown; 1.59–1.89 kg) were administered a single daily oral dose for 14 consecutive days at an average dose of 10.311 mg/kg (1:1 ratio of Benzamide carbonyl-¹⁴C and Pyrazole carbonyl-¹⁴C chlorantraniliprole) of feed. The hens were sacrificed ~23 hours after the final dose was administered.

Greater than 98% of the administered dose (AD) was eliminated by the hens, primarily in the excreta. An additional 5% AD was recovered in cage wash. Eggs and edible tissues contained *ca* 3% AD. The highest concentration of radioactivity in tissues was observed in the liver (0.515 ppm). TRRs in muscle, abdominal fat and skin with fat were 0.022, 0.035 and 0.052 ppm, respectively. The TRRs in egg white and yolk reached a plateau after 120 h (5 days; 1.327 ppm or 2.96% AD) and 192 h (8 days; 0.557 ppm or 0.38% AD), respectively, after the first dose.

Chlorantraniliprole and the metabolites were identified by HPLC through co-chromatography with reference standards and were confirmed in selected samples by LC-MS.

The metabolism of chlorantraniliprole in hens is well understood. See below for the description and flow chart (Figure 1) depicting the metabolic pathways.

Matrices	Mixture of [Benzamide Carbonyl- ¹⁴ C] and [Pyrazole Carbonyl- ¹⁴ C] in a 1:1 Ratio	
	TRRs (µg/g)	% of Administered Dose (%AD)
Excreta	Not reported	98.48
Egg white	Not reported	2.96
Egg yolk	Not reported	0.38
Liver	0.515	0.10
Muscle	0.022	0.02
Abdominal fat	0.035	0.01
Skin with fat	0.052	0.01
Cage wash	Not reported	5.00
Total recovery	Not reported	106.96

Metabolites Identified	Major Metabolites (>10% TRRs)	Minor Metabolites (<10% TRRs)	
Radiolabel Position	[BC- ¹⁴ C]:[PC- ¹⁴ C]	[BC- ¹⁴ C]:[PC- ¹⁴ C]	
Excreta	Chlorantraniliprole	IN-K7H29 IN-H2H20 IN-HXH44 IN-F9N04	IN-GAZ70 IN-DBC80 IN-HXH40 IN-GKQ52
Liver	None	Chlorantraniliprole IN-K9X71 IN-K7H29 IN-H2H20 IN-HXH44 IN-KAA24	IN-DBC80 IN-L8F56 IN-HXH40 IN-GKQ52 IN-F9N04
Muscle	None	Chlorantraniliprole IN-EQW78 IN-K7H29 IN-HXH44	IN-L8F56 IN-HXH40 IN-K3X21
Skin with fat	Chlorantraniliprole	IN-GAZ70 IN-EQW78 IN-K7H29	IN-HXH40 IN-K3X21
Egg white (Days 5–8)	Chlorantraniliprole (0.409 ppm; 31.6% TRRs) IN-GAZ70 (0.421 ppm; 32.6% TRRs)	IN-K7H29 IN-H2H20 IN-HXH44 IN-F9N04	IN-EQW78 IN-K3X21 IN-DBC80
Egg white (Days 9–14)	Chlorantraniliprole (0.355 ppm; 26.2% TRRs) IN-GAZ70 (0.548 ppm; 40.4% TRRs)	IN-K7H29 IN-F9N04	IN-EQW78
Egg yolk (Days 5–8)	Chlorantraniliprole (0.106 ppm; 22.7% TRRs) IN-K7H29 (0.112 ppm; 24.0% TRRs) IN-H2H20 (0.078 ppm; 16.6% TRRs)	IN-GAZ70	
Egg yolk (Days 9–14)	Chlorantraniliprole (0.059 ppm; 11.9% TRRs) IN-K7H29 (0.066 ppm; 13.1% TRRs) IN-H2H20 (0.054 ppm; 10.8% TRRs)	IN-HXH44 IN-DBC80 IN-K3X21 IN-EQW78	IN-GKQ52 IN-KAA24 IN-L8F56 IN-GAZ70
NATURE OF THE RESIDUE IN LACTATING GOAT		PMRA #1332521	
<p>One lactating goat (British Saanen variety; 15-month-old; ~40 kg) was administered a single daily dose for 7 consecutive days at levels of 10 mg/kg (1:1 ratio of Benzamide carbonyl-¹⁴C and Pyrazole carbonyl-¹⁴C chlorantraniliprole) of feed. The goat was sacrificed 23 hours after the final dose was administered.</p> <p>Greater than 94% of the administered dose (AD) was eliminated by the goat, primarily in the excreta (including GIT contents with cage wash accounting for 3.91% AD). Milk and edible tissues contained <i>ca</i> 1% AD. The highest concentration of radioactivity in tissues was observed in liver (0.640 ppm). TRRs in the other tissues were low (0.02–0.09 ppm). The predominant residue in tissues was chlorantraniliprole.</p> <p>The TRRs in milk reached a maximum level on Day 3 at 0.081 ppm and then decreased to 0.047 ppm by Day 7. The predominant residues in milk (1- to 7-day composite sample) were chlorantraniliprole (23.58% of the TRRs; 0.016 ppm), IN-K9T00 (26.10% of the TRRs; 0.017 ppm) and IN-HXH44 (26.92% of the TRRs; 0.018 ppm).</p> <p>Chlorantraniliprole and the metabolites were identified by HPLC through co-chromatography with reference standards and were confirmed in selected samples by LC-MS.</p>			

The metabolism of chlorantraniliprole in goats is well understood. See below for the description and the flow chart (Figure 1) depicting the metabolic pathways.

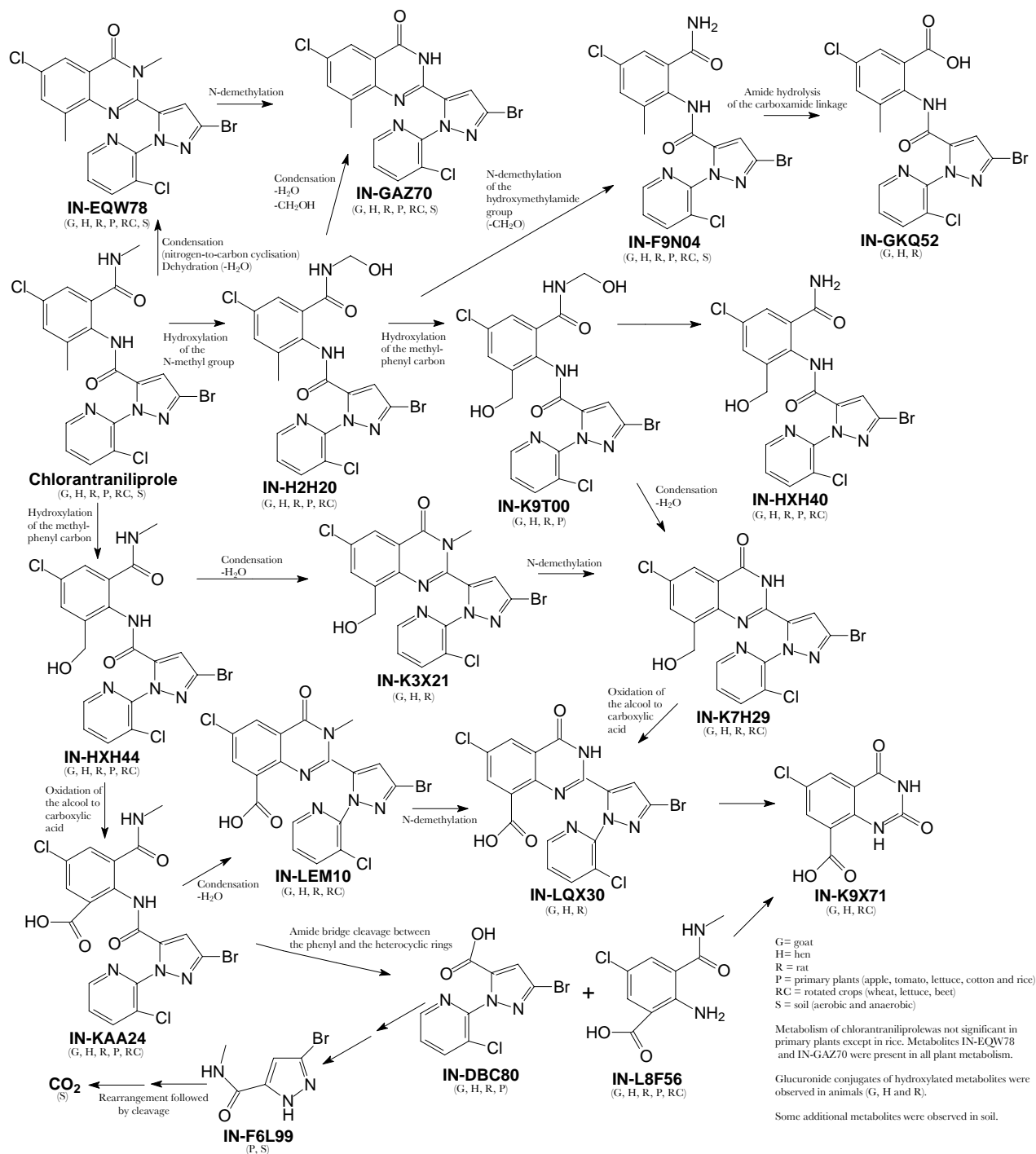
Matrices	Mixture of [Benzamide Carbonyl- ¹⁴ C] and [Pyrazole Carbonyl- ¹⁴ C] in a 1:1 Ratio	
	TRRs (µg/g)	% of Administered Dose (%AD)
Feces	Not reported	78.93
Urine	Not reported	10.73
Cage wash	Not reported	3.91
Bile	2.406	0.07
Milk*	0.067	0.79
Liver	0.640	0.45
Kidney	0.090	0.01
Muscle	0.017	Not reported
Omental fat	0.070	Not reported
Renal fat	0.067	Not reported
Subcutaneous fat	0.068	Not reported
Total	Not reported	94.89

* TRRs correspond to concentration determined for the Day 1–7 composite sample. The % AD value corresponds to the total recovery of radioactivity from milk collected over the entire study period.

Metabolites Identified	Major Metabolites (>10% TRRs)	Minor Metabolites (<10% TRRs)	
Radiolabel Position	[BC- ¹⁴ C]:[PC- ¹⁴ C]	[BC- ¹⁴ C]:[PC- ¹⁴ C]	
Feces	Chlorantraniliprole IN-HXH44 IN-K9T00	IN-K9X71 IN-H2H20	IN-HXH40 IN-K3X21
Urine	IN-K7H29 IN-HXH44-glucuronide	IN-HXH44 IN-HXH40 IN-DBC80 IN-K7H29-glucuronide IN-LQX30-glucuronide	IN-K9T00 IN-K9X71 IN-GKQ52 IN-LEM10
Bile	IN-K9X71 IN-HXH44-glucuronide	Chlorantraniliprole IN-HXH44 IN-K9T00 IN-K3X21 IN-K7H29-glucuronide	IN-HXH40 IN-LEM10 IN-GKQ52 IN-GAZ70 IN-EQW78
Milk	Chlorantraniliprole (0.016 ppm) IN-HXH44 (0.018 ppm) IN-K9T00 (0.017 ppm)	IN-HXH40	

Liver	None	Chlorantraniliprole IN-HXH44 IN-H2H20 IN-KAA24	IN-K9X71 IN-DBC80 IN-K3X21 IN-L8F56
Kidney	Chlorantraniliprole	IN-HXH44 IN-K9T00	IN-H2H20 IN-LEM10
Muscle	Chlorantraniliprole (0.007 ppm) IN-HXH44 (0.002 ppm)	IN-H2H20	IN-EQW78
Fat	Chlorantraniliprole	IN-HXH44 IN-HXH40 IN-K3X21 IN-DBC80 IN-KAA24 IN-K7H29 IN-LEM10	IN-K9X71 IN-H2H20 IN-L8F56 IN-GKQ52 IN-EQW78 IN-GAZ70

Figure 1 Summary of the Metabolic Pathways of Chlorantraniliprole in Plants, Animals (including Rat), Rotated Crops and Soil



CROP FIELD TRIALS ON POME FRUITS							PMRA #1332081			
<p>The field program was conducted in 2005 at 28 locations in Canada and the United States. The apple trials were conducted in NAFTA Zones 1 (3 trials), 1A (1 trial), 2 (1 trial), 5 (2 trials), 5A (1 trial), 5B (2 trials), 9 (1 trial), 10 (1 trial), 11 (3 trials) and 12 (2 trials) for a total of 17 trials. The pear trials were conducted in NAFTA Zones 1 (1 trial), 1A (1 trial), 5 (3 trials), 10 (2 trials), 11 (2 trials) and 12 (2 trials) for a total of 11 trials. Chlorantraniliprole (35 WG formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/ application at growth stage BBCH 75 to 89 for a seasonal application rate of 224 g a.i./ha (~100% maximum Canadian and American recommended seasonal rates of 225 and 221 g a.i./ha, respectively). The applications were made at 10-day intervals with the last application occurring approximately 14 days before normal harvest.</p>										
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)							
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.	
Apple fruit	217-232/ 35 WG	0	2	0.12	0.14	0.13	0.13	0.13	—	
		7	2	0.09	0.11	0.10	0.10	0.10	—	
		14	34	0.01	0.30	0.23	0.07	0.07	0.05	
		21	2	0.06	0.07	0.07	0.07	0.07	—	
		28	2	0.06	0.07	0.07	0.07	0.07	—	
Pear fruit	224-231/ 35 WG	14	22	0.01	0.14	0.13	0.07	0.07	0.04	
RESIDUE DECLINE IN APPLE							PMRA #1332081			
<p>At one site, treated samples were collected at -0, 0, 7, 14, 21 and 28 DALA (days after last application). Mean residues found in treated apple samples reached a maximum of 0.14 ppm at 0 DALA and declined to 0.067 ppm by 28 DALA.</p>										
CROP FIELD TRIALS ON STONE FRUITS							PMRA #1365392 and #1365536			
<p>Peaches: Field trials were conducted in 2005 at 17 locations in Canada and the United States. The peach trials were conducted in NAFTA Zones 1 (1 trial), 2 (3 trials), 4 (1 trial), 5 (4 trials), 5A (1 trial), 6 (1 trial), 10 (4 trials) and 11 (1 trial) for a total of 16 trials. At each trial, two foliar applications of chlorantraniliprole (35 WG formulation) were made to orchards with peach fruit present; each application was at the approximate rate of 112 g a.i./ha for a seasonal application rate of 224 g a.i./ha (~100% maximum Canadian and American recommended rates of 225 and 221 g a.i./ha, respectively). No adjuvant was added to the spray mixtures for 14 of the trials. In three trials, three treatments were tested—one treatment without adjuvant, one treatment with Hasten modified vegetable oil at a rate of 0.25% v/v, and one treatment with Induce non-ionic surfactant at a rate of 0.125% v/v. Applications were made at 7-day intervals with the last application occurring approximately 10 days before normal harvest.</p> <p>Plum and cherry (sweet and sour): Field trials were conducted in 2005 at 19 locations in Canada and the United States. The plum trials were conducted in NAFTA Zones 1A (1 trial), 5 (3 trials), 5A (1 trial), 10 (4 trials), 11 (1 trial) and 12 (1 trial) for a total of 11 trials. The cherry trials were conducted in Zones 1 (1 trial), 5 (1 trial), 5A (2 trials), 9 (1 trial), 10 (1 trial) and 11 (2 trials) for a total of 8 trials. Chlorantraniliprole (35 WG formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application at growth stage BBCH 75 to 87 for a seasonal application rate of 224 g a.i./ha (~100% maximum Canadian and American recommended rates of 225 and 221 g a.i./ha, respectively). No adjuvant was added to the spray mixtures for 14 of the trials. At three plum trials and two cherry trials, three treatments were tested—one treatment without adjuvant, one treatment with Hasten modified vegetable oil at a target rate of 0.25% v/v, and one treatment with Induce non-ionic surfactant at a rate of 0.125% v/v. The applications were made at 7-day intervals with the last application occurring approximately 10 days before normal harvest.</p>										
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)							
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.	
Peach fruit	224-232/	1	4	0.15	0.34	0.32	0.23	0.24	0.09	

	35 WG	3	4	0.09	0.29	0.26	0.18	0.18	0.10
		8	4	0.05	0.34	0.29	0.17	0.18	0.13
		9–11	34	0.06	0.35	0.31	0.12	0.14	0.07
		14–15	4	0.09	0.18	0.17	0.15	0.14	0.04
	225–230/ 35 WG + MVO	10	6	0.09	0.16	0.14	0.11	0.11	0.03
	225–232/ 35 WG + NIS	10	6	0.10	0.14	0.13	0.12	0.12	0.02
Plum fruit	213–224/ 35 WG	10	22	<0.01 (0.003)	0.08	0.07	0.01	0.02	0.02
	224/ 35 WG + MVO	10	6	0.01	0.06	0.05	0.02	0.03	0.02
	230–235/ 35 WG + NIS	10	6	0.01	0.09	0.08	0.03	0.04	0.03
	224/ 35 WG	0	2	<0.01 (0.004)	<0.01 (0.005)	<0.01 (0.004)	<0.01 (0.004)	<0.01 (0.004)	—
		5	2	<0.01 (ND)	<0.01 (0.004)	<0.01 (0.003)	<0.01 (0.003)	<0.01 (0.003)	—
		10	2	<0.01 (0.003)	<0.01 (0.005)	<0.01 (0.004)	<0.01 (0.004)	<0.01 (0.004)	—
		14	2	<0.01 (ND)	<0.01 (0.003)	<0.01 (0.003)	<0.01 (0.003)	<0.01 (0.003)	—
21	2	<0.01 (ND)	<0.01 (ND)	<0.01 (ND)	<0.01 (ND)	<0.01 (ND)	—		
Sour and sweet cherry	224/ 35 WG	10	16	0.04	0.48	0.45	0.20	0.22	0.13
	224/ 35 WG + MVO	10	4	0.14	0.49	0.48	0.32	0.31	0.20
	224/ 35 WG + NIS	10	4	0.16	0.61	0.57	0.37	0.38	0.22
Sweet cherry	224/ 35 WG	10	8	0.04	0.27	0.27	0.11	0.13	0.08
Sour cherry	224/ 35 WG	10	8	0.16	0.48	0.45	0.29	0.30	0.12

RESIDUE DECLINE IN PEACHES AND PLUMS**PMRA #1365392 and #1365536**

Peach: Samples were collected at the California and North Carolina trials, at 1, 3, 7 and 14 DALA. Residues declined over time, from an average of 0.318 ppm at Day 1 to 0.172 ppm at Day 15 in a North Carolina decline series. In a California decline series, average residues declined from 0.158 ppm at Day 1 to 0.114 ppm at Day 14. The decline in residues over time was not as apparent in the California trial.

Plum: At one site, treated samples were collected at –0, 0, 5, 10, 14 and 21 DALA. Mean residues in treated plum samples collected from the WA trial were all <LOQ. Therefore, a decline in residues could not be assessed.

CROP FIELD TRIALS ON GRAPES						PMRA #1365393			
Field trials were conducted in 2005 at 17 locations in Canada and the United States. The grape field trials were conducted in NAFTA Zones 1 (1 trial), 2 (1 trial), 5 (4 trials), 10 (8 trials), 11 (2 trials) and 12 (1 trial) for a total of 17 trials. At each trial, two foliar applications of chlorantraniliprole (35 WG formulation) were made to vines with grapes present; each application was at a rate of 112.4 g a.i./ha for a seasonal application rate of 224 g a.i./ha (~100% maximum Canadian and American recommended rates of 225 and 221 g a.i./ha, respectively). No adjuvant was added to the spray mixtures for 14 of the trials. At three trials, three treatments were tested—one treatment without adjuvant, one treatment with Hasten modified vegetable oil at a rate of 0.25% v/v, and one treatment with Induce non-ionic surfactant at a rate of 0.125% v/v. Applications were made at 7-day intervals with the last application occurring approximately 14 days before normal harvest.									
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Grape	224–235/ 35 WG	1	4	0.0362	0.591	0.429	0.155	0.234	0.261
		2–4	4	0.0291	0.376	0.296	0.130	0.166	0.164
		7	4	0.0367	0.345	0.335	0.183	0.187	0.171
		13–15	34	0.0115	0.591	0.522	0.112	0.175	0.157
		20–23	4	0.0123	0.385	0.320	0.137	0.168	0.184
	216–228/ 35 WG + MVO	14–15	6	0.0333	0.379	0.371	0.053	0.153	0.169
216–230/ 35 WG + NIS	14–15	6	0.0284	0.528	0.461	0.091	0.197	0.210	
RESIDUE DECLINE IN GRAPES						PMRA #1365393			
In two trials (New Jersey and California), the samples were collected at 2 to 4 days, 6 to 8 days, 13 to 15 days, and 20 to 22 days. Residues declined from a maximum of 0.591 ppm at 1 day to a maximum of 0.385 ppm at approximately 21 days. Chlorantraniliprole residues in grapes (application made with no added surfactant or adjuvant) declined with dissipation half-lives of 58 and 13 days.									
CROP FIELD TRIALS ON BRASSICA VEGETABLES						PMRA #1365544			
The field program was completed in 2005 at 27 locations in Canada and the United States. The broccoli trials were conducted in NAFTA Zones 1 (1 trial), 5 (2 trials), 5A (1 trial), 5B (1 trial), 10 (3 trials) and 12 (1 trial) for a total of 9 trials. The cabbage trials were conducted in NAFTA Zones 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (2 trials), 5B (2 trials), 6 (1 trial), 10 (1 trial) and 12 (1 trial) for a total of 10 trials. The mustard green trials were conducted in NAFTA Zones 2 (1 trial), 4 (1 trial), 5 (1 trial), 5A (2 trials), 6 (1 trial), 10 (1 trial) and 12 (1 trial) for a total of 8 trials. Chlorantraniliprole (20 SC formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application at growth stage BBCH 15 to 87 for a seasonal application rate of 224 g a.i./ha (102% maximum American recommended rate of 219 g a.i./ha and 112% maximum Canadian recommended rate of 200 g a.i./ha). Adjuvants were applied according to typical agricultural practices. The applications were made at 3-day intervals with the last application occurring approximately 3 days before normal harvest.									
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Broccoli	219–232/ 20 SC	0	2	0.34	0.58	0.46	0.46	0.46	—
		1	2	0.64	0.71	0.67	0.67	0.67	—
		3	18	0.11	0.71	0.56	0.37	0.35	0.13
		7	2	0.10	0.10	0.10	0.10	0.10	—

		10	2	0.034	0.050	0.042	0.042	0.042	—	
Cabbage (untrimmed)	223–234/ 20 SC	3	20	0.023	1.2	1.2	0.35	0.43	0.34	
Mustard greens	224–234/ 20 SC	3	16	1.1	6.1	5.6	3.7	3.4	1.6	
RESIDUE DECLINE IN BROCCOLI							PMRA #1365544			
Samples were harvested –0, 0, 1, 3, 7 and 10 DALA. Mean residues in samples of treated broccoli/cauliflower reached a maximum of 0.67 ppm at 1 DALA and declined to an average of 0.042 ppm by 10 DALA.										
CROP FIELD TRIALS ON CUCURBIT VEGETABLES							PMRA #1365547			
Field trials were conducted in 2005 at 20 locations in the United States. The cucumber trials were conducted in NAFTA Zones 2 (2 trials), 3 (1 trial), 5 (2 trials), 5A (1 trial) and 6 (1 trial) for a total of 7 trials. The cantaloupe trials were conducted in NAFTA Zones 2 (1 trial), 5A (1 trial), 6 (1 trial) and 10 (4 trials) for a total of 7 trials. The summer squash trials were conducted in NAFTA Zones 1 (1 trial), 2 (2 trials), 3 (1 trial), 5 (1 trial) and 10 (1 trial) for a total of 6 trials. Chlorantraniliprole (20 SC formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application at growth stage BBCH 71 to 89 for a seasonal application rate of 224 g a.i./ha (102% maximum American recommended rate of 219 g a.i./ha). The applications were made at 5-day intervals with the last application occurring approximately 1 day before normal harvest.										
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)							
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.	
Cucumber	224–236/ 20 SC	0	2	0.018	0.025	—	0.022	0.022	—	
		1	14	<0.01 (0.005)	0.083	0.076	0.013	0.030	0.030	
		3	2	<0.01 (0.009)	0.016	—	0.013	0.013	—	
		7	2	<0.01 (0.005)	<0.01 (0.006)	—	<0.01 (0.006)	<0.01 (0.006)	—	
		9	2	<0.01 (0.003)	<0.01 (0.004)	—	<0.01 (0.004)	<0.01 (0.004)	—	
Cantaloupe/ muskmelon	222–241/ 20 SC	1	14	<0.01 (0.008)	0.12	0.090	0.076	0.060	0.036	
Summer squash	220–235/ 20 SC	1	12	<0.01 (0.009)	0.093	0.081	0.047	0.048	0.027	
RESIDUE DECLINE ON CUCUMBERS							PMRA #1365547			
Samples were harvested –0, 0, 1, 3, 7 and 10 ± 1 day DALA. Mean residues in samples of treated cucumbers reached a maximum of 0.022 ppm at 0 DALA and declined to <0.01 ppm (0.004 ppm) by 10 DALA.										
CROP FIELD TRIALS ON FRUITING VEGETABLES							PMRA #1365551			
The field program was conducted in 2005–2006 at 40 locations in Canada and the United States. The tomato trials were conducted in NAFTA Zones 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (8 trials), 5B (1 trial) and 10 (7 trials) for a total of 20 trials. The bell pepper trials were conducted in NAFTA Zones 2 (1 trial), 3 (1 trial), 5 (5 trials), 5B (1 trial), 6 (1 trial) and 10 (2 trials) for a total of 11 trials. The non-bell pepper trials were conducted in NAFTA Zones 5 (5 trials), 5B (1 trial), 8 (2 trials) and 10 (1 trial) for a total of 9 trials. Chlorantraniliprole (20 SC formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application at a growth stage ranging from BBCH 89 to 93 for a seasonal application rate of 224 g a.i./ha (~100% maximum Canadian and American proposed seasonal rates of 219–225 g a.i./ha). The applications were made at 5-day intervals with the last application occurring approximately 1 day before normal harvest.										

Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Tomato	221–235/ 20 SC	0	2	0.11	0.16	0.14	0.14	0.14	—
		1	40	0.018	0.19	0.18	0.070	0.079	0.047
		3	2	0.044	0.071	0.058	0.058	0.058	—
		7	2	0.034	0.071	0.052	0.052	0.052	—
		10	2	0.070	0.071	0.070	0.070	0.070	—
Bell pepper	221–234/ 20 SC	1	22	0.012	0.19	0.18	0.088	0.082	0.058
Non-bell pepper	224–234/ 20 SC	1	18	0.017	0.43	0.41	0.070	0.12	0.12
RESIDUE DECLINE ON TOMATO							PMRA #1365551		
Samples were harvested –0, 0, 1, 3, 7 and 10 ± 1 DALA. Mean residues in samples of treated tomatoes reached a maximum of 0.16 ppm at 0 DALA, increased to 0.19 ppm by 1 DALA and by 3 DALA remained steady at 0.071 ppm.									
CROP FIELD TRIALS ON LEAFY VEGETABLES							PMRA #1365559		
The field program was conducted in 2005 at 28 locations in the United States. The head lettuce trials were conducted in NAFTA Zones 1 (1 trial), 3 (1 trial) and 10 (5 trials) for a total of 7 trials. The leaf lettuce trials were conducted in NAFTA Zones 1 (1 trial), 3 (1 trial) and 10 (5 trials) for a total of 7 trials. The celery trials were conducted in NAFTA Zones 3 (1 trial), 5A (1 trial) and 10 (5 trials) for a total of 7 trials. The spinach trials were conducted in NAFTA Zones 1 (1 trial), 2 (1 trial), 6 (1 trial), 9 (1 trial) and 10 (3 trials) for a total of 7 trials. Chlorantraniliprole (20 SC formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application at growth stage BBCH 19 to 89 for a seasonal application rate of 224 g a.i./ha (102% maximum American recommended rate of 219 g a.i./ha). The applications were made at 3-day intervals with the last application occurring approximately 1 day before normal harvest.									
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Head lettuce, untrimmed	220–228/ 20 SC	0	2	0.43	0.69	—	0.56	0.56	—
		1	14	<0.01 (0.003)	2.5	2.4	0.60	0.99	0.97
		3	2	0.27	0.64	—	0.46	0.46	—
		7	2	0.085	0.27	—	0.18	0.18	—
		10	2	0.029	0.067	—	0.048	0.048	—
Leaf lettuce	221–234/ 20 SC	1	14	3.0	6.3	6.2	4.2	4.4	1.0
Celery, untrimmed	225–234/ 20 SC	1	14	0.85	3.8	3.6	2.3	2.3	1.0
Spinach	221–234/ 20 SC	0	2	3.6	3.9	—	3.7	3.7	—
		1	14	3.4	9.7	8.9	7.3	6.9	1.9
		3	2	2.8	3.5	—	3.1	3.1	—
		7	2	2.1	2.7	—	2.4	2.4	—
		10	2	1.9	2.7	—	2.3	2.3	—

RESIDUE DECLINE ON SPINACH AND HEAD LETTUCE							PMRA #1365559		
Head lettuce and spinach samples were harvested -0, 0, 1, 3, 7 and 10 ± 1 DALA. Mean residues in samples of treated untrimmed head lettuce reached a maximum of 0.63 ppm at 0 DALA and declined to 0.048 ppm by 10 DALA. Mean residues in samples of treated spinach reached a maximum of 3.7 ppm at 0 DALA and declined to 2.3 ppm by 10 DALA. The calculated half-lives of chlorantraniliprole in head lettuce and spinach were 3 and 14 days, respectively.									
CROP FIELD TRIALS ON POTATO							PMRA #1365563 and #1365566		
The first field program was conducted in 2004 at two locations (Zones 5 and 11) in the United States. Chlorantraniliprole (35 WG formulation) was applied three times by foliar broadcast application at a rate of 50 g a.i./ha/application when the crop was at growth stage BBCH 42 to 92 for a seasonal application rate of 150 g a.i./ha (67% maximum Canadian and the American recommended rates of 222–225 g a.i./ha). Potato tuber samples were harvested immediately before the last application (-0 or -1 DBLA) and then 0, 7, 14–15, 21 and 28 days (BBCH 47–92) after the last application. Residues of chlorantraniliprole were not detected (ND; <0.003 ppm) in samples of treated potato tubers.									
A second field program was completed in 2005 at 27 locations in Canada and the United States. The trials were conducted in Zones 1 (5 trials), 1A (4 trials), 2 (1 trial), 3 (1 trial), 5 (3 trials), 5A (1 trial), 5B (1 trial), 7A (1 trial), 10 (1 trial), 11 (6 trials), 12 (1 trial) and 14 (2 trials) for a total of 27 trials. Chlorantraniliprole (35 WG formulation) was applied 3 times as a foliar broadcast spray at the rate of 75 g a.i./ha/application at growth stage BBCH 33 to 95 for a seasonal application rate of 225 g a.i./ha (100% maximum Canadian and American recommended rates of 222–225 g a.i./ha). The applications were made at 5- to 6-day intervals with the last application occurring approximately 14 days before normal harvest.									
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Potato tubers	148–235/ 35 WG	0	8	ND	ND	ND	ND	ND	—
		3	4	ND	0.004	0.003	ND	ND	—
		7	8	ND	ND	ND	ND	ND	—
		14–15	58	ND	0.005	0.004	ND	ND	—
		21	8	ND	ND	ND	ND	ND	—
		28	4	ND	ND	ND	ND	ND	—
RESIDUE DECLINE ON POTATO							PMRA #1365563 and #1365566		
First field program: Potato tuber samples were harvested immediately before the last application (-0 or -1 DBLA) and then 0, 7, 14–15, 21 and 28 days (BBCH 47 to 92) after the last application. Residues of chlorantraniliprole were not detected (ND; <0.003 ppm) in samples of treated potato tubers. Therefore, residue decline could not be assessed.									
Second field program: Samples were harvested -0, 0, 3, 7, 14 and 21 ± 1 DALA. Mean residues in samples of treated potato tubers reached a maximum of 0.003 ppm so no decline half-lives were determined.									
CROP FIELD TRIALS ON COTTON							PMRA #1365524		
The field program was conducted in 2005 at 14 locations in the United States. Chlorantraniliprole (35 WG formulation) was applied twice as a foliar broadcast spray at the rate of 112 g a.i./ha/application to cotton when the crop was at growth stage BBCH 81 to 89 for a seasonal application rate of 224 g a.i./ha (101% maximum American recommended rate of 221 g a.i./ha). The applications were made at 5-day intervals with the last application occurring approximately 21 days before normal harvest.									
Commodity	Total Rate/ End-Use Product (g a.i./ha)	Preharvest Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	HAFT	Median	Mean	Std Dev.
Undelinted	219–228/	0	4	0.077	0.24	0.23	0.15	0.15	0.087

cottonseed	35 WG	7	4	0.058	0.37	0.34	0.18	0.20	0.16
		14	4	0.025	0.26	0.24	0.13	0.14	0.12
		21	28	0.003	0.18	0.18	0.047	0.058	0.048
		28	4	0.012	0.23	0.21	0.11	0.11	0.12
Gin by-products	219–227/ 35 WG	21	14	0.94	15	13	4.1	6.0	4.6
RESIDUE DECLINE ON COTTON					PMRA #1365524				
<p>Samples were harvested from the plots immediately before the last application (–0 DALA) and then 0, 6–7, 14–16, 20–21 and 25–28 DALA. Mean residues in samples of treated undelinted cottonseed collected from the Louisiana site reached a maximum of 0.078 ppm at 0 DALA and declined to 0.014 ppm by 28 DALA. Mean residues in samples of treated undelinted cottonseed collected from the Texas site reached a maximum of 0.34 ppm at 7 DALA and declined to 0.21 ppm by 28 DALA. The average half-lives of chlorantraniliprole in cottonseed at the Louisiana site and Texas site were 9 and 59 days, respectively.</p>									
FREEZER STORAGE STABILITY					PMRA #1332079, #1365391 and #1365514				
<p>Apple fruit, grape berry, tomato fruit, lettuce leaf, cauliflower floret, potato tuber, wheat grain and straw, alfalfa hay and cotton seed: The data indicate the residues of chlorantraniliprole are stable at –20°C for 24 months in five diverse crops, including fruits, a fruiting vegetable, a root crop, a non-oily grain and an oilseed. The demonstrated stability in representative crops indicates residues of chlorantraniliprole are stable in all crops.</p> <p>Apple Juice, Tomato Ketchup, Cottonseed Oil, Cottonseed Meal and Raisins: The data in representative processed fractions, including raisins, ketchup, apple juice, cottonseed meal and cottonseed oil demonstrate that residues of chlorantraniliprole, IN-ECD73, IN-EQW78 and IN-F6L99 are stable when stored at –20°C for up to 12 months. The demonstrated stability in these various fractions indicates residues of chlorantraniliprole, IN-ECD73, IN-EQW78 and IN-F6L99 are stable in all processed crop matrices.</p> <p>Animal Matrices: The storage stability data demonstrated that residues of chlorantraniliprole, IN-K9T00, IN-HXH44, IN-GAZ70 and IN-EQW78 are stable in milk for at least 6 months and in liver, kidney, muscle and fat for at least 3 months when stored at –20°C.</p>									
SUMMARY OF RESIDUE DATA IN FIELD ROTATIONAL CROPS FOLLOWING SOIL TREATMENT WITH CHLORANTRANILIPROLE					PMRA #1365574, #1365575, #1365576, #1365577 and #1365578				
Commodity	Total Rate/ (g a.i./ha)	Plantback Interval (days)	Chlorantraniliprole Residue Levels (ppm)						
			No.	Min.	Max.	Median	Mean	Std Dev.	
Leafy vegetables (Swiss chard, lettuce, spinach)	200–225	14, 30	8	<LOQ (<0.01)	<LOQ	<LOQ	<LOQ	—	
		120	6	<LOQ	0.010	<LOQ	<LOQ	—	
	600	30	6	<LOQ	0.014	<LOQ	<LOQ	—	
		120	6	<LOQ	0.011	<LOQ	<LOQ	—	
Roots of root vegetables (radish, beet and turnip)	200–225	14, 30	12	<LOQ	<LOQ	<LOQ	<LOQ	—	
		120	4	<LOQ	<LOQ	<LOQ	<LOQ	—	
	600	30	6	<LOQ	0.010	<LOQ	<LOQ	—	
		120	4	<LOQ	<LOQ	<LOQ	<LOQ	—	

Tops of root vegetables (radish, beet and turnip)	200–225	14, 30	12	<LOQ	0.072	<LOQ	0.016	0.025
		120	4	<LOQ	0.030	0.017	0.017	0.016
	600	30	6	<LOQ	0.17	0.035	0.068	0.077
		120	4	<LOQ	0.078	0.036	0.040	0.035
Grain of cereal grains (wheat and oats)	200–225	30	6	<LOQ	<LOQ	<LOQ	<LOQ	—
		120	4	<LOQ	<LOQ	<LOQ	<LOQ	—
	600	30	4	<LOQ	<LOQ	<LOQ	<LOQ	—
		120	4	<LOQ	<LOQ	<LOQ	<LOQ	—
Forage of cereal grains (wheat and oats)	200–225	30	6	0.012	0.032	0.016	0.020	0.009
		120	4	<LOQ	0.032	0.010	0.015	0.012
	600	30	4	0.038	0.086	0.060	0.061	0.026
		120	4	0.020	0.055	0.035	0.036	0.019
Hay of cereal grains (wheat and oats)	200–225	30	6	<LOQ	0.054	0.043	0.033	0.022
		120	4	<LOQ	0.022	0.017	0.016	0.006
	600	30	4	0.027	0.16	0.093	0.093	0.072
		120	4	0.057	0.10	0.079	0.079	0.024
Straw of cereal grains (wheat and oats)	200–225	30	6	<LOQ	0.045	0.030	0.024	0.017
		120	4	0.011	0.020	0.017	0.016	0.004
	600	30	4	0.011	0.14	0.056	0.066	0.065
		120	4	0.028	0.086	0.057	0.057	0.029
Soybean seed	225	14	2	<LOQ	<LOQ	<LOQ	<LOQ	—
Soybean forage			2	0.019	0.035	0.027	0.027	0.011
Soybean hay			2	0.036	0.038	0.037	0.037	0.001

Based on the results of the field accumulation studies, as there are no quantifiable chlorantraniliprole residues in any of the human food commodities at any PBI (14, 30 or 120 days), no plantback restrictions are required on the end-use product labels.

PROCESSED FOOD AND FEED

PMRA #1332084, #1365395, #1365571, #1365570, #1365399, #1365398 and #1365566

Apples: Concentration of the chlorantraniliprole residues is observed in feed items: wet pomace (2.6×) and dried pomace (11×). Reduction of the chlorantraniliprole residues is observed in human food items: juice (<0.13×), puree (<0.14×), sauce (<0.19×), preserves (<0.17×) and canned apple (<0.13×).

Grapes: All four trials for each processed commodity (wine, juice and raisin) show a consistent residue profile with chlorantraniliprole residues concentrating in raisins (4.2×) relative to the raw fruit, remaining fairly constant in juice (0.9×) and red wine (1.2×) relative to the raw fruit, and not being detected in white wine (<0.22×).

Tomatoes: Average transfer factors are 1.5× (puree, range of 1.2–1.7), 1.5× (paste, range of 0.61–2.4), 1.0× (ketchup, range of 0.72–1.6), 0.84× (juice, range of 0.57–1.1), 0.39× (washed, range of 0.38–0.39) and <0.37× (canned tomatoes, range of 0.23–0.65).

Plums: The processing factor for chlorantraniliprole calculated for prunes is 1.9×

Cotton: Chlorantraniliprole residues do not concentrate upon processing to refined oil (0.25×) or meal (0.75×) but do concentrate in hulls (2.1×).

Potatoes: The mean residue of chlorantraniliprole found in the replicate field samples collected from the 5× treated potato trial was 0.003 ppm. Therefore, since no residues above the LOQ (0.01 ppm) were found, the processing phase of the study was not conducted.

LIVESTOCK FEEDING—DAIRY COW

PMRA #1332085 and
#1332086

In the feeding study, chlorantraniliprole (96.45% purity) was administered orally in gelatin capsules to four groups of lactating Holstein cows (three cows/group) twice daily for 28 consecutive days. Dosing was made at target treatment levels of 1 mg/kg feed, 3 mg/kg feed, 10 mg/kg feed and 50 mg/kg feed in the animal diet on a dry weight basis. An additional two cows were dosed at 50 mg/kg feed to obtain depuration data.

Matrix	Feeding Level (ppm)	Combined Residues of Chlorantraniliprole and Metabolites IN-HXH44 and IN-K9T00 (ppm)						
		No.	LOD	Min.	Max.	Median	Mean	Standard Deviation
Whole milk Day 1	1	3	0.003	<LOQ (<0.030)	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	50	5		<LOQ	<0.040	<LOQ	<0.032	0.004
Whole milk Day 7 (highest residues)	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<0.030	<0.037	<0.032	<0.033	0.004
	50	5		<0.059	<0.089	<0.077	<0.075	0.011
Whole milk Day 14	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<LOQ	<0.035	<0.030	<0.032	0.003
	50	5		<0.049	<0.086	<0.070	<0.068	0.014
Whole milk Day 21	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<LOQ	<0.036	<0.030	<0.032	0.003
	50	5		<0.038	0.079	<0.058	<0.059	0.015
Skim milk Day 14	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<LOQ	<0.037	<LOQ	<0.032	0.004
	50	3		<0.048	<0.072	<0.061	<0.060	0.012
Skim milk Day 21	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<LOQ	<LOQ	<LOQ	—
	10	3		<0.030	<0.036	<0.031	<0.032	0.003
	50	3		<0.044	<0.054	<0.053	<0.050	0.006

Cream Day 14	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<0.034	<LOQ	<0.031	0.002
	10	3		<0.039	<0.068	<0.048	<0.052	0.015
	50	3		<0.118	<0.241	<0.175	<0.178	0.062
Cream Day 21	1	3	0.003	<LOQ	<LOQ	<LOQ	<LOQ	—
	3	3		<LOQ	<0.051	<LOQ	<0.037	0.012
	10	3		<0.040	<0.051	<0.045	<0.045	0.006
	50	3		<0.098	<0.139	<0.112	<0.116	0.021
Matrix	Feeding Level (ppm)	Average Residues (ppm)						
		Chlorantraniliprole	IN-K9T00	IN-HXH44	IN-GAZ70	IN-EQW78		
Liver	1	0.004	ND	ND	ND	ND		
	3	0.010	ND	0.006	ND	ND		
	10	0.029	ND	0.016	ND	ND		
	50	0.13	0.005	0.045	ND	ND		
	50 (9-day depuration)	0.004	ND	ND	ND	ND		
	50 (23-day depuration)	ND	ND	ND	ND	ND		
Kidney	1	ND	ND	ND	ND	ND		
	3	0.006	ND	0.005	ND	ND		
	10	0.022	0.003	0.010	ND	ND		
	50	0.068	0.012	0.039	ND	ND		
	50 (9- and 23-day depuration)	ND	ND	ND	ND	ND		
Muscle	1	ND	ND	ND	ND	ND		
	3	0.003	ND	0.003	ND	ND		
	10	0.007	ND	0.005	ND	ND		
	50	0.019	ND	0.009	ND	ND		
	50 (9- and 23-day depuration)	ND	ND	ND	ND	ND		
Fat	1	0.003	ND	ND	ND	ND		
	3	0.009	ND	ND	ND	ND		
	10	0.029	ND	0.005	ND	ND		
	50	0.14	ND	0.012	ND	ND		
	50 (9- and 23-day depuration)	ND	ND	ND	ND	ND		
LIVESTOCK FEEDING—Poultry								
A poultry feeding study was not submitted as there were no poultry feed items associated with any of the proposed label uses.								
No MRLs will be promulgated for poultry matrices.								

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

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops (apple, tomato, lettuce, rice and cotton) Rotational crops	Chlorantraniliprole		
	Chlorantraniliprole		
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops Rotational crops	Chlorantraniliprole		
	Chlorantraniliprole		
METABOLIC PROFILE IN DIVERSE CROPS	Yes, metabolic profile similar among apple, tomato, lettuce, rice and cotton.		
ANIMAL STUDIES			
ANIMALS	Ruminant and Poultry		
RESIDUE DEFINITION FOR ENFORCEMENT	Chlorantraniliprole		
RESIDUE DEFINITION FOR RISK ASSESSMENT	In animal tissues: Chlorantraniliprole In milk and milk products: Chlorantraniliprole and the metabolites IN-HXH44 and IN-K9T00 In eggs: Chlorantraniliprole and the metabolites IN-H2H20, IN-GAZ70 and IN-K7H29		
METABOLIC PROFILE IN ANIMALS	Yes, metabolic profile similar among goat, hen, rat		
FAT SOLUBLE RESIDUE	Yes		
DIETARY RISK FROM FOOD AND WATER			
Basic chronic non-cancer dietary risk ADI = 1.58 mg/kg bw/day Estimated chronic drinking water concentration = 63.0 µg/L (groundwater) The dietary exposure (food + drinking water) for each of the population groups was ≤1.3%. Accordingly, a refined chronic assessment was not performed.	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Only	Food and Water
	Total population	0.5	0.6
	All infants <1 year	0.6	0.8
	Children 1–2 years	1.2	1.3
	Children 3 to 5 years	0.9	1.1
	Children 6–12 years	0.6	0.7
	Youth 13–19 years	0.4	0.5
	Adults 20–49 years	0.5	0.6
	Adults 50+ years	0.5	0.6
Female 13–49 years	0.5	0.6	

Figure 2 Transformation Pathway of Chlorantraniliprole (DPX-E2Y45) in Soil Under Aerobic and Anaerobic Conditions

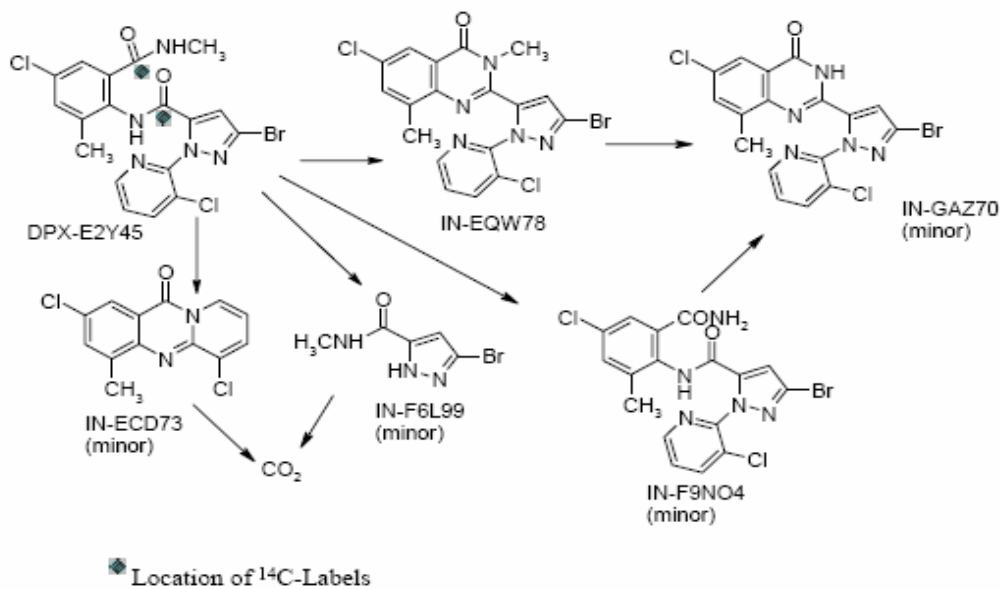


Table 7 Fate and Behaviour in the Environment

Property	Test Substance	Value	Comments
Terrestrial Environment			
Abiotic transformation			
Hydrolysis	Chlorantraniliprole	pH 4: stable pH 7: stable pH 9: DT ₅₀ : 10 days (25°C) 50 days (15°C)	Stable at pH 4 and pH 7 Slightly persistent at pH 9
Phototransformation on soil	Chlorantraniliprole	DT ₅₀ : 50 days (25°C) DT ₉₀ : 167 days (25°C)	Based on irradiated continuous lighting
Phototransformation in air	No data required		Not volatile under field conditions
Biotransformation			
Biotransformation in aerobic soil	Chlorantraniliprole	DT ₅₀ : 886 days (25°C) DT ₉₀ : 2940 days (25°C)	Persistent
	IN-EQW78	t _{1/2} : 646 –785 days	Persistent
Biotransformation in anaerobic soil	Chlorantraniliprole	DT ₅₀ : 208 days (25°C) DT ₉₀ : 692 days (25°C)	Persistent

Property	Test Substance	Value	Comments
Mobility			
Adsorption/ desorption in soil	Chlorantraniliprole	K_{OC} : 214–429 mL/g	Moderate mobility
	IN-EQW78	K_{OC} : 6366 – 19 626 mL/g	Immobile
Field studies			
Field dissipation (P.E.I)	DPX-E2Y45 35 WG	DT ₅₀ : 399 days DT ₉₀ : 2345 days	Persistent
Aquatic Environment			
Abiotic transformation			
Hydrolysis	Chlorantraniliprole	pH 4: stable pH 7: stable pH 9: DT ₅₀ : 10 days (25°C) 50 days (15°C)	Stable at pH 4 and pH 7 Slightly persistent at pH 9
Phototransformation in water	Chlorantraniliprole	DT ₅₀ : 0.31 days (natural water, pH 7, 25°C) 0.37 days (pH 7 butter, 25°C) DT ₉₀ : 1.01 days (natural water, pH 7, 25°C) 1.24 days (pH 7 butter, 25°C)	Based on irradiated continuous lighting
		DT ₅₀ : 33 days (pH 7, 25°C)	Based on natural summer sunlight in Delaware, USA (latitude of 39°41'N)
Biotransformation			
Biotransformation in aerobic water/sediment systems	Chlorantraniliprole	DT ₅₀ : 125–231 days (25°C, total system) DT ₉₀ : 414–768 days (25°C, total system)	Moderately persistent to persistent
	IN-EQW78	t _{1/2} : 121–680 days (25°C, total system) DT ₉₀ : 402–2260 days (25°C, total system)	Moderately persistent to persistent
Biotransformation in anaerobic water/sediment systems	Chlorantraniliprole	DT ₅₀ : 42 days (25°C, total system) DT ₉₀ : 814 days (25°C, total system)	Slightly persistent
	IN-EQW78	t _{1/2} : 701 days (25°C, total system) DT ₉₀ : 2330 days (25°C, total system)	Persistent

Table 8 Toxicity to Non-Target Species

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
Terrestrial Organisms				
Invertebrates				
Earthworm	14-d acute	DPX-E2Y45 (chlorantraniliprole)	NOEC = 1000 mg a.i./kg dw soil	No classification
		DPX-E2Y45 20 SC	NOEC = 200 mg a.i./kg dw soil	No classification
		DPX-E2Y45 35 WG	NOEC = 350 mg a.i./kg dw soil	No classification
		IN-EQW78	NOEC = 1000 mg/kg dw soil	No classification
		IN-ECD73	NOEC = 1000 mg/kg dw soil	No classification
		IN-GAZ70	NOEC = 1000 mg/kg dw soil	No classification
		IN-F6L99	NOEC = 250 mg/kg dw soil LC ₅₀ = 633 mg/kg dw soil	No classification
	56-d reproduction	DPX-E2Y45 35 WG	NOEC = 350 mg a.i./kg dw soil	No classification
		IN-EQW78	NOEC = 1000 mg/kg dw soil	No classification
		IN-ECD73	NOEC = 1000 mg/kg dw soil	No classification
		IN-GAZ70	NOEC = 1000 mg/kg dw soil	No classification
	Bee	48-h oral	DPX-E2Y45	NOEL = 0.0274 µg a.i./bee LD ₅₀ > 104 µg a.i./bee
DPX-E2Y45 20 SC			NOEL < 7.38 µg a.i./bee LD ₅₀ > 114 µg a.i./bee	Relatively non-toxic ¹
DPX-E2Y45 35 WG			LD ₅₀ > 119 µg a.i./bee	Relatively non-toxic ¹
48-h contact		DPX-E2Y45	NOEL = 0.125 µg a.i./bee LD ₅₀ > 4.0 µg a.i./bee	Relatively non-toxic ¹
		DPX-E2Y45 20 SC	NOEL < 6.25 µg a.i./bee LD ₅₀ > 100 µg a.i./bee	Relatively non-toxic ¹

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
		DPX-E2Y45 35 WG	NOEL = 100 µg a.i./bee LD ₅₀ > 100 µg a.i./bee	Relatively non-toxic ¹
Predatory mite <i>Typhodromus pyri</i>	7-d contact	DPX-E2Y45 20 SC	LR ₅₀ > 750 g a.i./ha (mortality)	No classification
		DPX-E2Y45 35 WG	LR ₅₀ > 750 g a.i./ha (mortality)	No classification
	14-d contact	DPX-E2Y45 20 SC	ER ₅₀ > 750 g a.i./ha (reproduction)	No classification
		DPX-E2Y45 35 WG	ER ₅₀ > 750 g a.i./ha (reproduction)	No classification
Parasitoid <i>Aphidius rhopalosiphi</i>	48-h contact	DPX-E2Y45 20 SC	LR ₅₀ > 750 g a.i./ha (mortality) ER ₅₀ > 750 g a.i./ha (reproduction)	No classification
		DPX-E2Y45 35 WG	LR ₅₀ > 750 g a.i./ha (mortality) ER ₅₀ > 750 g a.i./ha (reproduction)	No classification
Ladybird beetle <i>Coccinella septemunctata</i> L.	15-d contact on sprayed leaves	DPX-E2Y45 20 SC	LR ₅₀ = 79.5 g a.i./ha (mortality)	No classification
Hoverfly <i>Episyrphus balteatus</i>	21-d contact on sprayed leaves	DPX-E2Y45 20 SC	LR ₅₀ = 12.6 g a.i./ha ER ₅₀ > 13.3 g a.i./ha	No classification
		DPX-E2Y45 35 WG	LR ₅₀ = 4.64 g a.i./ha ER ₅₀ > 4.4 g a.i./ha	No classification
Predatory bug <i>Orius laevigatus</i>	9-d contact on sprayed leaves	DPX-E2Y45 20 SC	LR ₅₀ > 120 g a.i./ha ER ₅₀ > 120 g a.i./ha	No classification
Birds				
Bobwhite quail	Acute 14-d oral	DPX-E2Y45	NOEL = 2250 mg a.i./kg bw LD ₅₀ > 2250 mg a.i./kg bw	Practically non-toxic
		DPX-E2Y45 20 SC	NOEL = 432 mg a.i./kg bw (based on sublethal effects) LD ₅₀ > 2000 mg a.i./kg bw	Practically non-toxic
		DPX-E2Y45 35 WG	NOEL = 486 mg a.i./kg bw (based on sublethal effects) LD ₅₀ > 2250 mg a.i./kg bw	Practically non-toxic

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
		IN-EQW78	NOEL = 2250 mg IN-EQW78/kg bw LD ₅₀ > 2250 mg IN-EQW78/kg bw	Practically non-toxic
	5-d dietary	DPX-E2Y45	LC ₅₀ > 5620 mg a.i./kg diet	Practically non-toxic
		DPX-E2Y 20 SC	LC ₅₀ > 5620 mg a.i./kg diet	Practically non-toxic
	Reproduction	DPX-E2Y45	NOEC = 120 mg a.i./kg diet	No classification
Mallard duck	5-d dietary	DPX-E2Y45	LC ₅₀ > 5620 mg a.i./kg	Practically non-toxic
	Reproduction	DPX-E2Y45	NOEC = 500 mg a.i./kg diet	No classification
Mammals				
Rat	Acute oral	DPX-E2Y45	LD ₅₀ > 5000 mg/kg bw	Practically non-toxic
		DPX-E2Y45 20 SC	LD ₅₀ > 5000 mg/kg bw	Practically non-toxic
		IN-EQW78	LD ₅₀ > 2000 mg/kg bw	Practically non-toxic
	28-d dietary	DPX-E2Y45	NOAEL = 8000 ppm (584/675 mg/kg bw/day in M/F)	Practically non-toxic
	90-d dietary	DPX-E2Y45	NOAEL = 20 000 ppm (1188/1526 mg/kg bw/day in M/F)	Practically non-toxic
	2-year dietary	DPX-E2Y45	NOAEL = 20 000 ppm (805/1076 mg/kg bw/day in M/F)	Practically non-toxic
	Reproduction	DPX-E2Y45	NOAEL = 20 000 ppm (1199/1594 mg/kg bw/day in parent M/F)	Practically non-toxic
Mouse	Acute	IN-LBA24	LD ₅₀ > 2000 mg/kg bw	Practically non-toxic
		IN-ECD73	LD ₅₀ > 2000 mg/kg bw	Practically non-toxic
		IN-F6L99	LD ₅₀ > 2000 mg/kg bw	Practically non-toxic

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
	28-d dietary	DPX-E2Y45	NOAEL = 3000 ppm (538/658 mg/kg bw/day in M/F)	Practically non-toxic
	90-d dietary	DPX-E2Y45	NOAEL = 7000 ppm (1135/1539 mg/kg bw/day in M/F)	Practically non-toxic
	18-month dietary	DPX-E2Y45	NOAEL = 1200 ppm (158 mg/kg bw/day in male) NOAEL = 7000 ppm (1155 mg/kg bw/day in female)	Practically non-toxic
Vascular plants				
Vascular plant	21-d seedling emergence	DPX-E2Y45 20 SC	EC ₂₅ > 237 g a.i./ha (1.19 L EP/ha)	No classification
	Vegetative vigour	DPX-E2Y45 20 SC	EC ₂₅ > 270 g a.i./ha (1.35 L EP/ha)	No classification
Aquatic Organisms				
Freshwater Species				
<i>Daphnia magna</i>	48-h acute	DPX-E2Y45	NOEC = 0.00139 mg a.i./L EC ₅₀ = 0.0116 mg a.i./L	Very highly toxic
		DPX-E2Y45 20 SC	NOEC = 0.00145 mg a.i./L EC ₅₀ = 0.0071 mg a.i./L	Very highly toxic
		DPX-E2Y45 35 WG	NOEC = 0.0032 mg a.i./L EC ₅₀ = 0.011 mg a.i./L	Very highly toxic
		IN-EQW78	NOEC = 0.138 mg/L	Non-toxic up to solubility limit
		IN-ECD73	NOEC = 0.0138 mg/L	Non-toxic up to solubility limit
		IN-GAZ70	NOEC = 0.00987 mg/L	Non-toxic up to solubility limit
		IN-F6L99	NOEC < 7.51 mg/L EC ₅₀ = 46.8 mg a.i./L	Slightly toxic
		IN-F9N04	NOEC < 0.0121 mg/L EC ₅₀ = 0.030 mg a.i./L	Very highly toxic

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
	21-d chronic	DPX-E2Y45	NOEC = 0.00302 mg a.i./L EC ₅₀ = 0.00716 mg a.i./L	No classification
Mayfly <i>Centroptilum triangulifer</i>	48-h acute	DPX-E2Y45	LC ₅₀ = 0.0116 mg a.i./L	Very highly toxic
Caddisfly <i>Chimarra atterima</i>	48-h acute	DPX-E2Y45	LC ₅₀ = 0.0117 mg a.i./L	Very highly toxic
Stonefly <i>Soyedina carolinensis</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 0.978 mg a.i./L	Highly toxic
<i>Hyalella azteca</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 0.389 mg a.i./L	Highly toxic
<i>Gammarus pseudolimnaeus</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 0.035 mg a.i./L	Highly toxic
Crayfish <i>Oronectes virilis</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 1.420 mg a.i./L	Moderately toxic
<i>Chironomus riparius</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 0.0859 mg a.i./L	Very highly toxic
	28-d chronic (water-spiked)	DPX-E2Y45	NOEC = 0.0025 mg a.i./L EC ₅₀ = 0.0038 mg a.i./L	No classification
	28-d chronic (sediment-spiked)	DPX-E2Y45	NOEC = 0.0050 mg a.i./kg sediment EC ₅₀ = 0.013 mg a.i./kg sediment	No classification
Oligochaete <i>Lumbriculus variegatu</i>	48-h acute	DPX-E2Y45	LC ₅₀ > 1.49 mg a.i./L	Moderately toxic
Rainbow trout	96-h acute	DPX-E2Y45	NOEC = 13.8 mg a.i./L	Non-toxic up to solubility limit
		DPX-E2Y45 20 SC	NOEC < 2.16 mg a.i./L LC ₅₀ > 2.16 mg a.i./L	Slightly toxic
		DPX-E2Y45 35 WG	NOEC = 1.09 mg a.i./L	Non-toxic up to solubility limit

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
	90-d early life stage	DPX-E2Y45	NOEC = 0.110 mg a.i./L	Non-toxic up to solubility limit
Bluegill sunfish	96-h acute	DPX-E2Y45	NOEC = 15.1 mg a.i./L	Non-toxic up to solubility limit
		DPX-E2Y45 20 SC	NOEC = 1.84 mg a.i./L	Non-toxic up to solubility limit
		DPX-E2Y45 35 WG	NOEC = 1.19 mg a.i./L	Non-toxic up to solubility limit
Green algae <i>Pseudokirchneriella subcapitata</i>	120-h acute	DPX-E2Y45	NOEC = 2.09 mg a.i./L	No classification
	72-h acute	DPX-E2Y45 20 SC	NOEC = 4.0 mg a.i./L	No classification
		DPX-E2Y45 35 WG	NOEC = 1.78 mg a.i./L	No classification
Freshwater diatom <i>Navicula pelliculosa</i>	120-h acute	DPX-E2Y45	NOEC = 15.1 mg a.i./L	No classification
Vascular plant <i>Lemna gibba</i> G3	14-d acute	DPX-E2Y45	NOEC = 1.99 mg a.i./L	No classification
Marine Species				
Mysid <i>Americamysis bahia</i>	96-h acute	DPX-E2Y45	NOEC = 0.174 mg a.i./L LC ₅₀ = 1.15 mg a.i./L	Moderately toxic
	28-d chronic	DPX-E2Y45	NOEC = 0.695 mg a.i./L	No classification
Eastern oyster <i>Crassostrea virginica</i>	96-h shell deposition	DPX-E2Y45	NOEC < 0.0249 mg a.i./L EC ₅₀ = 0.0399 mg a.i./L	Very highly toxic
Sheepshead minnow <i>Cyprinodon variegates</i>	96-h acute	DPX-E2Y45	NOEC = 12.0 mg a.i./L	Non-toxic up to solubility limit
	36-d early life stage	DPX-E2Y45	NOEC = 1.28 mg a.i./L	No classification
Blue-green alga	120-h acute	DPX-E2Y45	NOEC = 1.79 mg a.i./L	No classification

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity ¹
Marine diatom <i>Skeletonema costatum</i>	120-h acute	DPX-E2Y45	NOEC = 14.6 mg a.i./L	No classification

¹ Atkins et al. (1981) for bees and USEPA classification for others, where applicable.

Table 9 Screening Level Risk Assessment on Non-target Species

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
Terrestrial Organisms					
Invertebrates					
Earthworm	14-d acute Chlorantraniliprole	NOEC = 1000 mg a.i./kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	14-d acute DPX-E2Y45 20 SC	NOEC = 200 mg a.i./kg dw soil	0.1 mg a.i./kg	0.0005	Not exceeded
	14-d acute DPX-E2Y45 35 WG	NOEC = 350 mg a.i./kg dw soil	0.1 mg a.i./kg	0.00029	Not exceeded
	14-d acute IN-EQW78	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	14-d acute IN-ECD73	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	14-d acute IN-GAZ70	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	14-d acute IN-F6L99	LC ₅₀ = 633 mg/kg dw soil	0.1 mg a.i./kg	0.00015	Not exceeded
	56-d reproduction DPX-E2Y45 35 WG	NOEC = 350 mg a.i./kg dw soil	0.1 mg a.i./kg	0.00029	Not exceeded
	56-d reproduction IN-EQW78	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	56-d reproduction IN-ECD73	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded
	56-d reproduction IN-GAZ70	NOEC = 1000 mg/kg dw soil	0.1 mg a.i./kg	0.0001	Not exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
Bee	48-h oral Chlorantraniliprole	LD ₅₀ > 104 µg a.i./bee (116.48 kg a.i./ha)	225 g a.i./ha	0.0019	Not exceeded
	48-h oral DPX-E2Y45 20 SC	LD ₅₀ > 114 µg a.i./bee (127.68 kg a.i./ha)	225 g a.i./ha	0.00176	Not exceeded
	48-h oral DPX-E2Y45 35 WG	LD ₅₀ > 119 µg a.i./bee (133.28 kg a.i./ha)	225 g a.i./ha	0.00169	Not exceeded
	48-h contact Chlorantraniliprole	LD ₅₀ > 4.0 µg a.i./bee (4.48 kg a.i./ha)	225 g a.i./ha	0.0502	Not exceeded
	48-h contact DPX-E2Y45 20 SC	LD ₅₀ > 100 µg a.i./bee (112 kg a.i./ha)	225 g a.i./ha	0.0020	Not exceeded
	48-h contact DPX-E2Y45 35 WG	LD ₅₀ > 100 µg a.i./bee (112 kg a.i./ha)	225 g a.i./ha	0.0020	Not exceeded
Predatory mite <i>Typhodromus pyri</i>	7-d contact DPX-E2Y45 20 SC	LR ₅₀ > 750 g a.i./ha (mortality)	225 g a.i./ha	0.30	Not exceeded
	7-d contact DPX-E2Y45 35 WG	LR ₅₀ > 750 g a.i./ha (mortality)	225 g a.i./ha	0.30	Not exceeded
	14-d contact DPX-E2Y45 20 SC	ER ₅₀ > 750 g a.i./ha (reproduction)	225 g a.i./ha	0.30	Not exceeded
	14-d contact DPX-E2Y45 35 WG	ER ₅₀ > 750 g a.i./ha (reproduction)	225 g a.i./ha	0.30	Not exceeded
Parasitoid <i>Aphidius rhopalosiphi</i>	48-h contact DPX-E2Y45 20 SC	LR ₅₀ > 750 g a.i./ha (mortality)	225 g a.i./ha	0.30	Not exceeded
	48-h contact DPX-E2Y45 35 WG	LR ₅₀ > 750 g a.i./ha (mortality)	225 g a.i./ha	0.30	Not exceeded
Ladybird beetle <i>Coccinella septemunctata</i> L.	15-d contact on sprayed leaves DPX-E2Y45 20 SC	LR ₅₀ = 79.5 g a.i./ha (mortality)	225 g a.i./ha	2.83	Exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
Hoverfly <i>Episyrphus balteatus</i>	21-d contact on sprayed leaves DPX-E2Y45 20 SC	LR ₅₀ = 12.6 g a.i./ha	225 g a.i./ha	17.86	Exceeded
	21-d contact on sprayed leaves DPX-E2Y45 35 WG	LR ₅₀ = 4.64 g a.i./ha	225 g a.i./ha	48.49	Exceeded
Predatory bug <i>Orius laevigatus</i>	9-d contact on sprayed leaves DPX-E2Y45 20 SC	LR ₅₀ > 120 g a.i./ha	225 g a.i./ha	1.875	Exceeded
Birds					
Bobwhite quail	Acute 14-d oral Chlorantraniliprole (FC = 24 g/ind/day; BWI = 192 g/ind)	LD ₅₀ > 2250 mg a.i./kg bw	39.39 mg a.i./kg dw (4.92 mg a.i./kg bw)	0.002	Not exceeded
	Acute 14-d oral DPX-E2Y45 20 SC (FC = 14 g/ind/day; BWI = 208 g/ind)	LD ₅₀ > 2000 mg a.i./kg bw	39.39 mg a.i./kg dw (2.65 mg a.i./kg bw)	0.001	Not exceeded
	Acute 14-d oral DPX-E2Y45 35 WG (FC = 14 g/ind/day; BWI = 208 g/ind)	LD ₅₀ > 2250 mg a.i./kg bw	39.39 mg a.i./kg dw (2.65 mg a.i./kg bw)	0.001	Not exceeded
	Acute 14-d oral IN-EQW78 (FC = 14 g/ind/day; BWI = 208 g/ind)	LD ₅₀ > 2250 mg IN- EQW78/kg bw	39.39 mg a.i./kg dw (2.65 mg a.i./kg bw)	0.001	Not exceeded
	5-d dietary Chlorantraniliprole	LC ₅₀ > 5620 mg a.i./kg diet	39.39 mg a.i./kg dw	0.007	Not exceeded
	5-d dietary DPX-E2Y 20 SC	LC ₅₀ > 5620 mg a.i./kg diet	39.39 mg a.i./kg dw	0.007	Not exceeded
	Reproduction Chlorantraniliprole	NOEC = 120 mg a.i./kg diet	39.39 mg a.i./kg dw	0.328	Not exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
Mallard duck	5-d dietary Chlorantraniliprole	LC ₅₀ > 5620 mg a.i./kg diet	7.61 mg a.i./kg dw	0.0014	Not exceeded
	Reproduction Chlorantraniliprole	NOEC = 500 mg a.i./kg diet	7.61 mg a.i./kg dw	0.015	Not exceeded
Mammals					
Rat	Acute oral Chlorantraniliprole	LD ₅₀ > 5000 mg/kg bw	113.51 mg a.i./kg dw (19.5 mg a.i./kg bw)	<0.1	Not exceeded
	Acute oral DPX-E2Y45 20 SC	LD ₅₀ > 5000 mg/kg bw	113.51 mg a.i./kg dw (19.5 mg a.i./kg bw)	<0.1	Not exceeded
	Acute oral IN-EQW78	LD ₅₀ > 2000 mg/kg bw	113.51 mg a.i./kg dw (19.5 mg a.i./kg bw)	<0.1	Not exceeded
	28-d dietary Chlorantraniliprole	NOAEL = 8000 mg a.i./kg dw (584/675 mg/kg bw/day in M/F)	113.51 mg a.i./kg dw	0.014	Not exceeded
	90-d dietary Chlorantraniliprole	NOAEL = 20 000 mg a.i./kg dw (1188/1526 mg/kg bw/day in M/F)	113.51 mg a.i./kg dw	0.0057	Not exceeded
	2-year dietary Chlorantraniliprole	NOAEL = 20 000 mg a.i./kg dw (805/1076 mg/kg bw/day in M/F)	113.51 mg a.i./kg dw	0.0057	Not exceeded
	Reproduction Chlorantraniliprole	NOAEL = 20 000 mg a.i./kg dw (1199/1594 mg/kg bw/day in parent M/F)	113.51 mg a.i./kg dw	0.0057	Not exceeded
Mouse	Acute IN-LBA24	LD ₅₀ > 2000 mg/kg bw	112.83 mg a.i./kg dw (20.5 mg a.i./kg bw)	<0.1	Not exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
	Acute IN-ECD73	LD ₅₀ > 2000 mg/kg bw	112.83 mg a.i./kg dw (20.5 mg a.i./kg bw)	<0.1	Not exceeded
	Acute IN-F6L99	LD ₅₀ > 2000 mg/kg bw	112.83 mg a.i./kg dw (20.5 mg a.i./kg bw)	<0.1	Not exceeded
	28-d dietary Chlorantraniliprole	NOAEL = 3000 mg a.i./kg dw (538/658 mg/kg bw/day in M/F)	112.83 mg a.i./kg dw	0.038	Not exceeded
	90-d dietary Chlorantraniliprole	NOAEL = 7000 mg a.i./kg dw (1135/1539 mg/kg bw/day in M/F)	112.83 mg a.i./kg dw	0.016	Not exceeded
	18-month dietary Chlorantraniliprole	NOAEL = 1200 mg a.i./kg dw (158 mg/kg bw/day in male) NOAEL = 7000 mg a.i./kg dw (1155 mg/kg bw/day in female)	112.83 mg a.i./kg dw	0.094 (male) 0.016 (female)	Not exceeded
Vascular Plants					
Vascular plant	21-d seedling emergence DPX-E2Y45 20 SC	EC ₂₅ > 237 g a.i./ha (1.19 L EP/ha)	225 g a.i./ha	0.949	Not exceeded
	Vegetative vigour DPX-E2Y45 20 SC	EC ₂₅ > 270 g a.i./ha (1.35 L EP/ha)	225 g a.i./ha	0.833	Not exceeded
Aquatic Organisms					
Freshwater Species					
<i>Daphnia magna</i>	48-h acute Chlorantraniliprole	EC ₅₀ = 0.0116 mg a.i./L	0.0281 mg a.i./L	4.84	Exceeded
	48-h acute DPX-E2Y45 20 SC	EC ₅₀ = 0.0071 mg a.i./L	0.0281 mg a.i./L	7.92	Exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
	48-h acute DPX-E2Y45 35 WG	EC ₅₀ = 0.011 mg a.i./L	0.0281 mg a.i./L	5.11	Exceeded
	21-d chronic Chlorantraniliprole	NOEC = 0.00302 mg a.i./L	0.0281 mg a.i./L	9.30	Exceeded
Mayfly <i>Centroptilum triangulifer</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0116 mg a.i./L	0.0281 mg a.i./L	4.84	Exceeded
Caddisfly <i>Chimarra atterima</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0117 mg a.i./L	0.0281 mg a.i./L	4.80	Exceeded
Stonefly <i>Soyedina carolinensis</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.978 mg a.i./L	0.0281 mg a.i./L	0.057	Not exceeded
<i>Hyaella azteca</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.389 mg a.i./L	0.0281 mg a.i./L	0.144	Not exceeded
<i>Gammarus pseudolimnaeus</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.035mg a.i./L	0.0281 mg a.i./L	1.61	Exceeded
Crayfish <i>Oreonectes virilis</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 1.420 mg a.i./L	0.0281 mg a.i./L	0.040	Not exceeded
<i>Chironomus riparius</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.0859 mg a.i./L	0.0281 mg a.i./L	0.654	Not exceeded
	28-d chronic (water- spiked) Chlorantraniliprole	NOEC = 0.0025 mg a.i./L	0.0281 mg a.i./L	11.2	Exceeded
Oligochaete <i>Lumbriculus variegatus</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 1.49 mg a.i./L	0.0281 mg a.i./L	0.0377	Not exceeded
Rainbow trout	96-h acute Chlorantraniliprole	NOEC = 13.8 mg a.i./L	0.0281 mg a.i./L	0.0020	Not exceeded
	96-h acute DPX-E2Y45 20 SC	LC ₅₀ > 2.16 mg a.i./L	0.0281 mg a.i./L	0.013	Not exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
	96-h acute DPX-E2Y45 35 WG	NOEC = 1.09 mg a.i./L	0.0281 mg a.i./L	0.0258	Not exceeded
	90-d early life stage Chlorantraniliprole	NOEC = 0.110 mg a.i./L	0.0281 mg a.i./L	0.255	Not exceeded
Bluegill sunfish	96-h acute Chlorantraniliprole	NOEC = 15.1 mg a.i./L	0.0281 mg a.i./L	0.00186	Not exceeded
	96-h acute DPX-E2Y45 20 SC	NOEC = 1.84 mg a.i./L	0.0281 mg a.i./L	0.015	Not exceeded
	96-h acute DPX-E2Y45 35 WG	NOEC = 1.19 mg a.i./L	0.0281 mg a.i./L	0.0236	Not exceeded
Green algae <i>Pseudokirchneriella subcapitata</i>	120-h acute Chlorantraniliprole	NOEC = 2.09 mg a.i./L	0.0281 mg a.i./L	0.0134	Not exceeded
	72-h acute DPX-E2Y45 20 SC	NOEC = 4.0 mg a.i./L	0.0281 mg a.i./L	0.0070	Not exceeded
	72-h acute DPX-E2Y45 35 WG	NOEC = 1.78 mg a.i./L	0.0281 mg a.i./L	0.0158	Not exceeded
Blue-green alga	120-h acute	NOEC = 1.79 mg a.i./L	0.0281 mg a.i./L	0.0157	Not exceeded
Freshwater diatom <i>Navicula pelliculosa</i>	120-h acute Chlorantraniliprole	NOEC = 15.1 mg a.i./L	0.0281 mg a.i./L	0.00186	Not exceeded
Vascular plant	14-d acute Chlorantraniliprole	NOEC = 1.99 mg a.i./L	0.0281 mg a.i./L	0.0141	Not exceeded
Amphibian (Rainbow trout early life)	Chronic EEC	NOEC = 0.110 mg a.i./L	0.15 mg a.i./L	1.36	Exceeded
Marine Species					
Mysid <i>Americamysis bahia</i>	96-h acute Chlorantraniliprole	LC ₅₀ = 1.15 mg a.i./L	0.0281 mg a.i./L	0.0244	Not exceeded
	28-d chronic Chlorantraniliprole	NOEC = 0.695 mg a.i./L	0.0281 mg a.i./L	0.0404	Not exceeded

Organism	Exposure: Test substance	Endpoint Value	EEC ¹	RQ ²	LOC ³ Exceeded/ Not Exceeded
Eastern oyster <i>Crassostrea virginica</i>	96-h shell deposition Chlorantraniliprole	EC ₅₀ = 0.0399 mg a.i./L	0.0281 mg a.i./L	1.41	Exceeded
Sheepshead minnow <i>Cyprinodon variegates</i>	96-h acute Chlorantraniliprole	NOEC = 12.0 mg a.i./L	0.0281 mg a.i./L	0.0023	Not exceeded
	36-d early life stage Chlorantraniliprole	NOEC = 1.28 mg a.i./L	0.0281 mg a.i./L	0.022	Not exceeded
Marine diatom <i>Skeletonema costatum</i>	120-h acute Chlorantraniliprole	NOEC = 14.6 mg a.i./L	0.0281 mg a.i./L	0.00192	Not exceeded

1. At the screening level, the following EECs were calculated for chlorantraniliprole (direct application):

For earthworm, soil EEC was calculated using a maximum seasonal cumulative rate of 225 g a.i./ha, assuming soil bulk density of 1.5 g/cm³ and that the product is evenly distributed in the 0–15 cm soil layer.

For terrestrial plants, bees and non-target arthropods, the EEC is the maximum cumulative seasonal rate on vegetation (225 g a.i./ha).

For birds and mammals, maximum EECs for chlorantraniliprole in food sources for a direct overspray scenario were determined using a nomogram developed by the USEPA from the data of Hoeger and Kenaga (1972) and Kenaga (1973), and modified according to Fletcher et al. (1994).

For aquatic organisms (except amphibian), water EEC was calculated using a maximum cumulative seasonal rate based on a half-life of 231 days with the assumption that the product is evenly distributed in the 80 cm meter water depth.

For amphibians, water EEC was calculated using a maximum cumulative seasonal rate based on a half-life of 231 days with the assumption that the product is evenly distributed in the 15 cm meter water depth.

EECs for transformation product were calculated assuming 100% conversion of chlorantraniliprole to any of the transformation products.

2. Risk quotient (RQ) is equal to exposure divided by toxicity and incorporates species sensitivity factors. A factor of 10 is applied to fish, a factor of 2 to aquatic invertebrates.

3. Level of concern (LOC) is exceeded when RQ is greater than or equal to 1.

Table 10 Refined Risk Assessment on Non-Target Species

Organism	Exposure	Endpoint Value	EEC	RQ	LOC Exceeded/Not Exceeded
Refinement based on drift from field boom sprayers					
<i>Daphnia magna</i>	48-h acute Chlorantraniliprole	EC ₅₀ = 0.0116 mg a.i./L	0.0031 mg a.i./L	0.54	Not exceeded
	48-h acute DPX-E2Y45 20 SC	EC ₅₀ = 0.0071 mg a.i./L	0.0031 mg a.i./L	0.88	Not exceeded
	48-h acute DPX-E2Y45 35 WG	EC ₅₀ = 0.011 mg a.i./L	0.0031 mg a.i./L	0.56	Not exceeded
	21-d chronic Chlorantraniliprole	NOEC = 0.00302 mg a.i./L	0.0031 mg a.i./L	1.02	Exceeded
Mayfly <i>Centroptilum triangulifer</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0116 mg a.i./L	0.0031 mg a.i./L	0.54	Not exceeded
Caddisfly <i>Chimarra atterima</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0117 mg a.i./L	0.0031 mg a.i./L	0.52	Not exceeded
<i>Gammarus pseudolimnaeus</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.035mg a.i./L	0.0031 mg a.i./L	0.178	Not exceeded
<i>Chironomus riparius</i>	28-d chronic (water-spiked) Chlorantraniliprole	NOEC = 0.0025 mg a.i./L	0.0031 mg a.i./L	1.24	Exceeded
Eastern oyster <i>Crassostrea virginica</i>	96-h shell deposition Chlorantraniliprole	EC ₅₀ = 0.0399 mg a.i./L	0.0031 mg a.i./L	0.16	Not exceeded
Amphibian (rainbow trout early life)	Chronic EEC	NOEC = 0.110 mg a.i./L	0.0165 mg a.i./L	0.15	Not exceeded

Organism	Exposure	Endpoint Value	EEC	RQ	LOC Exceeded/Not Exceeded
Refinement based on drift from airblast sprayers					
<i>Daphnia magna</i>	48-h acute Chlorantraniliprole	EC ₅₀ = 0.0116 mg a.i./L	0.0208 mg a.i./L	3.32	Exceeded
	48-h acute DPX-E2Y45 20 SC	EC ₅₀ = 0.0071 mg a.i./L	0.0208 mg a.i./L	5.86	Exceeded
	48-h acute DPX-E2Y45 35 WG	EC ₅₀ = 0.011 mg a.i./L	0.0208 mg a.i./L	3.78	Exceeded
	21-d chronic Chlorantraniliprole	NOEC = 0.00302 mg a.i./L	0.0208 mg a.i./L	6.88	Exceeded
Mayfly <i>Centroptilum triangulifer</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0116 mg a.i./L	0.0208 mg a.i./L	3.58	Exceeded
Caddisfly <i>Chimarra atterima</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0117 mg a.i./L	0.0208 mg a.i./L	3.55	Exceeded
<i>Gammarus pseudolim- naeus</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.035mg a.i./L	0.0208 mg a.i./L	1.19	Exceeded
<i>Chironomus riparius</i>	28-d chronic (water- spiked) Chlorantraniliprole	NOEC = 0.0025 mg a.i./L	0.0208 mg a.i./L	8.29	Exceeded
Eastern oyster <i>Crassostrea virginica</i>	96-h shell deposition Chlorantraniliprole	EC ₅₀ = 0.0399 mg a.i./L	0.0281 mg a.i./L	1.04	Exceeded
Amphibian (rainbow trout early life)	Chronic EEC	NOEC = 0.110 mg a.i./L	0.111 mg a.i./L	1.01	Exceeded
Refinement based on drift from aerial application					
<i>Daphnia magna</i>	48-h acute Chlorantraniliprole	EC ₅₀ = 0.0116 mg a.i./L	0.0073 mg a.i./L	0.63	Not exceeded

Organism	Exposure	Endpoint Value	EEC	RQ	LOC Exceeded/Not Exceeded
	48-h acute DPX-E2Y45 20 SC	EC ₅₀ = 0.0071 mg a.i./L	0.0073 mg a.i./L	1.03	Exceeded
	48-h acute DPX-E2Y45 35 WG	EC ₅₀ = 0.011 mg a.i./L	0.0073 mg a.i./L	0.66	Not exceeded
	21-d chronic Chlorantraniliprole	NOEC = 0.00302 mg a.i./L	0.0073 mg a.i./L	2.42	Exceeded
Mayfly <i>Centroptilum triangulifer</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0116 mg a.i./L	0.0073 mg a.i./L	0.63	Not exceeded
Caddisfly <i>Chimarra atterima</i>	48-h acute Chlorantraniliprole	LC ₅₀ = 0.0117 mg a.i./L	0.0073 mg a.i./L	0.62	Not exceeded
<i>Gammarus pseudolim- naeus</i>	48-h acute Chlorantraniliprole	LC ₅₀ > 0.035mg a.i./L	0.0073 mg a.i./L	0.21	Not exceeded
<i>Chironomus riparius</i>	28-d chronic (water- spiked) Chlorantraniliprole	NOEC = 0.0025 mg a.i./L	0.0073 mg a.i./L	2.92	Exceeded
Eastern oyster <i>Crassostrea virginica</i>	96-h shell deposition Chlorantraniliprole	EC ₅₀ = 0.0399 mg a.i./L	0.0073 mg a.i./L	0.18	Not exceeded
Amphibian (rainbow trout early life)	Chronic EEC	NOEC = 0.110 mg a.i./L	0.039 mg a.i./L	0.35	Not exceeded

Table 11 Alternatives

Pest ¹	Crop ²	Alternative Insecticide Active Ingredients
Codling moth	Pome fruits	Carbaryl, methomyl, azinphos-methyl, diazinon, malathion, phosalone, phosmet, endosulfan, lambda-cyhalothrin, cypermethrin, deltamethrin, permethrin, acetamiprid, thiacloprid, spinetoram, methoxyfenozide, tebufenozide, codling moth pheromone (E, E-8, 10-dodecadien-1-ol, 1-dodecanol, and 1-tetradecanol), <i>Cydia pomonella</i> granulovirus, kaolin

Pest ¹	Crop ²	Alternative Insecticide Active Ingredients
Oblique-banded leafroller	Pome fruits	Carbaryl, methomyl, azinphos-methyl, malathion, phosmet, cyhalothrin-lambda, cypermethrin, deltamethrin, permethrin, spinosad, spinetoram, methoxyfenozide, tebufenozide, z-11-tetradecen-1-yl acetate (the main component of leafroller pheromones), <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , mineral oil, kaolin
	Stone fruits	Carbaryl, azinphos-methyl, malathion, phosmet, spinosad, spinetoram, z-11-tetradecen-1-yl acetate (the main component of leafroller pheromones), <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , mineral oil
Three-lined leafroller	Pome fruits	Carbaryl, malathion, cypermethrin, spinosad, spinetoram, methoxyfenozide, tebufenozide, z-11-tetradecen-1-yl acetate (the main component of leafroller pheromones), <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , mineral oil, kaolin
	Stone fruits	Carbaryl, malathion, spinosad, spinetoram, z-11-tetradecen-1-yl acetate (the main component of leafroller pheromones), <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , mineral oil
Oriental fruit moth	Pome fruits	Carbaryl, deltamethrin, oriental fruit moth pheromone (z-8-dodecen-1-yl acetate, e-8-dodecen-1-yl acetate, z-8-dodecen-1-ol), acetamiprid, kaolin, methoxyfenozide, thiacloprid, novaluron, spinetoram
	Stone fruits	Carbaryl, permethrin, cypermethrin, malathion, deltamethrin, azinphos-methyl, phosalone, chlorpyrifos, phosmet, lambda-cyhalothrin, oriental fruit moth pheromone (z-8-dodecen-1-yl acetate, e-8-dodecen-1-yl acetate, z-8-dodecen-1-ol), spinetoram
Peach twig borer	Stone fruits	Azinphos-methyl, carbaryl, deltamethrin, diazinon, phosalone, phosmet
Spotted tentiform leafminer	Pome fruits	Methomyl, phosmet, tebufenozide, abamectin, lambda-cyhalothrin, permethrin, methoxyfenozide, thiamethoxam, thiacloprid, cypermethrin
Western tentiform leafminer	Pome fruits	Methoxyfenozide
Grape berry moth	Grapes	Carbaryl, diazinon, permethrin, azinphos-methyl, phosmet, spinosad, grape berry moth pheromone (z-8-dodecen-1-yl acetate), spinetoram, cypermethrin
Climbing cutworm	Grapes	None
Colorado potato beetle	Potatoes	Carbofuran, carbaryl, malathion, methamidophos, endosulfan, chlorpyrifos, permethrin, pyrethrins, piperonyl butoxide, cypermethrin, diazinon, deltamethrin, oxamyl, rotenone, phosmet, <i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> , imidacloprid, cyromazine, lambda-cyhalothrin, spinosad, acetamiprid, thiamethoxam, novaluron
	Fruiting vegetables	Carbaryl, malathion, acephate, endosulfan, permethrin, pyrethrins, piperonyl butoxide, cypermethrin, deltamethrin, rotenone, <i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> , imidacloprid, lambda-cyhalothrin, spinosad, acetamiprid
European corn borer	Potatoes	Carbaryl, permethrin, rotenone, deltamethrin, spinosad, novaluron
Cabbage looper	<i>Brassica</i>	Naled, methomyl, carbaryl, methamidophos, acephate, endosulfan, permethrin, cypermethrin, deltamethrin, lambda-cyhalothrin, diatomaceous earth, rotenone, pyrethrins, piperonyl butoxide, <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , spinosad, spinetoram
	Leafy vegetables	Naled, methomyl, carbaryl, malathion, methamidophos, acephate, endosulfan, lambda-cyhalothrin, rotenone, pyrethrins, piperonyl butoxide, <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , spinosad, spinetoram, tebufenozide

Pest ¹	Crop ²	Alternative Insecticide Active Ingredients
Imported cabbageworm	<i>Brassica</i>	Carbaryl, methomyl, endosulfan, malathion, cypermethrin, permethrin, rotenone, pyrethrins, piperonyl butoxide, spinosad, <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>
Diamondback moth	<i>Brassica</i>	Carbaryl, methamidophos, acephate, endosulfan, malathion, trichlorfon, diazinon, permethrin, deltamethrin, cypermethrin, pyrethrins, piperonyl butoxide, spinosad, spinetoram, <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>
Japanese beetle	Turf	Carbaryl, imidacloprid
European chafer	Turf	Carbaryl, imidacloprid
Black cutworm	Turf	None
Annual bluegrass weevil	Turf	Chlorpyrifos

¹ Each species of leafroller is considered to be included in non-specific claims for “leafrollers.”

² Listed insecticides may be registered only for specific crops within the indicated crop group.

Table 12.1 Altacor 35 WG Insecticide Acceptable Use (label) Claims

Crop	Accepted Use Pattern		
	Pest	Rate g product/ha (g a.i./ha)	Comments
Pome fruits Crop Group 11 Apple, crabapple, loquat, mayhaw, pear, Oriental pear, quince	Codling moth	145 to 215 (50 to 75)	Minimum finished spray volume of 450 L/ha by ground Max. 3 applications per season Not more than once every 10 days
	Oriental fruit moth		
	Spotted tentiform leafminer		
	Western tentiform leafminer		
	Oblique-banded leafroller	145 to 285 (50 to 100)	
	Three-lined leafroller		
Grapes	Grape berry moth	145 to 285 (50 to 100)	Minimum finished spray volume of 450 L/ha by ground Max. 3 applications per season. Not more than once every 7 days
	Climbing cutworm	215 to 285 (75 to 100)	
Stone fruits Crop Group 12 Apricot, sweet cherry, tart cherry, nectarine, peach, plum, chickasaw plum, damson plum, Japanese plum, plumcot, prune	Oriental fruit moth	215 to 285 (75 to 100)	Minimum finished spray volume of 450 L/ha by ground Do not apply more than 3 times per year. Not more than once every 7 days
	Peach twig borer		
	Oblique-banded leafroller	145 to 285 (50 to 100)	
Three-lined leafroller			

Table 12.2 Coragen 200 SC Insecticide Acceptable Use (label) Claims

Crop	Accepted Use Pattern		
	Pest	Rate mL product/ ha (g a.i./ha)	Comments
Fruiting vegetables Crop Group 8 Eggplant, groundcherry, pepino, pepper (bell, chili, cooking, pimento, sweet), tomatillo, tomato	Colorado potato beetle	250 to 375 (50 to 75)	Minimum finished spray volume of 100 L/ha by ground Max. 4 applications per season Not more than once every 5 days
<i>Brassica</i> vegetables Crop Group 5 Broccoli, broccoli (Chinese), broccoli raab, Brussels sprouts, cabbage, cabbage (Chinese, bok choy), cabbage (Chinese, napa), cabbage (Chinese, mustard, choy), cauliflower, cavalo broccolo, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens	Imported cabbageworm, diamondback moth and cabbage looper	250 (50) For optimum control, apply with a modified seed oil adjuvant such as Hasten or MSO.	Minimum finished spray volume of 100 L/ha by ground Max. 4 applications per season. Not more than once every 3 days
Leafy vegetables Crop Group 4 Amaranth, leafy; arugula, cardoon, celery, celery (Chinese), celtuce, chevril, chrysanthemum (edible leaved, garland), corn salad, cress (garland, upland), dandelion leaves, dock, endive, florencia fennel, lettuce (head and leaf), orach, parsley leaves, purslane (garden, winter), radicchio, spinach, spinach (vine, New Zealand), Swiss chard	Cabbage looper	250 (50)	Minimum finished spray volume of 100 L/ha by ground Max. 4 applications per season. Not more than once every 3 days

Potatoes	Colorado potato beetle	250 to 375 (50 to 75)	Minimum finished spray volume of 100 L/ha by ground , 50 L/ha by air . Do not apply more than 4 times per year. Not more than once every 5 days
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Table 12.3 DPX-E2Y45 20 SC Insecticide Acceptable Use (label) Claims

Crop	Accepted Use Pattern		
	Pest	Rate ml product/ha (g a.i./ha)	Comments
Turf	Japanese beetle and European chafer larvae (grubs)	560 to 880 (112 to 176)	Finished spray volume of 200–1600 L/ha (2–16 L/100 m ²) by ground. Max. 1 applications per season
	Black cutworm	145 to 290 (29 to 58)	
	Annual bluegrass weevil	880 to 1125 (176 to 225)	

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

Canadian raw agricultural commodity (RAC) MRLs are the same as the American RAC MRLs. No Codex MRLs have been established.

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4.0 Value

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PMRA 1378777	2007, Potato Efficacy Summary Tables, DACO: 10.2.3.1
PMRA 1378778	2007, Stone Fruit Efficacy Summary Tables, DACO: 10.2.3.1
PMRA 1378769	2007, Brassica Efficacy Summary Tables, DACO: 10.2.3.1
PMRA 1378770	2007, Fruiting Vegetable Efficacy Summary Tables, DACO: 10.2.3.1
PMRA 1378773	2007, Turf Efficacy Summary Tables, DACO: 10.2.3.1
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B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Impact on Human and Animal Health

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