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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Chlorantraniliprole:** Problem Formulation for Registration Review

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The Environmental Fate and Effects Division (EFED) has completed the preliminary problem formulation for the environmental fate, ecological risk, and drinking water exposure assessments to be conducted as part of the registration review of the insecticide chlorantraniliprole (CAS# 500008-45-7). Functioning as the first stage of the risk assessment process for registration review, this problem formulation provides an overview of what is currently known about the environmental fate and ecological effects associated with chlorantraniliprole. It also describes the preliminary ecological risk hypothesis and analysis plan for evaluating and characterizing risk to non-target species in support of the registration review of chlorantraniliprole. This document also recommends studies that should be included in a generic data call-in (DCI) to address uncertainties surrounding the environmental fate and potential ecological effects of chlorantraniliprole. There were no label ambiguities identified. Based on the conclusions of the problem formulation, the following ecotoxicity studies are recommended to reduce uncertainty in the risk assessment:

- 850.1740: Whole sediment chronic toxicity, marine invertebrates
- 850.1735: Whole sediment acute toxicity, freshwater invertebrates

The full suite of Tier I data are available for honeybees; however, some of the studies were conducted with TEP instead of TGAI, the latter of which is preferred according to the respective study guideline. To fulfill those data needs, adult chronic oral, larval acute and larval chronic studies with TGAI would be helpful. TEP studies can be used if TGAI studies are not available at the time of the assessment.

In order to evaluate the need for Tier II bee exposure and toxicity studies, a preliminary Tier I bee risk assessment was conducted **(Appendix A)**. This analysis indicates potential risk concerns when considering available Tier I toxicity data and default exposure assumptions. According to the bee risk assessment guidance (USEPA 2014[1]), higher tier exposure data would be useful to refine exposure estimates to be specific to chlorantraniliprole. This would include studies where concentrations of chlorantraniliprole are quantified in pollen and nectar from crops and application methods that represent the registered uses of this chemical. It may be possible to utilize data from other chemicals (e.g., other diamides that have similar physical and chemical properties) to represent potential exposures of bees to chlorantraniliprole. If refined Tier I analyses using residue data still suggest risk to bees, higher Tier data (e.g., a Tier II colony feeding study) may be needed. Below summarizes the higher Tier exposure and effects data that would be needed to refine the bee risk assessment for the registration review of chlorantraniliprole. Prior to the conduct of these studies, protocols should be reviewed by EFED.

- Non-guideline Tier II: Field trial of residues in pollen and nectar
    - Based on application method and crop group
- Non-guideline Tier II: Semi-field testing for pollinators (colony feeding study)
- 850.3040: Tier III: Full-field testing for pollinators

[1] USEPA/PMRA/CDPR. 2014. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs, United States Environmental Protection Agency, Washington, D.C.; Health Canada Pest Management Regulatory Agency Ottawa, ON, Canada California Department of Pesticide Regulation, Sacramento, CA. June 19. (available at: http://www2.epa.gov/pollinator- protection/pollinator-risk-assessment-guidance).

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1.0. Executive Summary

The Environmental Fate and Effects Division (EFED) has completed the preliminary problem formulation for the ecological risk, environmental fate, and drinking water assessments to be conducted as part of the round 2 registration review of chlorantraniliprole. The problem formulation describes the methods planned to be used during the completion of drinking water and ecological risk assessments in support of registration review and provides an overview of the environmental fate, ecological effects, and potential risks associated with the use of chlorantraniliprole as well as uncertainties unique to risk assessment of chlorantraniliprole.

The following ecotoxicity studies are needed to reduce uncertainty in the risk assessment:

- Non-guideline Tier I: Honeybee adult chronic oral exposure (TGAI)
- Non-guideline Tier I: Honeybee larval acute and chronic oral exposure (TGAI)
- 850.1740: Whole sediment chronic toxicity, marine invertebrates
- 850.1735: Whole sediment acute toxicity, freshwater invertebrates

The following Tier II studies are recommended (**Appendix A**), pending risks identified in Tier I studies (TEP):

- Non-guideline Tier II: Field trial of residues in pollen and nectar
- Non-guideline Tier II: Semi-field testing for pollinators (colony feeding study)
- 850.3040: Tier III: Full-field testing for pollinators

2.0. Introduction

Chlorantraniliprole is an anthranilic diamide insecticide. Chlorantraniliprole functions via activation of insect ryanodine receptor channels, leading to internal calcium store depletion, resulting in impaired regulation of muscle contraction. The ryanodine receptor channels regulate release of the internal calcium stores important for muscle contraction. The sustained release of calcium levels within the cytosol leads to paralysis and ultimately death of the insect[2].

EFED evaluated the most recent ecological risk assessments for chlorantraniliprole in association with the updated toxicity, exposure, and usage information to determine if sufficient data are available and if further updates are needed to support registration review. This problem formulation identifies data needs and outlines additional assessments needed. In addition, EFED considered current science policies and risk assessment methodologies. The structure of chlorantraniliprole, as well as its chemical names and other identifiers can be found in the chemical identity table attached to this document (**Appendix B**).

[2] Chlorantraniliprole Ecological Monographs Volume 3, Section B.9: Ecotoxicology

3.0 Use Characterization

Chlorantraniliprole is a non-selective insecticide used to control pests in brassica vegetables, cotton, cucurbits, fruiting vegetables, grapes, leafy vegetables, pome fruit, potato, stone fruit, ornamentals, and turf grass. It is formulated as a soluble concentrate (20 SC), emulsifiable concentrate (EC) and wettable granule (35 WG). Treatment equipment include aircraft, backpack sprayers, granule applicators, ground equipment, package applicators, product containers, shaker cans, and spreaders. The Screening Level Usage Analysis (SLUA) report produced by the Biological and Economic Analysis Division (BEAD), located in the docket, lists reported annual agricultural usage of chlorantraniliprole. The Pesticide Label Use Summary (PLUS) report produced by BEAD indicates the minimum single foliar application rates are 0.059 lbs a.i./A for ground and 0.05 lbs a.i./A for aerial application. The maximum foliar application rate for ground and aerial applications is 0.098 lb/a, except for turf which has a maximum ground application rate of 0.23 lbs a.i./A. EFED will use application scenarios that result in maximum exposure scenarios for a given use for the risk assessment. Any absence of information on the labels regarding the maximum single application rate, the application interval, the maximum annual use rate, or application method may result in conservative assumptions.

4.0 Conclusions from Previous Risk Assessments

Chlorantraniliprole, produced by DuPont, was registered in 2008 and was not included in the first round of registration review. Several Section 3 New Use Assessments and Section 18 Assessments have been conducted for chlorantraniliprole using a parent-only approach for residues of concern (ROC) (assessments summarized in **Table 1**).

Table 1. Summary of Previous Ecological Risk Assessments Conducted for Chlorantraniliprole

Assessment Type	Date	DP Barcode	Use(s)
Experimental Use Permit (EUP)	3/29/07	338512	Leafy vegetables, fruiting vegetables, cucurbits, apples and pears
Section 3 New Chemical (S3NC)	12/4/07	338512	Brassica (cole), leafy vegetables, cucurbits and fruiting vegetables, non-brassica leafy vegetables, cotton, grape, pome fruit, potato, stone fruits, turf, ornamentals and groundcovers
Emergency Exemption (S18)	1/24/08	348294, 348105, 348106, 346325	Seed treatment in rice (MO, LA, MS, and AR)
S18	5/14/08	351273 and 351658	Sweet corn (Minnesota and Illinois)
Section 3 New Use (S3NU)	4/2/09	363702	Crop group 14: tree almond hulls, and pistachio

Assessment Type	Date	DP Barcode	Use(s)
S3NU	7/27/09	361404, 361406, 361407	Rice (seed treatment), artichoke, asparagus, corn, forage, fodder, straw, grass forage, herbs, hops, legume vegetables, mint, animal feed, okra, peanut, protected seed, spices, strawberry, sugarcane, tuberous and corm vegetables, bananas, plantain, caneberry, small fruit vine/climbing subgroup, cacao, citrus, coffee, figs, olives, persimmons, pomegranate, prickly pear cactus, and tropical hits.
S3NU	1/4/11	381819, 381820, 381821	Field corn (seed treatment), leafy vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, okra, peanut, root and tuber vegetables (except potato), leaves of root and tuber vegetables, bushberry subgroup, large shrub/tree subgroup, low growing berry subgroup, tea, and ti palm
S3NU	4/20/11	377697	Seed and foliage application to lettuce and spinach
S3NU	5/11	377697 & 389521	Lettuce & spinach seed
Special Local Needs (S24(c))	2/17/12	397884	Rice seed in SW Louisiana
S3NU	7/24/12	397575 and 397576	Oilseed and Soybean
S3NU	2/26/13	404738, 404739, 404740	Citrus (group 10-10), pome fruit (group 11-10), cereal grain (group 15, except corn and rice), and cereal grain forage, fodder, and straw (group 16, except corn and rice)
S3NU	11/27/13	410516, 412426, 412427, 412479	Peanuts, subgroup additions, multiple crop seasons for numerous previous uses
S3NU	9/2/15	426109	Rice and proposed rate increase on existing (numerous) crops
S18	5/26/16	433376	*Eragrostis tef* (common name: teff or warm season annual bunchgrass)
S3NU	11/3/17	435999	Commercial ornamental plant nurseries

4.1 Ecological Risk Assessment

Overall, all previous assessments concluded that there were both acute (mortality based endpoints) and chronic (endpoints based on reductions in live young, adult dry weight, etc.) risk concerns for freshwater and estuarine marine invertebrates. Available information suggested a low acute risk concern to adult honeybees, however, the risk picture is incomplete due to a lack of toxicity data and the potentially increased sensitivity of larval bees. Additionally, chronic risks for birds (endpoints based on reductions in shell thickness, and reductions in live 3-week-old embryos) have been reported for some uses, specifically, rice (USEPA 2008), lettuce and spinach seeds (USEPA 2011a, USEPA 2011b), and outdoor nursery structures with multiple crop

cycles per year (USEPA 2017). Finally, the majority of the previous assessments indicated that direct effects to terrestrial plants (sensitive dicots) are possible but uncertain due to a lack of a definitive toxicity endpoint.

The likelihood of chronic risk concerns to birds is low and there is concern only for single applications (USEPA 2017). Finally, direct effects to terrestrial plants (sensitive dicots) are possible but uncertain due to a lack of a definitive toxicity endpoint. Treatment over multiple crop cycles could potentially lead to additional risk for terrestrial plants (monocots in semi-aquatic areas), additional acute dietary risk to adult honeybees (cannot preclude), and additional chronic risk to birds (increased likelihood). However, there is low certainty about these additional risks, in part due to the conservative assumptions about exposure. Furthermore, any increased risk from terrestrial exposure to birds and honeybees would be limited to a small spatial footprint within or around outdoor nursery structures.

4.2 Drinking Water Assessments

A drinking water exposure assessment for the proposed new use on commercial ornamental plant nurseries was conducted for chlorantraniliprole in 2017 (USEPA 2017; DP 441586). Exposure estimates of chlorantraniliprole from currently labeled uses that produce maximum exposure (ornamentals) were 714 µg/L (acute) and 647 µg/L (chronic and cancer) in ground water. For surface water, the EDWCs for ornamental use for all (6) cropping cycles per year *did not exceed* the previous EDWCs modeled for rice reported in the DWA (USEPA 2015; DP 427663). Therefore, the previous surface water EDWCs did not change.

In 2015, a drinking water exposure assessment was conducted for chlorantraniliprole use on rice (USEPA 2015; DP 427663). Exposure estimates from chlorantraniliprole use on rice were 73 µg/L (acute) and 51 µg/L (chronic and cancer) for surface water. For ground water, exposure estimates of chlorantraniliprole from use on leafy, root and tuber vegetables were 194 µg/L (acute) and 178 µg/L (cancer), which is less than the maximum estimates in the 2017 assessment.

4.3 Clean Water Act Programs

Chlorantraniliprole is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act. No Total Maximum Daily Load (TMDL) criteria have been developed for chlorantraniliprole. The Impaired Waters and Total Maximum Daily Loads (TMDL) can be consulted for more information. Aquatic benchmarks have been established for chlorantraniliprole[3], and any data submitted or otherwise located as part of the registration review process may be used to update aquatic life benchmarks if applicable.

[3] http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm

5.0 Environmental Fate and Transport

The major routes of dissipation are alkaline-based hydrolysis, photodegradation in water, leaching and runoff. Considering abiotic degradation, chlorantraniliprole's hydrolytic degradation appears to be pH dependent, with degradation increasing with increasing pH. The hydrolysis DT_{50} values are considered stable at pH 4 and pH 7 and is 10 days at pH 9 (25°C; MRID 46889017). Photodegradation appears to be a major degradation pathway in shallow, well-lit, translucent waters. The aqueous photolysis study shows a phototransformation half-life of about 7.4 hours or 0.31 days (MRIDs 46889122, 46889018). The soil photolysis half-life was longer than the half-life for aqueous photolysis, with a DT_{50} value of 43 days (MRID 43006801).

Chlorantraniliprole can be characterized as persistent and moderately mobile (mean K_{OC} =337 L/Kg_{oc}) in terrestrial and aquatic environments, with the Koc for chlorantraniliprole as a better predictor of soil mobility than Kd (CVs are 0.89 for Kd and 0.47 for Koc). Volatilization is not expected to be a major route of dissipation, based on its low vapor pressure (1.57×10^{-13} mm Hg at 25°C; MRID 46889130) and Henry's Law constant (3.1×10^{-15} atm*m^3/mol at 20°C; MRID 46889000). Bioaccumulation is not expected, based on the low octanol-water partitioning coefficient (log K_{ow} = 2.86 at pH 7; MRID 46889032) and low bioconcentration factor in fish (BCF = 14 in whole fish; MRID 46979308). Concentrations of chlorantraniliprole in contaminated fish that reach uncontaminated water was eliminated by 50% in 1.5 days.

Chlorantraniliprole is expected to be persistent in deeper, poorly lit, and/or opaque aquatic environments (DT_{50} values ranged from 210 to 493 days in aerobic aquatic metabolism studies conducted in the dark). In the anaerobic aquatic metabolism study, the DT_{50} in the total system ranged from 45-127 days. The laboratory degradation of chlorantraniliprole in soil is affected by soil aging (sequestration) and incubation temperature. Chlorantraniliprole degraded in test soils with DT_{50s} ranging from 210 to 493 days, respectively at 25°C.

Terrestrial field dissipation studies were conducted on turf in New Jersey and Georgia (MRIDs 46889023 and 46889131) with a water dispersible granule and a suspension concentrate. Two additional terrestrial field dissipation studies (MRIDs 46889019 and 46889020) were conducted on bare soil with an emulsifiable concentrate. The dissipation half-life on bare soil studies ranged from 108 to 188 days with leaching ranging from 6-36" supporting soil laboratory data that show the chlorantraniliprole persists and leaches. The field dissipation half-lives of chlorantraniliprole on turf ranged from 150 to 258 days when all sampling depths were considered. In the field, these rates are expected to be faster due to additional dissipation mechanisms dependent on pH and temperature variation. The structure of chlorantraniliprole, as well as its chemical names and other identifiers can be found in the chemical identity table attached to this document (**Appendix B**). A selection of environmental fate and transport properties of chlorantraniliprole are summarized in **Table 2**.

Table 2. Chemical Properties and Environmental Fate Parameters of Chlorantraniliprole

Parameter	Value		MRID (DuPont ID)	EFED Classification
Selected Physical/Chemical Parameters				
Molecular mass (molecular formula)	483.15 g/mol		46889000	N/A
Vapor pressure (25°C)	1.57 x 10^{-13} mm Hg		46889130 (16517)	N/A
Aqueous solubility (20°C)	1.023 mg/L (RO water) 0.972, pH 4 0.880, pH 7 0.971, pH 9		46889026 (13169)	Supplemental
Henry's Law Constant (20°C)	9.76 x 10^{-14} atm-m^3/mol		calculated using solubility, vapor pressure and molecular weight	N/A
Organic Carbon Partition Coefficient (Koc) (mL/g) Sorption Coefficient (Kd) (mL/g)	Koc (mL/g)	Kd(mL/g)	46889032 (14445)	Supplemental Koc better predictor of sorption based on lower CV
	152 (Loamy sand) 438(Silty clay loam) 535(Sandy loam) 268(Loamy Sand) 255(Loam)	1.22(Loamy sand) 7.88(Silty clay loam) 2.68Sandy loam) 0.803(Loamy Sand) 3.31(Loam)		
Octanol/Water Partition Coefficient (Log K_{ow}) (pH 7)	2.86		46889032 (13177)	Supplemental
Persistence				
Hydrolysis half-life (25°C)	No substantial degradation (pH 4 & 7) 10 d (pH 9)		46889017 (12782)	Acceptable
Aqueous photolysis half-life (25°C)	0.31 d^A		46889122 46889018 (12783) (13917)	Supplemental
Soil photolysis half-life (25°C)	43d (Loam) (SFO)		43006801 (12778)	Supplemental
Aerobic soil metabolism half-life [dissipation half-life ^{A}] (25°C)	493 d (sandy loam) (SFO) 409 d (Silty clay loam) (SFO) 364 d (Loam) (SFO) 210 d (Clay loam) (SFO)		46889014 46889015 46889124 (12779) (12780)	Supplemental
Anaerobic soil metabolism half-life (25°C)	208 d (SFO)		46889016 (14568)	Supplemental

Parameter	Value	MRID (DuPont ID)	EFED Classification
Anaerobic aquatic metabolism half-life (25°C)	45 d (loam) (SFO) 127 d (sand) (SFO) Major transformation product: IN-EQW78 125 d (loam) (SFO) 231 d (sand) (SFO)	46889016 (14568) (12995)	Supplemental
Aerobic aquatic metabolism half-life (25°C)	8.48 d (loam) (SFO) 38 d (sand) (SFO)	46889016 (18938) (12781)	Supplemental
Field Dissipation			
Terrestrial field dissipation half-life; leaching depth	Texas: emulsifiable concentrate, 188 d (SFO) (0-36" depth; Hidalgo clay); leached to 36" depth	46889019 (12784)	Supplemental
	California: emulsifiable concentrate, 108 d (FOMC) (0-6" depth; Cajon sandy loam); leached to 6" depth	46889020 (12785)	Supplemental
	Georgia: Bermuda grass/Fuquay sand 258 d (all depth) 10 d (grass to thatch) 80 d (, in thatch, 0- 2") 96 d (in soil, 6- 24"); leached to deepest sampling depth	46889023 46889131 (12789) (16522)	Supplemental
	New Jersey: Tall fescue/Penn silt loam 150 d (all depth) 29 d (grass to thatch) 57 d (in thatch, 0- 2") 46 d (in soil, 6-24 "); leached to deepest sampling depth	46889024 (12790)	Supplemental
Fish Bioconcentration			
Steady State Bioconcentration Factor (BCF)	Bluegill sunfish (*Lepomis macrochirus)* Steady state BCF: 13 to 15x (whole) Kinetic BCF: 12 to 21x (whole) depuration half-life: 1.5 d	46979308 (12410)	Acceptable

[A] The half-life of 0.31 days was observed from exposure to a xenon arc lamp experiment using continuous irradiation (MRID 46889018).

Aerobic aquatic metabolism unextracted residues reached a maximum of 6.51% for BC radiolabelled (benzamide carbonyl-^{14}C) and 7.42% for PC radiolabeled (pyrazole carbonyl-^{14}C) chlorantraniliprole. The maximum CO_2 formation was less than 1%. In a soil photolysis study, unextractable residues in the irradiated loamy sediment reached a maximum of 13.9% AR in the

BC label and 5% AR for the PC label, while CO_2 was undetectable. Under anaerobic aquatic and soil conditions, unextracted residues were < 5% and CO_2 was not detectable. Therefore, unextracted residues are not of concern for chlorantraniliprole.

5.1 Transformation Products

The three major degradates of chlorantraniliprole identified in submitted environmental fate studies were IN-EQW78, IN-ECD73, and IN-F6L99. The four minor degradates identified in submitted environmental fate studies were IN-EVK64, IN-LBA23, IN-LBA24, IN-F9N04. **Appendix B** summarizes the transformation products of chlorantraniliprole and their maximum amounts formed in laboratory and field studies. The major degradate in aerobic and anaerobic water-sediment systems was IN-EQW78 with a maximum formation of 34.7% in aerobic aquatic systems and a maximum formation of 67.8% in anaerobic aquatic systems. IN-EQW78 has a low solubility limit in water of 37.4 µg/L at pH 7 and a log P_{ow} of 3.9 (DuPont ID 16514). In addition, IN-EQW78 is the major degradate in soil and sediment systems (forms up to 9.5% of the applied in aerobic soil; 26.7% of the applied in anaerobic soil; and 29 to 42% of the applied in field dissipation studies). In irradiated water/sediment systems, the total system DT_{50} for IN-EQW78 irradiated samples ranged from 125 to 231 days, compared to 43 to 91 days in the comparable dark control samples.

There were two major degradates, IN-LBA23 (40.8-51 max %AR) and IN-LBA24 (90.2-94.4 max %AR) identified in aqueous photolysis studies. The transformation product IN-ECD73 had a max %AR of 8.2 in an aerobic soil study and a max formation of 9.5% in field dissipation studies. Chlorantraniliprole has minor degradates that form in aerobic soil studies, IN-EVK64 (5.2 max %AR), IN-F6L99 (5.2 max %AR) and IN-F6NO4 (4.8 max %AR). Carbon dioxide was < 5% or not detected in laboratory studies, therefore due to the persistence of the chlorantraniliprole and its degradates, mineralization was not observed and the terminal degradates of the parent are unknown.

6.0 Receptors

Consistent with the process described in the Overview Document (USEPA, 2004), the risk assessment for chlorantraniliprole will rely on a surrogate species approach. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, will be used to extrapolate the potential effects on a variety of species (receptors) included under these taxonomic groupings.

Acute and chronic toxicity data from studies submitted by pesticide registrants along with the available open literature will be used to evaluate the potential direct and indirect effects of chlorantraniliprole to aquatic and terrestrial receptors. This includes toxicity on the technical grade active ingredient, degradates, and when available, formulated products (*e.g.*, "Six-Pack" studies).

A summary of available toxicity data for chlorantraniliprole is provided in in the following tables for aquatic and terrestrial taxonomic groups. Open literature studies will be identified through EPA's ECOTOXicology (ECOTOX) database, which employs a literature search engine for locating chemical toxicity data. At that time of the DRA (Draft Risk Assessment), EFED will review the endpoints from open literature studies that are more sensitive than those from available guideline studies.

Chlorantraniliprole was part of a global joint review with the Pesticides Safety Directorate (PSD), UK. Effects studies submitted with the new chemical application were reviewed by PSD and EFED, as indicated in Volume 3 Annex B.9 (Ecotoxicology) of the regulatory monograph.

A review of ecological incidents associated with chlorantraniliprole is provided in **Section 6.3**.

6.1. Effects to Aquatic Organisms

Fish

Non-definitive LC_{50} values are only available for chlorantraniliprole toxicity to fish on an acute basis. It can be characterized as being practically non-toxic to both freshwater and estuarine/marine fish on an acute basis. However, on a chronic basis, there were reductions in larval survival, wet weight, total length in sheepshead minnows, and larval abnormalities in rainbow trout. The available information shows no indication that the formulated products are more toxic to fish than the active ingredient (**Table 3**).

Table 3. Summary of the Endpoints from Fish Toxicity Studies for Chlorantraniliprole[1]

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical (DPX-E2Y45)					
Acute Toxicity Test	Chlorantraniliprole (96.5%)	*Ictalurus punctatus* (Channel catfish)	96-hr LC_{50} > 13.4 (no mortality, limit test, mean measured)	46979339 (14278)	Acceptable
	Chlorantraniliprole (95.9%)	*Lepomis macrochirus* (Bluegill sunfish)	96-hr LC_{50} >15.1 (no mortality or sublethal effects observed, mean measured)	46889009 (12333)	Acceptable
	Chlorantraniliprole (95.9%)	*Oncorhynchus mykiss* (Rainbow trout)	96-hr LC_{50} > 13.8 (no mortality or sublethal effects observed, mean measured)	46889008 (12332)	Acceptable
	Chlorantraniliprole (95.9%)	Sheepshead Minnow *(Cyprinodon variegatus)*	96-hr LC_{50} > 12 (no mortality or sublethal effects, mean measured)	46979301 (12334)	Acceptable

Flow Through Early Life Stage (90-day)	Chlorantraniliprole (96.5%)	*Oncorhynchus mykiss* (Rainbow trout)	90-d NOAEC = 0.11* (based on larval abnormalities LOAEC=0.329	46979340 (14279)	Acceptable
Flow through early life stage (36-day)	Chlorantraniliprole (96.45%)	Sheepshead minnow (*Cyprinodon variegatus*)	36-d NOAEC= 1.28* LOAEC=2.53 (Most sensitive endpoint based on a 12% reduction in larval survival at hatching; also 20% reduction in survival, at end of test at a NOAEC of 5.23	46979350 (14394)	Acceptable
Chlorantraniliprole 35 WG Formulation					
Acute Toxicity Test	Chlorantraniliprole 35 WG (35.82%)	*Oncorhynchus mykiss* (Rainbow trout)	96-hr LC_{50} > 1.09 (no mortality or sublethal effects observed, mean measured)	46979437 (15386)	Acceptable
	Chlorantraniliprole 20SC (18.57%)	*Lepomis macrochirus* (Bluegill sunfish)	96-hr LC_{50} > 1.84 (no mortality, limit test, mean measured)	46979625 (18602)	Acceptable
	Chlorantraniliprole 35 WG (35.82%)	*Lepomis macrochirus* (Bluegill sunfish)	96-hr LC_{50} > 1.19 (no mortality, limit test, mean measured)	46979439 (15396)	Acceptable
Chlorantraniliprole 20SC Formulation					
Acute Toxicity Test	Chlorantraniliprole 20SC (18.57%)	*Oncorhynchus mykiss* (Rainbow trout)	96-hr LC_{50} > 2.16 (no mortality, limit test, mean measured)	46979624 (18601)	Acceptable

[1] Freshwater fish are considered to be surrogates for aquatic-phase amphibians.
*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments

Aquatic Invertebrates

Estuarine/Marine Invertebrates

Chlorantraniliprole is moderately toxic to mysid shrimp (*Americamysis bahia*), with a 96-hr LC_{50} of 1.15 mg a.i./L, which is based on 85% mortality at the highest tested concentration. On an acute basis, chlorantraniliprole is highly toxic to the eastern oyster (*Crassostrea virginica*), with a 48-hr EC_{50} of 0.0399 mg a.i./L. This endpoint was based on 37% reductions in shell growth. The only available chronic data was for mysid shrimp with a NOAEC of 0.695 mg a.i./L and a LOAEC of 1.38 mg a.i./L. There are no toxicity data available on chlorantraniliprole formulations or degradates for this taxon **(Table 4**).

Table 4. Summary of the Endpoints from Estuarine/Marine Invertebrate Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Estuarine/Marine Invertebrates					
Chlorantraniliprole Technical (DPX-E2Y45)					
Estuarine/ Marine Invertebrate Acute Toxicity Test	Chlorantraniliprole (95.6%)	*Americamysis bahia* (Mysid shrimp)	96-hr LC_{50} = 1.15* (based on 85% mortality at the highest tested concentration, lethargy observed in mysids in the highest test concentration, mean measured)	46979302 (12335)	Acceptable
	Chlorantraniliprole (96.45%)	*Crassostrea virginica* (Eastern oyster)	48-hr EC_{50} = 0.0399 (based on a 37% reduction in shell growth between 0.0249 mg a.i./L and 0.0406 mg a.i./L, mean measured)	46979309 (12412)	Acceptable
Chronic	Chlorantraniliprole (96.4%)	*Americamysis bahia* (Mysid shrimp)	28-d NOAEC=0.695* 28-d LOAEC=1.38 (based on 100% adult mortality and total live young at the highest tested concentration, mean measured)	46979401 (14397)	Acceptable

*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments

Freshwater Invertebrates

Three acute toxicity studies and a chronic study were available with chlorantraniliprole for the freshwater invertebrate *Daphnia magna*. Acute toxicity data for *Daphnia magna* for chlorantraniliprole formulations (20SC and 35 WG) indicate that they are of similar toxicity as the technical grade (**Tables 5 & 6**).

Table 5. Summary of the Endpoints from Aquatic Invertebrate Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical (DPX-E2Y45)					
Acute Toxicity	Chlorantraniliprole (96.45%)	*Daphnia magna*	48-hr EC_{50}=0.0166* (mean measured, based on immobility)	46979440 (15868)	Acceptable
	Chlorantraniliprole (95.9%)	*Daphnia magna*	48-hr EC_{50}=0.116 (mean measured, based on immobility)	46889011 (12411)	Acceptable
	Chlorantraniliprole (96.45%)	*Daphnia magna*	48-hr EC_{50}=0.0098 (mean measured, based on immobility)	46979607 (17653)	Acceptable
Freshwater Invertebrate Chronic Toxicity	Chlorantraniliprole (96.45%)	*Daphnia magna*	21-d NOAEC = 0.00302* 21-d LOAEC = 0.00477 (based on 20% reduction in adult survival; other effects include reduction in total live young, adult dry weight, length and delays in first day of reproduction)	46979443 (15874)	Acceptable
Chlorantraniliprole 35 WG Formulation					
Acute Toxicity Study	Chlorantraniliprole 35 WG (35%)	*Daphnia magna*	48-hr EC_{50}=0.011 (mean measured, immobility)	46979435 (15113)	Acceptable
Chlorantraniliprole 20SC					
Acute Toxicity Test	Chlorantraniliprole 20SC (18.5%)	*Daphnia magna*	48-hr EC_{50}=0.0071 (mean measured, based on immobility)	46979617 (18427)	Acceptable

[1]DuPont No. 12754 tested at concentrations too low for effects to be seen and was superseded by 46979443 (DuPont No. 15874)

*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments

Table 6. Additional Freshwater Invertebrate Water Column Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical (DPX-E2Y45)					
Acute Toxicity Test	Chlorantraniliprole (96.45%)	*Brachionus calyciflorus (*Rotifer)	48-hr EC_{50} > 1.00 (no mortality) (nominal)	46979618 (18428)	Supplemental
	Chlorantraniliprole (96.45%)	*Centroptilum triangulifer* (Mayfly)	48-hr LC_{50} = 0.0116 (based on mean measured concentrations and mortality, 100% mortality at 0.0242 mg a.i./L after 48 hours, and 45 % mortality at 0.11 mg a.i./L, lethargy reported in surviving mayflies at 0.00519 and 0.0116 mg a.i./L)	46979433 (15109)	Acceptable
	Chlorantraniliprole (96.45%)	*Chimarra atterima* (Caddisfly)	48-hr LC_{50} = 0.0117 (based on mean measured concentrations and mortality, 65% mortality at 0.0119 mg a.i./L)	4697960/ (17585)	Acceptable
	Chlorantraniliprole (96.45%)	*Copepods of the suborder Cyclopoida*	48-hr LC_{50} > 1.00 (nominal)	4697612 (18090)	Supplemental
	Chlorantraniliprole (96.45%)	*Soyedina carolinensis (Carolina forestfly/ stonefly)*	48-hr LC_{50} > 0.978 (mean measured, less than 50% mortality at highest tested concentration)	46979628 (18804)	Acceptable
	Chlorantraniliprole (96.45%)	*Gammarus pseudolim-naeus*	48-hr LC_{50} = 0.351 (mean measured, mortality)	46979444 (15877)	Acceptable
	Chlorantraniliprole (96.45%)	*Hyalella azteca*	48-hr LC_{50} > 0.389 (mean measured, no mortality)	46979436 (15114)	Acceptable
	Chlorantraniliprole (96.45%)	*Oronectes virilis (Crayfish)*	48-hr LC_{50} >1.42 (nominal, no mortality)	46979441 (15872)	Supplemental
Acute Toxicity to Sediment Dwelling Invertebrates	Chlorantraniliprole (96.45%)	*Chironomus riparius* (Midge)	48-hr LC_{50} = 0.0859 (based on mean measured concentrations and mortality, 90% mortality at 0.107 mg a.i./L)	46979434 (15112)	Acceptable
	Chlorantraniliprole (96.45%)	*Lumbriculus variegatus (California blackworm)*	48-hr LC_{50} > 1.49 (mean measured, no mortality)	46979442 (15873)	Acceptable

Benthic Invertebrates

A single chronic benthic invertebrate study for freshwater species (*Chironomus riparius*) is available. The most sensitive endpoint was based on an 8% reduction in the emergence ratio at 0.010 mg a.i./kg dw. Additional effects were reported on development rate and time (**Table 7**).

Table 7. Summary of the Benthic Invertebrate Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical (DPX-E2Y45)					
Chronic Toxicity to Sediment Dwelling Invertebrates	Chlorantraniliprole (96.45%)	*Chironomus riparius* (Midge)	Sediment 28-d NOAEC=0.005 mg a.i./kg dw 28-d LOAEC=0.010 mg a.i./kg dw* Overlying Water 28-d NOAEC=0.042 µg a.i./L 28-d LOAEC=0.108 µg a.i./L Pore Water 28-d NOAEC=0.741 µg a.i/L 28-d LOAEC=1.55 µg a.i./L (most sensitive endpoint based on an 8% decrease in emergence ratio at 0.010 mg a.i./kg dw). There were also effects on development rate and time)	46979729 (14396)	Acceptable

*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments

Degradate Toxicity

Eight degradates were identified in environmental fate studies as possibly forming or occuring in water under environmentally relevant conditions. Five soil degradates (IN-EQW78, IN-EDC73, IN-GAZ720, IN-F6L99, and IN-F9N04) could be transported to waterbodies where they could be released into the water column. Three water degradates (IN-LBA22, IN-LBA23, IN-LBA24) only form after photolysis under laboratory conditions. Although unlikely to occur in aquatic systems, the photolysis degradates were included in invertebrate toxicity testing. All tested degradates were less acutely toxic than the TGAI parent compound to *Daphnids* (**Table 8**).

Table 8. Comparison of acute toxicity of chlorantraniliprole and its degradates to *Daphnia magna*.

Study Type	Test Substance (% a.i.)	Duration	EC50 Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Freshwater Invertebrate Acute Toxicity Test	IN-ECD73 (99.8%)	48-hr	> 0.013 (limit test, mean measured immobility)	46979619 (18472)	Acceptable
	IN-F6L99 (98.6%)		46.8 (mean measured, immobility)	46979620 (18473)	Acceptable
	IN-F9N04 (95.6%)		0.03 (mean measured, immobility)	46979621 (18474)	Acceptable
	IN-GAZ70 (94.9%)		> 0.00987 (limit test, mean measured, immobility)	46979614 (18387)	Acceptable
	IN-EQW78 (99.8%)		>0.138 (mean measured, limit test, immobility)	46979438 (15388)	Acceptable
	LBA24-002 (ND)	24-hr	> 10 (nominal, immobility)	46979427 (14889)	Supplemental
	LBA22-002 (ND)		> 0.24 (nominal, two test concentrations, immobility)	46979428 (14890)	Supplemental
	LBA23-000 (ND)		> 0.001 (nominal, three test concentrations, immobility)	46979531 (16754)	Supplemental
Chlorantraniliprole TGAI					
Acute Toxicity	Chlorantraniliprole (96.45%)	48-hr	0.0166 (mean measured, based on immobility)	46979440 (12411)	Acceptable
	Chlorantraniliprole (95.9%)		0.116 (mean measured, based on immobility)	46979607 (17653)	Acceptable
	Chlorantraniliprole (96.45%)		0.0098 (mean measured, based on immobility)	46889011 (12411)	Acceptable

Note: ND=purity not determined in study

Aquatic Plants

Based on the available aquatic plant studies summarized in **Table 9** there is no evidence that chlorantraniliprole is toxic to aquatic plants.

Table 9. Summary of the Endpoints from Aquatic Plant Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value (mg a.i./L)	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical					
14-day toxicity test to freshwater vascular plant (static)	Chlorantraniliprole (95.9%)	*Lemna gibba*	14-day EC_{50} > 2 (limit test, nominal)	46979307 (12409)	Acceptable
120-hour toxicity to green algae (medium renewal)	Chlorantraniliprole (95.9%)	Green Alga *Pseudokirchneriella subcapitata*	120-hr EC_{25} > 2 (nominal, limit test) (for cell count, area under the curve and growth rate)	46979306 (12408)	Acceptable
	Chlorantraniliprole (96.45%)	Blue Green Alga (*Anabaena flos-aquae)*	120-hr EC_{25} > 2 (nominal, limit test)	46979348 (14390)	Acceptable
	Chlorantraniliprole (96.45%)	Freshwater Alga (*Navicula pelliculosa*)	120-hr EC_{50} > 15.1 (initial measured)	46979727 14392	Acceptable
120-hour toxicity test (static)	Chlorantraniliprole (96.45%)	Marine Diatom (*Skeletonema costatum*)	120-hr EC_{50} > 14.6 (initial measured)	46979349 (14391)	Acceptable
Chlorantraniliprole 20 SC					
72-hour toxicity test (static)	Chlorantraniliprole 20SC	Green Alga *Pseudokirchneriella subcapitata*	72-hr EC_{50} > 4 (nominal, limit test)	46979610 (18808)	Acceptable
Chlorantraniliprole 35 WG					
72-hour toxicity test (static)	Chlorantraniliprole 35 WG	Green Alga *Pseudokirchneriella subcapitata*	72-hr EC_{50} > 1.78 (nominal, limit test)	46979611 (18089)	Acceptable

6.2. Effects to Terrestrial Organisms

Birds and Mammals

Toxicity studies on passerines, mallard duck and northern bobwhite quail indicate that chlorantraniliprole and its formulations (20SC and 35WG) are practically non-toxic on a subacute and acute basis. There is no evidence that the degradate IN-EQW78 is more acutely toxic. For chlorantraniliprole, on a chronic basis, there are effects observed in both mallards and bobwhite quail including reductions in eggshell thickness and reductions in 3-week old embryos.

For mammals, there is no evidence of chlorantraniliprole toxicity, and all endpoints were non-definitive (**Tables 10 & 11**).

Table 10. Summary of the Endpoints from Avian Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole Technical					
Acute Oral Toxicity	Chlorantraniliprole (97.1%)	Zebra Finch (*Poephila guttata*)	LD_{50} > 2250 mg a.i./kg bw No mortality observed	48216601 NA	Acceptable
	Chlorantraniliprole (96.45%)	Northern Bobwhite (*Colinus virginianus*)	LD_{50} > 2250 mg a.i./kg bw (Nominal, no mortality)	46889117 (14378)	Acceptable
Subacute Dietary Toxicity	Chlorantraniliprole (96.45%)	Mallard *(Anas platyrhynchos*)	LC_{50} > 5620 mg a.i./kg diet (nominal, no mortality)	46979305 (14380)	Acceptable
	Chlorantraniliprole (96.45%)	Northern Bobwhite (*Colinus virginianus*)	LC_{50} > 5620 mg a.i./kg diet (nominal no mortality)	46889118 (14379)	Acceptable
Chronic	Chlorantraniliprole (96.45%)	Mallard *(Anas platyrhynchos*)	NOAEC=500 mg a.i./kg diet (62.1 mg a.i./kg-bw-day) LOAEC=1000 mg a.i./kg diet (133 mg a.i./kg-bw-day) Based reduction in live 3-week old embryos at 1000 mg a.i./kg-diet by 10%.	46979725 (14384)	Acceptable
	Chlorantraniliprole (96.45%)	Northern Bobwhite (*Colinus virginianus*)	NOAEC = 10.1 mg a.i./kg bw-day (120 mg a.i./kg diet)* LOAEC= 20.7 mg a.i/kg bw-day (250 mg a.i./kg diet) Based on 9% reduction in eggshell thickness)	46979724 (14383)	Acceptable
Chlorantraniliprole 20SC					
Acute Oral Toxicity	Chlorantraniliprole 20SC (18.5%)	Northern Bobwhite (*Colinus virginianus*)	LD_{50} > 2000 mg a.i./kg bw (nominal, no mortality)	46979822 (18945)	Acceptable
Subacute Dietary Toxicity	Chlorantraniliprole 20SC (18.5%)	Northern Bobwhite (*Colinus virginianus*)	LC_{50} > 5620 mg a.i./kg diet (nominal, no mortality)	46979831 (19420)	Acceptable

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
Chlorantraniliprole 35 WG					
Acute Oral Toxicity	Chlorantraniliprole 35 WG (35%)	Northern Bobwhite (*Colinus virginianus*)	LD_{50} > 2250 mg a.i./kg bw (nominal, no mortality)	46979823 (18946)	Acceptable
Degradate IN-EQW78					
Acute Oral Toxicity	IN-EQW78 (99.8%)	Northern Bobwhite (*Colinus virginianus*)	LD_{50} > 2250 mg EQW78/kg bw (nominal, no mortality)	46979633 (18859)	Acceptable

Birds are considered surrogates for terrestrial phase amphibians and reptiles
*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments

Table 11. Summary of the Endpoints from Mammalian Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID
Acute Oral Toxicity	Chlorantraniliprole	Rat	LD_{50} > 5000 mg a.i./kg (limit test)	NA
Chronic Toxicity	Chlorantraniliprole (96.45%)	Rat	NOAEC=20,000 mg a.i./kg-diet (1563/1886 mg a.i./kg-day males/females)* Lack of adverse effects; LOAEL not established	46889107 Acceptable
Inhalation Toxicity	Chlorantraniliprole	Rat	LC_{50} > 5.1 mg a.i./L	NA

*Indicates most sensitive endpoint to be used in risk quotient calculations in future risk assessments
NA=Not available

Terrestrial Plants

There were three terrestrial plant studies available for chlorantraniliprole TEP with plant seedling emergence and vegetative vigor study designs. None of the studies indicated that there were effects on terrestrial plants at the tested concentrations, which were greater than the maximum ground and aerial application rates for chlorantraniliprole (**Table 12**).

Table 12. Summary of the Endpoints from Terrestrial Plant Toxicity Studies for Chlorantraniliprole

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
Terrestrial Vascular Plants: Vegetative Vigor	Chlorantraniliprole DPX-E2Y45 20 SC (18.4%)	**Monocots:** Onion (*Allium cepa*) **Dicot:** Pea (*Pisum sativum*) & Sugarbeet (*Beta vulgaris*)	**Monocot & Dicot** EC_{50}>0.266 lbs a.i./A; Most sensitive species could not be determined	48516603	Acceptable
Terrestrial Plants: Seedling Emergence	Chlorantraniliprole DPX-E2Y45 20 SC (18.4%)	**Monocots:** Corn (*Zea mays*) Oat (*Avena sativa*) Onion (*Allium cepa*) Ryegrass (*Lolium perenne*)	EC_{25} >0.661 lbs a.i./A (based on all test parameters emergence, shoot height, shoot dry weight and visual response)	46979825 (19075)	Supplemental Control seedling emergence fell below 80% for cucumber, tomato and sugar beet
Terrestrial Plants: Vegetative Vigor		**Dicots:** Cucumber (*Cucumis sativa*) Oilseed rape (*Brassica napus*) Pea (*Pisum sativum*) Soybean (*Glycine max*) Sugarbeet (*Beta vulgaris*) Tomato (*Lycopersicon esculentum*)	EC_{25} and EC_{50} > 0.661 lbs a.i./A (nominal, limit test) For 10 species tested, no effect >12% was observed.	46979824 (19074)	Acceptable

Terrestrial Invertebrates

Honeybees

Two studies were available with the TGAI that indicated chlorantraniliprole is practically non-toxic to adult honeybees on an acute oral and contact basis. Additional studies were submitted for the TEP (20SC (Reg # 100-1319), 35WG (Reg No. 279-9607) and 5SC (Reg No. 279-9612)) that did not show any additional evidence of chlorantraniliprole toxicity to adults on a chronic basis. However, a study on bumblebees (*Bombus terrestris*) was available for the TEP 5SC that suggests that on an acute oral basis, adult bumblebees are more sensitive than honeybees.

No larval toxicity studies were conducted with the TGAI; however, two 22-day larval toxicity tests were available for the TEPs 20SC and 35WG. Based on the studies, chlorantraniliprole exposure caused reductions in adult emergence and mortality in both studies. The most sensitive larval NOAEC of 0.043 µg a.i./L (MRID 50837601) was based on 70% reductions in emergence and 92% mortality at the LOAEC of 0.087 µg a.i./L (**Table 13**).

Twelve extended laboratory and field studies with honeybees were described in the ecological monographs Vol 3 i on TEP 20 SC and 35 WG (summarized in **Appendix C**). Seven of the studies were tunnel studies with applications on wheat and *Phacelia tanacetifolia* at 0.05 lbs a/A during foraging activity. Two studies were tunnel studies with applications up to 0.04 lbs a.i./A on *P. tanacetifolia* before and after sowing onto soil and applications during bee flight/full flowering. One study was conducted as an extended lab study with alfalfa and applications up to 0.100 lbs a.i./A that were made before collecting foliage. The last two tunnel studies with *P. tanacetifolia* were conducted at an application rates of 0.13 and 0.2 lbs a.i./A. Only two of the eleven studies tested up to the maximum application rate (0.0984 lbs a.i./A), while the other studies did not. Tunnel studies focused on effects on mortality and flight intensity. Overall, the studies did not capture any treatment related brood effects or effects on mortality, behavior, or flight intensity, and were not sufficient to capture treatment related effects on larvae. As described in **Appendix A**, there are Tier I LOC exceedances for larvae on an acute and chronic basis. Therefore, additional data from a colony feeding study would be most effective in further understanding this effect.

Table 13. Summary of the Endpoints from Terrestrial Invertebrate Toxicity Studies for Chlorantraniliprole (Tier I)

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
Honeybees					
Chlorantraniliprole Technical					
48-hr Acute Oral	Chlorantraniliprole (96.45%)	Honeybee (*Apis mellifera*)	48-hr LD_{50} > 104.1 µg a.i./ bee	46979602 (17582)	Acceptable
48-hr Acute Contact			48-hr LD_{50} > 4.0 µg a.i./bee		
Chlorantraniliprole 20SC					
48-hr Acute Oral	Chlorantraniliprole 20 SC (18.5%)	Honeybee (*Apis mellifera*)	48-hr LD_{50} > 114.1 µg a.i./ bee	46979616 (18426)	Acceptable
48-hr Acute Contact			48-hr LD_{50} > 100 µg a.i. /bee Sublethal effects reported and bees were uncoordinated, moribund, but most recovered in 48 hrs		
72-hr Larvae Acute Oral	Chlorantraniliprole 20 SC (18.5%)	Honeybee (*Apis mellifera*)	LD_{50}: 1.6 µg a.i./larvae	49846601	Acceptable

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID (DuPont ID)	EFED Classification
22-day Larval Chronic Oral	Chlorantraniliprole 20 SC (18.5%)	Honeybee (*Apis mellifera*)	NOAEC=0.069 µg a.i./larva/ day LOAEC=0.139 µg a.i./larva/ day (most sensitive endpoint adult emergence based on an 83% reduction, and Day 8 and 15 mortalities by greater than 60%)	50853301	Acceptable
Chlorantraniliprole 35 WG					
48-hr Acute Oral	Chlorantraniliprole 35 WG (34.5%)	Honeybee (*Apis mellifera*)	48-hr LD50 > 119.2 µg a.i./bee	46889120 (14387)	Acceptable
48-hr Acute Contact			48-hr LD50 > 100 µg a.i./bee		
22-day Larval Chronic Oral	Chlorantraniliprole 35 WG (34.5%)	Honeybee (*Apis mellifera*)	NOAEL: 0.043 µg a.i./larva/ day LOAEL: 0.087 µg g a.i./larva/ day (most sensitive endpoint, adult emergence 70% reduction and Day 15 mortality by 92%)	50837601	Acceptable
Chlorantraniliprole E2Y45 5SC					
48-hr Acute Oral	Chlorantraniliprole 5SC (5.1%)	Bumble Bee (*Bombus Terrestris*)	LD_{50} = 0.459 µg a.i./bee	50763201	Acceptable
48-hr Acute Contact			LD_{50} > 225 µg a.i./bee		
10-day Adult Chronic Oral	Chlorantraniliprole 5SC (5.1%)	Honeybee (*Apis mellifera*)	LC_{50} > 9.03 µg a.i./bee/day or 294 mg a.i./kg NOAEL: 9.03 µg a.i./bee/day or 294 mg a.i./kg (no effects on mortality or food consumption)	50825001	Acceptable

Other Terrestrial Invertebrates

Earthworms

Overall, there were 7 acute 14-day toxicity tests on earthworms (*Eisenia fetida*) conducted with chlorantraniliprole technical, the 35WG, and 20SC formulations and four soil degradates (IN-EQW78, IN-ECD73, IN-GAZ70, IN-F6L99). All acute studies had non-definitive endpoints and LC_{50} values were > 1000 mg/kg dw soil, apart from IN-F6L99, which had 100% mortality at 1000 mg IN-F699/kg soil, and a LC_{50} of 632.5 mg IN-F6L99 kg dw soil (DuPont ID 17631, MRID 46979604). In addition, four chronic studies (56-day duration) were conducted with

earthworms with the 35 WG formulation, and the degradates IN-EQW78, IN-ECD73, and IN-GAZ70. No treatment related effects were observed and NOAECs were equivalent to the highest tested dose (350 mg/kg dw soil).

A suite of additional toxicity Tier I acute tests were available for oral and contact exposure for several species of predatory mites, and non-target arthropods. Tier II extended laboratory tests and field trials were also available for non-target terrestrial arthropods and will be used for additional characterizations of risks to terrestrial invertebrates in registration review.

6.3. Ecological Incidents

A review on October 23, 2019 of the Incident Data System (IDS), which is maintained by the Agency's Office of Pesticide Programs, indicates a total of 3 reported ecological incidents associated with the use of chlorantraniliprole (**Table 14**). Of the 3-total reported ecological incidents, only one was not classified as unlikely.

A single incident classified as possible was reported for plants. The incident 00538-00306 involved mortality to trees and shrubs during the spring of 2012 in New Hanover County, NC. The incident was reported to involve the application of Grubex1 (a.i. chlorantraniliprole) which killed > 45% of a customer's trees and shrubs after the product was applied to plants.

In addition to the incidents recorded in IDS, additional incidents are reported to the Agency in aggregated form. Pesticide registrants report certain types of incidents to the Agency as aggregate counts of incidents occurring per product per quarter. Ecological incidents reported in aggregate reports include those categorized as 'minor fish and wildlife' (W-B), 'minor plant' (P-B), and 'other non-target' (ONT) incidents. 'Other non-target' incidents include reports of adverse effects to insects and other terrestrial invertebrates. For chlorantraniliprole, registrants have reported *no* minor fish and wildlife incidents, minor plant incidents, or other non-target incidents as of November 1, 2019.

The number of actual incidents associated with chlorantraniliprole may be higher than what is reported to the Agency. Incidents may go unreported since side effects may not be immediately apparent or readily attributed to the use of a chemical. Although incident reporting is required under FIFRA Section 6(a)(2), the absence of reports in IDS does not indicate that the chemical has no effects on wildlife; rather, it is possible that incidents are unnoticed and unreported.

Table 14. Ecological Incidents Associated with Chlorantraniliprole

Incident, Year	State	Legality	Certainty[a]	Use Site	Species (# Affected)	Effects
000538-00306, 2012	New Hanover County, NC	Undetermined	Possible	Residential	>45% of shrubs and trees	Mortality

[a] Incidents classified as 'unrelated' and 'unlikely' are excluded.

7.0. Exposure Pathways of Concern

The environmental fate properties and use patterns of chlorantraniliprole indicate that direct spray, spray drift, leaching to ground water, atmospheric deposition, and runoff represent potential transport mechanisms of chlorantraniliprole to aquatic and terrestrial organisms.

Screening Tool for Inhalation Risk

The Screening Tool for Inhalation Risk (STIR v.1.0) was used to provide an upper-bound estimate of exposure of birds and mammals to pesticides through inhalation of spray drift or vapor. Based on the molecular weight, vapor pressure and maximum aerial and ground application rate (0.0984 lbs a.i./A), and toxicity endpoints (**Appendix D**), inhalation exposure alone is not a concern for birds and mammals.

Screening Imbibition Program

The Screening Imbibition Program (SIP v.1.0)[4] was used to estimate bird and mammal exposure to pesticides in drinking water. The model indicated that the different solubility values can drastically influence the toxicity of the compound. The LD_{50}'s were non-definitive for the avian and mammalian endpoints, but may potentially indicate no risk if there was no mortality at the highest level tested. Based on the available toxicity data and the solubility of chlorantraniliprole (1.0 mg/L), drinking water exposure alone is not a concern for birds and mammals (**Appendix E**).

8.0. Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment is estimated. The use, environmental fate, and ecological effects of chlorantraniliprole will be characterized and integrated to assess risk. This will be accomplished using a risk quotient (RQ; ratio of estimated exposure to effects endpoint) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA, 2004), the likelihood of effects to individual organisms from particular uses of chlorantraniliprole will be estimated using the probit dose-response slope and either the level of concern or actual calculated risk quotient value.

This analysis plan will be revisited and may be revised depending upon a full review of the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

[4] http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

8.1 Stressors of Concern

Ecological Risk Assessment

The residues of concern (ROC) in this assessment are based on multiple lines of evidence including chemical structure/fate properties, ecological toxicity data, and estimated toxicity values from the Ecological Structure Activity Relationship (ECOSAR) model[5]. The only empirical toxicity data available were acute *Daphnid* toxicity studies for a suite of 8 degradates (**see Table 8**). These data indicated low degradate toxicity to *Daphnia magna* compared to parent. Therefore, they are not considered ROCs for aquatic invertebrates.

ECOSAR Modeling

The decision regarding which degradates are residues of concern (ROCs) for fish and aquatic plants is based on the EFED guidance for using ECOSAR in combination with empirical data and fate characteristics. The ECOSAR Model (ECOSAR Version 2.0) was used to predict the toxicity of the major degradates. ECOSAR uses quantitative structure activity relationships (QSAR) to predict effects of acute exposure to aquatic species. Reliability of the predictive capacity of ECOSAR modeling is determined based on how closely the modeling program can estimate the empirical data.

The table below (**Table 15**) includes the estimated toxicity values for chlorantraniliprole parent compared to empirical data. The estimated toxicity values were modeled from a suite of functional groups including amides, halopyridines, and pyrroles/diazoles. For parent, ECOSAR predictions were compared to the empirical data. As compared to empirical data for the parent, estimated toxicity values were greater than an order of magnitude for the majority of taxa. This indicates that the ECOSAR estimates are a poor fit for freshwater fish (acute), estuarine/marine fish (acute and chronic), duckweed, and both freshwater and estuarine/ marine invertebrates. However, modeling results for the amide functional group were the best representative estimates and considered a good fit (estimate within 5x) for chronic freshwater fish endpoints. Therefore, ECOSAR analysis will focus on the degradate toxicity of the chronic freshwater fish endpoint.

[5] USEPA. 2018 *Guidance for Using ECOSAR as a line of evidence for identifying residues of toxicological concern*. September 26, 2018. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency.

Table 15. Comparison of ECOSAR modeling with Empirical Data in mg a.i./L

Compound	FW fish acute LC_{50}	EM Fish acute LC_{50}	Daphnid LC50	Duckweed EC_{50}	Duckweed NOAEC	FW Fish NOAEC	EM Fish NOAEC	Daphnid NOAEC	EM invertebrate (Mysid) LC_{50}	EM invertebrate (Mysid) NOAEC
Chlorantraniliprole (parent) *Empirical*	>13.4	>12	0.0098	>2	NA	0.11	1.28	0.00302	1.15	0.695
Chlorantraniliprole (Amides) ECOSAR	3.87*	5.02*	2.79*	0.966	1.48*	0.120	NA	0.956	0.592	0.011
Chlorantraniliprole (Halopyradines ECOSAR)	1.62*	NA	5.0*	NA	NA	0.083	NA	0.022[1]	NA	NA
Chlorantraniliprole (Pyrazoles/Diazoles ECOSAR)	0.291	NA	2.04*	0.290	0.163	0.045	NA	0.0305	0.140	NA

*Endpoints are greater than the solubility limit of 1.023 mg a.i./L (parent)

[1]Toxicity value estimated through application of acute to chronic ratios per methods

Empirical acute daphnid data were available for the degradates IN-ECD73, IN-F6L99, IN-F9N04, IN-GZZ70, IN-EQW78, LBA24-002, and LBA23-000. In comparison to parent, empirical data were non-definitive and indicated that daphnia are less sensitive to degradates compared to parent on an acute basis. Estimated toxicity values were modeled for the degradates IN-F9N04, IN-EQW78, IN-EVK64, IN-LBA23, IN-ECD73, IN-F6L99 for the freshwater fish chronic endpoint (**Table 16**).

After examining ECOSAR output for the suite of major degradates, there is evidence that IN-ECD73 may be more sensitive (~12X) to fish on a chronic basis compared to the parent. This degradate is only found in soil (with minimal aquatic exposure) with a max % AR (applied radioactivity) of 8.2 in aerobic soil study and a max formation of 9.5% in field dissipation studies. There was no evidence the major aquatic degradate IN-EQW78 was more toxic to fish on a chronic basis compared to parent (less than 1X). In combination with limited empirical data, predicted toxicity and model uncertainties, there is enough evidence to support the exclusion of this degradate and the use of parent as the ROC. This comparison will be used for characterization purposes only.

Table 16. Comparison of ECOSAR modeling results for freshwater fish chronic endpoints

FW Fish NOAEC (mg a.i./L)							
Parent Toxicity Estimates		ECOSAR Degradate Toxicity Estimates					
Compound	FW Fish NOAEC	IN-EQW78	IN-LBA23	IN-EVK64	IN-F9N04	IN-F6L99	IN-ECD73
Chlorantraniliprole (parent) *Empirical*	0.11	-	-	-	-	-	-
Chlorantraniliprole (Amides) ECOSAR	0.120	**0.052**	0.230	NA	0.220	3.79	NA
Chlorantraniliprole (Halopyradines ECOSAR)	0.083	**0.035**	NA	NA	0.155	NA	NA
Chlorantraniliprole (Pyrazoles/Diazoles ECOSAR)	0.045	**0.024**	0.072	4.50	NA	0.495	NA
Chlorantraniliprole (Phenols ECOSAR)	NA	NA	0.711	NA	NA	NA	NS
Chlorantraniliprole (Phenol/Amides ECOSAR)	NA	NA	0.030	NA	NA	NA	**0.0068**

NA= ECOSAR did not generate data for this functional group.
BOLD=degradate more sensitive than parent

Drinking Water Exposure Assessment

The Residues Of Concern Knowledgebase Subcommittee (ROCKS) recommended chlorantraniliprole only as the residue of concern for drinking water due to its persistence under environmental conditions (USEPA, 2008; DP 343519).

8.2 Measures of Exposure

Terrestrial Exposure

The most current models will be used at the time of the risk assessment. Current models relevant to terrestrial exposure pathways include:

- TerrPlant (v.1.2.2)[6] is used to calculate EECs for characterizing exposure to terrestrial and semi-aquatic plants.
- Bee-REX (v 1.0)[2] is used a screening-level tool to calculate EECs for use in a Tier I risk assessment
- T-REX (v 1.5.2)[4] is used to estimate avian and mammal exposure residues on terrestrial food items. For input into T-REX, the default foliar dissipation half-life of 35 days will be used in the absence of acceptable foliar dissipation rate data.

[6] http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Aquatic Exposure

There is potential for exposure to non-target organisms through wash off and contact with surface waters. This assessment will consider the introduction of the pesticide to the standard farm pond from a rainfall event that washes the compound from the field to the surface water. The most current models will be used to estimate residues in water at the time of the risk assessment. Based on fate properties there is no evidence that chlorantraniliprole bioaccumulates in the aquatic food web ($K_{ow} < 4$), therefore, this potential exposure will not be considered. The current models relevant to aquatic exposure pathways include:

- Pesticide in Water Calculator (PWC) (v.1.2)[7] is used to calculate EECs for characterizing exposure to surface and ground water.
- PFAM (v 1.0) is used to calculate EECs for use in a Tier I risk assessment for rice and cranberry
- AgDRIFT (v 1.5.2) is used to generate the spray drift fraction used for estimating exposure

Available Monitoring Data

The Agency is aware of monitoring conducted by federal and state agencies. Available monitoring data will be considered in the assessment to the extent that data on chlorantraniliprole are available.

8.3 Measures of Effect

Toxicity data presented in Section 3 of this problem formulation will be used to calculate risk quotients. Any additional information submitted by the registrant or found in the open literature prior to conduct of the risk assessment will also be considered.

8.4 Integration of Exposure and Effect

The exposure and effects data will be integrated in order to evaluate potential adverse ecological effects on non-target species. The risk quotient method will be used to compare exposure and measured toxicity values. EECs will be divided by acute and chronic toxicity values. The resulting RQs will be compared to the Agency's Levels of Concern (LOC) (USEPA, 2004).

8.5 Endangered Species Assessments

Consistent with EPA's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to federally listed threatened and endangered (listed) species from registered uses of pesticides in accordance with the Joint Interim Approaches developed to implement the

recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*.[8] The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA. EPA will address concerns specific to chlorantraniliprole in connection with the development of its final registration review decision for chlorantraniliprole.

In November 2013, EPA, the U.S. Fish and Wildlife Service, National Marine Fisheries (the Services), and USDA released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*.[9]

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological problem formulation supporting the Preliminary Work Plan for chlorantraniliprole does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the planned risk assessment for the registration review of chlorantraniliprole will describe the level of ESA analysis completed for this particular registration review case. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses of chlorantraniliprole as part of completing this registration review.

8.6 Drinking Water Assessment

EFED does not plan to conduct a new drinking water exposure assessment (DWA) at this time. There are no new submitted environmental fate data, nor are new modeling methods available with which to update previous EDWCs for surface water (DP 427663) and ground water (DP 441586), as summarized in the 2017 DWA. If warranted, to support future human health dietary risk assessments of chlorantraniliprole, a new DWA may be conducted if new environmental fate and/or toxicity data and/or modeling methods become available.

[8] https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides
[9] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report

9.0 Preliminary Identification of Data Gaps

Available studies submitted to fulfill environmental fate and ecological effects guideline requirements are tabulated below for each guideline requirement, as well as their study classifications and whether further data are needed in order to support the assessments.

9.1 Environmental Fate Data

There are no outstanding environmental fate data gaps (**Table 17**). EFED does not recommend submission of any additional studies to support the assessments.

Table 17. Submitted Environmental Fate Data for Chlorantraniliprole

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?
835.1230	Batch equilibrium	46889032	14445	Supplemental	No
835.2120	Hydrolysis	46889017	12782	Acceptable	No
835.2240	Aqueous photolysis	46889018	12783 13917	Supplemental	No
835.2410	Soil photolysis	46979316	12778	Supplemental	No
835.4100	Aerobic soil metabolism	46889014	12779 12780	Supplemental	No
835.4200	Anaerobic soil metabolism	46889016	14568	Supplemental	No
835.4300	Aerobic aquatic metabolism	46889016	18398 12781	Supplemental	No
835.4400	Anaerobic aquatic metabolism	46889016	14568 12781	Supplemental	No
835.6100	Terrestrial field dissipation	46889019 46889020 46889021 46889022	12784 12785 12789 12790 16522	Supplemental	No
835.6200	Aquatic field dissipation	48075302	30119	Unacceptable	No
		48075303	30120	Unacceptable	
		48930703	32431	Supplemental	
		48930704	32432	Supplemental	

Non-guideline	Sample storage stability in frozen soil	46979321	12955	Acceptable	No
850.6100	Environmental chemistry method in water	46979445	N/A	Supplemental	No
		46979530		Supplemental	
850.6100	Environmental chemistry method in soil	46889126	N/A	Supplemental	No
		46979431		Supplemental	
		48075302		Unacceptable	
850.1730	Fish BCF	46979308	12410	Supplemental	No

9.2 Ecological Effects Data

EFED recommends submission of the following studies to reduce uncertainty in the risk assessment:

- Non-guideline Tier I: Honeybee adult chronic oral exposure (TGAI)
- Non-guideline Tier I: Honeybee larval acute and chronic oral exposure (TGAI)
- 850.1740: Whole sediment chronic toxicity, marine invertebrates
- 850.1735: Whole sediment acute toxicity, freshwater invertebrates

Based on preliminary risk conclusions from the Tier I bee risk assessment, the following higher Tier studies are recommended (**Appendix A**):

- Non-guideline Tier II: Field trial of residues in pollen and nectar (TEP)
- Non-guideline Tier II: Semi-field testing for pollinators (colony feeding study) (TEP)
- 850.3040: Tier III: Full-field testing for pollinators (TEP)

Table 18. Submitted Aquatic Ecological Effects Data for Chlorantraniliprole

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
850.1075	Acute freshwater fish toxicity (cold water species)	46889008	12332	Acceptable	No	-
	Acute freshwater fish toxicity (warm water species)	46889009	12333	Acceptable	No	
	Acute estuarine/marine fish toxicity	46979301	12334	Acceptable	No	
850.1010	Acute toxicity to freshwater invertebrates	46979440	15868	Acceptable	No	-
		46889011	12411			
		46979601	17653			

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
850.1025	Acute estuarine/ marine mollusk toxicity	46979309	12412	Acceptable	No	-
850.1035	Acute estuarine/ marine invertebrate toxicity	46979302	12335	Acceptable	No	-
850.1300	Freshwater invertebrate life cycle	46979443	15874	Acceptable	No	-
850.1350	Saltwater invertebrate life cycle	46979401	14397	Acceptable	No	-
850.1400	Freshwater fish early life stage	46979340	14279	Acceptable	No	-
	Saltwater fish early life stage	46979350	143994	Acceptable	No	-
850.1500	Freshwater fish life cycle	NA	NA	NA	No	Early life stage studies are used to cover chronic risk to fish.
	Saltwater fish life cycle	NA	NA	NA	No	
850.1735	Whole sediment acute toxicity, freshwater invertebrates	NA	NA	NA	**Yes**	Due to the mode of action of chlorantraniliprole on invertebrates this study is recommended. If no data are available, EFED can use pore water EECs and compare to most sensitive water column species.
850.1740	Whole sediment chronic toxicity, marine invertebrates	NA	NA	NA	**Yes**	Due to the mode of action of chlorantraniliprole on invertebrates this study is recommended.
850.1740	Whole sediment chronic toxicity, freshwater invertebrates	46979729	14396	Acceptable	No	-
Non-guideline	Crayfish field toxicity	48075301	NA	Unacceptable	No	This study type is not needed for risk assessment
850.4500	Aquatic plant growth (freshwater green alga)	46979307	12409	Acceptable	No	-

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
	Aquatic plant growth (freshwater diatom)	46979727	14395	Acceptable	No	
	Aquatic plant growth (saltwater diatom)	46979349	14391	Acceptable	No	
850.4550	Aquatic plant growth (Cyanobacteria)	46979348	14390	Acceptable	No	
850.4400	Aquatic plant growth (vascular plants)	46979307	12409	Acceptable	No	

BOLD=recommended studies

Table 19. Submitted Ecological Effects Data for Terrestrial Plants Exposed to Chlorantraniliprole

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
850.4100[A]	Terrestrial plant toxicity (Tier I or Tier II seedling emergence)	46979825	19075	Supplemental	No	-
850.4150[B]	Terrestrial plant toxicity (Tier I or Tier II vegetative vigor)	48516603	NA	Acceptable	No	-
		46979824	19074	Acceptable		
		48216603	NA	Acceptable		

[A] As of July 2012 the Final Guideline 850.4100 contains both Tier I and Tier II test guidance.

[B] As of July 2012 the Final Guideline 850.4150 contains both Tier I and Tier II test guidance.

Table 20. Submitted Ecological Effects Data for Birds Exposed to Chlorantraniliprole

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
850.2100	Avian acute oral toxicity (upland game or waterfowl)	46889117	14387	Acceptable	No	-
	Avian acute oral toxicity (passerine)	48216601	NA	Acceptable	No	-
850.2200	Avian dietary toxicity (upland game)	46889118	14379	Acceptable	No	-
	Avian dietary toxicity (waterfowl)	46979305	14380	Acceptable	No	-
850.2300	Avian reproduction (upland game)	46979724	14383	Acceptable	No	-
	Avian reproduction (waterfowl)	46979725	14384	Acceptable	No	-

Table 21. Submitted Ecological Effects Data for Terrestrial Invertebrates Exposed to Chlorantraniliprole

OCSPP Guideline	Study Type	MRID	DuPont ID	Study Classification	Data Need?	Comments
850.3020	Adult honeybee acute contact toxicity (Tier 1)	46979602	17582	Acceptable	No	
Non-guideline	Adult honeybee acute oral toxicity (Tier 1)	46979602	17582	Acceptable	No	
Non-guideline	Adult honeybee chronic oral toxicity (Tier 1)	50825001	NA	Acceptable	**Yes**	Studies listed are available for TEP, but not TGAI; considered data gaps since TGAI tests are unavailable. If TGAI studies not available at time of risk assessment EFED will use the TEP based endpoints to calculate RQs.
	Larval honeybee acute (Tier I)	49846601	NA	Acceptable	**Yes**	
	Larval chronic toxicity (Tier 1)	50853301	NA	Acceptable	**Yes**	
Non-Guideline	Field trial of residues in pollen and nectar	46889129	16269	Acceptable	**Yes**	Based on risks to larvae in Tier I analysis, Tier II residue studies are recommended. Multiple studies may be needed to represent the potential exposures from the different registered uses (application methods and crops) of chlorantraniliprole.
		49346601	NA	Supplemental		
Non-Guideline	Tier II Semi Field Testing for Pollinators (Tunnel Studies)	46979422	14706	Supplemental	No	Tunnel studies were conducted however, they have two major limitations that limit their utility for the risk assessment: 1) many were conducted at rates that are lower than the max registered rates for chlorantraniliprole and 2) they were not designed to capture effects to larvae (brood), which, according to the Tier I risk assessment, is the primary concern for chlorantraniliprole.
		46979346	14388			
		46979806	18087			
		46979447	16272			
		46979446	16271			
		46979804	18085			
		46979744	17248			
		46979548	17247			
		46979805	18086			
		46980009	12753			
		46979304	17208			
Non-Guideline	Tier II Semi Field Testing for Pollinators (Colony Feeding Study)	NA	NA	NA	**Yes**	Based on results of Tier I analysis, there are acute and chronic concerns to larval honeybees that were

						not captured in tunnel studies
850.3040	Tier III full field testing for pollinators	NA	NA	NA	**Yes**	Recommendation pending risk identified in Tier II studies

10.0 References

U.S. EPA. 1999. Guidance for Use of the Index Reservoir in Drinking Water Exposure Assessments. Arlington, VA.

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Appendix A. Tier I Risk Assessment for Bees to Determine Tier II Data Requirements

A preliminary Tier I bee risk assessment was conducted in order to evaluate the need to recommend Tier II studies. In this analysis, BeeREX (1.0) was run using the minimum (0.0587 lbs a.i./A) and maximum (0.0987) foliar application rates. RQs were generated using the larval NOAEL for Chlorantraniliprole TEP 20 SC (MRID 50837601) of 0.069 µg a.i./bee. Both the minimum and maximum RQs (11.57 and 19.45 respectively) exceeded the chronic LOC (1.0) by an order of magnitude. Based on conclusions from the preliminary tier I risk assessments, it is clear that there are risk concerns for honeybee larvae on an acute and chronic basis. However, the available Tier II studies did not completely capture the treatment related effects at the larvae stage. Therefore, additional data from a colony feeding study would be recommend in order to completely capture the risk picture at the Tier II level.

Table 1a. User inputs (related to exposure) at the minimum foliar and ground application rates

Description	Value
Application rate	0.0587
Units of app rate	lb a.i./A
Application method	foliar spray
Are empirical residue data available?	no

Table 1b. Toxicity data

Description	Value (µg a.i./bee)
Adult contact LD50	4
Adult oral LD50	104.1
Adult oral NOAEL	9.08
Larval LD50	1.6
Larval NOAEL	0.069

Table 1c. Estimated concentrations in pollen and nectar

Application method	EECs (mg a.i./kg)	EECs (µg a.i./mg)
foliar spray	6.457	0.006457
soil application	NA	NA
seed treatment	NA	NA
tree trunk	NA	NA

Table 1d. Results (highest RQs)

Exposure	Adults	Larvae
Acute contact	0.039623	NA
Acute dietary	0.02	0.50
Chronic dietary	0.21	11.57

Table 2a. User inputs (related to exposure) at the maximum foliar/ground application rate

Description	Value
Application rate	0.0987
Units of app rate	lb a.i./A
Application method	foliar spray
Are empirical residue data available?	no

Table 2b. Toxicity data

Description	Value (µg a.i./bee)
Adult contact LD50	4
Adult oral LD50	104.1
Adult oral NOAEL	9.08
Larval LD50	1.6
Larval NOAEL	0.069

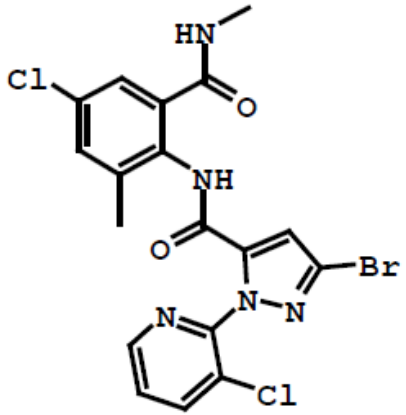
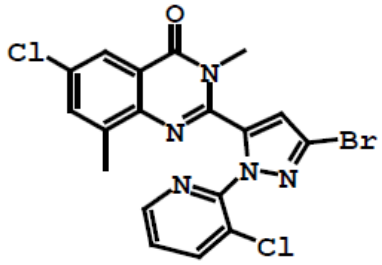
Table 2c. Estimated concentrations in pollen and nectar

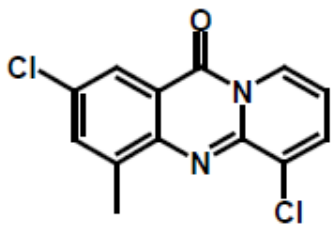
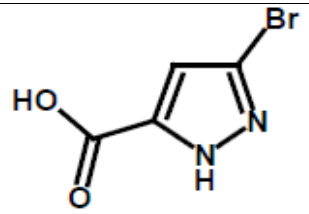
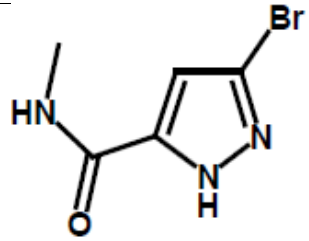
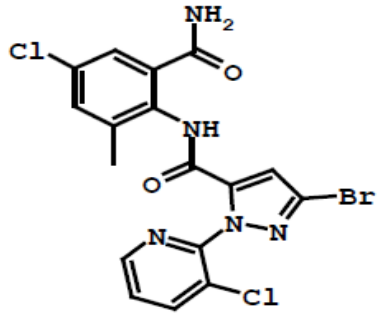
Application method	EECs (mg a.i./kg)	EECs (µg a.i./mg)
foliar spray	10.857	0.010857
soil application	NA	NA
seed treatment	NA	NA
tree trunk	NA	NA

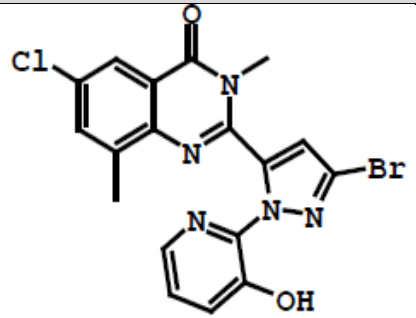
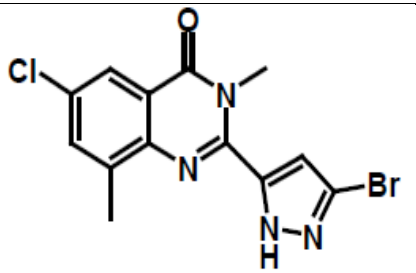
Table 2d. Results (highest RQs)

Exposure	Adults	Larvae
Acute contact	0.066623	NA
Acute dietary	0.03	0.84
Chronic dietary	0.35	19.45

Appendix B. Chemical Structures of Chlorantraniliprole and Its Degradates

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	Ref. (MRID)	Maximum %AR (day)[A]	Final %AR (study length)
PARENT COMPOUND						
Chlorantraniliprole **(DPX-E2Y45)** **CAS No.:** 500008-45-7 **Formula:** $C_{18}H_{14}BrCl_2N_5O_2$ **MW:** 483.15 g/mol **SMILES:** Cc1cc(cc(c1NC(=O)c2cc(nn2c3c(ccn3)Cl)Br)C(=O)NC)Cl	**IUPAC:**3-Bromo-N-[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide **CAS name:** 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide					
TRANSFORMATION PRODUCTS						
IN-EQW78 **CAS No.: not available** **Formula:** $C_{18}H_{12}BrCl_2N_5O$ **MW:** 465.14 g/mol **SMILES:** Cc1cc(cc2c1nc(n(c2=O)C)c3cc(nn3c4c(cccn4)Cl)Br)Cl	**CAS name:** 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3, 8-dimethyl-4(3H)-quinazolinone		Aerobic soil	46889014 46889015 46889124	9.54% (365 d)	9.54% (365 d)
			Anaerobic soil	46889016	26.68% (120 d)	26.68% (120 d
			Aerobic aquatic	46889016	34.69% (75 d)	7.22% (365 d)
			Anaerobic aq.	46889016	67.8% (181 d)	58.1% (365 d)
			Terr dissipation (California)	46889020 46889022	42%[B] (181 d)	42 [B] (540 d)
			Terr dissipation (Texas)	46889019 46889021	29%[B] (741 d)	29% [B] (741 d)
			Aq. field dissipation	48930703	2.0% [C] (0 d)	0.9% (94 d)
				48930704	13.7% [C] (0 d	4.8% [C] (90 d

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	Ref. (MRID)	Maximum %AR (day)[A]	Final %AR (study length)
IN-ECD73 **CAS No.: not available** **Formula:** $C13H8Cl_2N_2O$ **MW:** 279.13 g/mol **SMILES:** Cc1cc(cc2c1nc3c(cccn3c2=O)Cl)Cl	**CAS name:** 2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one		Aerobic soil	46889014 46889015 46889124	8.22 % (180 d)	4.93% (365 d)
			Terr. dissipation (California)	46889020 46889022	9.5% (540 d)	9.5% (540 d)
IN-EVK64 **CAS No.:** Not available **Formula:**C5H6BrN2O2 **MW:** 190.98 g/mol **SMILES:** C1=C(NN=C1C(=O)O)Br	**CAS name:** 5-Bromo-1H-pyrazole-3-carboxylic acid		Aerobic soil	46889014 46889015 46889124	5.15% (240 d)	5.15% (240 d)
IN-F6L99 **CAS No.:** Not available **Formula: C5H6BrN3O** **MW:** 204.03 g/mol **SMILES:** CNC(=O)C1=NNC(=C1)Br	**CAS name:** 5-Bromo-N-methyl-1H-pyrazole-3-carboxamide		Aerobic soil	46889014 46889015 46889124	5.2% (240 d)	5.2% (240 d)
IN-F9N04 **CAS No.:** Not available **Formula:**C17H12BrCl2N5O2 **MW:** 469.13 g/mol **SMILES:** C1=C(C(=C(C=C1Cl)C)NC(C2=CC(=N[N]2C3=NC=CC=C3Cl)Br)=O)C(N)=O	**CAS name:** N-[2-(Aminocarbonyl)-4-chloro-6-methylphenyl]-3-bromo-1-(3-chloro-2-pyridinyl)1H-pyrazole-5-carboxamide		Aerobic soil	46889014 46889015 46889124	4.8 % (300 d)	4.5% (365 d)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	Ref. (MRID)	Maximum %AR (day)[A]	Final %AR (study length)
IN-LBA23 **CAS No.:** Not available **Formula:**C18H13BrClN5O2 **MW:** 446.69 g/mol **SMILES:** CC1=C2C(=CC(=C1)Cl)C(N(C(=N2)C3=CC(=N[N]3C4=NC=CC=C4O[H])Br)C)=O	**CAS name:** 2-[3-Bromo-1-(3-hydroxy-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3H)-quinazolinone		Aq. photolysis	46889122 46889018	51.4% (5 d) (natural sterile water) 40.8% (15 d) @ pH 7 (buffer)	n.d. (2 d) (natural sterile water) n.d. (15 d) @ pH 7
IN-LBA24 **CAS No.:** Not available **Formula:** C13H10BrClN4O **MW:** 353.61 **SMILES:** c2c1nc(n(c2=O)C)c3cc(n[nH]3)Br)Cl	CAS name: 2-(5-Bromo-1H-pyrazol-3-yl)-6-chloro-3,8-dimethyl-4(3H)-quinazolinone		Aq. photolysis	46889122 46889018	94.4% (5 d) (natural sterile water) 90.2% (15 d) @ pH 7 (buffer)	89% (15 d) (natural sterile water) 90.2 %% (15 d) @ pH 7 (buffer

[A] n.d. means “not detected”.

[B] Terrestrial field study percentages represent the ratio of degradate concentration to the maximum parent concentration, both in the top layer of soil.

[C] Aquatic field study percentages represent the ratio of degradate concentration to the maximum parent concentration, both in the top layer of sediment

Appendix C. Summary of the Endpoints from Terrestrial Invertebrate Toxicity Studies for Chlorantraniliprole (Tier II)

Study Type	Test Substance (% a.i.)	Study Summary	MRID/DuPont ID	Study Classification[1]
Foliage residue toxicity study (850.3030)	Chlorantraniliprole 35 WG	When residues of DPX-E2Y45 35 WG is applied at 0.1 lbs a.i./A, there does not appear to be any mortality or sublethal effects on foraging worker honeybees.	46889129/ 16269	Acceptable
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	When exposure to *Phacelia tanacetifolia* foliage, treated with DPX-E2Y45 20 SC at 0.46 lbs a.i./a there were no treatment related effects survival, flight intensity, behavior, nor colonies (condition bee brood) on exposed bees or colony 7-8 days post exposure.	46979422/ 14706	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	When exposure to *Phacelia tanacetifolia* foliage, treated with DPX-E2Y45 20 SC at 0.46 lbs a.i./a (nominal) there were no treatment related effects on exposed bees or colony over 22 days.	46979346/ 14388	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20 SC when applied to 0.06 lbs a.i./A did not have a harmful effect when applied to flowering *Phacelia tanacetifolia* during honeybee flight over 7 days and the colony over 28 days.	46979806/ 18087	Supplemental
Semi Field Study – Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied on flowering *Phacelia tanacetifolia* at 0.05 lbs a.i./A during and after bee-flight did not have a harmful effect on honey bee mortality, flight intensity, behavior, nor on the honey bee colonies (condition, honey bee brood).	46979447/ 16272	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied on flowering *Phacelia tanacetifolia* at 0.05 lbs a.i./A during or after bee-flight did not have a harmful effect on honey bee mortality, flight intensity, behavior, nor on the honey bee colonies (condition of colony, honey bee brood).	46979446/ 16271	Supplemental

Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied on flowering *Phacelia tanacetifolia* at 0.05 lbs a.i./A during and after bee-flight did not have a harmful effect on honey bee mortality, flight intensity, behavior, nor on the honey bee colonies (condition of colony, honey bee brood).	46979804/ 18085	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied at 0.05 lbs a.i./A to winter wheat that had been treated with sugar solution to simulate honeydew during and after bee-flight did not have a harmful effect on honey bee mortality, flight intensity, behavior of the bees, nor on the honey bee colonies (condition, honey bee brood).	46979744/ 17248	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied at 0.05 lbs a.i./A to winter wheat that had been treated with sugar solution to simulate honeydew during and after bee-flight did not have a harmful effect on honey bee mortality, flight intensity, behavior of the bees in front of the hive and in the crop area, nor on the honey bee colonies (condition, honey bee brood).	46979548/ 17247	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC, applied at 0.05 lbs a.i./A to winter wheat that had been treated with sugar solution to simulate honeydew during and after bee-flight, did not have a harmful effect on honey bee mortality, flight intensity, behavior of the bees in front of the hive and in the crop area, nor on the honey bee colonies (condition, honey bee brood).	46979805/ 18086	Supplemental
Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20SC applied twice at 0.13 lbs a.i./A before *Phacelia* emergence (prior to direct bee exposure) and applied three times (twice before plant emergence and once during foraging activity of the honey bees on flowering *Phacelia tanacetifolia*) did not have a harmful effect on honey bees.	46980009/ 12753	Supplemental

Semi Field Study-Tunnel Test	Chlorantraniliprole 20 SC (18.5%)	DPX-E2Y45 20 SC was applied to create a proposed max residue level in soil and honeybees were subsequently exposed to *phacelia* grown in the soil plus flight dose. This pattern of exposure produced no clear adverse effects on the bees or their colony, however some difficulties with the study do not permit a definite conclusion that there were absolutely no treatment-related effects. The effects data should be looked at in conjunction with the residues data assessed separately below).	46979304/ 17208	Supplemental

Appendix D. STIR Inputs and Outputs

Table 1. STIR Input

Chemical Information	
Is the Application a Spray? (enter y or n)	Chlorantraniliprole
If Spray What Type (enter ground or air)	Both (Ran Max Aerial)
Enter Chemical Molecular Weight (g/mole)	483.15
Enter Chemical Vapor Pressure (mmHg)	1.5×10^{-13}
Enter Application Rate (lb a.i./acre)	0.0984
Toxicity Properties	
Bird	
Enter Lowest Bird Oral LD_{50} (mg/kg bw)	2250
Enter Mineau Scaling Factor	1.15
Enter Tested Bird Weight (kg)	1.58
Mammal	
Enter Lowest Rat Oral LD_{50} (mg/kg bw)	5000
Enter Lowest Rat Inhalation LC_{50} (mg/L)	5.1
Duration of Rat Inhalation Study (hrs)	4
Enter Rat Weight (kg)	0.155

Table 2. STIR Output

Results Avian (0.020 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	4.08E-09	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	5.13E-10	
Adjusted Inhalation LD_{50}	2.08E+02	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	2.46E-12	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	9.45E-03	

Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	4.54E-05	**Exposure not Likely Significant**
Results Mammalian (0.015 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	4.08E-09	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	6.45E-10	
Adjusted Inhalation LD_{50}	5.59E+02	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	1.15E-12	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	1.19E-02	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	2.12E-05	**Exposure not Likely Significant**

Appendix E. SIP Inputs and Outputs

SIP employs the following conservative assumptions to derive upper bound exposure estimates:
1) The chemical concentration in drinking water is at the solubility limit in water (at 25°C).
2) The assessed animals obtain 100% of their daily water needs through drinking water.
3) The daily water need is equivalent to the daily water flux rate as calculated by Nagy and Peterson (1988).
4) The body weight of the assessed bird is equivalent to the smallest generic bird modeled in T-REX (i.e., 20 g). This assumption results in the highest ratio of exposure to toxicity for the 3 assessed avian body weights of T-REX (i.e., 20, 100, 1000 g).
5) The body weight of the assessed mammal is equivalent to the largest generic mammal modeled in T-REX (i.e., 1000 g). This results in the highest ratio of exposure to toxicity for the 3 assessed mammalian body weights of T-REX (i.e., 15, 35, 1000 g).

Table 1. SIP Inputs

Parameter	Value
Chemical name	Chlorantraniliprole
Solubility (in water at 25°C; mg/L)	1.0 mg/L
Mammalian LD_{50} (mg/kg-bw)	5000*
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	NA
Mammalian NOAEL (mg/kg-bw)	1000[1*]
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Avian LD_{50} (mg/kg-bw)	2250*
Avian test species	Northern bobwhite quail
Body weight (g) of "other" avian species	
Mineau scaling factor	1.15
Mallard NOAEC (mg/kg-diet)	500
Bobwhite quail NOAEC (mg/kg-diet)	120

NOAEC (mg/kg-diet) for other bird species	
Body weight (g) of other avian species	
NOAEC (mg/kg-diet) for 2nd other bird species	
Body weight (g) of 2nd other avian species	

[1]NOAEC 20,000 mg a.i/kg-diet/20 as per SIP instructions
*=Non-definitive endpoint

Table 2. Mammalian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	0.1720	0.1720
Adjusted toxicity value (mg/kg-bw)	3845.8028	769.1606
Ratio of exposure to toxicity	0.0000	0.0002
Conclusion*	Drinking water exposure alone is NOT a potential concern for mammals	Drinking water exposure alone is NOT a potential concern for mammals

Table 3. Avian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	0.8100	0.8100
Adjusted toxicity value (mg/kg-bw)	1620.9664	12.7558
Ratio of exposure to acute toxicity	0.0005	0.0635
Conclusion*	Drinking water exposure alone is NOT a potential concern for birds	Drinking water exposure alone is NOT a potential concern for birds

*Conclusion is for drinking water exposure alone. This does not combine all routes of exposure. Therefore, when aggregated with other routes (*i.e.*, diet, inhalation, dermal), pesticide exposure through drinking water may contribute to a total exposure that has potential for effects to non-target animals.