# M E M O R A N D U M

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VIA: Shelley DuTeaux, PhD MPH, Chief
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DATE: December 20, 2022

SUBJECT: RISKS FROM HUMAN EXPOSURE TO CHLORANTRANILIPROLE RESIDUES IN GROUNDWATER

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On August 10, 2022, the Department of Pesticide Regulation's (DPR) Human Health Assessment (HHA) Branch was notified by the Environmental Monitoring (EM) Branch that monitoring conducted by the Groundwater Protection Program (GWPP) detected chlorantraniliprode in California's groundwater. The highest concentration detected in a domestic well was 0.266 ppb. EM requested that HHA determine whether the highest detection poses a significant risk to human health and to provide a human health reference level for chlorantraniliprode to use for screening detections (see request, Appendix 1). This memorandum is in response to that request.

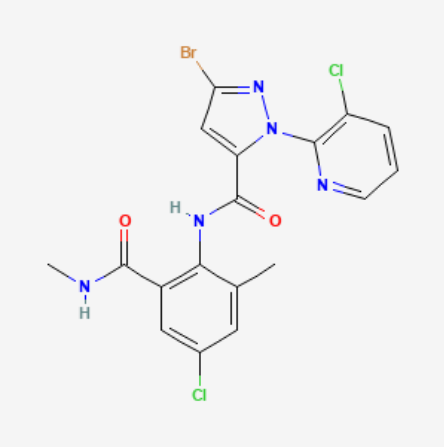
## Conclusions and Recommendations:

1. HHA calculated Human Health Reference Levels (HHRLs) to be used when residues are detected in surface water using (1) acute and chronic dietary exposure estimates based on consumption rates for drinking water from the National Health and Nutrition Examination Survey (NHANES) 2005-2010 database and (2) toxicological endpoints established by US EPA.

2. Residue levels of chlorantraniliprole equal to, or less than, the DPR HHRL of 8316 ppb are not expected to pose a risk to human health, including sensitive subpopulations, if ingested in drinking water. Thus, the highest detected chlorantraniliprole residue in California groundwater (0.226 ppb) should not be considered a human health concern.

## Background

**Technical Name:** Chlorantraniliprole
**Chemical Name:** 3-Bromo-*N*-[4-chloro-2-methyl-6- (methylcarbamoyl)phenyl]-1-(3-chloro-2-pyridine-2-yl)-1H-pyrazole-5-carboxamide
**Chemical Abstracts Service Registry Number (CASRN):** 500008-45-7 (NCBI, 2022)
**Chemical Structure:**




(NCBI, 2022)

Chlorantraniliprole is an anthranilic diamide insecticide that acts by disrupting normal muscle contraction through selective binding to the insect ryanodine receptor (RyR), leading to paralysis and death (USEPA, 2020). It has lower relative toxicity to mammals because of its specificity to insect RyR (USEPA, 2008a). Chlorantraniliprole was first registered in US and in California in 2008 (DPR, 2008a; USEPA, 2008b). It is registered for use on a variety of plant and livestock commodities in California. Agricultural uses include berries, *Brassica* vegetables, cereal grains, cotton, cucurbits, citrus fruits, fruiting vegetables, grapes, grass feedstuffs, herbs and spices, hops, leafy vegetables, legumes, oilseeds, onions, pome fruit, root and tuber vegetables, stone fruit, tea, tobacco, tree nuts, tropical and sub-tropical fruits, and seed treatments (DPR, 2022b). Non-agricultural uses include turf, landscape ornamentals and interiorscapes, and as a termiticide for post-construction applications (DPR, 2022b). From 2008 to 2021, the average annual application in California was approximately 105,755 pounds (DPR, 2022a) and there are currently 23 products with active registrations (DPR, 2022b).

## Review of Regulatory Documents and Databases

A review of pertinent regulatory documents and databases was performed to ensure that the most scientifically supportable toxicological data was used for the evaluation (summarized in Table 1, below). A comprehensive systematic review was beyond the scope of this evaluation.

**Table 1. Review of Regulatory Documents and Databases**

| Year | Agency | Title | Reference(s) |
|---|---|---|---|
| 2007 | USEPA | Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Apple, Celery, Cucumber, Head Lettuce, Leaf Lettuce, Pear, Pepper, Spinach, Squash, Tomato, and Watermelon Crops | USEPA (2007) |
| 2008 | USEPA | Chlorantraniliprole (DPX-E2Y45): Human Health Risk Assessment for Proposed Uses on Pome fruit, Stone fruit, Leafy vegetables, Brassica leafy vegetables, Cucurbit vegetables, Fruiting vegetables, Cotton, Grapes, Potatoes, Turf and Ornamentals | USEPA (2008a) |
| 2008 | USEPA | Pesticide Fact Sheet, Chlorantraniliprole. | USEPA (2008b) |
| 2008 | FAO/WHO | Pesticide residues in food – 2008, Joint FAO/WHO Meeting on Pesticide Residues, Evaluation 2008, Part II – Toxicological | FAO/WHO (2008) |
| 2008 | DPR | Summary of Toxicology Data, Chlorantraniliprole | DPR (2008b) |
| 2008 | APVM | Public Release Summary on Evaluation of the New Active Chlorantraniliprole in the Products DuPont Coragen Insecticide, DuPont Altacor Insecticide, DuPont Acelepryn Insecticide | APVM (2008) |
| 2008 | PMRA | Evaluation Report Chlorantraniliprole | PMRA (2008) |
| 2009 | USEPA | Chlorantraniliprole (DPX-E2Y45). Human Health Risk Assessment for Proposed Uses on the Tree Nut Crop Group and Pistachios and/or Increases in the Established Tolerances for Pome Fruits, Stone Fruits, Grapes, and Raisins due to the Removal of Adjuvant Restrictions from the Label for Pome Fruits. Stone Fruits, and Grapes. | USEPA (2009) |
| 2010 | USEPA | Chlorantraniliprole (DPX-E2Y45). Human Health Risk Assessment for Section 3 Registration Request to Expand Uses of Coragen, Altacor, and Dermacor™ X-100 labels on Various Field, Vegetable, and Fruit Crops. | USEPA (2010a) |
| 2010 | USEPA | Chlorantraniliprole; Human Health Risk Assessment for Proposed Use on Tobacco. | USEPA (2010b) |
| 2010 | VKM | Risk Assessment of the Pesticide Coragen 20 SC with the Active Substance Chlorantraniliprole | VKM (2010) |
| 2010 | NFSA | Evaluation of the Plant Protection Product, Coragen 20 SC-Chlorantraniliprole | NFSA (2010) |
| 2011 | USEPA | Chlorantraniliprole, add and/or revised multiple tolerances, HED risk assessment | USEPA (2011) |
| 2012 | USEPA | Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Oilseeds and Soybean | USEPA (2012) |
| 2013 | USEPA | Chlorantraniliprole Chronic Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Section (3) Registration Action on Cereal Grains, Except Rice, Cereal Grain Forage, Pome Fruit, and Citrus | USEPA (2013a) |
| 2013 | USEPA | Chlorantraniliprole Chronic Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Section (3) Registration Actions on Green Onion Subgroup 3-07b, and Peanut; and for the Requests to Update the Crop Groups of Stone Fruit, Tree Nut, and Spices; and to Shorten the Pre-Harvest Intervals for Papaya, Passionfruit, and Mayhaw | USEPA (2013b) |

**Table 1. Review of Regulatory Documents and Databases**

| Year | Agency | Title | Reference(s) |
|---|---|---|---|
| 2013 | USEPA | Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Green Onion Subgroup 3-07b, and Peanut; for the Requests to Update the Crop Groups of Stone Fruit, Tree Nut, and Spices; to Shorten the Pre-Harvest Intervals for Papaya, Passionfruit, and Mayhaw; and Evaluation of Condition of Registration Data on Rice, Coffee, Strawberry, and Tropical Fruits | USEPA (2013c) |
| 2013 | EFSA | Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Chlorantraniliprole | EFSA (2013) |
| 2016 | USEPA | Chlorantraniliprole. Aggregate Human Health Risk Assessment for the Proposed New Uses on Teff and Quinoa. | USEPA (2016) |
| 2017 | USEPA | Chlorantraniliprole: Human Health Risk Assessment for a Proposed Use on Commercial Ornamental Plant Nurseries | USEPA (2017) |
| 2019 | USEPA | Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Palm Oil without U.S. Registration. | USEPA (2019a) |
| 2019 | USEPA | Chlorantraniliprole: Tier I (Scoping) Review of Human Incidents and Epidemiology | USEPA (2019b) |
| 2019 | USDA | Final Human Health and Ecological Risk Assessment for Chlorantraniliprole Rangeland Grasshopper and Mormon Cricket Suppression Application | USDA (2019) |
| 2020 | EFSA | Review of the Existing Maximum Residue Levels for Chlorantraniliprole According to Article 12 of Regulation (EC) No 396/2005 | EFSA (2020) |
| 2020 | OEHHA | Health Assessment: Application of Chlorantraniliprole to Non-Commercial Turf for Japanese Beetle Treatment | OEHHA (2020) |
| 2020 | USEPA | Chlorantraniliprole Scoping Document and Draft Risk Assessments for Registration Review | USEPA (2020) |

APVM: Australian Pesticide and Veterinary Medicines Authority; PMRA: Health Canada Pest Management Regulatory Agency; VKM: Vitenskapskomiteen for mattrygghet (Norwegian Scientific Committee for Food Safety); NFSA: Norwegian Food Safety Authority; EFSA: European Food Safety Authority; USDA: United States Department of Agriculture; OEHHA: Office of Environmental Health Hazard Assessment.

## Summary of Toxicology

Chlorantraniliprole has an assigned acute Toxicity Category[a] of IV for oral toxicity, dermal toxicity, inhalation toxicity, eye irritation, and primary skin irritation, and is not a skin sensitizer (USEPA, 2008a; USEPA, 2020). Chlorantraniliprole is not genotoxic, neurotoxic, immunotoxic, carcinogenic or developmentally toxic (DPR, 2008b; USEPA, 2008a). It is classified as "Not likely to be Carcinogenic to Humans," as no treatment related increase in tumors was observed in carcinogenicity studies in rats and mice and there is no evidence of *in vivo* or *in vitro* mutagenicity (USEPA, 2008a; USEPA, 2020). Chlorantraniliprole is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list of

[a] Acute Toxicity Categories. US EPA Label Review Manual Chapter 7: Precautionary Statements. US Environmental Protection Agency, Office of Pesticide Programs, Registration Division. Revised March 2018. https://www.epa.gov/sites/production/files/2018-04/documents/chap-07-mar-2018.pdf

chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2022). Its potential as an endocrine disruptor has not been studied and there are no available bioactivity data from the US EPA Toxicity Forecaster (ToxCast) database (USEPA, 2022).

HHA has not conducted a human health risk assessment for chlorantraniliprole but has evaluated all required toxicity data that were submitted as part of registration in California. For purposes of this evaluation, HHA adopted the toxicological endpoints and point of departure (POD) established by US EPA (USEPA, 2008a; USEPA, 2020). US EPA did not establish an acute POD because no hazard was identified from acute exposure. The chronic POD was a no observed adverse effect level (NOAEL) of 158 mg/kg/day based on eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight in male mice seen at the lowest observed adverse effect level (LOAEL) (935 mg/kg/day) in a chronic 18-month oral study in mice (USEPA, 2008a; USEPA, 2020). The chronic NOAEL was divided by a total uncertainty factor ($UF_{TOTAL}$) of 100 to calculate a chronic RfD (cRfD[b]) of 1.58 mg/kg/day for all populations. The $UF_{TOTAL}$ included a 10x for interspecies extrapolation ($UF_A$) and a 10x for intraspecies variation ($UF_H$). HHA also uses this cRfD for evaluating risk from illegal flutriafol residues on fresh produce for the California Pesticide Residue Monitoring Program (CPRMP) (DPR, 2018).

**Calculation of DPR Human Health Reference Levels for Chlorantraniliprole**

HHA calculated acute and chronic screening levels (human health reference levels or HHRLs) for chlorantraniliprole and proposes that the lower of the two values (the acute HHRL of 8316 ppb) be used by GWPP as a guide when residues of chlorantraniliprole are detected in groundwater. This HHRL should be used for screening maximum detected residue levels in groundwater.

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. The reference levels were calculated using the chronic RfD for chlorantraniliprole as the maximum safe exposure and the acute ($95^{th}$ percentile) and chronic (mean) drinking water intake rates for non-nursing infants as the maximum water intake. Non-nursing infants are the population identified as having the highest consumption of drinking water per kilogram of body weight among the standard populations that HHA evaluates, including the general US population and other sensitive subpopulations such as children aged 1 – 2, and women of childbearing age (13 – 49 years old). The water consumption rates were extracted from the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID,

[b] An RfD is an estimate of a daily oral exposure for specific duration (acute or chronic) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (US EPA, 2011b).

version 4.02, 5-10c) and the What We Eat in America (WWEIA) database. WWEIA is the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES). It is a collection of two-day dietary survey data (including drinking water consumption) from 2005 to 2010 for the US population and select subgroups (USEPA, 2014).

The HHRLs for chlorantraniliprole in drinking water are summarized below (Table 2). The lowest reference value, the acute HHRL level of 8316 ppb, was selected as the HHRL for residues of chlorantraniliprole in groundwater and is intended to be used for screening maximum detected residue levels.

**Other Reference or Regulatory Levels**

Chlorantraniliprole does not have an enforceable US EPA maximum contaminant levels (MCL[c]), or a US EPA Health Advisories (HAs[d]) but it does have a chronic Human Health Benchmark for Pesticides (HHBP[e]) of 9350 ppb for the general population (Norman *et al.*, 2018; USEPA, 2018; USEPA, 2021) (Table 2). Chlorantraniliprole also has a chronic US Geological Survey (USGS) Health-Based Screening Level (HBSL[f]) of 10100 ppb based on a 2017 HHBP (Norman *et al.*, 2018). The DPR HHRLs and the US EPA HHBP differ because they were calculated using different parameters and assumptions. The DPR HHRL of 8316 ppb is the lowest reference level and the only one that is intended to be used for screening maximum detected residue levels in groundwater.

[c] MCLs are used for the protection of public drinking water systems and do not apply to privately owned wells or any other individual water system.

[d] HA are estimated acceptable drinking water levels for chemicals that are health effects-based on health effects information and are not a legally enforceable Federal standards, but rather serves as technical references to be used by federal, state, and local officials. USEPA, 2018. 2018 Edition of the Drinking Water Standards and Health Advisories Tables. https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf.

[e] The 2021 HHBPs contained 430 pesticides that currently have no federal drinking water standards. The HHBPs are not legally enforceable federal standards but rather provided by US EPA for pesticides that have no drinking water standards or health advisories (HAs). Available at https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf (USEPA, 2021).

[f] HBSLs are "non-enforceable water-quality benchmarks" that were developed using (1) the latest US EPA Office of Water methods for establishing drinking-water guidelines and (2) the most recent USEPA peer-reviewed publicly available toxicity information. Available at https://water.usgs.gov/water-resources/hbsl/ (USEPA, 2018).

**Table 2. Acute and Chronic DPR HHRLs for Chlorantraniliprole in Groundwater**

| Residue | Acute or Chronic | Water Consumption for Non-Nursing Infants[a] (L/kg-BW/day) | RfD[b] (mg/kg/day) | HHRL[c] (ppb) | USEPA HHBP[d] (ppb) |
|---|---|---|---|---|---|
| Chlorantraniliprole | Acute | 0.19 | 1.58 | **8316** | -- |
| | Chronic | 0.10 | 1.58 | 15800 | 9350 (General Population) |

[a] Acute and chronic water consumption for non-nursing infants were extracted from NHANES database (2005-2010) using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 5-10c); A residue level of 1 ppm consumption defaults to the consumption rates by dimensional analysis (acute = 0.194556 L water/kg BW and chronic = 0.099559 L water/kg BW). The values were rounded to two decimal points for the calculation of HHRLs.
[b] Chronic RfD for chlorantraniliprole for US EPA (USEPA, 2008a; USEPA, 2020)
[c] HHRL: human health reference level. HHRL (ppb) = [RfD (mg/kg/day) x 1000 (µg/mg)] / Daily water intake (L/kg/day). Daily water intake is 95$^{th}$ percentile for acute and mean value for chronic for non-nursing infants.
[d]HHBP: human health benchmark for pesticides. HHBP (ppb) for chronic exposure in general population = [RfD (mg/kg bw/day) x 1000 (µg/mg) x 0.2 RSC ] / 0.0338 (L/kg/day) Drinking Water Intake-Body Weight (DWI-BW) ratio and RSC= Relative Source Contribution assumed as 20% (USEPA, 2021)
The HHRL recommended for screening chlorantraniliprole residues in drinking water is **bolded**.

**Conclusion**

HHA calculated Human Health Reference Levels (HHRLs) to be used when residues are detected in surface water. Residue levels of chlorantraniliprole equal to, or less than, the DPR HHRL of **8316 ppb** are not expected to pose a risk to human health, including sensitive subpopulations, if ingested in drinking water. Thus, the highest detected concentration of chlorantraniliprole in California groundwater (0.266 ppb) should not be considered an acute or chronic human health concern.

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**Appendix 1: DPR Memo: Potential Health Effects of Chlorantraniliprole in Groundwater 10 August 2022 (1 page)**

Department of Pesticide Regulation

Julie Henderson
*Director*

Gavin Newsom
*Governor*

Jared Blumenfeld
*Secretary for Environmental Protection*

# MEMORANDUM

TO: Shelley DuTeaux
Environmental Program Manager II
Human Health Assessment Branch

VIA: Minh Pham *Original Signed By* *8/11/22*
Environmental Program Manager II
Environmental Monitoring Branch

FROM: Joy Dias *Original Signed By* *8/11/22*
Environmental Program Manager I
Environmental Monitoring Branch

DATE: August 10, 2022

SUBJECT: POTENTIAL HEALTH EFFECTS OF CHLORANTRANILIPROLE IN GROUNDWATER

The Environmental Monitoring Branch (EMB) monitors the environment to determine the fate of pesticides, protecting the public and the environment from pesticide contamination through analyzing hazards and developing pollution prevention strategies. Consistent with EMB's mission, the Groundwater Protection Program (GWPP) requested additional pesticides be added to analytical methods used to monitor for pesticides with the potential to contaminate groundwater.

During routine monitoring with the updated analytical method, the GWPP detected chlorantraniliprole in groundwater. To date, the highest concentration detected was 0.266 ppb (Table 1). The GWPP is currently conducting focused groundwater monitoring in high-use areas of this pesticide.

EMB requests the assistance of the Human Health Assessment Branch in determining whether the highest detection poses a significant risk to human health and to provide a human health reference level for chlorantraniliprole to use for screening detections.

**Table 1.** Summary of highest detection of chlorantraniliprole in California groundwater.

| Chemical | DPR Chemical Code | CAS Number | Maximum Concentration Detected (ppb) | Year |
|---|---|---|---|---|
| Chlorantraniliprole | 5964 | 500008-57-7 | 0.266 | 2021 |

cc: Carissa Ganapathy, Senior Environmental Scientist (Supervisory)