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# Acequinocyl

# Interim Registration Review Decision
# Case Number 7621

## December 2020

Approved by: _____

Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

Date: 11-23-2020

## Table of Contents

# I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for acequinocyl (PC Code 006329, case 7621), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on acequinocyl, can be found in EPA's public docket (EPA-HQ-OPP-2015-0203) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an ID for acequinocyl so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to improve the consultation process for national threatened and endangered (listed) species for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although EPA has not yet fully evaluated risks to federally listed species, the Agency will complete its listed species assessment and any necessary consultation with the Services for acequinocyl prior to completing the acequinocyl registration review. Likewise, the Agency will complete endocrine screening for acequinocyl, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

Acequinocyl is a contact quinolone miticide which acts by blocking cellular respiration. There is only one U.S. registered product containing acequinocyl, a soluble concentrate registered in 2003. The product containing acequinocyl is registered for uses on both agricultural and non-agricultural crops and can be applied via foliar spray application using a ground-based sprayer or handheld equipment. Aerial and chemigation applications are not allowed, and it is not labeled for indoor residential use. Registered agricultural use sites include citrus, berries, pome fruits and almonds, among other food crops. Additional registered use sites include commercial greenhouses and shadehouses, ornamentals, nurseries, ornamentals in outdoor landscapes around the perimeter of residences, businesses, public property, schools, ornamentals in non-residential interiorscapes, and other non-production areas. Since the product containing acequinocyl was first registered after 1984, acequinocyl was not subject to reregistration.

This document is organized in five sections: *Introduction*, which includes this summary, updates since the PID, a summary of public comments on the acequinocyl PID and EPA's responses; *Use and Usage,* which describes how and why acequinocyl is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments; *Interim Registration Review Decision*, which describes the mitigation measures required to address risks of concern and the regulatory rationale for EPA's ID; and, lastly, *Next Steps and Timeline* for completion of this registration review. This ID also describes any changes since the acequinocyl PID. Please refer to the PID for descriptions of past milestones for the acequinocyl registration review.

## A. Updates Since the Proposed Interim Decision was Issued

In September 2020, EPA published the PID for acequinocyl. There have not been additional updates to what was proposed in the PID, nor any updates to the draft risk assessments (DRAs). This document thus finalizes the agency's draft supporting documents *Acequinocyl: Human Health Draft Risk Assessment for Registration Review*, *Acequinocyl: Human Health Risk Assessment to Support the Petition for Tolerance for Residues in/on the Bushberry Subgroup 13-07B,* and *Acequinocyl: Draft Ecological Risk Assessment for Registration Review*, which are available in the public docket.

## B. Summary of Acequinocyl Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for acequinocyl with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of acequinocyl.

- June 2015 - The acequinocyl *Preliminary Work Plan* (PWP*)*, the *Acequinocyl Human Health Assessment Scoping Document in Support of Registration Review*, and the *Registration Review: Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Assessments for Acequinocyl* were posted to the docket for a 60-day public comment period.

- December 2015 - The *Final Work Plan* (FWP) for acequinocyl was issued. One comment on the PWP was received from the Center for Biological Diversity, which did not alter the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- June 2016 (GDCI-006329-1559)- A Generic Data Call-In (GDCI) for acequinocyl was issued for data needed to conduct the registration review risk assessments. All data have been submitted and the GDCI is satisfied, with the exception of the *Chronic (Repeat Dose) Toxicity Tests with the Honey Bee Larvae*, which was submitted but deemed supplemental, and the Tier 2/3 honeybee data (i.e., semi-field/field studies). See Section III for details.

- November 2019 - The agency announced the availability of the *Acequinocyl: Human Health Draft Risk Assessment for Registration Review* and the *Acequinocyl: Draft Ecological Risk Assessment for Registration Review* for a 60-day public comment period. Three comments were received from three different sources. These comments and the agency's responses are summarized in the PID. The comments did not change the risk assessments or registration review timeline for acequinocyl.

- September 2020 – The Agency opened a 60-day public comment period for the acequinocyl PID in the docket. In addition, as part of establishing tolerances for residues of acequinocyl in the bushberry crop subgroup 13-07B, the following updated Human Health Risk Assessment was also posted in the docket:
    - *Acequinocyl. Human Health Risk Assessment to Support the Petition for Tolerance for Residues in-on the Bushberry Subgroup 13-07B*[1]

- December 2020 – The Agency has completed the acequinocyl ID and will post it in the docket. Along with the acequinocyl ID, the following documents will also be available in the acequinocyl registration review docket:
    - *UPL Comment: Rationale to Support Status Change of Chronic (repeat dose) toxicity tests with the honey bee (Apis mellifera) larvae (MRID 50401605) from Supplemental to Acceptable*. June 11, 2020
    - *Acequinocyl: Response to Comments Suggesting Classification Change of a Chronic Toxicity Test with Larval Honey Bees.* October 14, 2020

## C. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period for the acequinocyl PID, which opened on September 2, 2020 and closed on November 2, 2020, the agency received three public comments.

**Comments Submitted by the Office of Pest Management Policy, United States Department of Agriculture (USDA), in EPA-HQ-OPP-2015-0203-0027**

**Comment:** USDA fully supports the mitigation proposed in EPA's PID of acequinocyl and notes that the mitigation proposed will address risks of concern while still retaining important

application flexibility for acequinocyl users. USDA is appreciative that EPA is processing pending tolerance petitions and proposed new uses for bushberries concurrently with registration review. USDA suggested that EPA consider taking this approach for other chemicals where label changes associated with IDs can be incorporated into routine label amendment actions to expedite the label amendment process.

**EPA Response:** EPA thanks the USDA for its comments and support. The Agency will take USDA's suggestions for label amendments into consideration.

**Comments Submitted by the Northwest Horticultural Council, in EPA-HQ-OPP-2015-0203-0029**

**Comments:** The Northwest Horticultural Council agrees with the mitigation proposed for acequinocyl and thanks EPA for its work.

**EPA Response:** The Agency thanks the Northwest Horticultural Council for their comments.

**Comments Submitted by The National Agricultural Aviation Association (NAAA), in EPA-HQ-OPP-2015-0203--0028**

**Comment**: The NAAA feels that aerial application of acequinocyl should be permissible and note that many of the acequinocyl use sites are treated aerially with other active ingredients. They provided information from the NAAA Aerial Application Industry survey and other support describing the advantages of aerially applying pesticides.

**EPA Response**: The Agency thanks the NAAA for their comments. The aerial application prohibition for acequinocyl is already present on the current acequinocyl label. This prohibition is not a result of the registration review process. Therefore, the risks associated with aerial application were not considered with this registration review. NAAA should discuss the addition of aerial applications with the registrant as the registrant would need to initiate that label change.

## II. USE AND USAGE

Acequinocyl is a contact quinolone miticide for the control of several species of plant-feeding mites. It acts by disrupting mitochondrial electron transport and energy metabolism. Acequinocyl is the only currently available miticide with this mode of action registered in the U.S. (IRAC[1] Group 20B). There is only one registered formulated product as a soluble concentrate (EPA Reg. No. 66330-38), which is registered for use on both agricultural and non-agricultural use sites and can be applied via foliar spray application using a ground-based sprayer or handheld equipment. Aerial and chemigation applications are not allowed. There are no products registered for indoor residential use.

[1] IRAC- Insecticide Resistance Action Committee.

Registered agricultural use sites for acequinocyl include avocados (except in California); caneberry (Crop Subgroup 13-07A); cherry (Crop Subgroup 12-12A); citrus fruit (Crop Group 10-10); cucurbit vegetables (Crop Group 9); dried shelled beans; edible podded beans; fruiting vegetables (Crop Group 8-10); guava (except in California); hops; low growing berries (Crop Subgroup 13-07G); tropical and subtropical, small fruit, inedible peel (Crop Subgroup 24A); pome fruits (Crop Group 11-10); small fruit vine climbing except fuzzy kiwifruit (Crop Subgroup 13-07F); succulent shelled beans; succulent soybean; and tree nut (Crop Group 14-12). Bushberry (Crop Subgroup 13-70B) became an approved use site on May 15, 2020.[2]

Non-agricultural registered use sites include commercial greenhouses and shade houses for ornamental, floral, foliage, and ornamental nursery crops; ornamentals in outdoor landscapes around the perimeter of residences, businesses, schools, and public property; and ornamentals in non-residential interiorscapes.

The maximum single application rate for acequinocyl is 0.3 lbs active ingredient per acre ((a.i.)/(A)) for all agricultural uses, with a maximum of two applications per year, separated by a 14 or 21-day interval, depending on the use site. For non-agricultural uses on nursery and landscape ornamentals, acequinocyl is used at a single maximum rate of 0.1 lbs a.i./A, with 2 applications per year and a 14-day minimum retreatment interval.

According to the Acequinocyl Screening Level Usage Analysis (SLUA) which covered the years 2002-2012, acequinocyl is used primarily on almonds, apples, oranges and strawberries. An average of approximately 1,000 lbs a.i. was used annually on each crop.[3] The crop with the highest percent crop treated (PCT) during that period was strawberries, with an average of 5 PCT and a maximum of 10 PCT. Acequinocyl is used on apples at an average of 2.5 PCT and maximum of 2.5 PCT. The average and maximum PCT for almonds and oranges was less than 1% and less than 2.5%, respectively.

More recent data indicate that acequinocyl usage on strawberries and caneberries has increased. For the periods 2014-2018, 3,000 lbs a.i. were reported to be used annually on strawberries with 15 PCT on average and a maximum of 30 PCT with acequinocyl. EPA's 2014 SLUA did not reflect any usage on caneberries; however, 2014-2018 data shows that 1,000 lbs a.i. was used annually on caneberries with an average of 10 PCT and a maximum of 15 PCT. A small amount of acequinocyl (less than 1,000 lbs a.i.) was also used on oranges and apples which amounts to less than 1% treated for each crop. No acequinocyl use was reported on almonds for the period 2014-2018. [4]

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[2] Federal Register for Friday, May 15, 2020 (85 FR 29338) (FRL–10007–38) EPA–HQ–OPP–2019–0387 Acequinocyl; Pesticide Tolerances. Available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0387-0011

[3] *Acequinocyl (006329) Screening Level Usage Analysis (SLUA). The Biological and Economic Analysis Division (BEAD). November 10, 2014. Available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0203-0008*

[4] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Data Subset: 2014-2018. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statistically valid results, typically at the state level.

Regarding non-agricultural use sites, there are no usage reports of acequinocyl in nurseries, greenhouses, or in outdoor landscapes in recent national studies[5]. However, there are small quantities of acequinocyl reported to be used in the state of California[6]. Overall, usage in these sites is likely very low. As for non-residential interiorscapes, there are no available surveys of pesticide use on this site, so the extent of acequinocyl usage is unknown.

# III. SCIENTIFIC ASSESSMENTS

## A. Human Health Risks

A summary of the Agency's human health risk assessment is presented below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of acequinocyl. The Agency did not identify dietary, residential, bystander, aggregate, occupational, or cumulative risks of concern for acequinocyl and its hydroxylated degradate R1 (hydroxy-acequinocyl).

Since the PID, there have been no changes to the Agency's previous human health risk conclusions. For additional details on the human health assessment for acequinocyl, see the *Acequinocyl: Draft Human Health Risk Assessment to Support Registration Review* and the *Acequinocyl: Human Health Risk Assessment to Support the Petition for Tolerance for Residues in/on the Bushberry Subgroup 13-07B*, which are available in the public docket.

### 1. Risk Summary and Characterization

*Dietary (Food + Water) Risks*
Unrefined acute and chronic dietary exposure and risk assessments were conducted for acequinocyl and its hydroxylated degradate R1 (hydroxy-acequinocyl), due to the rapid hydrolysis of acequinocyl. The results of such assessments for food and drinking water indicate that acute (≤56% of the acute population-adjusted dose (aPAD) and chronic (≤55% of the chronic population-adjusted dose (cPAD)) dietary risk estimates do not exceed the Agency's levels of concern (<100% of the aPAD and <100% cPAD for the U.S. population and all population subgroups). A cancer dietary exposure assessment was not conducted as acequinocyl was classified as "not likely to be carcinogenic to humans" by the Cancer Assessment Review Committee (CARC).

Dietary exposure estimates were updated to include the additional exposure from use of acequinocyl on the bushberry subgroup 13-07B.[7] Updated exposure assessments indicate 58% of the aPAD for children 1 to 2 years old (the population group of concern), and 54% of the cPAD

[5] Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities.
[6] California Department of Pesticide Regulation (CDPR). Pesticide Use Report (PUR) Data, 2013-2017. Accessed May 2020
[7] Federal Register for Friday, May 15, 2020 (85 FR 29338) (FRL–10007–38) EPA–HQ–OPP–2019–0387 Acequinocyl; Pesticide Tolerances. Available at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0387

for children 1 to 2 years old (the group with the highest exposure).[8] Dietary risks remain below the agency's level of concern (<100% of the aPAD and cPAD)

*Residential Handler and Post-Application Risks*
Although acequinocyl is currently registered for residential use sites (such as ornamental landscapes), labels require that handlers wear specific clothing and use personal protective equipment (PPE). Therefore, the Agency has assumed that these products are not for homeowner use and has not conducted a quantitative residential handler assessment. Post-application dermal exposures for previously registered uses were assessed using chemical-specific measured dislodgeable foliar residue (DFR) values.

Residential post-application dermal (adults and children 6 to <11 years old) exposures to gardens and trees treated with acequinocyl were assessed. Using the chemical specific DFR data the residential post-application dermal exposures did not result in risk estimates of concern. The margins of exposure (MOEs) range from 6,200 to 98,000; which are above the Agency's Level of Concern (LOC) of 100.

Post-application incidental oral exposures from ornamentals, gardens, or trees uses are not anticipated; therefore, they were not assessed.

*Bystander Risks*
A quantitative non-occupational spray drift assessment was conducted for the registered uses of acequinocyl to evaluate potential exposure to people who live adjacent to treated fields. Adult dermal and children's (1 to <2 year old) dermal and incidental oral risk estimates from indirect exposure related to spray drift are not of concern at the edge of the field (MOEs ≥100 for adult dermal, and MOEs ≥100 for children's incidental oral and dermal) at the edge of the field.

*Aggregate Risks*
The updated acute aggregate risk assessment considers exposures from food and drinking water and is equivalent to the acute dietary risk estimates and are not of concern (≤58% of the aPAD)[10]. Short-term aggregate risk considers dietary (food + drinking water) and residential exposures to acequinocyl. Only post-application dermal exposures are expected from registered uses of acequinocyl in residential areas. All short-term aggregate exposure estimates resulted in MOEs greater than the LOC and were not of concern. Short-term risk estimates are considered protective of intermediate-term because the endpoints are the same. There are no registered or proposed uses of acequinocyl that result in long-term residential exposures. Therefore, the chronic aggregate risk assessment only considers exposures from food and drinking water. The updated chronic dietary risk estimates are not of concern (≤54% of the cPAD).[9]

*Cumulative Risks*

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[8] *Acequinocyl. Human Health Risk Assessment to Support the Petition for Tolerance for Residues in/on the Bushberry Subgroup 13-07B.* Available at: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0387-0013

[9] *Acequinocyl. Human Health Risk Assessment to Support the Petition for Tolerance for Residues in/on the Bushberry Subgroup 13-07B.* Available in the Acequinocyl public docket (EPA-HQ-OPP-2015-0203*)*

The EPA has not made a common mechanism of toxicity to humans finding as to acequinocyl and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the EPA has not assumed that acequinocyl has a common mechanism of toxicity with other substances for this assessment.

*Occupational Handler and Post-Application Risks*
There is a potential for occupational exposure associated with handler (i.e., mixing, loading and applying) and post-application activities for the registered uses. Occupational handler dermal and inhalation exposure and risk estimates were calculated for the registered uses of acequinocyl. All occupational handler risk exposure estimates are not of concern, with MOEs ranging from 240 to 37,000 (LOC=100).

Based on the Agency's current practices, a quantitative non-cancer occupational post-application inhalation exposure assessment was not performed for the agricultural uses of acequinocyl for this assessment. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for acequinocyl.

HED expects that post-application dermal exposure will occur. Post-application short- and intermediate-term risk estimates are not of concern (MOEs>100) on the day of treatment (day 0 or 12 hours following application) for all activities. Post-application MOEs range from 170 to 84,000 on the day of application.

### 2. Human Incidents and Epidemiology

In the current Incident Data System (IDS) analysis from January 1, 2015 to July 10, 2019, no acequinocyl incidents were reported to Main IDS. There was one acequinocyl incident reported to Aggregate IDS, classified as minor severity. A query of Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides 2010-2015 also identified one case involving acequinocyl.

Based on the continued low frequency and severity of acequinocyl incidents reported to both IDS and SENSOR-Pesticides, there does not appear to be a concern. The Agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

### 3. Tolerances

Permanent tolerances for residues of acequinocyl have been established in 40 CFR §180.599 for a variety of crops and livestock commodities. The EPA anticipates corrections to a number of current tolerance levels to be consistent with the Organization for Economic Cooperation and Development (OECD rounding class practice and revise a commodity definition. A summary of these proposed tolerance revisions is presented in Table 1. The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug, and Cosmetic Act (FFDCA) authority.

| Table 1. Acequinocyl 40 CFR § 180.599: Summary of Proposed Tolerance Actions | | | |
|---|---|---|---|
| Commodity | Established Tolerance (ppm) | Proposed Tolerance (ppm) | Comments |
| **Almond, hulls** | 2.0 | 2 | Corrected values to be consistent with OECD Rounding Class Practice. |
| **Apple, wet pomace** | 1.0 | 1 | |
| **Avocado** | 0.50 | 0.5 | |
| **Bean, succulent shelled** | 0.30 | 0.3 | |
| **Berry, low growing, subgroup 13-07G** | 0.50 | 0.5 | |
| **Caneberry subgroup 13-07A** | 4.0 | 4 | |
| **Cherry, subgroup 12-12A** | 1.0 | 1 | |
| **Cowpea, forage** | 6.0 | 6 | |
| **Fruit, citrus, group 10-10, oil** | -- | 30 | Commodity definition revision. |
| Citrus, oil | 30 | remove | |
| **Fruit, pome, group 11-10** | 0.40 | 0.4 | Corrected values to be consistent with OECD Rounding Class Practice. |
| **Guava** | 0.90 | 0.9 | |
| **Tropical and subtropical, small fruit, inedible peel, subgroup 24A** | 2.0 | 2 | |
| **Vegetable, cucurbit, group 9** | 0.30 | 0.3 | |
| **Vegetable, fruiting, group 8-10** | 0.70 | 0.7 | |

* There are no U.S. registrations as of January 18, 2017 for use on tea.

## B. Ecological Risks

A summary of the Agency's ecological risk assessment is presented below. EPA is currently working with its federal partners and other stakeholders to implement a Revised Method[10] for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats have been fully implemented, the Agency will complete its endangered species assessment for acequinocyl. As such, potential risks for non-listed species only are described here.

The Agency did not identify risks of concern to mammals, terrestrial or aquatic plants, fish, aquatic-phase amphibians, or freshwater invertebrates and did not identify acute risks of concern to estuarine/marine invertebrates, adult terrestrial invertebrates (honey bees), or birds as a result of exposure to acequinocyl. The Agency concluded that exposures to acequinocyl pose chronic risks of concern to estuarine/marine invertebrates, adult terrestrial invertebrates (honey bees),

[10] https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084

and small birds, and acute risks of concern to larval honey bees. Since the PID, there have been no changes to the Agency's previous ecological risk conclusions. For additional details on the ecological assessment for acequinocyl, see the *Acequinocyl: Draft Ecological Risk Assessment for Registration Review*, which is available in the public docket.

## 1. Risk Summary and Characterization

*Terrestrial Risks*

Mammals

There are no acute or chronic risk concerns identified for mammals based on exposure to acequinocyl. Acute Risk Quotient (RQ) values were not calculated due to definitive endpoints not being available, as no mortalities were reported at concentrations tested for acute oral studies in rats. Estimated environmental concentrations (EECs) were over 100 times lower than the non-definitive endpoint.

Chronic RQs using the No Observed Adverse Effect Concentration (NOAEC) did not exceed the chronic LOC of 1.0 for mammals at any application rate. A Lowest Observed Adverse Effect Concentration (LOAEC) for the toxicity of acequinocyl was not established, as there were no identified treatment-related effects in performed rat studies.

Birds, Reptiles, and Terrestrial-Phase Amphibians

No acute risks of concern were identified for birds, which also serve as a surrogate for reptiles or terrestrial-phase amphibians. Acute dose-based RQs were not calculated due to non-definitive endpoints, but EECs were 20 times lower than the non-definitive endpoints. Chronic risks were identified for small birds eating short grass for multiple application scenarios at 0.3 lbs a.i./A., with RQs of 1.20 and 1.27 (LOC=1.0). This exceedance only occurred for small birds feeding on short grass for 0-5 days post application. There were no LOC exceedances using mean estimated exposures on food items at the NOAEC or the LOAEC (based on a 35% reduction in body weight). There were no risk concerns for fish-eating birds on an acute or chronic basis.

Terrestrial Invertebrates (honey bees)

Acequinocyl is currently registered for foliar application on a suite of crops that are bee-attractive and require the use of managed pollinators. Tier 1 toxicity data are available for acute and chronic exposures to honey bee adults and larvae. The Tier 1 data set for acequinocyl is nearly complete, with the exception of the larval chronic toxicity study, which is classified as supplemental and not suitable for calculation of RQs. This study was supplemental on the basis of not establishing a definitive LOAEC or testing highest labeled rates.

The Tier 1 assessment concluded that there is risk to honey bee larvae on an acute exposure basis and to adults on a chronic exposure basis (acute larvae RQs: 1-3; chronic adult RQs: 4-12; LOC=1.0) for all acequinocyl application rates (0.1 and 0.3 lbs a.i./A). Chronic risks to adults had an observed 80% mortality rate at the LOAEC. Assuming a high boom with very fine to fine droplet sizes, the estimated risk from spray drift risk extends as far as 33 feet (adult chronic) from the edge of the field.

Chronic risk to larvae remains uncertain because the available study was classified as supplemental due to confounding solvent effects that made the estimation of the LOAEC uncertain and the study tested well below maximum labeled rates. EECs at the highest acequinocyl application rate were estimated to be 33 mg a.i./kg-diet, but the larval chronic study only tested up to 11 mg a.i./kg diet, at which there were no effects. There are no reports of bee incidents involving acequinocyl.

Since EPA is unable to determine the risks associated with currently registered uses, a new chronic larval toxicity study should be submitted with treatment levels high enough to evaluate the US registrations. Given the risk concerns to honey bees identified at the Tier 1 level with the available data, additional higher-tier honey bee data for acequinocyl, such as nectar and pollen residue data, are needed to help refine the understanding of potential exposure of bees to acequinocyl, and colony-level risk.

Terrestrial Plants

No risks of concern were identified for terrestrial plants. No effects were observed for any test species using the maximum application rate (0.3 lbs a.i./A).

*Aquatic Risks*

Freshwater Fish and Aquatic-Phase Amphibians

No acute or chronic risks of concern were identified for freshwater fish or aquatic-phase amphibians. All acute based endpoints were non-definitive and/or greater than the solubility limit. Maximum EECs were over 30,000 times lower than the highest tested level with no mortality. There were no chronic RQ exceedances for freshwater fish (RQs $\leq$ 0.12; LOC =1.0).

Estuarine/Marine Fish

No acute or chronic risks of concern were identified for estuarine/marine fish. Acute exposure-based endpoints were non-definitive. Maximum EECs were approximately 85 times lower than the highest tested level with no mortality. There were no chronic RQ exceedances for estuarine/marine fish (RQs $\leq$ 0.05; LOC =1.0).

Freshwater Invertebrates

No acute or chronic risk estimates of concern were identified for freshwater invertebrates.

Estuarine/Marine Invertebrates

No acute risk estimates of concern were identified for estuarine/marine invertebrates. There were no acute RQ exceedances (RQs $\leq$ 0.45; LOC =0.5). Chronic toxicity estimates were derived from an acute to chronic ratio (ACR) based NOAEC. Chronic risks were identified for beans, cherries, pome fruits, small fruit vine climbing subgroup, succulent soybean vegetables, and tree nuts when acequinocyl is applied at the maximum annual rate of 0.6 lbs a.i./A via boom spray or airblast (RQs 0.08-2.37; LOC=1). Additional chronic risk estimates of concern were identified under the mentioned application conditions based on the LOAEC for small vine fruits (RQ=1.31).

Aquatic Vascular and Non-Vascular Plants

The assessment determined that there were no risk concerns for aquatic plants when using the most sensitive endpoint across all application scenarios (LOCs <1.0).

### 2. Ecological Incidents

A review of the Incident Data System (IDS), which is maintained by the EPA's Office of Pesticide Programs, indicates no ecological incidents associated with the use of acequinocyl. The search reflects reported incidents since its registration and includes any reports in the database as of June 19, 2019. In addition, the registrant for acequinocyl has reported no minor fish and wildlife incidents, minor plant incidents, or other non-target incidents as of February 27, 2019.

The Agency will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

## C. Benefits

Acequinocyl is a quinolone miticide which acts by disrupting mitochondrial function in spider mites and is the only member of its mode of action group that is registered in the United States (Mode of Action Group 20B, IRAC 2020). As a result of mitochondrial disruption, affected mites produce less energy, which initially results in cessation of feeding, and eventually death. As a unique mode of action, acequinocyl can be useful in managing resistance to miticides in other Mode of Action Groups by acting as a component that pest managers can use in a sequential treatment scheme across the growing season. Species within the spider mite group are known to rapidly develop pesticide resistance[11].

The antifeedant effect of acequinocyl is a desirable trait for farmers since it quickly halts crop damage that can reduce the marketability of the harvested commodity. Among agricultural mite pests, most usage of acequinocyl targets spider mites, a group of arthropods that includes the two-spotted spider mite (*Tetranychus urticae*), a pest that feeds on hundreds of plant species[11], and the citrus red mite (*Panonychus citri*), a serious pest of all citrus crops[12]. Spider mites injure host plants by inserting their piercing-sucking mouthparts into individual plant cells and removing sap. The primary infested tissues are leaves, and after substantial feeding, the injured leaves desiccate and drop. Fruits can also be damaged by mite feeding, and depending on the crop, this can render the fruit unmarketable or reduce its sale price.

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[11] Evans, B., K. Krey, and J. Renkema. 2018. Susceptibility of Phytoseiulus persimilis and Neoseiulus californicus (Acari: Phytoseiidae) to Commonly Used Insecticides Approved for Managing Arthropod Pests in Florida Strawberries. Publication no. ENY-996. Available at: http://edis.ifas.ufl.edu/pdffiles/in/in121600.pdf

[12] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Data Subset: 2014-2018. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statistically valid results, typically at the state level.

Acequinocyl is effective against all mite life stages, including eggs, immatures, and adults[13]. It is also a contact chemical with relatively long residual activity (i.e., it remains active against mites on treated surfaces for extended periods of time). For example, acequinocyl has activity against spider mite pests for at least four to six weeks, depending on the host plant[13, 14]. This may afford the grower an opportunity to reduce not only the number of applications but extend the period of control if they do not have to reapply a miticide for recently hatched individuals. Finally, acequinocyl is highly selective for plant-feeding mites, which is a benefit to growers who want to conserve predatory insects and mites as part of an integrated pest management program[9]. Due to the selectivity of acequinocyl, beneficial insects and mites survive better in agricultural settings that use this miticide and this provides additional control of not only subsequent plant-eating mites but other pest insects.

# IV. INTERIM REGISTRATION REVIEW DECISION

## A. Required Risk Mitigation and Regulatory Rationale

The Agency has reviewed the uses, risks, and benefits of acequinocyl. As discussed in Section III of this document, EPA identified potential risks to estuarine/marine invertebrates and terrestrial invertebrates (honey bees). The addition of advisory spray drift language and an update to surface water runoff advisory language is necessary to address potential ecological risks from the use of acequinocyl to ensure that acequinocyl is compliant with the FIFRA standard. Label changes to address generic labeling requirements are also necessary to ensure that acequinocyl is compliant with the FIFRA standard. The technical registrant has agreed to the label changes outlined in Appendix B.

### 1. Spray Drift Management

Advisory language is necessary to describe ways to reduce off-target spray drift and establish a baseline level of protection against spray drift. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target organisms. Although the Agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of acequinocyl. The registrant must ensure that any existing advisory language left on the label does not contradict or modify the new spray drift statements required in this ID, once effective.

### 2. Surface Water Runoff Advisory Language

Updated surface water runoff advisory statement on acequinocyl product labels are necessary to help address potential risks of concern for estuarine/marine invertebrates. The updated required

[13] Chong, J.C., B. Klingeman, and F. Hale. 2017. The insecticide and miticide mode of action field guide. Publication no. W 415. Available at: https://extension.tennessee.edu/publications/Documents/W415.pdf
[14] Grafton-Cardwell, E.E., R.A. Baldwin, J.O. Becker, A. Eskalen, C.J. Lovatt, S. Rios, J.E. Adaskaveg, B.A. Faber, D.R. Haviland, K.J. Hembree, J.G. Morse, and B.B. Westerdahl. 2017. Selectivity of Insecticides and Miticides In UC IPM Pest Management Guidelines: Citrus. UC ANR Publication 3441. Oakland, CA. Available at: https://www2.ipm.ucanr.edu/agriculture/citrus/Selectivity-of-Insecticides-and-Miticides/

language to be included is provided in Appendix B under "Surface Water Runoff Advisory Language".

### 3. Pesticide Resistance Management

Pesticide resistance occurs when genetic or behavioral changes enable a portion of a pest population to tolerate or survive what would otherwise be lethal doses of a given pesticide. The development of such resistance is influenced by a number of factors. One important factor is the repeated use of pesticides with the same mode (or mechanism) of action. This practice kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers. These individuals will eventually be unaffected by the repeated pesticide applications and may become a substantial portion of the pest population. An alternative approach, recommended by resistance management experts as part of integrated pest management (IPM) programs, is to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population. This approach may delay and/or prevent the development of resistance to a particular mode (or mechanism) of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

EPA has determined that resistance-management labeling, as listed in Appendix B, for products containing acequinocyl, is necessary in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides. Additional information on EPA's guidance for resistance management can be found at the following website: https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management.

## B. Tolerance Actions

The acequinocyl tolerances established in 40 CFR §180.599 are required to be updated to reflect OECD rounding class practices and appropriate commodity definitions. Refer to Section III.A.3. for additional details. The Agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances.

## C. Interim Registration Review Decision

The Agency is issuing this ID in accordance with 40 CFR §§ 155.56 and 155.58. EPA has made the following interim decision: (1) EPA requires that registrants submit Tier II pollinator data in accordance with the DCI; and (2) acequinocyl does not meet the FIFRA registration standard without changes to the affected registrations and their labeling.

The Agency has conducted detailed draft human health and ecological risk assessments. In these risk assessments, EPA has observed a few risks to continuing to register acequinocyl. The pollinator and estuarine/marine invertebrate risks of concern from acequinocyl are addressed by adding advisory spray drift language and surface water runoff advisory language, respectively, on all product labels. EPA has also determined that continuing to register acequinocyl provides benefits

including a unique mode of action (among miticides registered in the U.S.), rapid antifeedant effects, and effectiveness against all mite life stages.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[1] Here, EPA proposes that acequinocyl does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A and B.

In this ID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of acequinocyl. Similarly, the Agency is not making a complete endangered species finding for acequinocyl. Although the Agency is not making a complete endangered species finding at this time, EPA expects that the mitigation will reduce the extent of environmental exposure and may reduce risk to listed species whose range or critical habitat co-occur with the use of acequinocyl. The Agency intends to complete a listed species assessment and any necessary Endangered Species Act (ESA) Section 7 consultation with the services, and an EDSP FFDCA Section 408(p) determination, before issuing a final registration review decision for acequinocyl.

### D. Data Requirements

A Generic Data Call-In (GDCI) was issued for acequinocyl for data needed to conduct the registration review risk assessments. All data requirements have been satisfied with the exception of the chronic honey bee larval toxicity study and the Tier II and III honey bee data[15]. EPA is requiring development of Tier II honey bee data for acequinocyl based on the results of the Tier I data and other lines of evidence. The need for Tier III pollinator data will be evaluated and determined after a review of Tier II data.

## V. NEXT STEPS AND TIMELINE

### A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for acequinocyl. A final decision on the acequinocyl registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination, and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

### B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the acequinocyl registrants must submit amended labels that include the label changes described in Appendix A. The revised

[1] 40 C.F.R. § 155.40(a). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

[15] Acequinocyl: Response to Comments Suggesting Classification Change of a Chronic Toxicity Test with Larval Honey Bees. Available in the Acequinocyl public docket (EPA-HQ-OPP-2015-0203).

labels and requests for amendment of registrations must be submitted to the Agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the acequinocyl Interim Registration Review Decision and EPA regulations at 40 CFR Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the DMDS Interim Registration Review Decision and 40 CFR Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) using the following link: https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Rachel Eberius at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

VIA Courier
Pesticide Re-evaluation Division
c/o Front End Processing
Room S-4910, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

## Appendix A: Summary of Required Actions for Acequinocyl

Registration Review Case #: 7621
PC Code: 006329
Chemical Type: Miticide
Chemical Family: Quinolones
Mode of Action: Mitochondrial function disruption; IRAC Group 20B

| Affected Population(s) | Source of Exposure | Route of Exposure | Duration of Exposure | Potential Risk(s) of Concern | Required Actions | Comments |
|---|---|---|---|---|---|---|
| Pollinators | Residues | Ingestion | Acute; Chronic | Acute larval toxicity; Chronic adult toxicity (mortality) | Require advisory spray drift language | |
| Estuarine/marine invertebrates | Surface Water | Ingestion; Dermal | Chronic | Chronic toxicity (mortality) | Require advisory spray drift language<br><br>Update surface water advisory | |

# Appendix B: Required Labeling Changes for Acequinocyl Products

<table>
<tr><th>Description</th><th>Required Label Language for Acequinocyl Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>End Use Products</td><td></td></tr>
<tr><td>Mode of Action</td><td>Note to registrant:<ul><li>Include the name of the ACTIVE INGREDIENT in the first column</li><li>Include the word “GROUP” in the second column</li><li>Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action); for Herbicides this is SITE OF ACTION</li><li>Include the type of pesticide (i.e., HERBICIDE or FUNGICIDE or INSECTICIDE) in the fourth column.</li></ul><table><tr><td>ACEQUINOCYL</td><td>GROUP</td><td>20B</td><td>INSECTICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.<br>All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</td></tr>
<tr><td>Resistance-management labeling statements for insecticides and acaricides</td><td>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</td><td>Directions for Use, prior to directions for specific crops</td></tr>
<tr><td>Surface Water Runoff Advisory Language</td><td>“This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several days after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features including ponds, streams, and springs will reduce the potential loading of acequinocyl from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours. Sound erosion control practices will reduce this product’s contribution to surface water contamination.”</td><td>Environmental Hazards</td></tr>
</table>

| Description | Required Label Language for Acequinocyl Products | Placement on Label |
|---|---|---|
| **Advisory Spray Drift Management Language** for all products delivered via liquid spray application | **"SPRAY DRIFT ADVISORIES**<br>THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT.<br>BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.<br><br>**IMPORTANCE OF DROPLET SIZE**<br>An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions.<br><br>**Controlling Droplet Size – Ground Boom** *(**note to registrants:** remove if ground boom is prohibited on product labels)*<br>• Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate.<br>• Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size.<br>• Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.<br><br>**Controlling Droplet Size – Aircraft** *(**note to registrants:** remove if aerial application is prohibited on product labels)*<br>• Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight.<br><br>**BOOM HEIGHT – Ground Boom** *(**note to registrants:** remove if ground boom is prohibited on product labels)*<br>For ground equipment, the boom should remain level with the crop and have minimal bounce.<br><br>**RELEASE HEIGHT - Aircraft** *(**note to registrants:** remove if aerial application is prohibited on product labels)*<br>Higher release heights increase the potential for spray drift.<br><br>**SHIELDED SPRAYERS**<br>Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.<br><br>**TEMPERATURE AND HUMIDITY**<br>When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.<br><br>**TEMPERATURE INVERSIONS** | Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories" |

| Description | Required Label Language for Acequinocyl Products | Placement on Label |
|---|---|---|
| | Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.<br><br>**WIND**<br>Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift." | |
| **Advisory Spray Drift Management Language** for products that are applied as liquids and allow boom-less ground sprayer applications | **"SPRAY DRIFT ADVISORIES**<br>**Boomless Ground Applications:**<br>Setting nozzles at the lowest effective height will help to reduce the potential for spray drift." | Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories" |
| **Advisory Spray Drift Management Language** for all products that allow liquid applications with handheld technologies | **"SPRAY DRIFT ADVISORIES**<br>**Handheld Technology Applications:**<br>• Take precautions to minimize spray drift." | Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories" |