Docket Number EPA-HQ-OPP-2014-0414
www.regulations.gov

Etridiazole

Proposed Interim Registration Review Decision
Case Number 0009

June 2020

Approved by: _____

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Date: 06-25-2020

Table of Contents

I. INTRODUCTION 3
A. Summary of Etridiazole Registration Review 4
B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses 5
II. USE AND USAGE 7
III. SCIENTIFIC ASSESSMENTS 8
A. Human Health Risks 8
1. Risk Summary and Characterization 8
2. Human Incidents and Epidemiology 13
3. Tolerances 13
4. Human Health Data Needs 14
B. Ecological Risks 14
1. Risk Summary and Characterization 15
2. Ecological Incidents 17
3. Ecological and Environmental Fate Data Needs 18
C. Benefits Assessment 18
IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION 19
A. Proposed Risk Mitigation and Regulatory Rationale 19
1. Prohibition Against Using Certain Equipment, EPA Registration 400-575 19
2. Updated Glove and Respirator Statements 20
3. Pesticide Resistance Management 21
4. Label Clarification 21
B. Tolerance Actions 21
C. Proposed Interim Registration Review Decision 22
D. Data Requirements 22
V. NEXT STEPS AND TIMELINE 22
A. Proposed Interim Registration Review Decision 22
B. Implementation of Mitigation Measures 23
Appendix A: Summary of Proposed Actions for Etridiazole 24
Appendix B: Proposed Labeling Changes for Etridiazole Products 25
Appendix C: Endangered Species Assessment 27
Appendix D: Endocrine Disruptor Screening Program 28

I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Proposed Interim Registration Review Decision (PID) for etridiazole (PC Code 084701, case 0009), 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 require new risk mitigation measures, impose 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 etridiazole, can be found in the EPA's public docket (EPA-HQ-OPP-2014-0414) 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 the 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.

The EPA is issuing a PID for etridiazole 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 develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the 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 etridiazole prior to completing the etridiazole registration review. Likewise, the agency will complete endocrine screening for etridiazole, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the etridiazole registration review.

Etridiazole is a conventional use thiazole fungicide (Fungicide Resistance Action Committee—FRAC—Group 14), with products registered for use in preventing and treating diseases caused by soil fungi. Products containing etridiazole were first registered in 1962 and a Reregistration

Eligibility Decision for etridiazole was issued in 2000. Products containing etridiazole are registered for use on cotton, nursery stock, and greenhouse ornamentals, for applications to turf (golf course tees and greens only), for mixing with potting soil in commercial greenhouses, and for tobacco float bed seedling treatments. There are also Special Local Need (SLN) registrations for soil-directed applications to greenhouse tomatoes. Product formulations include liquids, granules, and wettable powders. There are no registered residential uses for etridiazole.

This document is organized in five sections: *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why etridiazole is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA's PID; and, lastly, *Next Steps and Timeline* for completion of this registration review.

A. Summary of Etridiazole Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for etridiazole 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 etridiazole. Copies of the documents listed below and of other documents pertaining to the etridiazole Registration Review are available in the Etridiazole Registration Review Docket (docket ID: EPA-HQ-OPP-2014-0414) at www.regulations.gov.

- June 2014 - The *Etridiazole Preliminary Work Plan* (PWP*)*, *Etridiazole Human Health Risk Assessment Scoping Document in Support of Registration Review*, and *Registration Review: Draft Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Etridiazole* were posted to the docket for a 60-day public comment period.

- December 2014 - The *Etridiazole Final Work Plan* (FWP) was issued. During the 60-day public comment period on the etridiazole PWP, the agency received six comments. These comments did not address the schedule of registration review outlined in the PWP. Comments did address the planned ecological and human health risk assessments and data requirements for registration review but did not change these requirements. For more information, please see the FWP, available in the public.

- April 2016 - GDCI-084701-1477 - A Generic Data Call-In (GDCI) for etridiazole was issued for data needed to conduct the registration review risk assessments. The following studies remain outstanding:

    - OCSPP 850.6100: Environmental Chemistry Methods in Soil – Data were submitted to fulfill this requirement but were classified as "Unacceptable". Details of the agency's classification of the data and of the requirements for

upgrading its classification are available in the *Etridiazole: Draft Ecological Risk Assessment for Registration Review*.
  - Non-Guideline/OECD 213 Honey Bee Adult Acute Oral Toxicity Study – Data were submitted to fulfill this requirement but were classified as "Unacceptable".

- November 2019 - The agency announced the availability of the *Etridiazole. Draft Human Health Risk Assessment (DRA) in Support of Registration Review* and the *Etridiazole: Draft Ecological Risk Assessment for Registration Review* for a 60-day public comment period. EPA received two comments during the comment period. These comments and the agency's responses are summarized below. The comments did not change the risk assessments or registration review timeline for etridiazole; however, the agency has produced a Revised Draft Human Health Risk Assessment to account for new worker exposure modeling methods, as described below.

- June 2020 - The agency has completed the PID for etridiazole. The PID is posted to the docket for a 60-day public comment period. Along with the PID, the following documents are also posted to the etridiazole docket:

  - *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review*
  - *Etridiazole: Addendum to the Draft Risk Assessment – Honey Bee Risk Assessment*

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the *Etridiazole. Draft Human Health Risk Assessment (DRA) in Support of Registration Review* and the *Etridiazole: Draft Ecological Risk Assessment for Registration Review*, which opened on November 18, 2019 and closed on January 17, 2020, the agency received public comments from two sources. Comments were submitted by MacDermid Agricultural Solutions, Inc, c/o UPL NA Inc., the technical registrant of etridiazole products, and by the USDA Office of Pest Management Policy. Substantive comments, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below. The agency thanks all commenters for their comments and has considered them in developing this PID.

Comments Submitted by the USDA Office of Pest Management Policy (Docket ID: EPA-HQ-OPP-2014-0414-0034)

Comment: The USDA summarized the uses of etridiazole and its economic benefits in controlling fungal infections in golf courses and in ornamental flower and tobacco production. Comments focused on the lack of alternatives to etridiazole, grower testimonials, and economic figures.

The comments generally agree with the conclusion of the EPA's risk assessments, with some qualifications. The commenters express concern that the EPA's use of the golf course scenario

for calculations of groundwater estimated drinking water concentrations (EDWCs) is overly conservative. The USDA states that it would be unlikely that water wells located on or near a golf course would provide the sole source of an individual's drinking water. The commenters also question the EPA's decision to merge runoff from separate areas of treated golf course with drinking water contamination. Moreover, the USDA takes issue with the EPA's assumptions about etridiazole treatment duration and area, noting that label restrictions to tees and greens are not taken into consideration in the EDWC modeling, resulting in overestimation of drinking water exposure.

Additionally, the commenters state that the EPA overestimates risks to occupational handlers by assuming higher application rates for etridiazole than what are routinely used, particularly when spot treatments are made to nursery stock and greenhouse ornamentals. The USDA also cites recent survey data from the Agricultural Handlers Exposure Task Force (AHETF) that indicate default assumptions about the amount of pesticide handled by users of certain handheld equipment in the risk assessment overstate exposure. The commenters ask the EPA to consider further refinements and characterizations of its human health risk estimates.

On EPA's ecological risk conclusions, the commenters are generally in agreement with the characterization of potential risks. The USDA believes that mammalian exposure from etridiazole applications to cotton are ameliorated by the timing of application, incorporation of the pesticide, and the limited extent of the fungicide's use on cotton.

EPA Response: The agency thanks the Office of Pest Management Policy for its comments. In developing the risk mitigation measures proposed in this PID, the EPA has considered the benefits of etridiazole to users (see section III.C of this document for a discussion of etridiazole's benefits).The agency agrees with the commenters that the etridiazole groundwater EDWC likely overestimates actual drinking water exposure. Moreover, no dietary (food + water) risks of concern were identified from registered uses of etridiazole. A discussion of the groundwater EDWC and the dietary risk assessment can be found in section III.A, below. While the USDA correctly notes that new exposure data are now available from the AHETF, these data had not been reviewed for use in the agency's exposure models before the etridiazole human health risk assessment was conducted. These data have since been incorporated into the *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review*, now available in the public docket. These updates are discussed below.

The EPA's characterization of the ecological risk is discussed in section III.B, below. In developing this PID and its associated mitigation of potential ecological risks from, the agency considered aspects such as the likelihood of a potential exposure pathway in real world situations, the biological relevance of toxicity endpoints, and management practices that might minimize exposure. Such considerations include the timing of applications (*e.g.* in cotton), management practices that may reduce the amount of etridiazole entering the ecosystem (*e.g.* in turf), and the likelihood of repeated applications at the maximum rate (multiple uses).

Comments Submitted by MacDermid Agricultural Solutions, Inc, c/o UPL NA Inc. (Docket ID: EPA-HQ-OPP-2014-0414-0035)

Comment: The technical registrant's comments largely focus on the conclusions of the human health risk assessment, specifically the risk conclusions for occupational handlers involved in mixing, loading, and applying etridiazole by mechanically pressurized handguns. Like the USDA (see comments above), the registrant believed that the agency overestimates application amounts of etridiazole by mechanically pressurized handgun. The registrant states that users of etridiazole report soil drench as the most common use pattern of etridiazole in nurseries and greenhouses. Moreover, these same users report that etridiazole products are applied in highly diluted quantities, often through irrigation systems, greatly reducing potential worker exposure. Finally, the registrant states that the agency's use of the maximum label-permitted application rate for etridiazole does not reflect typical applications rates, which are much less than the maximum rates on labels. Based on these concerns, the registrant concludes that the agency has overestimated worker exposure and, in turn, risk.

EPA Response: The agency thanks the registrant for its comments. To assess exposures and risks to workers, the agency conducts modeling based on known data, such as labeled applications rates, formulations, and use patterns. The agency also makes assumptions about the exposure to workers resulting from different application methods. These assumptions are informed by surveys of pesticide users, measurements in the field, experimental data, and other data sources. Though data may exist that show typical usage or worker exposure values to be less than those assumed by the agency, the agency evaluates the risks in a manner that is intended to be protective of all workers. Where data are available, the agency has refined or characterized its risk conclusions. For example, the agency recently incorporated the new AHETF data into a revised assessment.

II. USE AND USAGE

Etridiazole is currently registered for use on cotton, tobacco, tomatoes (greenhouse grown), golf course turf (tees and greens), and greenhouse and outdoor grown ornamentals.

There is little usage of etridiazole on agricultural use sites. Less than 500 pounds of active ingredient (lbs a.i.) of etridiazole were used to treat less than 500 acres (A) of tobacco per year between 2014-2018. The average percentage of the crop treated (PCT) for tobacco is less than 1%. There was no recorded usage on cotton between 2014-2018.[1]

The majority of documented etridiazole usage is applied on non-agricultural sites, primarily on turf and ornamentals. In 2012, approximately 50,000 lbs a.i. of etridiazole were used on turf and ornamental sites, including those in greenhouses and nurseries.[2]

The Golf Course Superintendents Association of America (GCSAA) recently gave EPA information from various regions about the use of etridiazole on golf course turf. Use of etridiazole was reported to be regionally- and weather-dependent. Etridiazole is an important tool

[1] Kynetec USA, Inc. 2019, The AgroTrak Study, Database Subset: 2014-2018.
[2] Kline and Company. 2013. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2012. [Accessed June 2019.]

for control of pythium-related diseases in golf course turf in certain regions of the U.S. The Mid-Atlantic and Southeastern regions of the U.S. have high levels of precipitation, temperatures, and relative humidity, conditions that allow pythium diseases to flourish. In the Northeast region of the U.S., this chemical was typically used only in 'wet' or high precipitation years, and not used much in drier years. The other regions did not report much use of etridiazole.[3]

Use of etridiazole is limited to putting greens and tees, which make up less than 5% of the area of a typical golf course. Etridiazole is typically applied at a high rate of 4 pounds active ingredient per acre (lbs a.i./A), one to two times a year based on responses from all regions reporting.[4]

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 etridiazole. For additional details on the human health assessment for etridiazole, see the *Etridiazole. Draft Human Health Risk Assessment (DRA) in Support of Registration Review* and *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review*, which are available in the public docket.

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

An acute dietary exposure analysis was not conducted for etridiazole. No appropriate endpoint could be identified from a single exposure for the general population or any subpopulation; therefore, acute risks from dietary exposure are not expected from registered uses of etridiazole.

No potential chronic dietary risks were identified from registered uses of etridiazole. The unrefined chronic dietary assessment yielded risk estimates of less than 1% of the chronic population-adjusted dose (cPAD). The level of concern (LOC) for chronic dietary risk assessment is 100% of the cPAD for the general population and all subpopulations.

EPA has classified etridiazole as "Likely to Be Carcinogenic to Humans", based on an observed increase in tumors among rats treated with etridiazole. The partially refined cancer dietary (food + water) assessment resulted in a risk estimate of 2×10^{-6} for the highest exposed adult population (adults aged 20-49 years). Drinking water is the major contributor to dietary cancer risk. The cancer risk is 5.0×10^{-7} from food alone and is 1.8×10^{-6} from drinking water alone.

[3] Golf Course Superintendents Association of America (GCSAA). 2020. Response to US EPA questions on etridiazole use on golf courses. May 18, 2020.
[4] Golf Course Superintendents Association of America (GCSAA). 2020. Response to US EPA questions on etridiazole use on golf courses. May 18, 2020

The EDWC for groundwater is based on golf course applications of etridiazole and assumes that application at the maximum labeled application rate for turf is made to entire golf courses. Labels allowing golf course treatments limit application to course tees and greens only, which would account for 5% of the golf course being treated. Therefore, the assumption that entire courses are treated likely overestimates the groundwater EDWC. Moreover, the cancer risk estimate assumes that etridiazole is applied at the maximum label rate, with the maximum permitted number of repeat applications, and that the exposure duration is equal to a lifetime which likely provides a high-end estimate of exposure. Therefore, the agency concludes that dietary cancer risk is not of concern.

Residential Handler Risks

Residential handler exposure is not anticipated from the registered uses of etridiazole, and therefore, a residential handler assessment was not conducted.

Residential Post-Application Risks

No potential residential post-application risks were identified. Etridiazole can be used on golf courses which could result in potential short-term post-application dermal exposure to golfers (adults and older children 6 to <16 years old). None of the residential short-term non-cancer post-application scenarios are of concern, with Margins of Exposure (MOEs) greater than the level of concern (LOC) of 100 (ranging from 18,000 to 25,000).

An adult residential post-application cancer assessment was also conducted for the etridiazole use on golf courses. The cancer assessment used an annual average turf residue that was calculated assuming two applications are made at the maximum application rate 10 days apart based on label information. The estimated residential post-application cancer risk estimate for adult golfers is 1×10^{-8} and is not of concern.

Bystander Risks

Groundboom applications to cotton, golf courses, and ornamentals were modeled to evaluate potential risks to bystander from spray drift. Dermal exposure risks were estimated for adults, while dermal and incidental oral exposure risks were estimated for children 1 to <2 years. No potential risks to bystander from spray drift were identified from registered uses of etridiazole. The calculated MOEs for all scenarios and age groups are above the LOC of 100. The lowest MOE is 1,400, from combined incidental oral and dermal exposure in children 1 to <2 years, resulting from groundboom applications to ornamentals.

Aggregate Risks

FQPA mandates that EPA evaluate the aggregate exposures and risks from three sources: food, drinking water, and residential exposures. An aggregate risk assessment also considers multiple exposure durations (*e.g.* acute, short-term, chronic). In the case of etridiazole, an acute aggregate assessment was not conducted. As described above in the section on acute dietary risk, no toxicologic effects could be attributed to a single etridiazole exposure.

The short-term aggregate assessment considered the combined risks from residential dermal post-application exposure for adult and child golfers with dietary exposure. The short-term aggregate MOEs for adults (18,000), children 11 to <16 years old (17,000), and children 6 to <11 years old (14,000) are above the LOC (100) and are not of concern.

Chronic aggregate risk assessments consider exposures that occur continuously for greater than six months. Registered uses of etridiazole are not expected to result in residential exposure greater than six months; thus, chronic exposure is not expected. As a result, the chronic aggregate risk estimates are equivalent to the dietary (food and drinking water), risk estimates and are not of concern.

The aggregate cancer risk assessment combined residential post-application exposure for adult golfers (based on expected lifetime exposure) with the dietary (food and water) exposure. The aggregate cancer risk estimate is 2×10^{-6}. Drinking water exposure is the greatest source of aggregate cancer risk. The estimate of etridiazole exposure from drinking water was calculated using golf course turf applications and assumed that entire courses were treated. As labels limit golf course turf applications to tees and greens only (or approximately 5% of golf course turf), the EDWCs are likely an overestimate. Moreover, as discussed above, the aggregate cancer risk estimate assumes that etridiazole is applied at the maximum label rate, with the maximum permitted number of repeat applications, and that the exposure duration is equal to a lifetime which likely provides a high-end estimate of exposure. Therefore, the agency concludes that aggregate cancer risk is not of concern.

Cumulative Risks

The EPA has not made a common mechanism of toxicity to humans finding as to etridiazole 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 etridiazole has a common mechanism of toxicity with other substances for this assessment.

Occupational Handler Risks

Potential occupational handler non-cancer and cancer risks of concern from registered uses of etridiazole were originally assessed in the *Etridiazole. Draft Human Health Risk Assessment (DRA) in Support of Registration Review*. That assessment was later revised, based on new estimates of exposure and amounts handled for users of mechanically pressurized handguns and handheld equipment from the Agricultural Handlers Exposure Task Force (AHETF). These updates are reflected in the *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review*. Both the original and revised assessments are available in the public docket. The summary of etridiazole occupational handler risks presented below reflects the revised risk assessment.

Potential occupational handler non-cancer risks were identified for several registered etridiazole use scenarios, listed below. Both short- and intermediate-term exposures are anticipated from registered uses of etridiazole. The established points of departure (PODs) are the same for both

short- and intermediate-term exposures, and so short-term exposure risk estimates are protective of longer-term exposure risks. Exposure was assessed via the dermal and inhalation routes. The risk estimates for these two exposure routes were combined, because the toxicological effects for these exposures were the same. The toxicological endpoints were selected from a two-generation reproduction study in rats. This study showed changes to T3 hormone levels and decreased pup bodyweights. In all scenarios below, the dermal route is the predominate driver of risk.

All current registrations of etridiazole require minimum personnel protective equipment (PPE) of single layer clothing, chemical-resistant gloves, and a respirator (SL/G/R). High-pressure handwand sprayer applications require mixers, loaders, and applicators to wear PPE of double layer clothing, gloves, and a respirator (DL/G/R). The scenarios listed below represent only those risks not adequately mitigated by current PPE requirements.

Current PPE requirements are adequately protective of occupational handler exposures, except for several mixer/loader scenarios. The potential risks associated with these scenarios were of concern at maximum PPE, so the effect of engineering controls on the risks was evaluated. For all scenarios listed, the assumed application rate is 13.6 lbs a.i./A, the maximum rate allowed on any etridiazole label. This maximum application rate is only on one label (EPA registration 400-575) and the next highest rates are significantly lower (4.08 lb ai/A on turf and 1.74 lb ai/A on ornamentals).

- While risks of concern were identified for mixing/loading liquids for chemigation and mixing/loading for groundboom application in greenhouses and nurseries, the modeled rate was from a label with use only as a soil drench to ornamentals. Moreover, chemigation is currently prohibited on this label. Therefore, these scenarios do not represent relevant risks of concern to occupational handlers.

- Mixing/loading liquids for groundboom application to field grown ornamental crops: SL/G MOE = 98 (LOC = 100). Current labels require minimum PPE of SL/G/R for this scenario. While the MOE was less than the LOC, given the conservative assumptions in the DRA, the agency does not consider this a risk of concern.

Two mixer/loader/applicator scenarios for mechanically pressurized handgun applications produce risk estimates of concern even when the maximum feasible PPE (DL/G/R) is considered. Mitigation measures beyond maximum PPE, such as closed loading systems, are not applicable or practical for handheld use scenarios. Moreover, such engineering controls would not mitigate exposure from applicator activities. Current label requirements are DL/G/R for those handlers using mechanically pressurized handwands. For all the scenarios listed, the assumed application solution concentration is 0.136 lb ai/gallon application solution, equivalent to 13.6 lbs a.i./A, the maximum rate allowed on any etridiazole label. As mentioned above, this maximum application rate is only on one label (EPA registration 400-575) and the next highest rate is significantly lower. These lower application rates do not produce risks of concern.

- Mixing/loading/applying liquids, as a drench or soil/ground-directed spray via mechanically pressurized handgun to greenhouse crops (*e.g.* ornamentals, roses, cut flowers, container stock, vegetables: DL/G/R MOE = 27 (LOC = 100).

- Mixing/loading/applying liquids, as a drench or soil/ground-directed spray via mechanically pressurized handgun to nursery crops (*e.g.* ornamentals, vegetables, trees, container stock): DL/G/R MOE = 16 (LOC = 100).

As noted above, the EPA has classified etridiazole as "Likely to Be Carcinogenic to Humans" based on an observed increase in tumors among rats treated with etridiazole. To assess cancer risks to occupational handlers, the agency assumed that private handlers are exposed to etridiazole 10 days per year and that commercial handlers are exposed 30 days per year. The lifetime exposure duration was assumed to be 35 years out of a 78-year lifespan. It was also assumed that applications were made at the maximum label-permitted rate of 13.61 lbs a.i./A. As with non-cancer risks, occupational cancer risks were assessed on a combined dermal and inhalation exposure basis.

Assuming the current label PPE requirements, cancer risk estimates range from 1.5×10^{-9} to 1.7×10^{-4} for private applicators and from 4.4×10^{-9} to 4.9×10^{-4} for commercial applicators. The highest cancer risk estimates are associated with mechanically pressurized handgun applications at the highest label rate of 13.6 lbs a.i./A in greenhouses and nurseries. As described above, these risk estimates were derived assuming maximum application rates made regularly, over a lifetime. Assuming regular application at the maximum rate every year likely overestimates typical usage of etridiazole, and thus overestimates the potential cancer risk. Given the assumptions of the exposure modeling, the risk estimates presented here likely overestimate actual cancer risks. For handheld use scenarios with lower application rates, when DL/G/R are considered, risk estimates are all less than 1×10^{-6}. Therefore, the agency concludes that occupational cancer risks are not of concern for etridiazole.

Occupational Post-Application Risks

Because etridiazole is designed for soil incorporation (rather than foliar application), occupational post-application risks are not expected for scenarios that assume no worker-soil contact. As a result, occupational post-application risks were not quantitatively assessed for most registered uses of etridiazole, including agricultural uses.

Quantitative occupational post-application risk assessments were conducted for registered uses of etridiazole that may result in occupational post-application exposure. These include golf course turf applications and applications to potting soil in greenhouses and nurseries. In golf course settings, treatments are made to turf (rather than to bare soil), so workers may be exposed to residues on the leaf surface. In greenhouses and nurseries, workers may handle treated soil and become exposed. In all assessed scenarios, the non-cancer MOEs were well above the LOCs and no potential non-cancer occupational post-application risks were identified from registered golf course turf and greenhouse/nursery uses of etridiazole.

Occupational post-application cancer risk estimates for golf course workers range from 1.6×10^{-8} to 2.3×10^{-8} when assuming a 30-day average residue value and maximum application rates. The highest occupational post-application cancer risk estimate from handling treated potting soil in

nurseries and greenhouses was 2.4 x 10^{-7}. Therefore, the agency concludes that post-application cancer risks are not of concern.

Based on its toxicity profile, a 12-hour restricted entry interval (REI) is recommended for etridiazole. All registered products with etridiazole currently require a post-application REI of 12 hours and are considered protective.

2. Human Incidents and Epidemiology

The Incident Data System (IDS) and the National Institutes for Occupational Safety and Health (NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides were reviewed in 2014. This review found that, based on the low frequency and severity of etridiazole incident cases, further investigation was not warranted. In the current IDS analysis from January 1, 2014 to January 31, 2019, no incidents involving etridiazole were reported to Main IDS; there was one etridiazole incident reported to Aggregate IDS. A query of SENSOR-Pesticides from 2011-2015 identified three cases involving Etridiazole. All three cases involved multiple active ingredients. Two cases were low in severity. One case was high in severity and involved the intentional swallowing of EPA registration 264-319 (multiple active ingredients, including etridiazole). This product, Temik™ TSX Granular, was cancelled in 2002.

Etridiazole is not included in the Agricultural Health Survey (AHS), and so the AHS does not inform the incidents report for etridiazole. The AHS is a long-term epidemiological study of associations between pesticide exposures and various health outcomes, conducted by a partnership of federal agencies, including EPA.

The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

3. Tolerances

Tolerances for etridiazole and its monoacid metabolite (3-carboxy-5-ethoxy-1,2,4,-thiadiazole) are established under 40 CFR §180.370(a) on cotton and tomato commodities. The agency recommends that the tolerance expression be updated to read:

> "(a) *General.* Tolerances are established for residues of the fungicide etridiazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of etridiazole, (5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole), and its metabolite etridiazole acid, (3-carboxy-5-ethoxy-1,2,4,-thiadiazole), calculated as the stoichiometric equivalent of etridiazole, in or on the commodity:"

The agency anticipates the following change to the tolerances for etridiazole, summarized in Table 1, below. This change is recommended based on etridiazole use patterns established in Special Local Need (SLN) registrations, the use on tomatoes imported from Europe, and on new residue data submitted by the registrant. These data indicate that a tolerance for etridiazole on

tomatoes of 0.04 mg/kg (part per million; ppm) is protective. The current tolerance enforcement method for etridiazole has a combined limit of quantitation (LOQ) of 0.1 ppm. The agency cannot set a tolerance below the LOQ. Therefore, the agency anticipates proposing that the tolerance for etridiazole on tomato be changed to 0.1 ppm.

There are no Codex or Canadian maximum residue levels (MRLs) established for etridiazole on tomatoes. However, there are European MRLs established on tomatoes at 0.05 ppm for the etridiazole parent compound only. The agency cannot propose to harmonize with the European MRL because the residue definitions are dissimilar. The agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Table 1: Summary of Proposed Tolerance Actions

Etridiazole 40 CFR § 180.370(a): Summary of Proposed Tolerance Actions			
Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments
(a) General			Because the currently available data show no measurable residues in tomatoes, the tolerance can be decreased to the enforcement method LOQ.
Tomato	--	0.1	
Tomato	0.15	--	

4. Human Health Data Needs

The agency does not anticipate any further human health data needs for etridiazole; however, reference standards for etridiazole residues of concern (parent etridiazole and etridiazole acid) are not in supply at the EPA National Pesticide Standards Repository. The stock of the parent etridiazole has expired, and no sample of the acid is in stock. The registrant must supply these analytical standards in support of their 40 CFR published tolerances for etridiazole to the EPA National Pesticide Standards Repository (NPSR) which is located at Fort Meade, to the attention of Theresa Cole or Greg Verdin at the following address (note that mail will be returned if the extended zip code is not used):

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

B. Ecological Risks

A summary of the agency's ecological 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 etridiazole. For additional details on the ecological assessment for etridiazole, see the *Etridiazole: Draft Ecological Risk Assessment for Registration Review* and the *Etridiazole: Addendum to the Draft Risk Assessment - Honey Bee Risk Assessment*, which are available in the public docket.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach 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 are finalized, the agency will complete its endangered species assessment for etridiazole. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

Terrestrial Risks

Mammals

Calculated risk quotients (RQs) exceeded their respective Levels of Concern (LOCs) on both an acute and chronic exposure basis for several modeling scenarios of registered uses of etridiazole. RQ exceedances were identified from uses on golf course turf (acute and chronic exceedances) and on cotton (chronic exceedances only). Mammals may become exposed to etridiazole by consuming residues following spray applications to golf course tees and greens and in agriculture settings.

Acute dose-based RQs from golf course turf applications slightly exceed the acute LOC for small and medium mammals eating short grass. Mammalian chronic RQ exceedances resulted from modeling of etridiazole uses on cotton and golf course turf. Cotton use modeling yielded slight exceedances for small- and medium-sized mammals feeding on insects. Golf course turf uses yielded a range of RQ exceedances as high as 138 (LOC = 1.0), based on animal size and feeding habit.

Chronic mammalian toxicity estimates are based on a 6-9% reduction in pup body weight observed in the two-generation study with rats. The biological relevance of this effect is uncertain. The chronic RQs summarized above were calculated based on the no-observed-adverse-effect level (NOAEL). When RQs are instead calculated on the lowest-observed-adverse-effect level (LOAEL; 6-9% reduction in pup body weight), chronic risk estimates for cotton uses fall below the chronic risk LOC. Similarly, the RQs from golf course turf uses also decrease when calculated from the LOAEL, but are still above the chronic risk LOC for some scenarios.

Although there are mammalian RQ exceedances for etridiazole use on golf course tees and greens, the likelihood of mammalian exposure through this route is low. In assessing acute and chronic mammalian exposure, a default foliar dissipation half-life of 35 days was used because foliar dissipation half-life data for etridiazole are not available. Actual foliar dissipation in the field may be faster due to volatilization given that etridiazole may significantly volatilize from soil and water, particularly soon after application. Moreover, applications to golf courses are limited to tees and greens while the exposure models assume that the entire course is treated. Golf courses, especially tees and greens, are also subject to frequent mowing and intense management practices, such as the removal of clippings after mowing. These factors would

likely limit the availability of etridiazole residues in the environment and in turn limit exposure and consequent risk to mammals from etridiazole use.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Acute and chronic RQ exceedances resulted from avian modeling scenarios (the surrogate for reptiles and terrestrial-phase amphibians) for registered uses of etridiazole. Birds may become exposed to etridiazole through consumption of residues following spray applications to golf course tees and greens and in agriculture settings. Risks of concern were only identified as a result of registered etridiazole uses on golf course turf.

Potential acute RQ exceedances resulted from registered golf course turf uses of etridiazole the highest calculated RQ was 5.1 (acute LOC = 0.5). Slight subacute dietary-based RQ exceedances were also identified from registered golf course turf uses of etridiazole. When RQs are based on mean Kenaga exposure values rather than upper-bound Kenaga values, the dietary-based RQs for turf use are all be below the acute risk LOC.

There were also chronic dietary-based RQ exceedances for birds from golf course turf uses of etridiazole. Birds feeding on short grasses yielding the highest RQs, and no chronic exposure modeling scenario yielded RQs below the LOC. Toxicity estimates were based on a 23% reduction in the number of normal hatchlings, reduced hatchling survival, and a 17% reduction hatchling weight observed in a 22-week feeding study. When chronic dietary-based RQs are estimated using the lowest-observed-adverse-effect concentration (LOAEC), rather than the no-observed-adverse-effect concentration (NOAEC), the resulting RQs are all below the chronic LOC and no potential chronic dietary-based risks of concern are identified.

Although there are exceedances for etridiazole use on turf, the likelihood of avian exposure through this route is low. As discussed in the section on risks to mammals, there is uncertainty in estimates of avian exposure. All RQ exceedances for birds resulted from applications to golf courses, where application restrictions to tees and greens and turf management practices would limit exposure to birds.

Terrestrial Invertebrates (honey bees)

Several acute and chronic oral exposure RQ exceedances were identified for larval honey bees (*Apis mellifera;* the surrogate species for both *Apis* and non-*Apis* bees) from registered uses of etridiazole on golf course turf. Bees may become exposed to etridiazole through direct contact and ingestion of residues at the treatment site or through off-site drift. Cotton, though considered pollinator-attractive by the USDA, is not an expected source of exposure because cotton treatments are soil-incorporated. Though not listed as pollinator-attractive by the USDA, both turf and ornamental crop applications may result in exposure to honey bees, either through on-site exposure or off-site drift. In the case of golf courses, tees and greens consist entirely of grass, and not flowering plants.

No potential acute risks of concern were identified for foraging adult honey bees from contact with etridiazole residues at treatment sites. There were acute risk LOC exceedances for adults

(RQ = 1.4; LOC = 0.4) and larvae (RQ = 8.5; LOC = 0.4) as a result of oral exposure to etridiazole residues on golf course turf. Chronic RQs for honey bees were not calculated in the ecological risk assessment as chronic bee toxicity data were submitted after its completion. The review of the chronic toxicity data is included in the *Etridiazole: Addendum to the Draft Risk Assessment - Honey Bee Risk Assessment*. There were chronic LOC exceedances for adults (RQ = 27; LOC = 1) and larvae (RQ =21; LOC = 1) for the turf use.

Etridiazole is a non-systemic soil fungicide that belongs to the thiazole family. It is classified by the Fungicide Resistance Action Committee (FRAC) as a Group 14 fungicide. The mode of action has not been definitively identified, although FRAC indicates that it may work by damaging cell membranes through lipid peroxidation. The chemical is registered for use on several bee-attractive crops; however, the full suite of Tier 1 honey bee toxicity data is incomplete as there are no acceptable honey bee adult acute oral toxicity data. Although RQs exceed the acute risk level of concern for both adult and larval bees and the chronic risk for adult and larvae, no ecological incidents have been reported for etridiazole involving bees. Given the limited extent of potential risk, additional higher-tier honey bee data for etridiazole are not required; however, the suite of Tier 1 data should be completed by submission of an acute oral toxicity test with adult bees. Alternatively, the current acute oral toxicity test with adult bees could be upgraded if the registrant is able to address concerns regarding regurgitation of the test material.

Terrestrial Plants

No risks of concern were identified to terrestrial plants from registered uses of etridiazole. Tests conducted with exposures higher than label-permitted maximum application rates did not result in any toxic effects to terrestrial plants. It is therefore unlikely that risk of concern would result from registered uses of etridiazole.

Aquatic Risks

Freshwater Fish and Aquatic-Phase Amphibians and Estuarine/Marine Fish

No risks of concern to fish were identified from registered uses of etridiazole.

Freshwater Invertebrates and Estuarine/Marine Invertebrates

No risks of concern to aquatic invertebrates were identified from registered uses of etridiazole.

Aquatic Vascular and Non-Vascular Plants

No risks of concern to aquatic plants were identified from registered uses of etridiazole.

2. Ecological Incidents

A search of the EPA's Incident Data System (IDS) for ecological incidents on March 5, 2019, identified no incident reports for etridiazole. However, incidents may have occurred due to

etridiazole exposures but may not have been reported due to various factors. Therefore, the lack of incident reports does not necessarily indicate the absence of incidents.

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.

3. Ecological and Environmental Fate Data Needs

The *Etridiazole: Draft Ecological Risk Assessment for Registration Review* and the *Etridiazole: Addendum to the Draft Risk Assessment - Honey Bee Risk Assessment* identified the following data needs for etridiazole:

- OCSPP 850.6100: Environmental Chemistry Methods in Soil – Data were submitted and classified as "Unacceptable" with the possibility of a classification upgrade if modifications identified in the independent laboratory validation were incorporated;
- Non-Guideline/OECD 213: Honey Bee Adult Acute Oral Toxicity Study – Data were submitted to fulfill this requirement but were classified as "Unacceptable". The current study could be upgraded if the registrant is able to address concerns regarding regurgitation of the test material.

The DRA also notes that only one aerobic soil metabolism (OCSPP 835.4100) study is available.

C. Benefits Assessment

Etridiazole is a FRAC Group 14 thiadiazole fungicide. In general, Group 14 fungicides have a low to medium risk of developing resistance and, therefore, etridiazole may serve as a rotation or tank-mix partner in a resistance and disease management program.

Etridiazole is used for control of damping-off, root rot, and stem rot caused primarily by soil-borne fungal species of *Pythium* on use sites/crops such as cotton, turf, and ornamentals (CDMS, 2020; UC, 2020).[5, 6]

Etridiazole functions as a protectant contact fungicide and may have curative properties against *Pythium* spp. for tobacco transplants. Etridiazole is labeled and has potential for use in a widely adopted float-bed system by growers for producing tobacco transplants[7]. It is effective against *Pythium* diseases that are perennial problems in tobacco transplant float-beds. Etridiazole may be used to treat soil in-furrow prior to planting cotton, especially where cotton has been planted year

[5] CDMS. 2020. Crop Data Management Systems (CDMS). Accessed March 2020 at https://www.cdms net/.
[6] UC. 2020. Pest Management Guidelines. Statewide Integrated Pest Management (IPM) Program, University of California (UC) Agriculture and Natural Resources. Accessed March 2020 at http://ipm.ucanr.edu/IPMPROJECT/pubsmenu.html.
[7] Pfeufer E, Hinton C. 2017. Pythium Damping-off & Root Rot in Tobacco Float Systems. Plant Pathology Fact Sheet. University of Kentucky College of Agriculture, Food & Environment. Accessed May 2020 at https://plantpathology.ca.uky.edu/files/ppfs-ag-t-01.pdf.

after year and where damping-off is known to be a problem. Alternative fungicides such as mefenoxam may be used similarly to manage damping off for soil and transplant treatments and seed treatments with metalaxyl or azoxystrobin may be used to protect against damping-off. All three fungicides have high risk for developing resistance.[8] Etridiazole also plays a role in control of *Pythium* and *Phytophthora* root rot in greenhouse tomatoes by drip irrigation with special local need (SLN) registrations under FIFRA Section 24(c) in a number of states including Florida, Texas, and Tennessee.[9]

The primary benefit of etridiazole in golf courses is as a resistance management tool for control of pythium-related diseases. Etridiazole is a multisite fungicide, thus there is a low risk of pathogens developing resistance to it. This is particularly important in regions or periods of high precipitation, temperature, and humidity because pythium flourishes under these conditions.[10]

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The human health risk assessment identified possible non-cancer risks of concern to certain occupational handlers from registered uses of etridiazole. These risks to mixer/loader/applicators arise from the use of mechanically pressurized handguns to treat ornamentals in nurseries and greenhouses. To mitigate these potential occupational handler risks, the agency is proposing to prohibit the use of mechanically pressurized handguns for one product (EPA registration 400-575) for which the label allows a maximum application rate of 13.6 lbs a.i./A. All other products registered for the affected uses have lower application rates that do not result in risks of concern for occupational handlers. Lastly, the agency is proposing removal of language currently on some etridiazole labels that limits the hours per month that these products can be handled by workers and require record keeping of that time since the agency believes is unenforceable.

The registrant of the sole technical grade etridiazole product has been informed of these proposed mitigation measures. The EPA is also proposing label changes to address generic labeling requirements for all etridiazole products and uses.

1. Prohibition Against Using Certain Equipment, EPA Registration 400-575

The *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review* identified potential non-cancer risks of concern to occupational handlers involved in mixing, loading, and applying liquids by mechanically pressurized handguns to ornamental crops in greenhouses and nurseries at a rate of 0.136 lbs a.i./gallon application solution (13.6 lbs

[8] FRAC. 2019. Fungicide Resistance Action Committee (FRAC) - FRAC Code List© 2019: Fungal control agents sorted by cross resistance pattern and mode of action (including FRAC Code numbering). Accessed March 2019 at http://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2019.pdf.

[9] USDA. 2014. Crop Profile for Tomatoes in Tennessee. United States Department of Agriculture (USDA) Integrated Pest Management Center.

[10] Golf Course Superintendents Association of America (GCSAA). 2020. Response to US EPA questions on etridiazole use on golf courses. May 18, 2020.

a.i./A). In order to mitigate these risks, EPA is proposing a prohibition on the use of mechanically pressurized handguns on the label for product registration 400-575, the only currently registered etridiazole product that allows application at this rate. Current label language refers to "high-pressure handwand" applications. For consistency with the agency's terminology, the agency's proposal to prohibit application by mechanically pressurized handgun also requires the term "high pressure handwand" be replaced with "mechanically pressurized handgun".

The prohibition of the use of mechanically pressurized handguns on ornamental crops in greenhouse and nursery production on EPA registration 400-575 will likely result in users choosing other etridiazole products without this restriction. While applicators could apply this product using manually pressurized sprayers, the small number of containers that could be treated before refilling the sprayer (about 128 6-inch containers using a 4-gallon backpack sprayer) would increase costs of production. While growers could select other active ingredients to control soil-borne diseases, the availability of other etridiazole products makes this unlikely.

The EPA seeks comment on the proposal to prohibit application by mechanically pressurized handgun on the label for EPA registration 400-575. The agency seeks data on how this product is used and the value of the high application rate of 13.6 lbs a.i./A.

2. Updated Glove and Respirator Statements

The agency is proposing an update to gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, the agency is proposing the removal of reference to specific categories in EPA's chemical-resistance category selection chart and proposing that labels specify the appropriate glove types to use. For example, this statement from the label is required to be removed:

> "For more options, follow the instructions for Category H on the chemical-resistance category selection chart."

This statement is required: "When performing tasks with potential for contact with liquid fumigant, all handlers (including applicators) must wear: [insert all PPE, insert correct chemical-resistant glove type]." Product registrants are required to update the gloves statements to be consistent with Chapter 10 of the Label Review Manual.

All statements that refer to the chemical resistance category selection chart are required to be removed from etridiazole labels, as they might cause confusion for users. These statements are required to be replaced with specific chemical-resistant glove types, as appropriate. This minor clarification does not fundamentally change the personal protective equipment that workers are currently required to use.

The agency is proposing to update the respirator statement currently on labels. The proposed new respirator language, found in Appendix B does not fundamentally change the personal protective equipment that workers needs to use, and therefore should impose no impacts on users.

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.

The EPA is proposing resistance-management labeling, as listed in Appendix B, for products containing etridiazole, in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides. Additional information on the 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.

4. Label Clarification

Currently, two labels for etridiazole products (EPA registrations 400-507 and 400-575) contain language that limits the time that occupational handlers can work with these products and requires logging of all time spent handling these products. The following statement is an example of such language from the label for EPA registration 400-575:

> "The handler must not work more than 15 hours in a 30-day period. The employer must retain the record of hours worked by handler."

The agency's position is that such restrictions and requirements are not enforceable, and therefore proposes removing this language from all etridiazole products. The EPA invites comment on the proposal to remove limits on time spent handling etridiazole products.

B. Tolerance Actions

The agency anticipates that the tolerance expression for etridiazole will be revised to be consistent with the agency's Interim Guidance on Tolerance Expressions. In addition, the agency also anticipates revisions to the tolerance established for etridiazole residues on tomatoes, as a result of etridiazole use on tomatoes permitted in the U.S. by Special Local Need (SLN) registrations and in Europe by registrations there. The specifics of these changes are outlined in Section III.A.3 of this document. The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the agency has made the following proposed interim decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of etridiazole, nor is it making a complete endangered species finding. Although the agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of etridiazole. The agency's final registration review decision for etridiazole will be dependent upon the result of the agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

The suite of Tier 1 data should be completed by submitting an additional Honey Bee Adult Acute Oral Toxicity Study (Non-Guideline/OECD 213) or upgrading the current study by addressing concerns regarding regurgitation of the test material.

Additionally, the analytical reference standards for etridiazole need to be refreshed. The analytical reference standard for etridiazole has expired. The agency also lacks analytical reference standard for etridiazole acid. Reference standards for etridiazole and etridiazole acid must be submitted to the EPA's National Pesticide Standards Repository (see https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository).

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for etridiazole and will allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the agency to change its proposed interim decision, the EPA may issue an interim registration review decision for etridiazole. However, a final decision for etridiazole may be issued without the agency having previously issued an interim decision. A final decision on the etridiazole 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 etridiazole registrants must submit amended labels that include the label changes described in Appendices A and B. The revised 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.

Appendix A: Summary of Proposed Actions for Etridiazole

Registration Review Case#: 0009
PC Code: 084701
Chemical Type: Fungicide
Chemical Family: Not Applicable
Mode of Action: Group 14: Lipid Peroxidation Inhibitors

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment (use to briefly clarify or elaborate on risk or mitigation)
Occupational handlers	Applications by mechanically pressurized handguns in greenhouses and nurseries	Dermal, inhalation	Short-, intermediate-term	Non-cancer	Prohibit use of mechanically pressurized handguns on label 400-575	Risks of concern result only from highest permitted application rate on one label

Appendix B: Proposed Labeling Changes for Etridiazole Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Etridiazole Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>End Use Products</td><td></td></tr>
<tr><td>Mode of Action Group Number</td><td>Note to registrant:
• Include the name of the ACTIVE INGREDIENT in the first column
• Include the word “GROUP” in the second column
• 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
• Include the type of pesticide (i.e., HERBICIDE or FUNGICIDE or INSECTICIDE) in the fourth column.
<table><tr><td>ETRIDIAZOLE</td><td>GROUP</td><td>14</td><td>FUNGICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.
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>Updated Gloves Statement</td><td>Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</td></tr>
<tr><td>Updated Respirator Language</td><td>[Note to registrant: If your end-use product only requires protection from particulates only (low volatility), use the following language:]
“Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters.”
*Drop the “N” option if there is oil in the product’s formulation and/or the product is labeled for mixing with oil-containing products.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements</td></tr>
</table>

Description	Proposed Label Language for Etridiazole Products	Placement on Label
	[**Note to registrant:** For respiratory protection from organic vapor **and** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	
Resistance-management for fungicides and bactericides **Applies to all products with agricultural uses**	Include resistance management label language for fungicides/bactericides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops
Label Clarification	Remove restrictions on hours spent handling products and associated record keeping requirements from labels.	Directions for Use
	EPA Product Registration 400-575	
Prohibition of Mechanically Pressurized Handgun Applications	Remove all references to high-pressure handwand applications currently on label. Add the following text: "Do not apply this product by any type of mechanically pressurized handgun."	Directions for Use

Appendix C: Endangered Species Assessment

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated Revised Method for conducting national level BEs in March 2020.[11]
Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for etridiazole does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although the EPA has not yet completed effects determinations for specific species or habitats, for this PID, the EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of etridiazole. This will allow the 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 that occurs, these methods will be applied to subsequent analyses for etridiazole as part of completing this registration review.

[11] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for etridiazole, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), etridiazole is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[12] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Etridiazole is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[13]

In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of etridiazole. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

[12] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[13] https://www.epa.gov/endocrine-disruption