



**Dithiopyr**  
**Interim Registration Review Decision**  
**Case Number 7225**

**December 2020**

Approved by: \_\_\_\_\_

A handwritten signature in blue ink that reads "Mary Elissa Reaves".

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Date: \_\_\_\_\_ 12-08-2020 \_\_\_\_\_

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## I. INTRODUCTION

This document is the Environmental Protection Agency's (hereafter noted as EPA or the Agency) Interim Registration Review Decision (ID) for dithiopyr (PC Code 128994, case 7225), 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 necessary to complete the review, and include schedules for submitting the necessary data, conducting the new risk assessment and completing the registration review. Additional information on dithiopyr, can be found in EPA's public docket (EPA-HQ-OPP-2013-0750) at [www.regulations.gov](http://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 dithiopyr 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 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 dithiopyr prior to completing the dithiopyr registration review. Likewise, the Agency will complete endocrine screening for dithiopyr, 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 dithiopyr registration review.

Dithiopyr is a pyridine-based class 3 herbicide according to the Weed Science Society of America (WSSA),<sup>1</sup> with selective toxicity to broadleaf weeds. While most herbicides in the pyridine group are in class 4 and work as synthetic auxins (plant hormones), dithiopyr works by inhibiting microtubule assembly. It is registered for use on the following sites: residential, recreational, and commercial turf (including sod farms), landscape, field grown, and container-grown ornamentals, Christmas trees, rights of ways, and non-crop areas such as fencerows/hedgerows and airports/landing fields. Dithiopyr products are formulated as an emulsifiable concentrate, flowable concentrate, granule, ready-to-use liquid, soluble concentrate, or wettable powder. Dithiopyr is applied via backpack sprayer, foam applicator, granule applicator, handgun, ground sprayers, and spreader.

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

### **A. Summary of Dithiopyr Registration Review**

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

- December 2013- The *Dithiopyr Preliminary Work Plan (PWP)*, *Dithiopyr Human Health Assessment Scoping Document in Support of Registration Review*, and the *Registration Review Problem Formulation for Dithiopyr* were posted to the docket for a 60-day public comment period.
- July 2014- The *Final Work Plan (FWP)* for dithiopyr was issued. Comments were received from dozens of lawn care operators, vegetation management specialists, and university extension specialists attesting to the benefits of dithiopyr use. Comments were also received from the FIFRA Endangered Species Task Force (FESTF) with respect to data compensation for FESTF data. The Center for Biological Diversity (CBD) submitted comments on EPA's obligations under ESA. The comments did not result in changes to the data needs or the registration review timeline presented in the FWP.

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<sup>1</sup>Weedscience.org. 2013. <http://www.weedscience.org/summary/Herbicide.aspx>. Date Accessed. June 6, 2013 or WSSA link. <https://wssa.net/wp-content/uploads/WSSA-Herbicide-SOA-2020-7-17.xlsx>

- November 2014- A *Generic Data Call-In* (GDCI-128994-1426) for dithiopyr was issued for data needed to conduct the registration review risk assessments. All data requirements have been satisfied, except the non-guideline (OECD 237) honey bee larvae acute oral toxicity study.
- August 2018- The Agency announced the availability of *Dithiopyr: Human Health Draft Risk Assessment for Registration Review* and the *Dithiopyr: Preliminary Ecological Risk Assessment for Registration Review to the dithiopyr docket* for a 60-day public comment period. Two comments were received during the comment period from Corteva AgriScience (formerly Dow AgroSciences), the technical registrant, and the U.S. Department of Agriculture. These comments did not directly result in changes to the risk assessments. However, thyroid weight of evidence and benchmark dose information submitted in January 2020 resulted in revisions to the human health risk assessment. The ecological risk assessment was also revised to correct a unit conversion error for aquatic invertebrates.
- June 2020- The Agency announced the availability of the *Proposed Interim Registration Review Decision* (PID) in the docket for dithiopyr, for a 60-day public comment period which opened on September 2, 2020 and closed on November 2, 2020. Along with the PID, the following documents were also posted to the dithiopyr docket:
  - *Dithiopyr: Revised Human Health Risk Assessment for Registration Review*, dated May 29, 2020.
  - *Dithiopyr: Revised Draft Ecological Risk Assessment for Registration Review*, dated May 28, 2020.
  - *Dithiopyr: Response to Comments and Transmittal of Data Evaluation Record for Non-guideline Groundwater Monitoring Study*, dated March 30, 2020.
  - *Response to Public Comments on the Preliminary Ecological Risk Assessment for Dithiopyr*, dated August 6, 2019.
  - *Dithiopyr: Response to Comments from the United States Department of Agriculture on the Preliminary Ecological Risk Assessment for Registration Review*, dated June 16, 2020.
  - *Response to Public Comments on the Draft Human Health Risk Assessment for Dithiopyr*, dated May 29, 2020.
  - *Dithiopyr Use, Usage, Benefits and Impacts of Potential Mitigations*, dated June 17, 2020.
- December 2020 – The Agency has completed the dithiopyr ID and will post it in the dithiopyr registration review docket (EPA-HQ-OPP-2013-0750).

## **B. Summary of Public Comments on the Proposed Interim Decision and Responses**

During the 60-day public comment period for dithiopyr PID, which opened on September 2, 2020 and closed on November 2, 2020, the Agency received six public comments. Comments were received from the United States Department of Agriculture (USDA), Harrell's, LLC,

SiteOne Landscape Supply, the Scotts Company, LLC, the National Association of Landscape Professionals (NALP) and an anonymous commenter. Substantive public comments are summarized below, along with the Agency's responses. The Agency thanks all commenters and has considered all comments in the development of this ID.

**Comments submitted by the United States Department of Agriculture (EPA-HQ-OPP-2013-0750-0077)**

**Comment:** USDA provided some general information on the use and benefits of dithiopyr. USDA generally supported proposed language in the dithiopyr PID that address spray drift mitigation, environmental hazards for pollinators, surface and groundwater advisories, and herbicide resistance management measures.

USDA noted that in the PID, the Agency asked for stakeholder feedback and information on dithiopyr's behavior in vegetative matter and potential persistence in compost. USDA also noted that the Agency implied that dithiopyr poses risks in recycled organic products (i.e., compost, mulch, or manure) because it is in the pyridine class of herbicides. USDA was concerned with the Agency's assumption since there have been no compost incidents of record and no evidence to suggest that dithiopyr might be persistent in such materials. USDA noted there are current dithiopyr product labels (e.g., EPA Reg. No. 62719-542) that already contain use restrictions for treated plant materials: "Do not use clippings from treated turf for mulching around vegetables or fruit trees."

USDA compiled comments from representatives in the professional landscape industry and weed scientists and none of the experts interviewed had heard of a single case where dithiopyr had been implicated as contaminant of green manure and other recycled plant materials. USDA suggested that there is no realistic risk of dithiopyr contaminating recycled organic materials based on its use pattern and current turf management best practices and urged the Agency to reflect this on product labels until there is reliable evidence for a plausible exposure pathway of concern.

USDA also commented on the proposed environmental hazard language for pollinators which refers to indirect risks to pollinators from the use of herbicides. USDA urged the Agency to consider whether such language is warranted for herbicides such as dithiopyr that have relatively small ranges of activity on weeds that are not generally pollinator attractive and given dithiopyr's specific use pattern and minimal risks to pollinators.

**EPA Response:** The Agency appreciates the information provided by USDA concerning the benefits of dithiopyr as well as additional stakeholder feedback on the compost issue. Dithiopyr's behavior in vegetative matter and potential persistence in compost is still an uncertainty. While synthetic auxin herbicides (WSSA class 4) such as aminocyclopyrachlor, aminopyralid, clopyralid, and picloram have reported compost incidents, it is unknown if this issue may affect herbicides with other modes of action. The Agency is working to develop a method to screen herbicides for potential compost contamination concerns. The Agency did not propose compost labeling for dithiopyr and is not requiring any compost labeling as part of this ID. USDA's concern focuses on the fact that EPA merely considered the compost issue in relation to

dithiopyr. The Agency reserves the right to consider and assess potential effects to non-target plants in relation to any pesticide.

The Agency is retaining the nontarget organism advisory (which USDA refers to as the environmental hazard for pollinators), as this statement is added for all pesticides that are toxic to plants. As an herbicide, dithiopyr may impact pollinator forage and habitat through spray drift. There are use sites that may contain pollinator forage: ornamentals, rights of ways, and residential/industrial turf.

**Comments Submitted by Harrell's, LLC (EPA-HQ-OPP-2013-0750-0080) and SiteOne Landscape Supply (EPA-HQ-OPP-2013-0750-0078)**

**Comment:** Harrell's, LLC, a manufacturer and distributor of fertilizer and turf pesticide products noted the importance of dithiopyr as a preemergent herbicide in the turf and ornamental market. Dithiopyr has low odor, is non-staining, and provides effective control of crabgrass. Harrell's further noted that the Agency's PID sought public comment on the potential for dithiopyr residues to be present in compost source materials, including green waste composed of grass clippings. Harrell's is not aware of any concerns related to residues of dithiopyr in green waste. Harrell's suggested that placing restrictions on grass clippings from dithiopyr treated turf would be costly and place an undue burden on homeowners living in communities that require collection of grass clippings. Harrell's noted that any decision to manage grass clippings from turf treated with dithiopyr should be based on science with conclusive evidence of persistence in compost. Harrell's stated that premature restrictions would place an unnecessary and costly burden on turf managers and consumers and on the entire composting industry.

SiteOne Landscape Supply supported the continued availability of dithiopyr as an herbicide in the turf and ornamental markets. SiteOne noted the benefits and importance of dithiopyr in the lawn care sector for selective control of weeds and as an additional herbicide tool for users in a weed resistance management program. SiteOne noted it was not aware of any concerns for residues of dithiopyr in compost materials and encouraged the Agency not to add compost restrictions.

**EPA Response:** The Agency appreciates the concerns about potential compost restrictions and the benefits information provided by Harrell's and OneSite and has considered these comments in the development of this ID. As noted previously, the Agency did not propose any compost restriction labeling for dithiopyr in the PID nor is compost labeling being added as part of this ID.

**Comments submitted by the Scotts Company, LLC (EPA-HQ-OPP-2013-0750-0076)**

**Comment:** The Scotts Company sought clarification on the necessary labeling for residential consumer products. The Scott's Company noted that the mode of action and other resistance management information is not applicable to residential consumer products.

**EPA Response:** The Agency agrees with the Scotts Company that mode of action information and other resistance management labeling is not necessary for residential consumer products.

The Agency appreciates the information provided and has added clarification to the Appendix B label table.

**Comment Submitted by National Association of Landscape Professionals (NALP) (EPA-HQ-OPP-2013-0750-0082)**

**Comment:** The National Association of Landscape Professionals noted the importance of dithiopyr to the lawn care and landscaping industry. NALP stated their appreciation of the agency's efforts to understand the lawn care industry's use pattern and application methods. Herbicides such as dithiopyr allow landscape professionals to maintain their customer's properties in a manner that maximizes environmental benefits while using the least amount of pesticide inputs possible. NALP also provided some general information on the use and benefits of dithiopyr, as well as how dithiopyr is typically applied by lawn and landscape professionals. NALP supported the adoption and implementation of turfgrass best management practices that guide practitioners to reduce the amount of pesticides that are used on turf. NALP also noted that professional landscapers do not use grass clippings as mulch. NALP stated that the retention of grass clippings created during the mowing process is encouraged because it recycles nutrients. In addition, customers dislike it when mowers deposit clippings in plant beds because the clippings are unattractive, straw colored, and odiferous.

**EPA Response:** EPA thanks NALP for its comments on the dithiopyr PID. The agency agrees that the education of applicators and land managers on turf best management practices are important.

## II. USE AND USAGE

Products containing dithiopyr are registered to control grasses and broadleaf weeds on landscape, field, and container grown ornamentals, including Christmas trees, located in ornamental gardens, parks, golf courses, and residential areas; on turf sites (residential and institutional lawns, athletic fields, commercial sod farms, and golf course turf); and uncultivated nonagricultural areas including roadsides, utility rights-of-way, railways, and industrial areas. There are no food or feed uses for dithiopyr. Dithiopyr's mode of action is to inhibit the formation and function of microtubulin resulting in the disruption of normal cell division of susceptible plants [classified as a group 3 herbicide by the WSSA]. Affected plants do not grow and develop through their normal cycle of vegetative growth followed by reproduction (flowering and seed setting) and roots are stunted and fail to function.

Registered formulations of dithiopyr include emulsifiable, flowable, and soluble concentrates, dry flowable, wettable powder, granular, and ready-to-use products, as well as impregnated mulches. Products are applied via groundboom sprayer, drop or rotary spreader, and manually or mechanically pressurized hand sprayer equipment. No products are applied via chemigation applications; chemigation applications are prohibited on some, but not all registrations. Aerial applications are not prohibited on labels, but there are no specific label directions on how to apply dithiopyr products using aerial application equipment. It is expected that ground



applications would be the most likely method of application given typical practices and the nature of the use sites.

Dithiopyr is used primarily in the professional turf and ornamental markets as a pre-emergence herbicide, but can be used for post-emergence control of some weeds as well. Usage data are available for the following categories: lawn herbicides (i.e., those applied by homeowners), institutional turf facilities, golf courses, lawn care operators, turf farms, and roadway rights-of-ways. Usage data suggests that most usage of dithiopyr is by lawn care operators who maintain turf through application of fertilizers and pesticides in residential, commercial, and industrial areas. In 2013, 609,000 pounds of dithiopyr were applied by lawn care operators<sup>2</sup> on a national level to residential, commercial, and industrial lawns. In 2016, consumers applied about 48,000 pounds of dithiopyr to residential lawns<sup>3</sup>. The second largest use category is use on golf course turf. Data from 2013 shows 117,000 lbs of dithiopyr were applied on golf courses<sup>2</sup> on a national level. Additionally, dithiopyr was used on institutional turf facilities, with about 69,000 pounds dithiopyr used in 2013<sup>1</sup> on a national level. Usage of dithiopyr was minimal on roadway rights of ways.<sup>4</sup>

For additional information on the use and usage of dithiopyr, see the document entitled *Dithiopyr Use, Usage, Benefits and Impacts of Potential Mitigations*, which is available in the public docket.

### 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 dithiopyr. For additional details on the human health assessment, see the *Dithiopyr: Human Health Draft Risk Assessment for Registration Review* and the *Dithiopyr: Revised Human Health Draft Risk Assessment for Registration Review* which are available in the public docket.

The 2018 *Dithiopyr: Human Health Draft Risk Assessment for Registration Review* applied a 10X database uncertainty factor (UF) for lack of a comparative thyroid assay (CTA). Risks of concern were identified in the 2018 assessment for chronic dietary exposure, residential post-application exposure, and occupational handler exposure. Since the 2018 risk assessment, new information allowed the Agency to refine its risk assessment and reduce the UF to 1X.

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<sup>2</sup> Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities. [Accessed February 2020.]

<sup>3</sup> Non-Agricultural Market Research Proprietary Data. 2017a. Studies conducted and sold by a consulting and research firm. Report on Consumer Markets for Pesticides and Fertilizers. [Accessed February 2020.]

<sup>4</sup> Non-Agricultural Market Research Proprietary Data. 2017b. Studies conducted and sold by a consulting and research firm. Report on Industrial Vegetation Management of Pesticides. [Accessed April 2020.]

The revised human health draft risk assessment was updated to reflect these changes. Therefore, there are no risks of concern for dietary, residential post-application, aggregate, or occupational handler exposures.

## 1. Risk Summary and Characterization

An acute dietary risk assessment was not needed because no endpoint attributable to a single exposure was observed for dithiopyr and, as a result, potential acute dietary risks are not expected.

A chronic dietary risk assessment was conducted. The 2018 human health risk assessment noted that chronic dietary risk estimates were above the Agency's LOC. The chronic dietary risk estimates were equal to 680% of the cPAD for the general U.S. population and equal to 1,700% of the cPAD for all infants < 1 year old (where risk estimates above 100% are of concern). Infants <1 year old was the population subgroup with the highest exposure. The Agency assessed the maximum application parameters on dithiopyr labels (3 applications at 0.5 lb ai/A and 90-day retreatment interval).

Since the issuance of the 2018 human health risk assessment, a revised human health risk assessment was completed in 2020 to reflect the decision to reduce the database UF from 10X to 1X and reflect new benchmark dose (BMD) information to further inform the dietary risk assessment. When the database UF is reduced to 1X, the revised dietary risk estimates are not of concern for all population subgroups, except for the most at risk population subgroup, all infants <1-year-old, where risk estimates are equal to 170% of the cPAD, assuming the maximum application parameters. The large dose spacing (10X) between the NOAEL and LOAEL of the 2-year rat study indicates that the chronic dietary point of departure (POD) is conservative. In addition, the registrant, Corteva Agriscience, submitted a benchmark dose (BMD) Modeling report (MRID 51053301) that discussed BMD modeling that focused on endpoints used in establishing the current POD in the 2-year rat study. Although not all endpoints were suitable for BMD modeling (the BMD model does not fit due to large dose spacing and/or no dose response and therefore cannot be used for POD selection), it provides characterization of the risk assessment. Endpoints that were modeled provided reliable BMDLs (BMD lower confidence limits) that were 2 to 12-fold higher than the current POD of 0.36 mg/kg/day. This suggests that the current POD is conservative and protective. This further supports the current chronic dietary assessment as being based on a conservative POD.

In addition, the estimated drinking water concentrations (EDWC) used for dietary risk assessment are considered a high-end, health protective estimates based on maximum use rates in a region of the U.S. with the highest leaching potential to groundwater sources. Therefore, actual exposure from registered uses of dithiopyr are lower than those calculated for the vast majority of the population. The resulting risk estimates reflect compounding conservatisms from both the hazard and exposure components. Based on the weight of the evidence approach that considers the conservatisms of the chronic endpoint and the modeled EDWC, the Agency concludes that the actual chronic dietary risks from registered uses of dithiopyr are lower than those calculated and are not of concern with the modeled application parameters (3 applications per year at 0.5 lb

ai/A, with 90-day retreatment interval). Some labels note different application parameters than those modeled (*e.g.*, 6 applications, 5 week retreatment interval, with a maximum yearly application rate of 1.5 lb ai/A/year). However, variations in the frequency of applications or the interval between applications is not expected to change the dietary risk conclusion as long as the maximum yearly application rate remains at 1.5 lb ai/A/year.

### *Residential Handler Risks*

For residential handlers, dermal exposure was not assessed since no dermal hazard was identified. Inhalation exposure was assessed and all scenarios yielded inhalation margins of exposure (MOEs) that were not of concern. The MOEs range from 67,000 to 19,000,000. The original LOC was 1,000 in the 2018 human health risk assessment, the revised 2020 risk assessment reflects a revised LOC of 100. However, the risk conclusions have not changed.

### *Residential Post-Application Risks*

Residential post-application dermal exposure was not assessed since no dermal hazard was identified. Post-application incidental oral exposure was assessed for applications to lawns and turf from both liquid and granular formulations. The 2018 human health risk assessment identified post-application risks to children 1 to 2 years old from hand-to-mouth exposure from treated lawns/turf. Residential post-application MOEs for children (aged 1 to <2 years old) ranged from 610 to 300,000. The lowest MOE of 610 was potentially of concern (the LOC was 1,000). The 2020 risk assessment was updated to reflect a change in the database UF from 10X to 1X, and the LOC changed from 1,000 to 100. With the change in the LOC, residential post-application risk estimates are no longer of concern.

### *Aggregate Risks*

Aggregate risk combines risks from food, drinking water, and residential exposure. In the 2018 risk assessment, an acute aggregate assessment was not required because no endpoint attributable to a single exposure was identified. A short-term aggregate risk assessment was not performed because risks of concern were identified for all drinking water exposure scenarios. The 2018 chronic aggregate risk assessment considers exposures to dithiopyr from drinking water only, and was equal to the chronic dietary risk estimates, which were of concern.

Since 2018, the acute aggregate assessment remains unchanged and is still not required due to lack of an appropriate endpoint for this scenario. The revised 2020 human health risk assessment reflects a new short-term aggregate assessment for both adults and children. The short-term combined (drinking water and residential exposures) assessment results in MOEs of 2,000 and 430 for adults and children, respectively, and are not of concern (LOC=100).

Since revised chronic aggregate risk estimates are equal to the revised chronic dietary risk estimates, chronic aggregate risks are no longer of concern based on the characterization provided earlier.

### *Non-Occupational Spray Drift Risks*

Off-target movement of pesticides can occur via spray drift. Spray drift can deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children playing on lawns where residues have deposited next to treated fields). In the 2018 assessment, a spray drift assessment was conducted assuming the highest labeled application rate (0.5 lb ai/A). Incidental oral risk estimates were calculated for children 1-2 years old, the highest exposed population subgroup. Risk estimates were not of concern at the field edge for aerial, airblast, and groundboom applications. MOEs ranged from 2,600 to 4,600, where the original LOC from the 2018 risk assessment is 1,000.

The revised 2020 human health risk assessment has been updated to reflect a change in the LOC from 1,000 to 100. In the revised 2020 assessment, spray drift exposure and risk were not quantified because direct risk estimates for residential and turf exposures are considered protective of this scenario for both adults and children. MOEs from the turf residential post-application assessment were not of concern; therefore, there are no non-occupational spray drift risks of concern.

### *Cumulative Risks*

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

### *Occupational Handler Risks*

Occupational handlers are individuals involved in the pesticide application process. A quantitative dermal risk assessment was not required since there is no dermal hazard for dithiopyr. Only inhalation risks were assessed. The 2018 risk assessment identified occupational handler risks of concern for the following scenario: mixing/loading water soluble packets for aerial application, where the MOE is 880 (where MOEs below the LOC of 1,000 are of concern).

The revised 2020 human health risk assessment reflects a change in the LOC from 1,000 to 100. With the revised LOC of 100, all scenarios yielded MOEs that do not represent risks of concern. The occupational handler MOEs range from 880 to 2.7 million.

### *Occupational Post-Application Risks*

Occupational post-application dermal exposure was not assessed for dithiopyr because there is no dermal hazard identified. Technical dithiopyr is classified as being in Toxicity Category IV via the dermal route and Toxicity Category IV for skin irritation potential. Chemicals in these categories are assigned a 12-hour restricted entry interval (REI). The current REI on the labels is 12 hours and is adequate to protect agricultural workers from post-application exposure to dithiopyr.

## **2. Human Incidents and Epidemiology**

A search for human incidents was conducted in 2018 in preparation for risk assessment. From January 1, 2013 to March 1, 2018, there were two incidents (classified as moderate severity) reported for dithiopyr alone in the main Incident Data System (IDS). There were four additional incidents involving pesticide products containing dithiopyr co-formulated with another pesticide. A search was conducted in aggregate IDS. From January 1, 2012 to April 28, 2017, there were a total of 36 incidents reported involving dithiopyr. Thirty-three of these incidents were classified as minor severity and three had no or unknown severity.

A query of the Center for Disease Control's National Institute for Occupational Health (CDC/NIOSH) SENSOR-Pesticides database, identified a total of 25 cases involving dithiopyr from 1998 to 2014. Seven cases involved a single active ingredient and eighteen cases involved multiple pesticides. Fifteen cases occurred in occupational settings and ten cases were residential. Six cases were moderate in severity and 19 cases were low in severity.

Based on the low frequency and severity of incident cases reported for dithiopyr, in both the Main and Aggregate IDS and SENSOR-Pesticides, there does not appear to be a concern at this time that would warrant further investigation. The Agency will continue to monitor the incident information and if a concern is triggered, additional analysis will be conducted.

## **3. Tolerances**

Dithiopyr is not registered for use on food or feed crops; therefore, there are no tolerances established.

## **4. Human Health Data Needs**

A guideline 875.1000 turf transferable residue study for dithiopyr was previously identified as a data gap. However, since no risks of concern resulted from the existing turf uses, the Agency does not anticipate requiring this study to support registration review.

## **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 dithiopyr. For additional details on the ecological assessment for dithiopyr, see the May 28, 2020 document, *Dithiopyr: Revised Draft Ecological Risk Assessment for Registration Review*, which is available in the public docket.

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 dithiopyr. 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

Risk quotients (RQs) for mammals are not of concern on an acute exposure basis. Chronic RQs were calculated assuming upper-bound estimates of residues in food items, and the maximum application parameters: three applications of dithiopyr at 0.5 lb ai/A, with a 90-day interval between applications. Dose-based chronic RQs exceed the level of concern (LOC) of 1 and ranged from 0.2-36.9 for all uses. Chronic dietary-based RQs also exceed the LOC of 1 and ranged from 0.4 to 5.8 for all uses. Dietary-based RQs directly compare the pesticide concentration consumed by the animal in the diet to the estimated concentration on food items. The dose-based RQs account for the fact that small animals need to consume more food relative to their body weight than large animals and that differential amounts of food are consumed depending on the water content and nutritional value of food.

The Agency refined the mammalian exposure assessment by considering mean estimates of residue levels in food items (e.g., mean Kenaga estimates). RQs are lower when using mean Kenaga estimates. Dose-based RQs (0.1-11) and dietary-based RQs (0.1-1.7) based on mean Kenaga estimates still exceed the chronic LOC of 1.

Since one of the formulations of dithiopyr is granular, the Agency estimated chronic risk to mammals consuming granules. Risk estimates based on consuming granules takes into account the number of granules that must be consumed to achieve the no observable adverse effect concentration (NOAEC). The Agency determined that a small mammal would need to consume between 110,000 small granules and 2,000 large granules to reach the toxicity threshold. These numbers are >100% of the daily diet of an animal that eats seeds as the main part of its diet, therefore risks from consumption of granules is estimated to be low.

Distances where risk extends from the edge of the field were calculated by considering spray drift exposures. If applications at the maximum single application rate, 0.5 lb ai/A, are made via high boom ground spray with very fine to fine droplets, risks to mammals extend 95 feet from the edge of the treated field. If applications at the same rate are made via high boom and fine to medium coarse droplets, risks would extend 20 feet from the edge of the field.

A bioaccumulation analysis for mammals consuming fish contaminated with dithiopyr did not identify risks of concern for most scenarios, except for large river otters which slightly exceed the LOC of 1 (RQ=1.1).

#### Birds, Reptiles, and Terrestrial-Phase Amphibians

The Agency has not identified acute or chronic risks of concern for birds, reptiles, or

terrestrial-phase amphibians exposed to dithiopyr. Therefore, there are no risks of concern.

### Terrestrial Invertebrates (honeybees)

No potential acute risks of concern to adult bees from acute contact or oral exposure were identified (acute contact RQ for adults=0.02; LOC is 0.4). Overall, there are uncertainties for acute risk to honeybee larvae and chronic honeybee risk due to the absence of the majority of the Tier 1 bee toxicity data.

Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for dithiopyr, the problem formulation and registration review GDCI for dithiopyr were both issued prior to the EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*<sup>5</sup>. This 2014 guidance lists additional pollinator studies that were not included in the dithiopyr registration review DCI. Therefore, EPA is currently determining whether additional pollinator data are needed for dithiopyr. If the Agency determines that additional pollinator exposure and effects data are necessary for dithiopyr, then EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 1 below.

Table 1: Potential Pollinator Data Requirements

OCSP Guideline #	Study Description
Tier 1*	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline (OECD 245)	Honey bee adult chronic oral toxicity
Non-Guideline (OECD 239)	Honey bee larvae chronic oral toxicity
Tier 2 <sup>†</sup>	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3 <sup>†</sup>	
850.3040	Full-Field testing for pollinators

<sup>†</sup> The need for higher tier tests for bees will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

\*The following bee studies have been submitted and are acceptable: guideline 850.3020 honeybee adult acute contact toxicity and non-guideline honeybee adult acute oral toxicity. Guideline 850.3030 honeybee toxicity of residues on foliage is not needed because the tier I adult acute contact RQs were not of concern.

<sup>5</sup> Available at [https://www.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf)

### Terrestrial and Wetland Plants

The Agency has identified potential risks to non-target terrestrial plants from the use of dithiopyr, as expected for an herbicide. Runoff and spray drift RQs ranged from 0.4 to 21.3 for liquid foliar applications (where the LOC=1). Spray drift only RQs ranged from 0.2 to 1.9. For granule applications, RQs ranged from 0.2 to 19.4 and exceeded the LOC of 1.

The distance from the edge of the field to reach below the toxicity threshold was calculated using spray drift modeling. Distances from the edge of the field vary depending on the droplet size and release height. For ground application at high boom (4 ft release height) using very fine to fine droplets, the distance to below the toxicity threshold reaches up to 407 ft. With low boom (2 ft release height) and fine to medium/coarse droplets, the distance to below the toxicity threshold is up to 82 ft.

### *Aquatic Risks*

#### Fish and Aquatic-Phase Amphibians

No potential acute or chronic risks of concern for freshwater fish and estuarine/marine fish exposed to dithiopyr have been identified. Fish are surrogates for aquatic-phase amphibians, and no risks of concern are expected for this taxon.

#### Aquatic Invertebrates

Risks to freshwater invertebrates are not of concern.

No acute risks of concern were identified for saltwater invertebrates. Chronic RQs exceed the LOC slightly for saltwater invertebrates for nursery and rights-of-way use, RQs are 1.1 and 1.3 respectively (where the LOC is 1).

Benthic invertebrates are those residing at the bottom of water bodies or in the sediment. No acute risks of concern were identified for freshwater benthic invertebrates exposed to dithiopyr. Chronic risk RQs for freshwater benthic invertebrates from nurseries and rights-of-way use slightly exceeded the chronic LOC of 1.0, RQs ranged from <0.01 to 1.29.

In the 2018 ecological risk assessment, risks to saltwater benthic invertebrates were identified. However, an error in the endpoint used for risk calculation was found and the Agency has recalculated saltwater benthic invertebrate RQs. Acute RQs for saltwater benthic invertebrates ranged from 0.3 to 0.7 and slightly exceed the acute LOC of 0.5. Chronic RQs for saltwater benthic invertebrates were not of concern. Revised RQs are posted in the docket in the *Dithiopyr: Revised Draft Ecological Risk Assessment for Registration Review*.

#### Aquatic Plants

The Agency has identified risk to aquatic vascular plants. RQs ranged from 0.4 to 3.1 exceeding the LOC of 1.0 for most uses. No potential risks of concern were identified for aquatic non-vascular plants.



## **2. Ecological Incidents**

A search of the Incident Data System (IDS) was conducted on March 8, 2018 in support of the risk assessment. Incidents are categorized according to the likelihood that use of dithiopyr was associated the incident, and the classification categories are: unrelated, unlikely, possible (i.e., the pesticide possibly could have caused the incident but there are other possible explanations), probable (i.e., circumstances indicate that the pesticide was the cause, but confirming evidence is lacking), and highly probable (i.e., pesticide was confirmed as the cause through reliable evidence). From the time at which the Agency began requesting incident reports until March 8, 2018, when a search was conducted, 32 non-target plant incidents have been reported; two were classified as “possible” and 30 incidents were classified as “probable”. One of the incidents was considered a registered use at the time of the incident, two involved accidental misuses, and the legality of use was undetermined in 28 incidents. Two of the incidents involved additional pesticides mixed with dithiopyr. Overall, most reported incidents are from use on golf course turf and involve damage to grass. The aggregate incident database for dithiopyr contains 38 incidents (7 minor fish and wildlife and 31 minor plant incidents), but no additional information is available for those incidents.

The Agency will continue to monitor ecological incident information as it is reported to the Agency. A detailed analysis of these incidents will be conducted if reported information indicates concerns for risk to non-target organisms.

## **3. Ecological and Environmental Fate Data Needs**

The Agency issued a generic data call-in notice (GDCI-128994-1426) in December 2014. The environmental fate and ecological effects data requirements have been satisfied, except for the non-guideline larval honeybee acute oral toxicity study, which is considered outstanding. The Agency did not call-in the entire suite of bee studies in the GDCI, therefore, the Agency is evaluating the need for additional bee studies. No other data requirements are anticipated for registration review at this time.

### **C. Benefits**

Dithiopyr is predominantly used in golf courses and in the professional turf management sector (e.g., lawn care). Dithiopyr can be used to treat a variety of problematic weed species such as crabgrass, barnyardgrass, goosegrass, foxtails, carpetweed, chickweed, henbit, prostrate knotweed, and redroot pigweed.

In golf course settings, dithiopyr is applied to fairways, roughs, tee boxes, and putting greens. Major weeds targeted are crabgrass, spurge, oxalis, and bluegrass. Dithiopyr provides niche benefits for post-emergent crabgrass control in warm-season turf grass. It provides effective control on crabgrass up to the 5-leaf stage, which is the leading weed species in golf courses. Dithiopyr also provides benefits in the lawn care sector for selective control of weeds. In lawn care, it is used for both pre- and post-emergence control of crabgrass in established lawns and ornamental turf. Similar to golf course settings, crabgrass is the leading weed targeted by lawn care operators.

There are other herbicides used in turfgrass for both pre- and post-emergence weed control, such as ethofumesate, indaziflam, mesotrione, pronamide, and sulfentrazone. Dithiopyr provides an additional tool for users in a weed resistance management program.

Additional information on benefits is available in the *Dithiopyr Use, Usage, Benefits and Impacts of Potential Mitigations*, available in the docket (EPA-HQ-OPP-2013-0750).

## **IV. INTERIM REGISTRATION REVIEW DECISION**

### **A. Risk Mitigation and Regulatory Rationale**

The Agency has determined that there are no human health risks of concern for dithiopyr. The Agency is requiring updated labeling for products packaged in water soluble bags to meet current standards. As discussed in Section III of this document, potential risks of concern were identified primarily to mammals, as well as aquatic and terrestrial plants. Slight RQ exceedances were also noted for aquatic invertebrates. Risk to non-target organisms may be outweighed by the niche benefits of dithiopyr use in turf management. To address the potential ecological risks, the Agency is requiring mandatory spray drift management language and updated environmental hazards and water advisories. In discussions with the Agency on May 20, 2020 the technical registrant, Corteva AgriScience, agreed to the risk mitigation measures with minor editorial comments. The labeling changes for dithiopyr are not likely to adversely impact stakeholders. All mitigation measures are detailed in Appendices A and B.

#### **1. Updated Labeling for Water Soluble Packages**

Dithiopyr is formulated in water soluble packages (WSP). The Agency has recently updated labeling instructions for products formulated in water soluble packaging to meet current labeling standards. This language includes updated mixing instructions, updated handling instructions, and updated engineering controls statement. Details of these label changes are set forth in Appendix B.

#### **2. Enforceable Spray Drift Management**

The Agency is requiring enforceable spray drift mitigation language be included on all dithiopyr product labels for products applied by liquid spray application to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all dithiopyr products. Reducing spray drift through a number of labeling elements, including droplet size, release height, and wind speed restriction for groundboom will reduce the extent of dithiopyr environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete endangered species finding at this time, these labels 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 dithiopyr. The spray drift language is intended to be mandatory, enforceable statements and supersede any existing mandatory language already on product labels covering the same topics. The mandatory spray drift management measures that are necessary as determined by the Agency are as follows:

- Applicators must not spray during temperature inversions.
- For groundboom applications, the applicator must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. Boomless ground sprayers (*e.g.*, those for roadside applications) and fixed-height ground boom sprayers are exempt from the required 4 ft release height since coarser droplet sizes are likely to be used with these types of equipment.
- Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572.3).
- Do not apply when wind speeds exceed 15 miles per hour at the application site.

Mandatory wind speed restrictions complicate weed and crop management by reducing the available time to make applications and make it more likely that a grower may need to alter pest control plans. However, dithiopyr is primarily used in residential and commercial landscapes with mixtures of many plant species in the general application area. Areas to be treated tend to be small and applications must be precise to avoid damage to non-target plants. Therefore, the impacts of the drift reduction requirements may be minimal to these users because they correspond to common practice.

The Agency is also requiring standardizing all advisory spray drift language on dithiopyr product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements noted in this ID, once effective. For the advisory spray drift language to be incorporated on dithiopyr labels, see Appendix B.

In addition to including the spray drift restrictions on dithiopyr labels, all references to volumetric mean diameter (VMD) information for spray droplets are to be removed from all dithiopyr labels where such information currently appears.

### **3. Environmental Hazards**

#### Non-target Organism Advisory

The Agency is adding a non-target organism advisory. The protection of pollinating organisms is a priority for the Agency. Risk to pollinators from the use of dithiopyr is uncertain. It is possible that pollinators may be exposed to dithiopyr from residues in pollen or nectar through spray drift. Bees may also be exposed to pollen and nectar through uptake into treated plants (*e.g.*, ornamentals) or blooming weeds present in residential lawns. This may negatively impact forage and habitat of pollinators and other non-target organisms. It is the Agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, EPA a non-target organism advisory language is necessary to be placed on dithiopyr labels to address this potential concern:

"This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."

### Water Advisories

Dithiopyr has fate properties which indicates that it may persist in both surface and groundwater. Therefore, the Agency has determined that it is necessary to add groundwater and surface water advisories to warn users of the potential for groundwater/surface water contamination. The water advisories are as follows:

#### *Groundwater Advisory:*

“This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.”

#### *Surface Water Advisory:*

“This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground. This product is classified as having a high potential for reaching a surface water via runoff for several weeks after application.”

## **4. Herbicide Resistance Management**

On August 24, 2017, EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management<sup>4</sup>. Consistent with the Notice, EPA is requiring the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide ID.

The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide resistant weeds have been known since the 1950s, the number of species and their geographical extent, has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide resistant weeds, both in mitigating established herbicide resistant weeds and in slowing or preventing the development of new herbicide resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researchers, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

## **5. Label Clarifications**

Some dithiopyr labels do not provide adequate information on application parameters. A number of products are missing maximum yearly application rates. In discussions with the technical registrant, Corteva AgriScience, on May 20, 2020, the maximum yearly application rate being supported is 1.5 lb ai/A for all use sites. The Agency has determined that it is necessary for this information to be added to existing labels where missing. Labels that may be missing this information include EPA Reg. Nos. 279-9540, 8660-159, and 83822-1.

### **B. Tolerance Actions**

Dithiopyr is not registered for use on food crops; therefore, there are no tolerances and no anticipated tolerance actions for dithiopyr.

### **C. Interim Registration Review Decision**

In accordance with 40 CFR § 155.56 and § 155.58, the Agency is issuing this ID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the Agency has made the following ID: (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 ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of dithiopyr, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the risk 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 dithiopyr. The Agency's final registration review decision for dithiopyr 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**

All data required as part of registration review (GDCI-128994-1426) have been submitted, except for a non-guideline (OECD 237) honeybee larval acute oral toxicity study. The Agency will work with the registrant to ensure the submission of this study. No additional data are anticipated to be needed to be called-in for this registration review at this time. The Agency will consider requiring submission of additional pollinator data as a separate action.

## **V. NEXT STEPS AND TIMELINE**

### **A. Interim Registration Review Decision**

A Federal Register Notice will announce the availability of this ID for dithiopyr. A final decision on the dithiopyr 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 dithiopyr 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.

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 Dithiopyr 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 Dithiopyr 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 who wish to send paper copies of amended products labels should contact Veronica Dutch ([dutch.veronica@epa.gov](mailto:dutch.veronica@epa.gov)) to make the necessary arrangements for paper delivery.

**Appendix A: Summary of Risk Mitigation for Dithiopyr**

Registration Review Case#: 7225 PC Code: 128994 Chemical Type: Herbicide Chemical Family: Pyridine Mechanism of Action: Inhibition of microtubule assembly						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions	Comment
Mammals	Residues at site of application, spray drift	Ingestion	Chronic	Growth	Enforceable spray drift management measures	Risks are limited to the site of application and 20 ft from the edge of the treatment area with revised spray drift labeling
Aquatic Invertebrates	Spray Drift Runoff	Residues in surface water	Chronic	Survival, reproduction, and growth	Enforceable spray drift management measures	
Aquatic Plants	Spray Drift and Runoff	Foliar absorption Root uptake	N/A	Growth	Enforceable spray drift management measures	
Non-target Terrestrial Plants	Spray Drift	Foliar absorption Root uptake	N/A	Growth	Enforceable spray drift management measures	Risks extend to 148 ft from the edge of the treatment area with revised spray drift labeling

## Appendix B: Labeling Changes for Dithiopyr Products

Description	Label Language for Dithiopyr Products	Placement on Label				
<b>End Use Products</b>						
<p>Site of Action Group Number</p> <p>[Applies to all products except those for residential consumer use.]</p>	<p><b>Note to registrant:</b></p> <ul style="list-style-type: none"> <li>• Include the name of the <b>ACTIVE INGREDIENT</b> in the first column</li> <li>• Include the word “<b>GROUP</b>” in the second column</li> <li>• Include the <b>SITE OF ACTION CODE</b> in the third column (for herbicides this is the Site of Action)</li> <li>• Include the type of pesticide (<i>i.e.</i>, <b>HERBICIDE</b>) in the fourth column.</li> </ul> <table border="1" data-bbox="422 532 1304 743" style="width: 100%; text-align: center;"> <tr> <td data-bbox="422 532 674 743"><b>DITHIOPYR</b></td> <td data-bbox="674 532 848 743"><b>GROUP</b></td> <td data-bbox="848 532 1304 743" style="background-color: black; color: white;"><b>3</b></td> <td data-bbox="1304 532 1682 743"><b>HERBICIDE</b></td> </tr> </table>	<b>DITHIOPYR</b>	<b>GROUP</b>	<b>3</b>	<b>HERBICIDE</b>	<p>Front Panel, upper right quadrant.</p> <p>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.</p>
<b>DITHIOPYR</b>	<b>GROUP</b>	<b>3</b>	<b>HERBICIDE</b>			
<p><b>HERBICIDE RESISTANCE MANAGEMENT:</b> Weed Resistance Management</p> <p>[Applies to all products except those for residential consumer use.]</p>	<p>Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (<a href="https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year">https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year</a>)</p>	<p>Directions for Use, prior to directions for specific crops under the heading “<b>WEED RESISTANCE-MANAGEMENT</b>”</p>				
<p><b>Non-target Organism Advisory</b></p>	<p>“NON-TARGET ORGANISM ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift. For further guidance and instructions on how to minimize spray drift, refer to the Spray Drift Management section of this label.”</p>	<p>Environmental Hazards</p>				
<p><b>Groundwater Advisory</b></p>	<p>“This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.”</p>	<p>Environmental Hazards</p>				
<p><b>Surface Water Advisory</b></p>	<p>“This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground. This product is classified as having a high potential for reaching surface water via runoff for several weeks after application.”</p>	<p>Environmental Hazards</p>				



Description	Label Language for Dithiopyr Products	Placement on Label
<b>Application Rate Clarification</b>	“Do not apply more than 1.5 lb ai/A of dithiopyr per year.” “Maximum single application rate at 0.5 lb a.i./A”.	Directions for Use
<b>Additional Required Labelling Action</b> [Applies to all products delivered via liquid spray applications.]	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
<b>Label Language for pesticide products in Water- Soluble Packaging (WSP) intended to be diluted directly in a spray tank prior to application</b>	<p>Instructions for Introducing Water Soluble Packages Directly into Spray tanks:</p> <p>"Water Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)].</p> <p>Handling Instructions  Follow these steps when handling pesticide products in WSPs.</p> <ol style="list-style-type: none"> <li>1. Mix in spray tank only.</li> <li>2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions.</li> <li>3. Keep the WSP in outer packaging until just before use.</li> <li>4. Keep the WSP dry prior to adding to the spray tank.</li> <li>5. Handle with dry gloves and according to the label instructions for PPE.</li> <li>6. Keep the WSP intact. Do not cut or puncture the WSP.</li> <li>7. Reseal the WSP outer packaging to protect any unused WSP(s).</li> </ol> <p>Mixing Instructions  Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions.</p> <ol style="list-style-type: none"> <li>1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.</li> <li>2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray.</li> </ol>	Directions for Use

Description	Label Language for Dithiopyr Products	Placement on Label
	<ol style="list-style-type: none"> <li>3. Stop adding water and stop any agitation.</li> <li>4. Place intact/unopened WSP into the tank.</li> <li>5. Do not spray water from a hose or fill pipe to break or dissolve the WSP.</li> <li>6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.</li> <li>7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.</li> <li>8. Stop agitation before tank lid is opened.</li> <li>9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution.</li> <li>10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.</li> <li>11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation.</li> <li>12. Use the spray solution when mixing is complete.</li> <li>13. Maintain agitation of the diluted pesticide mix during transport and application.</li> <li>14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label.</li> </ol>	
<p><b>Engineering Controls for pesticide products in WSP intended to be diluted directly in a spray tank prior to application</b></p>	<p>For Toxicity Category I and II products:</p> <p>“ENGINEERING CONTROLS STATEMENT  Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p> <p>For Toxicity Category III and IV products:</p> <p>“ENGINEERING CONTROLS STATEMENT  Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p>	<p>Precautionary Statements under the “Personal Protective Equipment” section</p>

Description	Label Language for Dithiopyr Products	Placement on Label
<p><b>Spray Drift Management Application Restrictions</b> for products that are applied as liquids and allow ground boom applications</p>	<p><b>“MANDATORY SPRAY DRIFT MANAGEMENT</b>  <b>Ground Boom Applications:</b></p> <ul style="list-style-type: none"> <li>• User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy.</li> <li>• Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572).</li> <li>• Do not apply when wind speeds exceed 15 miles per hour at the application site.</li> <li>• Do not apply during temperature inversions.”</li> </ul>	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Ground Boom Applications”</p>
<p><b>Spray Drift Management Application Restrictions</b> for products that are applied as liquids and allow boom-less ground sprayer applications or fixed height groundboom sprayer applications</p>	<p><b>“MANDATORY SPRAY DRIFT MANAGEMENT</b>  <b>Boomless Ground Applications:</b></p> <ul style="list-style-type: none"> <li>• Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572).</li> <li>• Do not apply when wind speeds exceed 15 miles per hour at the application site.</li> <li>• Do not apply during temperature inversions.”</li> </ul>	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Boomless Ground Applications”</p>
<p><b>Advisory Spray Drift Management Language</b> for all products delivered via liquid spray application</p>	<p><b>“SPRAY DRIFT ADVISORIES</b>  THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT.  BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.</p> <p><b>IMPORTANCE OF DROPLET SIZE</b>  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.</p> <p><b>Controlling Droplet Size – Ground Boom</b> (<i>note to registrants: remove if ground boom is prohibited on product labels</i>)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size.</li> <li>• Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Label Language for Dithiopyr Products	Placement on Label
	<p><b>BOOM HEIGHT – Ground Boom</b> (<i>note to registrants: remove if ground boom is prohibited on product labels</i>)  For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p><b>SHIELDED SPRAYERS</b>  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.</p> <p><b>TEMPERATURE AND HUMIDITY</b>  When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p> <p><b>TEMPERATURE INVERSIONS</b>  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.</p> <p><b>WIND</b>  Drift potential generally increases with wind speed. <b>AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS.</b>  Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.”</p>	
<p><b>Advisory Spray Drift Management Language</b> for products that are applied as liquids and allow boom-less ground sprayer applications</p>	<p><b>“SPRAY DRIFT ADVISORIES</b>  <u><b>Boomless Ground Applications:</b></u></p> <ul style="list-style-type: none"> <li>Setting nozzles at the lowest effective height will help to reduce the potential for spray drift.”</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>
<p><b>Advisory Spray Drift Management Language</b> for all products that allow liquid applications with handheld technologies</p>	<p><b>“SPRAY DRIFT ADVISORIES</b>  <u><b>Handheld Technology Applications:</b></u></p> <ul style="list-style-type: none"> <li>Take precautions to minimize spray drift.”</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

## 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<sup>6</sup>. 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. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been required based on experience conducting the first three pilot BEs. Public input on those required revisions is currently being considered.

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 ID for dithiopyr does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this ID, 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 dithiopyr. This will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for dithiopyr as part of completing this registration review.

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<sup>6</sup> <https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process>

## Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, 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, 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 dithiopyr, 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), dithiopyr is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

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 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, 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 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,<sup>7</sup> 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. Dithiopyr 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 EPA website.<sup>8</sup>

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

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<sup>7</sup> See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

<sup>8</sup> <https://www.epa.gov/endocrine-disruption>