Memorandum Supporting Final Decision to Approve Registration for the New Active Ingredient, Diflufenican

Approved by:

Digitally signed by EDWARD MESSINA
Date: 2026.06.30 09:51:22 -04'00'

Ed Messina, Esq., Director
Office of Pesticide Programs
US Environmental Protection Agency

Table of Contents

I. INTRODUCTION

This memorandum presents the rationale to support the final decision of the U.S. Environmental Protection Agency (referred hereafter as EPA or the Agency) to register under 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the new active ingredient (a.i.), diflufenican, for use on corn and soybean.

Diflufenican, (*N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide), is a new active ingredient herbicide for preplant and preemergence control of waterhemp, Palmer amaranth, and other pigweed species in corn and soybean. Diflufenican is a selective contact herbicide with a pesticidal mode-of-action that acts via inhibition of phytoene desaturase (PDS) enzyme. This interferes with carotenoid biosynthesis which leads to bleaching and death in susceptible plants. The Weed Science Society of America (WSSA) classifies diflufenican as a Group 12 herbicide, which makes diflufenican the first effective PDS inhibitor herbicide for control of waterhemp, Palmer amaranth, and other pigweed species in corn and soybean. This is a novel mechanism of action (MOA) that could be a valuable rotation tool for pest resistance management in the registered crops.

Diflufenican is formulated into one technical product, Diflufenican TC (99% diflufenican) and one end-use product, Diflufenican SC500 Herbicide (42.01% diflufenican). Diflufenican TC (EPA registration number 264-1217) is registered for manufacturing or formulating into end-use products for agricultural uses on corn and soybean. Diflufenican SC500 Herbicide (EPA registration number 264-1213) is a suspension concentrate containing 4.17 pounds of active ingredient per gallon of product. Uses are summarized in Table 1. Both registrations are diflufenican-only products, not combined with any other active ingredients.

EPA determined diflufenican is a reduced risk pesticide for use on soybean. Commonly used registered pesticide alternatives for the intended target pests in soybean include sulfentrazone, flumioxazin, s-metolachlor, pyroxasulfone, and saflufenacil. Comparatively, diflufenican presents a generally less or equal hazardous human health profile.

II. REQUESTED ACTION

On February 25, 2021, the EPA received an application from Bayer to register one technical (EPA Symbol 264-RERT) and four end-use products (264-RERG, 264-RERU, 264-RERA & 264-RERL) containing diflufenican (CAS Number 83164-33-4) for use on corn and soybean. Bayer submitted a separate application for review by Health Canada's Pest Management Regulatory Agency (PMRA). Although not part of a formal joint review, EPA collaborated with PMRA during the residue study reviews.

Under FIFRA section 3(c)(4), EPA is required to notify the public when a request for registering a new active ingredient is made and allow a 30-day comment period. The EPA published a notice of receipt (NOR) on August 27, 2021, in the Federal Register for applications requesting

registrations of diflufenican. In addition, the EPA published a notice of filing (NOF) on August 24, 2021, in the Federal Register announcing the receipt of the initial filing of the diflufenican petition by Bayer under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting the establishment of tolerance regulations for residues of diflufenican in/on corn and soybean. Each notice gave the public 30 days to review and comment. The public comment period for the NOR closed on September 27, 2021, with two comments, and the public comment period for the NOF closed on September 23, 2021, with three comments received. For more information on the public comments refer to Section V: Public Comments.

Bayer requested reduced risk status and provided the information necessary for EPA to determine whether it met this requirement. Pursuant to FIFRA section 3(c)(10), EPA granted reduced risk status[1] for soybean.

On September 19, 2022, subsequent to the initial submission, the proposed premix products, 264-RERU, 264-RERA, 264-RERL, were voluntarily withdrawn by Bayer. Therefore, the agency moved forward with evaluating only two products, the technical product (EPA Symbol 264-RERT) and one end-use product (264-RERG).

III. USE PROFILE

The diflufenican end-use product (264-1213) is a suspension concentrate and can be applied via groundboom as a broadcast or in a band. Diflufenican is intended to provide preplant and preemergence control of weeds on corn and soybean. The maximum single and yearly application rates are 0.134 lb a.i./A for corn and 0.16 lb a.i./A for soybean, respectively, with a maximum of one application per year. The restricted-entry interval (REI) is 12 hours, and rainfall and runoff restrictions must also be adhered to. Workers are required to wear baseline attire; defined as long-sleeved shirt, long pants, and shoes plus socks, along with personal protective equipment (PPE) including chemical-resistant gloves. **Table 1** provides a summary of the registered use patterns for diflufenican.

[1] Diflufenican Reduce Risk Determination Letter 20211116

Table 1. Summary of Directions for Use for Diflufenican.					
Crop/Use Site	**Application Method[1]**	**Max # Apps. per Year**	**Timing**	**Max. App Rate (lb a.i./A)[2]**	**Use Directions and Restrictions[3]**
Corn	Broadcast (ground), Band (ground)	1	Preplant, Preemergent	0.134	• REI = 12 hours. • Aerial application is not permitted. • Do not apply to frozen soil. • Do not apply during rain. • Do not apply under conditions that favor runoff. • Do not apply if soil is saturated with water or when rainfall that may exceed soil field capacity is forecasted to occur within 48 hours.
Soybean	Broadcast (ground), Band (ground)	1	Preplant, Preemergent	0.16	• REI = 12 hours. • Aerial application is not permitted. • Do not apply to frozen soil. • Do not apply during rain. • Do not apply under conditions that favor runoff. • Do not apply if soil is saturated with water or when rainfall that may exceed soil field capacity is forecasted to occur within 48 hours.

[1] Vocabulary: Broadcast is the uniform application of a pesticide or other material over an entire field or area; band is an application made to the furrow or trench in the soil which is opened for planting crop seeds.
[2] Lbs a.i./A is pounds of active ingredient per acre
[3] Vocabulary: REI is restricted-entry interval.

IV. EVALUATION

In evaluating a pesticide registration application, the EPA assesses a wide variety of exposure information (i.e., where and how the pesticide is used) and environmental-fate (i.e., persistence and mobility of the chemical in the environment) and toxicity (i.e., effects on humans and other non-target organisms) to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the registered use of the product. Risk assessments are developed to evaluate the environmental fate of the compound as well as how it might affect a wide range of non-target organisms including humans, terrestrial and aquatic wildlife (plants and animals). In addition, a benefits assessment may be conducted.

When EPA grants a registration, EPA determines that the pesticide does not cause "unreasonable adverse effects on the environment." This standard consists of two parts: the pesticide may neither cause an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" nor, in the case of a pesticide resulting in residues in food and feed, cause a "human dietary risk" that is not safe.

Sections IV.A and IV.B describe the costs of the use of the pesticide in terms of the risk imposed by use of the pesticide on human health or the environment. These 'costs' of the use are; a) measured using terms such as margins of exposure (MOEs) for human health and risk quotients (RQs) for ecological risks, b) can be described qualitatively, or c) may be described in both quantitative and qualitative terms. Risk assessments also describe who or what organism bears the identified risk. Section IV.D describes the benefits associated with the use of the pesticide. Benefit assessments use a weight of evidence approach to describe who will use the pesticide and how it will potentially improve outcomes (e.g., agricultural production, recreation, urban or residential aesthetics, or habitat restoration).

On the basis of these assessments, EPA evaluates and approves language for each pesticide label to ensure the directions for use are appropriate to mitigate potential risks to a level that they are not unreasonable. In this way, the pesticide label communicates essential limitations and mitigations that are necessary to avoid unreasonable adverse effects to the public and environment. It is a FIFRA violation to use a registered pesticide in a manner inconsistent with its labeling. Consistent with Endangered Species Act (ESA) Section 7(a)(2), EPA also assessed the potential effects of the use of diflufenican on federally listed threatened or endangered (hereafter referred to as "listed") species and their designated critical habitats (CHs).

A. Assessment of Risks to Human Health

The EPA requires a wide range of studies to assess a pesticide use scenario. For the registered uses of diflufenican on corn and soybean, the database of studies required to support the assessment of risk to human health is complete and adequate. EPA uses this complete database to make conclusions regarding diflufenican and support the assessment of risk to human health.

This section summarizes EPA's *Diflufenican. Human Health Risk Assessment for Diflufenican. New Active Ingredient*. The complete assessment can be found in docket ID number EPA-HQ-OPP-2021-0435 at www.regulations.gov.

i. Toxicology Profile

Diflufenican is a selective contact herbicide with a pesticidal mode-of-action that acts via inhibition of phytoene desaturase (PDS) enzyme. This leads to bleaching and death in susceptible plants by interfering with carotenoid biosynthesis.

The most sensitive toxicological effect observed in both subchronic and chronic studies was decreased body weight in rodents, with no specific target organ identified. In the subchronic and chronic oral studies, decreased body weights were seen in both rats and mice, and adverse decreases in body weight occurred at doses lower than those causing additional toxicological effects. There were no adverse effects seen in the subchronic or chronic dog studies up to the limit dose of 1000 mg/kg/day. A dermal endpoint was not selected. There did not appear to be a difference in toxicity by sex in any species.

There was no evidence of neurotoxicity in the subchronic and chronic studies in mice, rats, and dogs. There is no evidence of increased qualitative or quantitative life stage susceptibility observed in the available reproduction or developmental toxicity studies. The Food Quality Protection Act (FQPA) Safety Factor (SF) for diflufenican was reduced from 10X to 1X for all exposure scenarios based on the following considerations: (1) the toxicity database for diflufenican is complete; (2) there is no evidence of increased qualitative or quantitative susceptibility observed in the available reproduction or development toxicity studies; (3) there was no evidence of neurotoxicity, and (4) there are no residual uncertainties in the exposure database. Study waivers for the acute and subchronic neurotoxicity battery, immunotoxicity, subchronic dermal, and subchronic inhalation studies were evaluated, and all studies were recommended to be waived (HASPOC memo, TXR 0058242, A. Britt, 02/02/2022). EPA has since granted these waivers, as communicated to the registrant via official correspondence. Diflufenican is classified as "*Not Likely to be Carcinogenic to Humans,"* and there is no evidence of mutagenicity *in vivo* or *in vitro*.

The technical product for diflufenican (264-1217) has low acute toxicity via the oral and inhalation routes (Toxicity Category IV) and moderate acute toxicity via the dermal route (Toxicity Category III). It is not an eye or dermal irritant (Toxicity Category IV). It is not a dermal sensitizer. The signal word for Diflufenican TC is Caution.

The end-use product (264-1213) has a moderate acute toxicity profile (Toxicity Category III) for acute oral toxicity, acute dermal routes, and primary eye irritation. It has a low acute toxicity (Toxicity Category IV) for acute inhalation toxicity and primary dermal irritation. The end-use

product is not a dermal sensitizer. The signal word for the end-use product, Diflufenican SC500 Herbicide, is Caution.

A summary of the points of departure (POD) selected for human health risk assessments for diflufenican can be found in **Table 2** and **Table 3**. This section, *Assessment of Risks to Human Health,* is a summary of the standard assessment that the agency conducts; the full Human Health Risk Assessment can be found in docket ID number EPA-HQ-OPP-2021-0435 at www.regulations.gov. Additionally, EPA has concluded that no additional estrogen, androgen, or thyroid data are needed at this time. For additional information, please see *Appendix F* of the Human Health Risk Assessment.

Table 2. Summary of Toxicological Doses and Endpoints for Diflufenican for Use in Dietary and Non-Occupational Human Health Risk Assessments.

Exposure/ Scenario	POD	Uncertainty/FQPA SFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All populations, including infants, children and females 13-49)	An acute dietary endpoint was not selected as there were no adverse effects in the database which could be attributed to a single dose.			
Chronic Dietary (All Populations)	NOAEL = 37 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.37 mg/kg/day cPAD = 0.37 mg/kg/day	**MRID 51458819**: Two-generation reproduction study in SD rats Parental/Offspring LOAEL = 187/215 mg/kg/day [M/F] based on decreased parental body weights and offspring body weights
Incidental Oral/Adult Oral Short-and Intermediate-Term (1-30 days and 1-6 months)	NOAEL = 37 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC for MOE = 100	**MRID 51458819**: Two-generation reproduction study in SD rats Parental/Offspring LOAEL = 187/215 mg/kg/day [M/F] based on decreased parental body weights and offspring body weights
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	A dermal endpoint was not selected. There was no evidence of increased quantitative susceptibility in the database. Although a route-specific study is not available, the dermal-equivalent dose based on an oral POD from the two-generation reproduction study and the DAF of 5% exceeds the limit dose of 1000 mg/kg/day. Therefore, a dermal assessment is not required.			

Table 2. Summary of Toxicological Doses and Endpoints for Diflufenican for Use in Dietary and Non-Occupational Human Health Risk Assessments.				
Exposure/ Scenario	**POD**	**Uncertainty/FQPA SFs**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans"; therefore, a cancer risk assessment is not required.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. DAF = dermal-absorption factor. MOE = margin of exposure. LOC = level of concern. SD = Sprague Dawley rat.

Table 3. Summary of Toxicological Doses and Endpoints for Diflufenican for Use in Occupational Human Health Risk Assessments.				
Exposure Scenario	**POD**	**Uncertainty Factors**	**LOC for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	A dermal endpoint was not selected. There was no evidence of increased quantitative susceptibility in the database. Although a route-specific study is not available, the dermal-equivalent dose based on an oral POD from the two-generation reproduction study and the DAF of 5% exceeds the limit dose of 1000 mg/kg/day. Therefore, a dermal assessment is not required.			
Inhalation Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL = 37 mg/kg/day (Inhalation absorption factor = 100%)	UF_A = 10X UF_H = 10X	Occupational LOC for MOE = 100	**MRID 51458819**: Two-generation reproduction study in SD rats Parental/Offspring LOAEL = 187/215 mg/kg/day [M/F] based on decreased parental body weights and offspring body weights
Cancer (oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans"; therefore, a cancer risk assessment is not required.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). DAF = dermal-absorption factor. MOE = margin of exposure. LOC = level of concern. SD = Sprague Dawley rat.

One of diflufenican metabolites (2,4-difluoroaniline malonate, BCS-BT38895) was found to be more toxic than the parent, diflufenican, with a different toxicological profile based on the available toxicity data. As a result, this soybean seed metabolite has been evaluated separately. BCS-BT38895 is a metabolite that was identified in some of the diflufenican soybean metabolism studies. It was found in some samples of soybean seed only (i.e., it was not found in the forage or the hay) and appears to be specific to soybean. It is a malonic acid conjugate of 2,4-

difluoroaniline, an anaerobic soil and aerobic aquatic metabolism metabolite of diflufenican. A subchronic (28-day) oral rat study was submitted for BCS-BT38895, and there were no effects on body weight at the doses tested. The target organ appeared to be the spleen with effects shown on the hematopoietic system. Relative and absolute spleen weights were significantly increased and were associated with an increased incidence of spleen discoloration, spleen congestion, and extramedullary hemopoiesis at 28 mg/kg/day. Microscopic changes in the kidney and liver were also seen at a higher dose (139 mg/kg/day). BCS-BT38895 contains an aniline moiety, and the adverse effects in the spleen and blood observed in the subchronic rat study are consistent with the known effects associated with aniline toxicity.

No effects of BCS-BT38895 administration (up to 2000 mg/kg) were observed in the acute oral toxicity study in rats, and three genotoxicity studies and in-silico analysis show no specific concerns for mutagenicity for BCS-BT38895.

Due to the similar subchronic toxicity between BCS-BT38895 and aniline, and that the EPA has classified aniline as Group B2 (Probable human carcinogen - based on sufficient evidence of carcinogenicity in animals), EPA conducted a conservative cancer assessment for the metabolite using the oral slope factor for aniline from Integrated Risk Information System (IRIS) since there are no long-term studies available for BCS-BT38895. There are no available metabolism data or ecological fate data to suggest that there is further metabolism/degradation to form aniline *in vitro* or *in vivo.* In the absence of empirical data demonstrating effects of chronic exposure to BCS-BT38895, and to conservatively account for the fact that BCS-BT38895 contains an aniline moiety in its structure, EPA applied the aniline oral slope factor (5.7×10^{-3} (mg/kg/day) as a proxy toxicity value to quantitate potential cancer risks due to BCS-BT38895 long-term exposure. When comparing the oral slope value of aniline to the unrefined estimated exposure of the highest exposed adult subpopulation (adults 20-49, 50+) to BCS-BT38895 (0.000005 mg/kg/day), highly conservative cancer risk estimates are 3×10^{-8}, which is below the Agency's level of concern (LOC). Based on the limited exposure potential (only observed in some soybean seed residue data and no other crops), and the highly conservative exposure and hazard assumptions used to quantitate risk estimates for BCS-BT38895, the Agency considers the cancer risk estimates from diflufenican-derived BCS-BT38895 residues not to be of concern.

For more detailed information on the cancer assessment for BCS-BT38895 *please see Appendix C* (pages 103-106) of the Human Health Risk Assessment.

ii. Dietary (Food + Water) Risks

In estimating acute and chronic dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2005-2010 *National Health and Nutrition Examination Survey, What We Eat in America*, (NHANES/WWEIA). For acute dietary exposure, a quantitative assessment is unnecessary because no adverse effects in diflufenican's database could be attributed to a single dose. Chronic dietary (food and drinking water) (non-cancer, parent only) exposure did not exceed EPA's LOC (<100% of the chronic population-adjusted dose or cPAD) for the general U.S. population and all population subgroups. The chronic dietary

exposure analysis assumed 100% crops treated and combined residues of diflufenican and the metabolites diflufenican-amide and DFF-amide (<0.02 ppm) in all samples of corn, field grain, and soybean, except for soybean seed (average of diflufenican metabolite, BCS-BT38895, 0.011 ppm). The processing factor used for soybean flour was 1.3x. The EPA default processing factor was used for corn bran. Based on residues being below the limit of quantitation (<LOQ) of the analytical method at a 5X treatment rate, processing factors for all other commodities were set to 1.

The chronic dietary assessment included conservative modeled estimated drinking water concentrations (EDWCs) for groundwater of diflufenican (parent compound) and two additional residues of concern, diflufenican-acid (DFF-acid) and diflufenican-amide (DFF-amide). Available data for both transformation products show that they are of no greater toxicity than that of diflufenican. Based on the totality of the available data and to conservatively account for potential exposure to all relevant residues, the Agency assumed that DFF-acid and DFF-amide have similar toxicity to the parent; therefore to facilitate a more streamlined analysis, a total toxic residue (TTR) approach was used for modeling.

The chronic dietary risks for the general U.S. population and all population subgroups for diflufenican exposure are estimated at <1% of the cPAD. Diflufenican, the parent compound, is "not likely to be carcinogenic to humans"; therefore, quantification of cancer risk was not conducted. However, in addition to the residues of concern assessed for the chronic dietary assessment for all uses, the soybean seed metabolite BCS-BT38895 is a residue of concern specifically assessed for soybean. In soybean field trials, BCS-BT38895 was observed above the LOQ (0.010 ppm) in 4 of 22 trials, at a maximum concentration of 0.022 ppm. There is no expectation for BCS-BT38895 to be found in drinking water and there is no expectation of exposure to BCS-BT38895 from residential or occupational exposure scenarios. The only potential route of exposure for BCS-BT38895 is via the dietary route.

The available toxicology data do not demonstrate a concern for effects attributable to a single exposure at this time; therefore, an acute non-cancer dietary assessment is not necessary for BCS-BT38895. In the subchronic oral toxicity study, effects were seen at doses ≥28 mg/kg/day. Even if a 10X uncertainty factor were applied to extrapolate from subchronic to chronic exposure duration, estimated chronic exposures to BCS-BT38895 are orders of magnitude below any potential chronic non-cancer reference dose for BCS-BT38895. Therefore, a quantitative chronic non-cancer dietary risk assessment for BCS-BT38895 residues is not necessary to conclude with reasonable certainty that chronic exposures from BCS-BT38895 residues do not pose a non-cancer dietary risk.

iii. Occupational Risks

Based on the anticipated use patterns and current labeling and types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the registered uses of diflufenican on corn and soybean. The quantitative exposure/risk assessment developed for occupational handlers is based on the following anticipated scenarios:

- Mixing/loading liquid formulations for groundboom applications to corn and soybean (field crop, high-acreage);
- Applicator spray activity with starting formulations via groundboom to corn and soybean (field crop, high-acreage).

Since no endpoint was identified for the dermal route of exposure, only inhalation exposures and risk estimates were calculated for non-cancer occupational handler and post-application exposures. Occupational handler inhalation risk estimates were measured using baseline attire (i.e., long-sleeved shirt, long pants, shoes plus socks) and no respirator. There are no occupational handler non-cancer scenarios of concern (i.e., inhalation margins of exposure (MOEs) ≥ the LOC of 100) with label directed PPE (i.e., no-respirator or engineering controls) with MOEs ranging from 270,000 to 420,000. In accordance with the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for diflufenican because handler exposure resulting from application of pesticides outdoors is likely to result in higher exposure than post-application exposure. Therefore, it is expected that handler inhalation exposure estimates would be protective of occupational post-application inhalation exposure scenarios. The minimum REI on the label is 12 hours, which is considered protective of post-application exposure.

The EPA concludes there are no occupational handler and post-application non-cancer dermal or inhalation risks of concern.

iv. Residential Risks

Diflufenican is not registered for direct applications to residential use sites; therefore, no residential handler risk assessment has been conducted for diflufenican.

v. Aggregate Risk

The aggregate risk estimates are equivalent to the dietary exposures (food and drinking water only) since there are no registered or anticipated residential uses for diflufenican. The risk estimates are below the LOC for all aggregate routes of exposure.

vi. Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to diflufenican and any other substances. For the purposes of this action, therefore, EPA has not assumed that diflufenican has a common mechanism of toxicity with other substances. As a result, a cumulative risk assessment has not been conducted at this time.

vii. Non-Occupational Spray Drift Exposure and Risk

The Agency conducts human health spray drift assessments to determine potential risk from indirect exposure to pesticides that may drift during or immediately after an application. Pesticide applications made in the form of a spray and applied via groundboom may result in pesticide drift and deposition in non-target areas adjacent to the application site.

To evaluate the drift potential and associated risks, an approach based on drift modeling coupled with techniques used to evaluate residential uses of pesticides was utilized. Essentially, a residential turf assessment based on exposure to deposited residues has been completed to address drift from the agricultural applications of diflufenican. Exposures were considered for 50 feet wide lawns where the nearest side of the property was directly adjoining the treated field (at field edge) and at varied distances up to 300 feet downwind of a treated field. Results indicate that there are no children's incidental oral risks of concern at the field edge (i.e., all MOEs ≥ LOC of 100).

B. Endocrine Disruptor Screening Program

The FFDCA §408(p) requires EPA to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." (21 U.S.C. 346a(p)). In carrying out the Endocrine Disruptor Screening Program (EDSP), FFDCA section 408(p)(3) requires that EPA "provide for the testing of all pesticide chemicals," which includes "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1) and 346a(p)(3)). However, FFDCA section 408(p)(4) authorizes EPA to, by order, exempt a substance from the EDSP if the EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." (21 U.S.C. 346a(p)(4)).

As described in Appendix F of the human health risk assessment, there were no adverse estrogen, androgen, or thyroid hormone-related effects observed for diflufenican. EPA has concluded at this time that the points of departure for human health risk assessment to evaluate the registered uses of diflufenican are protective of potential adverse estrogen, androgen, and thyroid effects in humans. Therefore, EPA has completed its FFDCA section 408(p)(6)-related commitments and obligations "to ensure the protection of public health" at this time.

C. Assessment of Environmental Fate and Ecological Risks

The ecological risk assessment (ERA) examines the potential for adverse effects to non-listed non-target organisms associated with registered uses of diflufenican. EPA also conducted an assessment that evaluates effects on listed species and includes EPA's predictions of the potential likelihood of future jeopardy (J) for federally threatened or endangered (listed) species or adverse

modification (AM) of designated critical habitats (CH), as well as EPA's assessment of how mitigations are predicted to avoid such findings. However, while EPA is making predictions about the likelihood of J/AM, the U.S. Fish and Wildlife Service or the National Marine Fisheries Service (collectively referred to as the Services) are responsible for making the actual J/AM findings for these species and have the sole authority to do so.

EPA's assessment accounts for any mitigations on the label as submitted by the registrant in their application as well as additional mitigations proposed by EPA and agreed to by the registrant and incorporated in the final accepted label subsequent to the original application.

The taxa evaluated in the ERA include mammals, birds (which serve as surrogates for reptiles and terrestrial-phase amphibians), terrestrial invertebrates, fish (where freshwater fish serve as surrogates for aquatic-phase amphibians), aquatic invertebrates, and aquatic, terrestrial and wetland plants. Ecological risk characterization integrates environmental exposure and ecotoxicity data to evaluate the potential for adverse ecological effects using a risk quotient (RQ) method. For this method, RQs are calculated by dividing point estimates of exposure (*i.e.*, estimated environmental concentration [EEC]) by point estimates of toxicity (RQ = EEC/toxicity endpoint), for both acute and chronic effects. The RQs are then compared to EPA's acute and chronic risk Levels of Concern (LOCs) for each taxon.

The LOC indicates whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. RQs below a LOC indicate there are no risks of concern for that taxon. The LOCs for non-listed species are meant to be protective of community-level effects. If the RQ exceeds the LOC, then the EPA further characterizes and describes the associated risk of concern.

These findings can also play a role in EPA's assessment of potential effects to listed species, as required by the Endangered Species Act (ESA). Where RQs have been calculated, if the RQs are below a listed species LOC (indicating potential exposures are below threshold doses) for a particular taxon, then EPA does not expect direct effects to listed species in that taxon. However, further analysis may be necessary to complete an effects determination for listed species within that taxon because there may be effects to a listed species from potential direct effects to another taxon on which the listed species depends for prey, pollination, habitat, and/or dispersal (referred to as "PPHD"). In making its effects determinations, EPA evaluates both potential direct and PPHD effects to listed species and designated critical habitats.

EPA has determined that all relevant data requirements specified in 40 CFR Part 158 based on the registered use patterns of diflufenican discussed in this document have been satisfied (completed, waived, or not triggered). The database required to evaluate the environmental fate and ecological effects of the uses of diflufenican is complete and is considered adequate.

This section summarizes EPA's *"Diflufenican: Environmental Fate and Ecological Risk Assessment (ERA) for the FIFRA Section 3 Registration and Biological Evaluation (BE) with Associated Effects*

Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat." The complete assessment can be found in docket ID number EPA-HQ-OPP-2021-0435 at www.regulations.gov.

i. Environmental Fate Profile

Diflufenican will enter the environment via direct application to use sites with subsequent off-site movement of the compound via spray drift and runoff of from erosion. While diflufenican is persistent, concentrations in surface water are expected to be low, and it is not expected to leach into groundwater. The major route of dissipation is transformation to diflufenican-acid (DFF-acid), diflufenican-amide (DFF-amide), and difluoroaniline through soil metabolism with an aerobic soil half-life of 21.2-273 days and anaerobic soil half-life of 229-1,100 days (parent compound). These degradates are not considered residues of concern for ecological risk. While these degradates are more soluble and mobile, and therefore may reach both surface water and groundwater, they are expected to be much less persistent and less than or equally toxic as diflufenican. The major route of dissipation for the degradates is aerobic soil metabolism with half-lives of 9-18 days, 14-59 days, and 0.5-1 hour for DFF-acid, DFF-amide, and 2,4-difluoroaniline, respectively.

Diflufenican is stable to hydrolysis and photolysis and persistent in aqueous environments, with aerobic aquatic half-lives of 126-1,250 days and anaerobic aquatic half-lives of 251-526 days. Diflufenican is not expected to bioaccumulate as 90% of the bioconcentrated residues are eliminated after 10.3 days. With a low vapor pressure of 3.2×10^{-8} torr (20 °C) and a Henry's Law constant of 1.18×10^{-2} atm m^3 mol^{-1} (20 °C), diflufenican is not expected to volatilize from soil or water as a major route of dissipation. Batch equilibrium data suggest that diflufenican is slightly mobile. Terrestrial field dissipation studies indicate that diflufenican dissipates via transformation or relocation from fields with half-lives of 12-115 days.

ii. Ecological Effect Profile and Risks

EPA took a comprehensive approach in evaluating potential risk concerns for all taxa (including freshwater and estuarine/marine fish and invertebrates, aquatic vascular and nonvascular plants, birds, mammals, terrestrial invertebrates, and terrestrial and wetland plants) using available data. These studies included registrant-submitted acute and chronic toxicity data on diflufenican.

In the following sections, the toxicity of diflufenican to various taxonomic groups is summarized. Since diflufenican has not been in use in the U.S., no incident data are available on the compound. A search of the open literature in the ECOTOX database did not result in more sensitive toxicity endpoints. As discussed above, EPA integrates effects data with exposure estimates to generate RQ values and characterize potential risk. **Table 4** summarizes RQs and LOC exceedances for listed and non-listed species associated with the registered uses of diflufenican.

Aquatic Vertebrates

The available data indicate the likelihood of adverse effects, resulting from the registered uses of diflufenican, is expected to be low for aquatic animals on an acute and chronic exposure basis. Acute RQs were not calculated for freshwater and estuarine/marine fish due to the lack definitive endpoints. In this case, the endpoints are non-definitive because effects in toxicity tests did not reach 50%, and the LC_{50} is therefore considered to be greater than (>) the highest test level. An RQ cannot be calculated using a non-definitive endpoint and EPA therefore characterized risk by evaluating whether EECs fall above or below the tested concentrations. When the EEC is lower than an acute non-definitive (>)-endpoint, EPA does not expect effects to reach 50%. The highest 1-in-10 year daily mean EEC across both diflufenican uses (corn and soybean), is less than the limit concentration used in both the freshwater fish (LC_{50} > 32 µg ai/L) and estuarine/marine fish (LC_{50} > 35.2 µg ai/L). No mortality was detected at the highest concentrations tested in either study. Chronic RQs for freshwater and estuarine/marine fish are below the LOC (1.0). Therefore, the registered uses of diflufenican are not expected to result in risk to fish and aquatic-phase amphibians.

Aquatic Invertebrates

For acute toxicity for freshwater invertebrates, the endpoints are not quantitatively determinable and so RQs were not calculated. Regardless, the submitted acute invertebrate toxicity data for diflufenican indicate that its registered uses pose a low risk to freshwater invertebrates. For estuarine/marine invertebrates, the acute toxicity endpoints are also non-definitive, as tested concentrations up to 39.1 µg a.i./L showed no effects for the Eastern oyster and the 96h LC_{50} for a saltwater crustacean (mysid) is greater than 43 µg a.i./L. The highest daily mean EEC across both diflufenican uses is more than 27 times lower than the lowest non-definitive endpoint, and EPA therefore expects acute risk to estuarine/marine invertebrates to be low.

For chronic toxicity for freshwater invertebrates, RQs were calculated and were below the chronic risk LOC of 1.0. For estuarine/marine invertebrates, chronic RQ values were not determined because the available study on mysids was not suitable for quantitative use due to potential confounding effects of the solvent used. However, there were no adverse effects observed up to ~ 6 µg a.i./L, which is over five times higher than the highest EEC across both diflufenican uses. Overall, given the low magnitude of the percent solvent effect, similar results overall when the test levels are compared to the solvent control, and the EECs for both uses, chronic risk is expected to be low for estuarine/marine invertebrates.

Overall, risk to aquatic invertebrates is not expected based on the available data for diflufenican.

Aquatic Plants

Toxicity data for vascular aquatic plants and non-vascular plants (marine and freshwater diatoms, and cyanobacteria) indicate that non-vascular aquatic plants are more sensitive than vascular

plants towards diflufenican. Aquatic non-vascular plants exhibit a range of sensitivity to diflufenican technical grade active ingredient (TGAI). The most sensitive non-vascular endpoint is freshwater green algae *Raphidocelis subcapitata* (96-hr EC_{50} of 0.283 µg ai/L; NOAEC of 0.00264 µg ai/L). For vascular aquatic plants, a study on plant duckweed *Lemma gibba* with TGAI detected no effects, resulting in an EC_{50} of >48.2 µg ai/L and a NOAEC of 48.2 µg ai/L.

For diflufenican degradates and the formulated product SC500 (42.01% a.i.), all studies for vascular and non-vascular aquatic plants show less toxicity than the corresponding diflufenican TGAI endpoint, and therefore are expected to pose low risk to aquatic plants.

Terrestrial Vertebrates

Mammals. For acute risk, the highest expected dose-based exposure for mammals is 136x lower than the acute non-definitive toxicity endpoint (rat LD_{50} > 5,000 mg ai/kg-bw). The highest dietary-based exposure for mammals (38.4 mg ai/kg-diet) does not exceed the highest tested level in the rat acute oral toxicity study. Therefore, the likelihood of adverse effects on mammals from acute exposure as a result of the registered uses of diflufenican is expected to be low.

For chronic risk, dietary-based RQs do not exceed the chronic risk LOC of 1; however, dose-based RQs exceed the chronic risk LOC for small and medium-sized mammals feeding on short grass.

Two chronic toxicity studies with rats were considered to establish chronic toxicity endpoints (90-d feeding study and two-generation reproduction study). In the 90-d chronic feeding study, oral exposure to diflufenican resulted in reduced bodyweight. For the registered uses on soybean, this results in dose-based RQs of 1.5 and 1.3 for small and medium-sized mammals feeding on short grass, respectively. The RQs for small and medium mammals feeding on short grass from the registered corn use are 1.3 and 1.1, respectively**.** Although the upper bound EEC exceeds the NOAEL for both small and medium-sized mammals feeding on short grass, exposure does not reach the LOAEL at which 6 – 18% reductions bodyweight occurred. Therefore, there is uncertainty that a chronic exposure will occur to mammals, as they would need to feed exclusively on short grass from a treated site with upper bound residues within 3-4 weeks after the application. Even then, it is uncertain that effects would occur because though exposures are above a no effect level they do not exceed levels where effects were observed. When RQ values are based on the longer-term rat two-generation reproduction study with NOAELs of 37/45 mg/kg bw/day for males/females, chronic RQs are below the LOC across all sized-mammals and foraging categories. Thus, although the screening level assessment identified an LOC exceedance for small and medium mammals under certain conditions, EPA expects those conditions to be unlikely and risk to small and medium mammals to be low. EPA also expects direct risk to non-listed mammals to be low for large mammals, as there are no RQ exceedances.

Overall, given the uncertainty that chronic exposure would have an effect on bodyweight under field conditions, EPA considers direct effects to mammals unlikely to occur.

Birds, Reptiles, and Terrestrial-phase Amphibians. For acute risk, acute RQs were not calculated due to non-definitive acute oral and subacute dietary toxicity endpoints, where the LC_{50} was

greater than the highest concentrations tested (*i.e.*, mortality did not reach 50% in the tests). However, since EECs are orders of magnitude below the highest test concentrations, acute risks to birds, which also serve as surrogates for reptiles and terrestrial phase amphibians are not expected based on the available data. The subacute dietary study also provided information on sublethal effects, in addition to the non-definitive mortality endpoint. Although effects on bodyweight were observed in the study, the concentrations they were observed at were 8 times higher than the highest dietary EEC modeled. Therefore, acute risk to birds is not expected for the registered uses of diflufenican.

For chronic risk, the most sensitive chronic toxicity study with birds reported a statistically significant ($p<0.05$) effect (30% to 43% reductions in the number of eggs laid per female) resulting in a non-definitive NOAEC of <111 mg/kg-diet and a lowest observed adverse effect concentration (LOAEC) of 111 mg/kg-diet. RQs were not calculated because the study resulted in a nondefinitive endpoint. However, a second Mallard study showed no effects up to the highest tested level (NOAEC = 1096 mg/kg-diet), which was higher than the EECs. While some uncertainty remains due to the results of the two mallard studies, overall chronic risk to birds is not expected for the registered uses.

Terrestrial Invertebrates

Bees. Acute and chronic toxicity data are available for adult and larval honey bees. Diflufenican is registered for use on soybean and corn, both of which are considered attractive to bees. Off field, both contact and oral routes of exposure are expected through drift to blooming plants.

Diflufenican is practically non-toxic[2] to adult honey bees on an acute exposure basis. Acute contact and oral toxicity studies show no effects to adult honey bees from exposure to diflufenican TGAI up to 100 µg ai/bee and 107.4 µg ai/bee, respectively. Acute contact EECs are expected to be more than 200x lower than test levels that resulted in no effects in adult bees. Therefore, risk to adult honey bees from acute contact and oral exposure is not expected for either of the registered uses.

Chronic oral toxicity data for adult honey bees show no statistically significant effects up to the highest level tested (NOAEL= 0.49 µg ai/bee) when testing the formulated product SC500. An additional chronic oral study with adult bees using diflufenican TGAI resulted in a NOAEL of 113 µg ai/bee. Thus, chronic risk to adult honey bees is also not expected.

Honey bee larvae are more sensitive than the adults to diflufenican on an acute exposure basis. The available acute oral toxicity data show that diflufenican is practically non-toxic to honey bee larvae, with an LD_{50} = 51.8 µg ai/larva. The acute larval RQ is 0.04 and does not exceed the acute

[2] Ecotoxicity Categories for Terrestrial and Aquatic Organisms

risk LOC of 0.4 for honey bees. Consequently, acute risk to larval honey bees from oral exposure is not expected for the registered uses of diflufenican.

A chronic oral toxicity study of honey bee larvae tested up to 5.9 µg ai/larva/day with no statistically significant effects detected. Comparison of the NOAEL to the expected oral dose results in an RQ of 0.37, which does not exceed the chronic risk LOC of 1.0. Therefore, chronic risk to larval honey bees is not expected.

Off-field exposure is expected to be lower than on-field exposure. Therefore, off-field risk to honey bees is not expected, because on-field risk is not expected.

Other Terrestrial Invertebrates. Acute contact and oral toxicity tests using bumblebees (*Bombus terrestris*) showed no effects up to 100 and 122 µg a.i./bee, respectively. Acute toxicity studies of the formulated product SC500 on a parasitic wasp *A. rhopalosiphi* and a predatory mite *T. pyri* both reported non-definitive LD_{50} values equivalent to application rates >0.55 lb a.i./A. Diflufenican was observed to have no significant treatment-related effects on mortality or reproduction up to 1,000 and 426 mg ai/kg-dry-soil on predatory mites (*H. aculeifer).* A subchronic toxicity study of diflufenican's toxicity to earthworms (*E. fetida*) reported that the TGAI had no effect on mortality up to 1,000 mg ai/kg-dry-soil. A chronic toxicity test using the SC500 formulation resulted in a 32% reduction of the number of juvenile earthworms produced at 42.6 mg ai/kg-dry-soil, though the effect was not dose responsive. An acute toxicity test with a collembolan species *F. candida* tested diflufenican TGAI resulting in an EC_{50} = 16.92 g ai/kg-dw, based on effects to the number of juveniles and 40% mortality at the highest test level, 20 g ai/kg-dw.

Overall, on- and off-field risk to terrestrial invertebrates from the registered uses is not expected. The highest RQs are 0.04 and 0.34, for acute risk and chronic risk to honey bee larvae, respectively. These RQs do not exceed the listed LOCs for terrestrial animals (0.05 and 1 for acute and chronic risk, respectively).

Terrestrial Plants

The available toxicity data for the formulated product SC500 show reduced plant growth and survival in seedling emergence and vegetative vigor studies. Seedling emergence endpoints are more sensitive than those from vegetative vigor studies. For seedling emergence endpoints, monocots are more sensitive than dicots. The most sensitive seedling emergence endpoint come from reduction in onion (*Allium cepa*) dry weight (IC_{25} = 0.004 lb ai/A; NOAEC = 0.0016 lb ai/A). In vegetative vigor tests, dicots are more sensitive than monocots. The most sensitive vegetative vigor endpoint comes from reduction in tomato (*Solanum lycopersicum*) dry weight (IC_{25} = 0.042 lb ai/A; NOAEC = 0.01 lb ai/A). Diflufenican is an herbicide and potential risk to terrestrial plants is expected (RQs range 13-19 (Non-Listed)). However, population-level impacts are not likely to extend off treated field when considering the registered mitigations required on the label.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Freshwater Fish	Acute	NC	NC	NC	RQs not calculated due to non-definitive (>) toxicity endpoint. EECs are ~42x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.
	Chronic	0.073 – 0.105	No	No	Effects are not reasonably certain to occur.
Estuarine/ Marine Fish	Acute	NC	NC	NC	RQs not calculated due to non-definitive (>) toxicity endpoint. EECs are ~47x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.
	Chronic	0.22 – 0.32	No	No	Effects are not reasonably certain to occur.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Freshwater Invertebrates (Water-Column Exposure)	Acute	NC	NC	NC	RQs not calculated due to non-definitive (>) toxicity endpoint. EECs are >50x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.
	Chronic	0.013-0.020	No	No	Effects are not reasonably certain to occur.
Estuarine/ Marine Invertebrates (Water-Column Exposure)	Acute	NC	NC	NC	RQs not calculated due to non-definitive (>) endpoint. EECs are >50x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
	Chronic	NC	NC	NC	Uncertainty remains because of solvent effects potentially increasing toxicity. The most sensitive NOAEC from this study 5.97 µg a.i./L is ~8x higher than the highest EEC across all registered diflufenican uses (0.75 µg/L). Effects are not reasonably certain to occur.
Freshwater Invertebrates (Sediment Exposure)	Acute[2]	NC	NC	NC	Effects are not reasonably certain to occur.
	Chronic	0.004-0.007	No	No	RQs are based on bulk sediment endpoints. Sediment porewater endpoints were not suitable for quantitative use but the highest 21-day porewater NOAEC is (~200 µg/L). Effects are not reasonably certain to occur.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Estuarine/Marine Invertebrates (Sediment Exposure)	Acute[2]	NC	NC	NC	Based on the absence of significant risk to other estuarine/marine taxa, risk to sediment dwelling estuarine/marine organisms is not anticipated, and these data are considered low value. Effects are not reasonably certain to occur.
	Chronic	NC	NC	NC	Based on the absence of significant risk to other estuarine/marine taxa, risk to sediment dwelling estuarine/marine organisms is not anticipated, and these data are considered low value.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Mammals	Acute	NC	NC	NC	RQs not calculated due to non-definitive (>) endpoint. Exposure is >100x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.
	Chronic	0.04 – **1.5**	Yes	Yes	Based on up to 15% reduction bodyweight at the LOAEL (57/64 mg/kg-bw/day [male/female]). Upper bound Kenaga EECs are below the LOAEL, no exceedances for mean Kenaga EECs. For non-listed species, risk is not expected. For listed species, the RQ exceeds the LOC.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Birds, Reptiles, and Terrestrial-Phase Amphibians	Acute	NC	NC	NC	RQs not calculated due to lack of mortality in acute studies. Exposure is ~4x lower than levels where no effects were observed in toxicity tests. Effects are not reasonably certain to occur.
	Chronic	NC	NC	NC	The most sensitive avian chronic study saw 30-40% reduction in the number of eggs laid per female across all treatment groups, though the effect was not dose responsive. Because the maximum upper bound EECs are 66% lower than the LOAEC from this study (111 mg/kg-diet), the decline of these residues over time, and availability of an additional study that shows no effects in the same species at the same test levels, chronic risk to birds is not expected.

Table 4. Summary of Risk Quotients (RQ) for Taxonomic Groups from Registered Uses of Diflufenican.					
Taxa	**Exposure Duration**	**Risk Quotient (RQ) Range[1]**	**RQ Exceeding the LOC for Non-listed Species**	**RQ Exceeding the LOC for Listed Species**	**Additional Information/ Lines of Evidence**
Terrestrial Invertebrate[3]	Acute Adult	NC	NC	NC	Exposure is >20x orders of magnitude lower than levels where no effects were observed in acute toxicity tests. Effects are not reasonably certain to occur.
	Chronic Adult	NC	NC	NC	
	Acute Larval	0.04	No	No	
	Chronic Larval	0.37	No	No	
Aquatic Vascular Plants	N/A	<0.02	No	No	Effects are not reasonably certain to occur.
Aquatic Non-Vascular Plants		**2.8**	Yes	N/A	RQ exceeds the LOC for all uses for non-vascular species only. Effects include decreased biomass for algae, freshwater diatoms. There are no listed non-vascular aquatic plants.
Terrestrial Plants	N/A	Non-Listed: **13-19** Listed: **32-47**	Yes	Yes	RQ exceeds the LOC for all uses.
Wetland Plants	N/A	Non-Listed: **6.6 - 13** Listed: **17 – 33**	Yes	Yes	

EEC=estimated environmental concentration; LOAEC=lowest observed adverse effect concentration; N/A=not applicable; NC = not calculated; NOAEC=no-observed adverse effect concentration.

Non-Listed Species Level of Concern (LOC) Definitions: Aquatic Animals: Acute=0.5, Chronic=1.0; Terrestrial Vertebrates: Acute=0.5, Chronic=1.0; Terrestrial Invertebrates: Acute=0.4, Chronic=1.0; Plants: 1.0

Listed Species LOC Definitions: Aquatic Animals: Acute=0.05, Chronic=1.0; Terrestrial Vertebrates: Acute=0.1, Chronic=1.0; Terrestrial Invertebrates: Acute=0.1, Chronic=1.0; Plants: 1.0

[1] RQs reflect exposure estimates for parent only and maximum application rates allowed on labels.

[2] Based on water-column toxicity data compared to pore-water concentration.

[3] RQs for terrestrial invertebrates are applicable to honey bees, which are also a surrogate for other species of bees. Risks to other terrestrial invertebrates (*e.g.*, earthworms, beneficial arthropods) are only characterized when toxicity data are available.

D. Final Effects Determinations under the Endangered Species Act

Consistent with ESA Section 7(a)(2), EPA assessed the potential effects of diflufenican on listed species and designated critical habitats (CHs). The federal action area is the overall geographic extent or footprint of the federal action plus any additional areas where effects are reasonably expected to occur and is based on the registered agricultural uses on corn and soybean. EPA conducted an overlap analysis to determine which listed species and designated CHs occur within this action area. EPA also considered life history (including factors such as diet and body weight), toxicity, and exposure information to determine whether diflufenican will have no effect (NE) or may affect (MA) to an individual of each listed species or its designated critical habitat.

Based on EPA's screening-level assessment, there are potential risk concerns for mammals (chronic RQ range: 0.04 – 1.5), aquatic plants (RQ range: 0.94 – 4.1), terrestrial plants (RQ range 13 – 19 for non-listed species; RQ range 32 – 47 for listed species), and wetland plants (RQ range 6.6 – 13 for non-listed species; RQ range 17 – 33 for listed species).

This analysis identified 1,734 listed species and 954 designated CHs within the action area. Of these, EPA made NE determinations for 1,134 listed species and 7698 designated CHs. EPA made NE determinations if the registered use indicates that the likely overlap of exposure sites and range/CH is less than (<) 1% (based on overlap analysis) or no direct or PPHD effects are expected (including effects to the physical or biological features [PBF]) of any CH). EPA made MA determinations for the remaining 600 listed species and 253 designated CHs.

For those listed species and designated CHs with MA determinations, EPA further distinguished whether diflufenican is not likely to adversely affect (NLAA) or likely to adversely affect (LAA) an individual of the listed species or any designated CH. EPA made NLAA determinations for 507 listed species and 191 CHs. EPA made these NLAA determinations when exposure is considered highly unlikely due to the habitat of the species or when PBFs are not likely to be adversely impacted by the registered uses of diflufenican. EPA made LAA determinations for 93 listed species and 62 CHs. For those species with LAA determinations, the species ranges, or CHs have >1% overlap with areas where potential exposure to diflufenican may occur. For all designated CHs with LAA determinations, the following are PBFs that may be affected by the uses of diflufenican: terrestrial and/or wetland habitat quality and function (for plants), reliance on terrestrial and/or wetland plants for food and/or habitat, and reliance on aquatic non-vascular plants for food and/or habitat.

EPA further evaluated the LAA species and CH, adopting an approach based on existing methodology to predict the potential likelihood of future jeopardy to any listed species or

adverse modification of any CH from the registered use of diflufenican before implementation of mitigations. Overall, risk from direct toxicity drive the J/AM predictions for listed plants. Listed animals with a J/AM prediction are due to expected population-level effects to plants on which those animals depend. Of the species with LAA determinations, EPA initially predicted a potential likelihood of future jeopardy for 30 listed species. EPA also initially predicted a potential likelihood of future adverse modification of 22 CHs. The predicted potential likelihood of future J/AM for listed species and designated CHs is summarized in **Table 5** and **Table 6** respectively.

Table 5. Number of Listed Species Effects Determinations and Predictions of Potential Likelihood of Future Jeopardy or Adverse Modification by Taxon

Taxon[1]	**No Effect**	**May Affect**	**Not Likely to Adversely Affect**	**Likely to Adversely Affect**	**Preliminary Jeopardy before implementation of proposed mitigation**	**Preliminary Jeopardy after implementation of proposed mitigation**	**Totals**
Mammals	43	53	51	2	0	0	96
Birds	55	41	32	9	0	0	96
Amphibians[2]	21	26	23	3	1	0	47
Reptiles[2]	17	42	33	9	3	0	59
Fish	94	78	71	7	4	0	172
Plants	776	166	115	51	16	0	942
Aquatic Invertebrates	49	153	145	8	4	0	202
Terrestrial Invertebrates[3]	79	41	37	4	2	0	120
Total	1134	600	507	93	30	0	1734
Percent of total	65%	35%	29%	5%	2%	0%	

*The total number of listed species was 1,735 as of October 2024.

1 Reflects the species federally listed as endangered or threatened and critical habitats designated as of October 2024.

2 "Amphibians" and "Reptiles" include those species that have both a terrestrial and aquatic phase.

3 "Terrestrial Invertebrates" includes species with both a terrestrial and aquatic phase.

Table 6. Number of Critical Habitat Effects Determinations and Predictions of Potential Likelihood of Future Jeopardy or Adverse Modification by Taxon

Taxon[1]	**No Effect**	**May Affect**	**Not Likely to**	**Likely to Adversely Affect**	**Preliminary Adverse Modification**	**Preliminary Adverse Modificatio**	**Totals**

Table 6. Number of Critical Habitat Effects Determinations and Predictions of Potential Likelihood of Future Jeopardy or Adverse Modification by Taxon							
			Adverse y Affect		**before implementation of proposed mitigation**	**n after implementation of proposed mitigation**	
Mammals	27	24	21	3	1	0	51
Birds	21	14	4	10	1	0	35
Amphibians [2]	19	12	7	5	7	0	31
Reptiles[2]	13	16	12	4	1	0	32
Fish	58	63	59	4	2	0	121
Plants	465	41	12	29	5	0	506
Aquatic Invertebrates	39	74	71	3	2	0	113
Terrestrial Invertebrates[3]	56	9	5	4	3	0	65
Total	698	253	191	62	22	0	954*
Percent of total	73%	24%	14%	10%	2%	0%	

*The total number of designated critical habitat was 954 as of October 2024.
1 Reflects the species federally listed as endangered or threatened and critical habitats designated as of October 2024.
2 "Amphibians" and "Reptiles" include those species that have both a terrestrial and aquatic phase.
3 "Terrestrial Invertebrates" includes species with both a terrestrial and aquatic phase.

EPA proposed several mitigations for the registered uses of diflufenican, and these mitigations are incorporated into the labels by the registrant. EPA ultimately predicted no likelihood of jeopardy for any listed species and no likelihood of adverse modification to any designated CH, based on use of diflufenican consistent with the final accepted label. The mitigations are described in Section VI.B.

E. Benefits Assessment

As part of the registration process, the EPA provides a review regarding the benefits of the registration of diflufenican. The EPA assesses the benefits of the new pesticide as compared to available conventional control methods for waterhemp, Palmer amaranth, and other pigweeds in soybean and corn based on benefits information submitted by the registrant and publicly available scientific literature.

The EPA concludes that diflufenican is the first effective phytoene desaturase inhibitor (WSSA Group 12) herbicide for control of waterhemp, Palmer amaranth, and other pigweeds in soybean

and corn. From the data provided by the registrant, diflufenican provides similar preemergence control of pigweeds as other alternative preemergence herbicides used in soybean including metribuzin, sulfentrazone, flumioxazin, and S-metolachlor with reported control ratings ranging from 69% to 83%, depending on soil type. The level of pigweed control provided by diflufenican suggests that it would be a valuable herbicide that could be incorporated into corn and soybean weed management programs for control of pigweed species.

Furthermore, the efficacy of diflufenican against problematic pigweed species, along with the unique mode of action in soybean and corn, can aid in the development of Integrated Pest Management (IPM) and Resistance Management (RM) programs in the crops and delay the onset of further herbicide resistance in these species.

For more detailed information on benefits for diflufenican, refer to the following document in the docket EPA-HQ-OPP-2021-0435 "*Review of Benefits for the Proposed New Registration of the Herbicide Diflufenican in Corn and Soybean*."

F. Greater than Additive Effects

The technical registrant (Bayer) conducted independent analyses of U.S. patents to identify any incidence of greater-than additive (GTA; synergy) claims for diflufenican with other agricultural chemicals. The registrant based their analysis on the EPA interim guidance document entitled "Process for Receiving and Evaluating Data Supporting Assertions of Greater Than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants" (USEPA 2019). Based on the registrant's analyses of the patent search results, EPA determined only one out of the 35 identified patents met all five of the relevancy criteria discussed in the EPA guidance document. The identified patent describes synergistic claims for a combination product between diflufenican and isoxaflutole. However, since there are currently no proposed or registered formulations containing both active ingredients (diflufenican and isoxaflutole), this patent is not relevant to the current ecological risk assessment of diflufenican. To address any potential greater than additive effects during tank mixing, the end use product label prohibits tank mixing with any product containing isoxaflutole.

V. PUBLIC COMMENTS

On August 27, 2021, EPA published a Notice of Receipt (NOR) in the Federal Register (Docket ID: EPA-HQ-OPP-2021-0435) notifying that EPA was in receipt of an application to register pesticide products containing the active ingredient diflufenican, not included in any currently registered pesticide products and announced a public comment period of 30 days. EPA received two comments on the NOR, one from the Center for Biological Diversity and one from the United States Department of Agriculture. These comments can be found in docket ID EPA-HQ-OPP-2021-0435 at www.regulations.gov. The comments are addressed in the Response to Public Comments (RTC) document published to the docket alongside this Final Decision Memo.

The Memorandum Supporting Proposed Decision to Approve Registration for the New Active Ingredient of Diflufenican was available for 34-day public comment on June 03, 2025, closing on July 07, 2025. The Agency received 21 comments to the docket. The Agency responded to the comments received on the NOR, NOF, and proposed decision document in the RTC and can be found in docket ID number EPA-HQ-OPP-2021-0435 at www.regulations.gov. None of the comments received changed the Agency's final regulatory decision to approve the registration.

VI. FINAL REGULATORY DECISION

In accordance with FIFRA, EPA registers a pesticide unconditionally when it determines that it will not cause unreasonable adverse effects on humans or the environment, while taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA, EPA is charged with balancing risks posed by the use of a pesticide against its benefits. EPA must determine if the benefits in light of its use outweigh the risks for EPA to register the pesticide. FIFRA 3(c)(5) requires EPA to approve registration if the Agency determines that:

(a) its composition is such as to warrant the proposed claims for it;
(b) its labeling and other material required to be submitted comply with the requirements of this subchapter;
(c) it will perform its intended function without unreasonable adverse effects on the environment; and
(d) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment

i. FIFRA Determination and Mitigation

EPA is issuing unconditional registrations under FIFRA section 3(c)(5) for the following products:

- Diflufenican TC (EPA File Symbol 264-1217) as a TGAI for the end-use product below.
- Diflufenican SC500 Herbicide (EPA File Symbol 264-1213) for use on corn and soybean.

To determine whether the products will cause unreasonable adverse effects under FIFRA, EPA is charged with considering the economic, social, and environmental costs and benefits of the use of the pesticide. To determine the risks and benefits, the Agency reviewed a large body of information to determine how these products will be used according to the final labeling. EPA determines whether a product will generally cause unreasonable adverse effects by considering whether the benefits of the product outweigh any potential risks of concern or adverse impacts from its use.

EPA has determined that the database is complete for assessment of risks to human health and the environment for the registered diflufenican crop uses. Based on these data, EPA has not

identified any dietary, aggregate, non-occupational or occupational risks of concern for potential human health exposure.

Additionally, EPA has not identified any risks of concern for non-listed birds, reptiles, terrestrial-phase amphibians, bees, aquatic and non-bee terrestrial invertebrates, and freshwater and estuarine/marine fish on an acute or chronic exposure basis. There were no acute risks to non-listed mammals; however, the EPA identified risks of concern for aquatic, terrestrial, and wetland plants and chronic risk to mammals (based on reductions in growth). The risk to aquatic plants is limited to non-vascular plants, due to low diflufenican toxicity to vascular aquatic plants. Risks to plants adjacent to the treated field are expected via drift and runoff for both registered uses. For both listed and non-listed plants in terrestrial, wetland, and aquatic environments, additional risk from runoff also extends off field.

Based on the initial FIFRA assessment, the registrant included geographical restrictions, spray drift, and runoff mitigations on the label. The label prohibited use of the product in the states of California, Alaska, Hawaii, and most of Florida. The registrant updated the label to include a maximum boom height of 24 inches and the use of coarse or coarser droplet size to reduce potential impacts from drift. To further reduce runoff potential, the label was updated with restrictions for when rainfall is anticipated, and a list of potential mitigations. These changes were incorporated into the current RQs summarized in Table 5. Further, to address the identified effects to listed species, the Agency believes the mitigations to reduce runoff, described in the ESA section below, address the initial prediction of the potential likelihood of future jeopardy for listed species and/or adverse modification of designated critical habitats. The inclusion of these mitigations will also reduce the likelihood of adverse effects to individual non-listed species in those areas where the mitigations are implemented.

Diflufenican is a PDS inhibitor herbicide for control of broadleaf weeds, including waterhemp, Palmer amaranth, and other pigweeds. Diflufenican provides a unique mode of action (WSSA Group 12) for control (not just suppression) of these weed species and can aid in the development of Integrated Pest Management and Resistance Management programs as well as delay the onset of further herbicide resistance in these weeds.

The Agency finds the benefit of having the first PDS inhibitor herbicide for effective control of problematic weed species (waterhemp and Palmer amaranth) in corn and soybean, partnered with the mitigation measures for any environmental risks, outweighs any potential risks of concern. EPA reviewed the compositions of the registered products and determined that the claims made are warranted as the data and product label support the approval of the registrations. The final labeling, which has been revised to include additional mitigation measures to address ecological risks, contains all the necessary requirements and restrictions, and complies with the requirements of FIFRA.

Therefore, based on these considerations, consistent with the requirements of FIFRA section 3(c)(5), EPA determined that diflufenican meets the regulatory standard under FIFRA and

concludes that registering the products and the use of diflufenican as a selective herbicide for weed control of broad leaf weeds including waterhemp, Palmer amaranth, and other pigweeds in corn and soybean would not cause unreasonable adverse effects on human health or the environment when the herbicides are used in accordance with the labels.

ii. Endangered Species Assessment and Mitigation for Listed Species

ESA section 7(a)(2) provides that *"[e]ach Federal agency shall, in consultation with [FWS] insure that any action authorized, funded, or carried out by such agency. . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species. . . ."*

EPA completed effects determinations for federally listed threatened and endangered species (listed species) for the registered uses of diflufenican in the areas where it may be applied. EPA evaluated whether the registration of this active ingredient poses any reasonable expectation of discernible effects to listed species and designated critical habitats within the action area in the listed species effects determination. The ESA effects determination makes use of the best available scientific and commercially available information and considered both direct and PPHD effects. The term "direct effects" refers to decreases in the survival, growth, or reproduction of individuals of a listed species due to exposure to diflufenican. The term "PPHD effects" refers to impacts on individuals of a listed species that may be the result of the effects of diflufenican to organisms on which the listed species depends upon for prey, pollination, habitat, and/or dispersal.

In the *Final* effects determination (Diflufenican: Final Environmental Fate and Ecological Risk Assessment (ERA) for the FIFRA Section 3 Registration and Biological Evaluation (BE) with Associated Effects Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat), EPA concluded that the use of the registered diflufenican products may affect, and are Likely to Adversely Affect (LAA), multiple listed species and designated critical habitats. When considering an action (*e.g.,* the registration of a pesticide product), the ESA directs federal agencies to avoid jeopardizing listed species or adversely modifying their designated critical habitats. An LAA determination is not equivalent to a jeopardy determination; however, EPA can predict the potential likelihood for future jeopardy or adverse modification (J/AM) to help inform the formal consultation with the Services and resulting Biological Opinion developed by the Services. *See 50.C.F.R.402.40(b)(1).* The purpose of the EPA evaluation of the potential likelihood of future J/AM is to inform mitigations to avoid and minimize exposures to listed species earlier in the consultation process. Therefore, for those species and critical habitats with preliminary LAA determinations, EPA further assessed the potential likelihood that the registered diflufenican products would lead to future J/AM determinations. The Services will make the final determination as to any jeopardy to listed species and any adverse modification to designated critical habitats.

In the effects determination, EPA initially predicted that the label uses were likely to jeopardize 30 species and adversely modify 22 CH. The main risk concern for diflufenican is direct effects (via spray drift and runoff) to listed plants and PPHD effects to listed animals that rely on terrestrial plants and/or aquatic non-vascular plants. To address the predicted potential likelihood of future jeopardy of listed species and adverse modification of designated critical habitat, EPA used the Herbicide Strategy (HS) framework to inform the level of mitigations necessary to reduce runoff/erosion. EPA used the Magnitude of Difference (MoD) analysis to determine the level of mitigation needed to avoid population-level impacts from the labeled uses. For both uses, EPA identified a low potential for population-level impacts to certain listed wetland species from runoff/erosion exposure and further identified a level of mitigation that EPA expects addresses those potential impacts. Diflufenican has a Koc range of 4,074 to 7,197 mL/g_{oc} and is therefore considered erosion prone under the HS.

Overall, EPA identified two points of runoff/erosion mitigation as sufficient to make population- and community-level effects to listed species not likely from the registered uses of diflufenican. Users must select mitigations that total two points from the website (https://www.epa.gov/pesticides/mitigation-menu). As described in the Herbicide Strategy (HS), EPA first calculated buffer distances using default assumptions of High Boom and a Very Fine to Fine droplet size distribution. This distance is provided for context but does not include the spray drift reduction practices that are already included on the label. The submitted label includes restrictions on droplet size (coarse or coarser) and boom height (24" above the ground or crop canopy), thus population-level impacts to listed plants and listed animals that rely on plants are not likely to extend off the treated field. Therefore, EPA identified that no buffers are necessary for the registered uses.

The mitigations identified for the product label under the HS eliminated the predicted potential likelihood of future jeopardy for all but one listed vulnerable[3] species. Specifically, Spring Creek bladderpod (*Lesquerella perforata*) has been identified by EPA as particularly vulnerable and likely to establish on agricultural fields where diflufenican is labeled for use. For this on-field species, geographically specific mitigations as mandated by species-specific Pesticide Use Limitation Areas (PULAs) that will be implemented through Bulletins Live! Two (BLT), is expected to reduce exposure so that there is no predicted potential likelihood of future J/AM. Through this mitigation spray applications are prohibited in specific areas of Wilson County, TN between September 15th and May 15th. The label includes directions to obtain any applicable Bulletins within six months prior to or on the day of application before using diflufenican products.

EPA predicts that the mitigation measures on this registration and labeling, that have been agreed upon by the registrant (Section VI.D below), reduce the effects on listed species and their designated critical habitats to the extent that the registration of products containing diflufenican would not result in predictions of a potential likelihood of future jeopardy for any listed species

[3] EPA defines a vulnerable species as a listed species that is particularly vulnerable to pesticides due to a combination of factors including a declining population trend, small number of individuals or small number of populations (*e.g.*, groups of individuals or sub-populations), limited distribution (*e.g.*, endemic, constrained and/or isolated populations), and occurrence in areas that may be exposed to pesticides (https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides#species).

or likelihood of adverse modification for its designated CHs. However, the Services have the sole authority to make a final determination of whether these registration actions will likely cause jeopardy of any listed species or adverse modification of any designated CHs. The Services provide their determinations in their biological opinions and may determine that additional mitigations are necessary.

In cases where EPA determines that initiating formal consultation is appropriate on a FIFRA action, as here, the Agency may still be able to proceed with the action before completing consultation if it determines that doing so will not result in "any irreversible or irretrievable commitment of resources . . . [that] has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate [ESA section 7(a)(2)]." See 16 U.S.C. § 1536(d). As stated above, EPA initiated formal consultation with the Services. EPA will work with the Services to complete the consultation process as expeditiously as possible. Acknowledging that the final determination on jeopardy and adverse modification is made by the Services and that either (or both) of the Services may not fully adopt EPA's prediction that this action will avoid jeopardy and adverse modification, the registration includes a term to allow EPA to address any further mitigation determined to be necessary following consultation. The Agency has also concluded that granting the registrations for diflufenican prior to the completion of formal consultation with the Services will not result in any irreversible or irretrievable commitment of resources that would have the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures, in accordance with ESA section 7(d)[4].

iii. Label Requirements

The following statements are included on the end-use product label.

1. For all use sites:
    a) DO NOT use this product in the states of California, Alaska, or Hawaii.
    b) DO NOT use this product in the state of Florida, except for the counties of: Escambia, Santa Rosa, Okaloos, Walton, Holmes, Washington, Jackson, Calhoun, Gadsden, Leon, Jefferson, Madison, Hamilton, Suwannee, Columbia, Baker, Lafayette, Union, Bradford, Clay, Gilchrist, Dixie, Levy, Alachua, Putnam, and Marion.
    c) DO NOT apply aerially.

2. The following is included in the "Precautionary Statements" section:
    a. Mixers, loaders, applicators and other handlers must wear:
        i. Long-sleeved shirt and long pants
        ii. Shoes plus socks

[4] Endangered Species Act Section 7(d) Consistency Determination with Respect to the Application for the Registration of Products Containing the New Active Ingredient Diflufenican.

iii. Chemical-resistant gloves made of any waterproof material such as polyethylene or polyvinyl chloride.

3. The following text is included in the "Environmental Hazards Statement" section:

   - This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. For terrestrial uses, Do Not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do Not apply when weather conditions favor drift from areas treated. Do Not contaminate water when disposing of equipment wash waters or rinsate. Do Not use the same spray equipment for other purposes unless thoroughly cleaned. Do Not contaminate water used for irrigation or domestic purposes.

   - 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 groundwater. This product is classified as having a medium potential for reaching both surface water and aquatic sediment via runoff for several months or more after application.

4. To address potential Greater than Additive Effects during tank mixing, the end use product includes the following Tank Mixing restriction:

   - DO NOT TANK MIX ANY PRODUCT CONTAINING ISOXAFLUTOLE WITH THIS PRODUCT.

5. To address the potential effects to non-target vulnerable species, specifically the listed plant species Spring Creek bladderpod, included in the "Bulletins Live! Two" web-based system (BLT), in the "Directions for Use" Section, the end-use product directs all users to access the BLT prior to application, according to the label statement below:

   - "***ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS****: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at* https://www.epa.gov/pesticides/bulletins. *When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."*

6. REPORTING ECOLOGICAL INCIDENTS: For guidance on reporting ecological incidents, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticideincidents.

7. To minimize runoff/erosion from use sites the following language is required in the "Directions for Use-Under the Restriction or Use Restriction" section. Please note that the EPA's mitigation menu website noted below should be utilized.

    - **MANDATORY RUNOFF/EROSION MITIGATION:**
      Applicators must access and search Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins within six months prior to or on the day of the application to determine whether the application site falls within a Pesticide Use Limitation Area (PULA). If you are located inside a PULA, follow the instructions in the BLT bulletin.

      If the application site is located outside of a PULA, follow the instructions in the section below.

        - 2 mitigation points are required for all field crops listed on this label. Follow the steps below to achieve points.

      Step 1. To achieve the mitigation points specified above, visit EPA's mitigation menu website (www.epa.gov/pesticides/mitigation-menu) for a full list of mitigation and mitigation relief options.

      Step 2. Determine if you are eligible for mitigation relief. Runoff/erosion mitigation is NOT required if certain field/application parameters are present at the time of application (*e.g.*, subsurface or tile drains with controlled outlet, perimeter berm systems, irrigation tailwater return systems, spot treatment, etc).

      Step 3. If the application site does not meet the field/application parameters specified on EPA's mitigation menu website, choose among the mitigation and/or mitigation relief options on EPA's mitigation menu website to meet or exceed the required points noted here before applying this product.

      Step 4. To achieve mitigation points for the application, the mitigation and mitigation relief measures must be:
        - Employed in accordance with the instructions and descriptions on EPA's Mitigation Menu Website.
        - In place during the application unless a different timing (such as before or after application) is specifically provided in the measure's description on EPA's Mitigation Menu Website. EPA may periodically update the Mitigation Menu Website, for example, by adding new mitigation measures or updating a mitigation measure description.

Step 5. Additional restrictions may be present in bulletins—always follow the most restrictive bulletin instructions. If you are located in an area where PULAs overlap, follow the most restrictive requirements across all bulletins. When tank mixing, the most restrictive requirements must be followed between the products' labels and bulletins.

8. The following language is included under Directions for Use Section with a **"Mandatory Spray Drift Mitigations**" header:

MANDATORY SPRAY DRIFT MANAGEMENT

- DO NOT apply this product aerially.

Ground Boom Applications

- During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 15 miles per hour.
- Wind speed and direction must be measured on location using a windsock or anemometer (including systems to measure wind speed or velocity using application equipment).
- Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.
- Do not release spray at a height greater than 2 feet above the ground or crop canopy.
- Applicators must select nozzle and pressure that deliver coarse or coarser depending on team discussions] droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASAE S572).
- Do not apply during temperature inversions.

SPRAY DRIFT ADVISORIES

THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. Be aware of nearby non-target sites and environmental conditions.

- **Importance of droplet size**
  An effective way to reduce spray drift is to apply large droplets. Consider 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.

- **Controlling Droplet Size – Ground boom**

- Volume – Increasing the spray volume so that larger droplets are produced will reduce spray drift. Consider using the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate.
- Pressure – Using the lowest spray pressure recommended for the nozzle will produce the target spray volume and droplet size.
- Spray Nozzle – Consider using a spray nozzle that is designed for the intended application, as well as using nozzles designed to reduce drift.

- **Release height – Ground Boom**
  For ground equipment, the boom should remain level with the crop and have minimal bounce. Automated boom height controllers are recommended with large booms to better maintain optimum nozzle to canopy height. Excessive boom height will increase the potential for spray drift.

- **Hooded (or shielded) sprayers**
  Shielding the boom or individual nozzles can reduce spray drift. Consider using hooded sprayers. Applicators should verify that the shields are not interfering with the uniform deposition of the spray on the target area.

- **Temperature and humidity**
  When making applications in hot and dry conditions, consider using larger droplets to reduce effects of evaporation.

- **Temperature inversions**
  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.

- **Wind**
  Drift potential generally increases with wind speed.
  Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.

VII. SUPPORTING DOCUMENTS

All supporting documents can be found in docket ID number EPA-HQ-OPP-2021-0435 at www.regulations.gov.