UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 27, 2020

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MEMORANDUM

SUBJECT: **Broflanilide:** Ecological Risk Assessment for the Proposed Section 3 New Chemical Registration

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TO: Jennifer Gaines, Risk Manager
Beth Fertich, Product Manager
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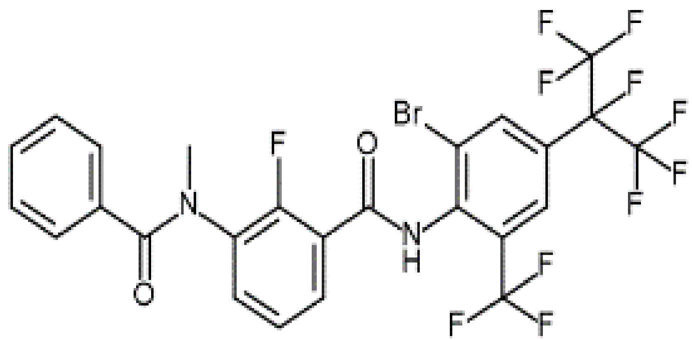
The Environmental Fate and Effects Division (EFED) has completed the environmental fate and ecological risk assessment in support of the proposed Section 3 New Chemical Registration of the insecticide, broflanilide ((N-(2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl)-2-fluoro-3-(N-methylbenzamido)benzamide); CAS Registry Number: 1207727-04-5; PC Code: 283200). The risk assessment is attached.

Ecological Risk Assessment for the Section 3 New Chemical Proposed Registration of Broflanilide



N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide
CAS No. 1207727-04-5
USEPA PC Code: 283200

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1 Executive Summary

1.1 Overview

Broflanilide (N-(2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl)-2-fluoro-3-(N-methylbenzamido)benzamide) is a diamide insecticide that has larvicidal activity against many chewing pests. Nakao and Banba (2016) suggested that broflanilide is metabolized to desmethyl-broflanilide within the insect, which acts as a noncompetitive resistant-to-dieldrin (RDL) γ-aminobutyric acid (GABA) receptor antagonist. The binding site of desmethyl-broflanilide was demonstrated to be distinct from that of conventional noncompetitive antagonists.

Broflanilide is being proposed for registration by BASF Corporation for control of a broad range of insects in corn, tuberous and corm vegetables (Crop subgroup 1C), cereal grains (wheat (all types), barley, oats, rye, triticale, etc.), and a variety of non-agricultural uses including crack and crevice treatments, insect baits, and localized (spot/partial) area termiticide uses. For agricultural use, the maximum proposed use rate (in-furrow) is 0.045 lb a.i./A using soluble concentrate (SC) and water-dispersible granule formulations with one yearly application. The maximum proposed seed treatment rate is 0.005 lb a.i./100 lb-seed for cereal grain crops. Non-agricultural uses include soluble concentrates (SC) for termiticide uses, and granular and ready-to-use formulated products for ant and fly baits. In addition, gel formulations are proposed for ants and cockroaches, and a foam is proposed for indoor and outdoor crack and crevice spot treatments for termites and carpenter ants (**Table 3-2**).

A draft ecological risk assessment was completed in 2019 which described the risks associated with the proposed uses in the initial submission package (Executive Summary provided in **Appendix A**). These risks were discussed with the Registration Division (RD) and BASF. Since these discussions, BASF resolved several risk concerns by amending the proposed labels regarding use directions for uses on corn, tuberous and corm vegetables (Crop subgroup 1C), and termitidicide uses (revised labels received on 7/6/20). These revised labels removed T-band application and added a 10-ft vegetative buffer strip for corn and Crop subgroup 1C uses. In addition, the termitidicide label Terinda™ SC was revised to limit the application to spot treatment rather than the originally proposed perimeter treatment. These label changes significantly changed the potential environmental exposure. Additionally, BASF proposed several risk assessment refinements regarding aquatic exposure modeling inputs. These refinements, sent to EPA on 6/11/2020, included revisions to the assumptions and model inputs for spray drift, soil half-life, incorporation of a 10-ft vegetative buffer, PRBEN (suspended sediment particle adhesion fraction), and sediment burial. EFED explored the proposed modifications and provided a response (**Appendix F**).

The ecological risk assessment provided here reflects the changes to the proposed uses and refinements to model inputs for the proposed new chemical registration of broflanilide. Since there is no concern with recommended EDWCs (Estimated Drinking Water Concentrations) to the Health Effects Division (HED) for the dietary risk assessment, the drinking water assessment (USEPA, 2019, DP 446353) was not revised.

This Ecological Risk Assessment (ERA) examines the environmental fate and the potential for adverse effects on non-target plants and animals from exposure associated with the proposed uses of broflanilide. Note that effects determinations for federally listed threatened and endangered species are not made in this ERA. Because this is a new chemical risk assessment, a comprehensive approach was taken to evaluate potential risk concerns for all taxa using the available data. Evaluated taxa include freshwater and estuarine/marine fish and invertebrates, aquatic vascular and nonvascular plants, birds, mammals, terrestrial invertebrates, and terrestrial plants. The potential for greater than additive (GTA) effects were not evaluated in this assessment as potentially relevant patent data submitted by the registrant for evaluation (received 5/19) did not result in any synergy claims for US registrations. Although broflanilide forms several degradates in the environment, the residue of concern (ROC) evaluated for assessing exposure is broflanilide alone because empirical toxicity data suggest that the environmental degradates are much less toxic than broflanilide and that formation of these degradates is minimal because of the persistence of broflanilide in terrestrial and aquatic sediments.

1.2 Risk Conclusions Summary

Table 1-1 summarizes potential risks associated with the use of broflanilide. For aquatic organisms, there are no level of concern (LOC) exceedances for freshwater or estuarine/marine fish, nor for aquatic plants. LOCs for water column freshwater invertebrates are not exceeded, based on water column or pore water comparisons to the available acute and chronic *Daphnia* endpoints. Estuarine mollusk (eastern oyster) acute data suggest risk to mollusks when compared to modeled EECs. Acute and chronic water column estuarine/marine invertebrate endpoints from the mysid studies result in RQs that exceed acute and chronic LOCs based on modeled water column and pore water EECs. Similarly, all sub-acute and chronic endpoints for three species of freshwater and estuarine benthic invertebrates are exceeded by modeled EECs, therefore there are risks identified for all invertebrates that interact with sediments in aquatic habitats. Aquatic risk quotients (RQs) are based upon the 1 in 10 year concentration from 30-years of weather data and use. Because the modeling suggests that broflanilide will accumulate in the sediments over this period of time these RQs reflect the risks associated with that accumulation (*i.e.,* the last few years of the modeling simulations yield the highest EECs). While the PWC modeling and subsequently the RQs consider 30-years of annual use, it is important to note that after a single application the first year of some model simulations result in acute and chronic EEC that exceed the estuarine/marine endpoints (for furrow application to MS corn at 0.045 lbs a.i./A first year acute RQ = 1.9 and chronic RQ = 16).

A revised 90th percentile aerobic soil metabolism half-life of 2198 days based of 365 days dataset was used in estimating aquatic exposoures and resulted in reduced RQs of 5 to 15% but did not impact chronic risk conclusions in comparison to initial findings. Alternative model assumptions for PRBEN (sediment adhesion factor) did not impact the conclusions for chronic risks because this parameter only impacts the acute EECs. Furthermore, assumptions of sediment burial were considered but determined to be inappropriate for many aquatic systems (e.g., streams, high turnover lake/pond beds) because of sediment mixing and continual disturbance of the buried layers. These results reflect that a single application of broflanilide has the potential to result in risk to water column estuarine/marine invertebrates. Due to the persistence of broflanilide, repeated use can considerably increase these risks over time.

Based on the available data, there is low potential for effects on birds and mammals on a chronic exposure basis through diet from the proposed use of broflanilide as a spray or injection, or from the consumption of treated seeds on an acute basis. However, on a chronic basis, the numbers of treated seeds to reach the avian and mammalian chronic LOCs are reasonably achievable for small and medium sized birds (28 to 170 seeds/day) and mammals (416 to 786 seeds/day). Because the treated seeds are cereal grains, the availability of seed would be high, with at most a light covering of soils. Therefore, chronic risk from consumption of broflanilide treated seeds is within reason. Given the conservatism of the KABAM estimated BCFs as compared to the empirically based BCFs (discussed in section 9.2), the results suggest that bioaccumulation is not a concern for broflanilide.

Broflanilide's propensity to sorb to lipids and sediments suggest that it is not likely systemic in plants and therefore exposure to bees through pollen and nectar contamination would only occur through direct spray of flowering attractive vegetation. This assumption is supported by empirical data generated to provide measured residues in pollen and nectar following in-furrow and seed treatment uses. The studies resulted in only one detection in pollen, which when compared to toxicity endpoints for honey bees or bumble bees, does not result in risk concerns. Acute and chronic risks to individual bees were identified following potential spray drift to flowering vegetation for ground furrow proposed uses. Additionally, any non-target terrestrial invertebrates, including bees that come into contact with or consume terrestrial sediments (*e.g.*, ground dwelling/nesting bees), are at risk from the proposed uses. Because of the persistence of broflanilide in sediments, the risks to sediment dwelling/interacting invertebrates would increase with every subsequent use of broflanilide.

Risks to terrestrial plants are considered low. The proposed furrow rates for corn, and tuberous and corm vegetables are below the concentrations that did not achieve a 25% effect level. So risks for these uses are low.

1.3 Environmental Fate and Exposure Summary

There are no environmental fate data gaps for broflanilide. Broflanilide has a low solubility in water (0.71 mg/L at 20°C) and has low mobility in soil and sediment. Its vapor pressure of 6.6 x 10^{-11} torr and Henry's law Constant of 3.0 x 10^{-14} atm-m^3/mol suggest volatilization is not a major dissipation pathway. Broflanilide is persistent in terrestrial and aquatic environments. Broflanilide is stable to hydrolysis and soil photolysis. Under anaerobic and aerobic conditions, the chemical persists in soil and water bodies, with metabolism half-lives on the orders of months to years. There were no major (>10% of applied radioactivity (AR)) degradation products but several minor transformation products were detected in soil. Major routes of dissipation are expected to be photodegradation in acidic and alkaline water and runoff of eroded sediment containing broflanilide and its degradates.

The Log Kow of 5.2 at pH 4 and 7 suggests broflanilide has the potential for bioaccumulation. The bioconcentration factors in rainbow trout whole fish tissues are 266-364X. Depuration was gradual, with >95% of the total residues accumulated during 28 days of exposure eliminated in 10 days.

The overall stability/persistence profile for broflanilide suggests that it has potential to accumulate in soil and aquatic environments with each successive application. As described earlier, the PWC model-predicted exposure from a single use of broflanilide has the potential to result in risk to aquatic invertebrates. Repeated use can considerably increase these risks over time due to the persistence of broflanilide in aquatic environments.

1.4 Ecological Effects Summary

The ecological effects database is incomplete for chronic exposures to freshwater fish and estuarine/marine invertebrates. The available chronic freshwater fish study did not use the most sensitive species (e.g., bluegill or rainbow trout) based on acute toxicity, therefore there is uncertainty regarding the protectiveness of the available endpoint. Additionally, the available chronic mysid study did not achieve a NOAEC. Since a NOAEC was not available for the assessment, the concentration of broflanilide in water that would not result in chronic effects to aquatic invertebrates could not be determined. The implications of these uncertainties and the risk to fish and aquatic invertebrates is discussed below.

Several acute freshwater fish studies were submitted to the Agency. The most sensitive of these was a test on the bluegill (*Lepomis macrochirus*) which resulted in an LC_{50} of 251 µg a.i./L. A similar response was observed with rainbow trout. The steep dose responses contribute to uncertainty in the estimated acute endpoints for these studies. These data suggest that broflanilide is classified as highly toxic to freshwater fish on an acute exposure basis. Two early life-stage chronic fish toxicity studies testing the sensitivity of fathead minnow (*Pimphales promelas*) and sheepshead minnow (*Cyprinodon variegatus*) were submitted. In the fathead minnow study, there were statistically significant 9% and 85% reductions in larval survival at 147 and 475 µg a.i./L. respectively; therefore, the NOAEC was established at 51 µg a.i./L. In the sheepshead minnow study, the NOAEC was established at 11 µg a.i./L., based on reduced length (4%), dry weight (10-13%), wet weight (10%), and time to hatch (16%) at 25.2 µg a.i./L. Given the apparent contrast in toxicity reflected in the available acute data for freshwater fish, it is unknown if bluegill or rainbow trout would result in more sensitive endpoints that those provided in the fathead minnow test. Typically, an acute to chronic ratio would be used to estimate the NOAECs for these taxa: however, in this case the acute fathead minnow and sheepshead studies did not result in definitive LC_{50} and had little mortality. This uncertainty has little impact on the evaluation of risk for freshwater fish because the EECs are orders of magnitude below the lowest available endpoitns for acute or chronic data, suggesting that any new chronic endpoint would need to be more toxic by orders of magnitude to result in a risk conclusion. Therefore, the absence of these data have little impact on the risk conclusions for fish.

Water Column Invertebrates

Acute freshwater invertebrate data testing daphnia (*Daphnia magna*) and estuarine/marine mollusk, eastern oyster (*Crassostrea virginica*) showed no effects up to the highest tested concentrations, 322 and 440 µg a.i./L, respectively. In contrast, an acute study with mysid resulted in a LC_{50} of 0.0215 µg a.i./L, with a steep dose response (35%, 95% and 100% mortality at 0.0202, 0.0284, and 0.0428 µg a.i./L respectively). Based on the mysid data, broflanilide is classified as very highly toxic aquatic estuarine marine invertebrates. Chronic *Daphnia* and mysid toxicity studies showed at low concentrations, statistically significant differences were observed compared to the controls. The *Daphnia* NOAEC of 5.93 µg a.i./L was based upon 6-8% reductions in length, total offspring, birth rate, and time to first brood at 11.6 µg a.i./L. The mysid study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female. The lack of a definitive NOAEC for the mysid is an uncertainty in the risk conclusions. Given the robust dataset for benthic invertebrates, the predominant sediment pathway of exposure, and the magnitude of the exceedance of the lowest test concentration in the mysid study by the EECs, there is little doubt about the potential risks to aquatic invertebrates from the proposed uses. Therefore, while the guideline requirement remains to be fulfilled, the impact on the conclusions of risk in this assessment are considered low.

Benthic Invertebrates

Three sub-chronic (10-day) toxicity studies on benthic invertebrates were submitted. Studies with freshwater species *Chironomus dilutus* and *Hyalella azteca*, and the estuarine/marine species *Leptocheirus plumulosus* resulted in LC_{50s} of 9.99, 13.5, and 14 µg ai/kg dry sediment. Chronic toxicity studies with these three species were also submitted. In a 60-day static-renewal sediment test with *Chironomus dilutus*, the overall NOAEC was 1.5 µg ai/kg dry sediment based on 20% reduced survival and 36% reduced percent emergence. In a 42-day reproduction study on *Hyalella azteca* the overall NOAEC was non-definitive (< 1.7 µg ai/kg dry sediment) based on a 46% reduction in male to female ratio. NOAECs were also determined for survival (6.7 µg ai/kg dry sediment; >20% reductions) and reproduction (3.3 µg ai/kg dry sediment; >45% reductions). In a 28-day spiked sediment test with *Leptocheirus plumulosus*, the NOAEC was determined to be 3.8 µg ai/kg dry sediment based on 12% reduced survival at the LOAEC.

Aquatic Plants

The most sensitive aquatic non-vascular plant toxicity study (of 5) was a static toxicity study with *Skeletonema costatum* (marine diatom), in which there were significant reductions in cell density (IC_{50} is 570 µg a.i./L and a NOAEC of 160 µg a.i./L). A toxicity study with freshwater vascular plant *Lemna gibba* (duckweed) observed no chemical inhibition (IC_{50} > 630 µg a.i./L)

Birds/Terrestrial Phase Amphibians/Reptiles

Acute oral toxicity tests of TGAI with bobwhite quail (*Colinus virginianus*), mallard duck (*Anas platyrhynchos*), and canary (*Serinus canaria*) reported no effects in response to broflanilide at 2000 mg a.i./kg-bw. No mortalities or sublethal effects were observed in subacute dietary toxicity studies with bobwhite quail or mallard duck (LC_{50s} are >5000 mg a.i./kg-diet). Based on these data, broflanilide is classified as practically non-toxic to birds, and their surrogate taxa (*i.e.,* reptiles and terrestrial-phase amphibians) on an acute oral or subacute dietary exposure basis. A reproduction study with mallard ducks resulted in reduced eggs laid and 14% reduction in surviving hatchlings at 87.4 mg a.i./kg-diet (NOAEC = 29.7 mg a.i./kg-diet). A reproduction study with bobwhite quail showed significant (5-6%) inhibitions in 14-day survivors/hatchling at 506 and 1021 mg ai/kg diet treatment groups, and in 14-day survivor weight at 1021 mg ai/kg diet (NOAEC = 254 mg a.i./kg-diet).

Mammals

An acute oral toxicity study with rats (*Rattus norvegicus*) reported no chemical related effects at the highest tested concentration (LD_{50} > 5000 mg a.i./kg-bw). Therefore, broflanilide is considered practically non-toxic to mammals on an acute oral exposure basis. In a two-generation reproduction study with rats, there were no observed effects related to growth or survival of adults; however decreased pup weights were observed in both male and female F1 pups (5-7%) and this increased in F2 pups (6-10%) at the LOAEL (1500 mg a.i./kg-diet) and at 15000 mg a.i./kg-diet (NOAEC = 300 mg a.i./kg-diet).

Terrestrial Invertebrates (Bees)

Broflanilide is highly toxic to honey bees (*Apis mellifera*) and bumble bees (*Bombus terrestris*) on both an acute contact and oral exposure basis. In an acute (single dose) contact and acute oral combined toxicity study with adult honey bees (*Apis mellifera*), the 48-hr contact LD_{50} = 0.0088 µg a.i./bee and acute oral LD_{50} = 0.0149 µg a.i./bee. Two additional acute oral and acute contact toxicity studies on adult honey bees with technical grade active ingredient (*i.e*., broflanilide technical; TGAI) and a typical end-use product (TEP; 9.6% a.i.) reported acute contact LD_{50s} from 0.012 to 0.017 µg a.i./bee and acute oral LD_{50}s ranging from 0.045 to 0.0693 µg a.i./bee. Additional broflanilide toxicity studies were conducted using TGAI and TEP (9.6% a.i.) with bumblebees, resulting in contact LD_{50s} of >0.120 and 0.122 µg a.i./bee respectively, and acute oral LD_{50s} of 0.0195 and 0.0139 µg a.i./bee respectively. An acute larval honey bee toxicity study conducted with TGAI resulted in an 8-day LD_{50} of >0.029 µg a.i./larva/day. Mortality (36%) was observed at the highest tested concentration 0.029 µg a.i./larva/day. Based on these results, broflanilide is considered very highly toxic to adult and larval bees. A 10-day chronic (repeat dose) TGAI toxicity test with adult honeybees resulted in NOAEL of 0.00062 µg a.i./bee/day and LOAEL of 0.0011 µg a.i./bee/day based on 30% mortality. The next two doses 0.00237 and 0.0049 µg a.i./bee/day resulted in 93 and 100% mortality. A 22-day chronic larval toxicity test conducted with TGAI resulted in a NOAEC of 0.000080 µg a.i./larva/day based on 18% larval mortality at 0.00027 µg a.i./larva/day.

Terrestrial Plants

Submitted terrestrial plant seedling emergence (MRID 50325617) and vegetative vigor (MRID 50325616) studies were conducted on *Allium cepa* (onion), *Lolium perenne* (ryegrass), *Triticum aestivum* (wheat), *Zea mays* (corn), *Beta vulgaris* (sugar beet), *Brassica napus* (rape), *Brassica oleracea* (cabbage), *Glycine max* (soybean), *Lactuca sativa* (lettuce), *and Lycopersicon esculentum* (tomato) with a TEP (9.6% a.i.). In the vegetative vigor study, the most sensitive dicots were sugar beet (NOAEC < 0.0023 lb a.i./acre) and cabbage (NOAEC = 0.014 lb a.i./acre); however, the observations did not manifest in a dose response manner and regression-based toxicity endpoints (IC_{25s}) were highly uncertain. No other plants tested in the vegetative vigor or seedling emergence studies responded to the formulations; therefore, the IC_{25}s for monocots and dicots for both studies were determined to be >0.091 lbs a.i./A.

Table 1-1. Summary of Risk Quotients (RQ) for Taxonomic Groups Based on Proposed Uses of Broflanilide.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Freshwater Fish	Acute	<0.01	No	--
	Chronic	<0.1	No	--
Estuarine/ Marine Fish	Acute	NC	NA	Endpoint was non-definitive, EECs orders of magnitude lower than highest tested concentration
	Chronic	<0.1	No	--
Freshwater Invertebrates (Water-Column Exposure)	Acute	NC	NA	Endpoint was non-definitive, EECs orders of magnitude lower than highest tested concentration
	Chronic	<0.1	No	--
Estuarine/ Marine Invertebrates (Water-Column Exposure)	Acute	9.3-21.4	Yes	RQs for all modeled uses exceed LOC based on mysid data. No risks to mollusks based on eastern oyster data.
	Chronic	>101 to >239	Yes	RQs exceed LOC for water-column species for all uses. NOAEC was not established in available study so RQs based on LOAEC of 0.0018 µg a.i./L, where there was 17% reduced survival for offspring and 22% reduced reproduction.
Freshwater Invertebrates (Sediment Exposure)	Acute[2]	1 – 2.2	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.
	Chronic	16.3 to >10	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Estuarine/ Marine Invertebrates (Sediment Exposure)	Acute[2]	5.8	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates.
	Chronic	18.3	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates. Non-definitive mysid endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female.
Mammals	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint – no effects in study
	Chronic	<0.4	No	Potential chronic risk from consumption of treated seed; 416-786 seeds/day to reach LOC
Birds	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint – no effects in study
	Chronic	<0.4	No	Potential chronic risk from consumption of treated seed; 28-170 seeds/day to reach LOC
Terrestrial Invertebrates[3]	Acute Adult	NC	Yes	Acute and chronic risk concerns for bees is limited to foraging nectar and/or pollen contaminated by spray drift. Broflanilide is not likely systemic and submitted residues in pollen and nectar studies support low risk from systemic transport. Current proposed uses will not likely generate spray drift to exspose flowering vegetation, therefore risk to honey bees is considered low. All non-target invertebrates that interact with soils for foraging diet, nesting, reproduction etc. are at risk. These risks follow a single application and because of broflanilide' s persistence in soils, will likely increase with each annual application.
	Chronic Adult	NC	Yes	
	Acute Larval	NC	Yes	
	Chronic Larval	NC	Yes	
Aquatic Plants	Not Applicable	<0.01	No	--
Terrestrial Plants	Not Applicable	<0.01	No	--

Level of Concern (LOC) Definitions:
Terrestrial Animals: Acute=0.5; Chronic=1.0; Terrestrial invertebrates=0.4
Aquatic Animals: Acute=0.5; Chronic=1.0
Plants: 1.0
[1] RQs reflect exposure estimates for parent 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.

1.5 Identification of Data Needs

There are no additional environmental fate or ecological effects data needed for risk assessment.

2 Introduction

This Ecological Risk Assessment (ERA) examines the environmental fate and the potential for adverse effects on non-listed species from exposure associated with proposed uses of broflanilide. The ERA uses the best available scientific information on the use, environmental fate and transport, and ecological effects of broflanilide. The general risk assessment methodology is described in the *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs* ("Overview Document") (USEPA, 2004). Additionally, the process is consistent with other guidance produced by the Environmental Fate and Effects Division (EFED). When necessary, potential risks identified through standard risk assessment methods are further refined using available models and data. This ERA incorporates the available exposure and effects data and the most current modeling and methodologies.

3 Problem Formulation

The purpose of problem formulation is to provide the foundation for the environmental fate and ecological risk assessment being conducted for the proposed uses of broflanilide. The problem formulation identifies the objectives for the risk assessment and provides a plan for analyzing the data and characterizing the risk.

3.1 Mode of Action for Target Pests

Broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests (wireworm, maggot, root worm, *etc.*). Nakao and Banba (2016) suggested that broflanilide is metabolized in insects to desmethyl-broflanilide, which acts as a noncompetitive resistant-to-dieldrin (RDL) γ-aminobutyric acid (GABA) receptor antagonist. The binding site of desmethyl-broflanilide was demonstrated to be distinct from that of conventional noncompetitive antagonists.

3.2 Label and Use Characterization

Broflanilide is a diamide insecticide being proposed for registration by BASF Corporation for the control of a broad range of insects through soil treatment prior to crop emergence for corn and tuberous and corm vegetables (Crop subgroup 1C) using in-furrow applicaiton, and as a seed treatment for cereal grains (wheat (all types), barley, oats, rye, triticale, amaranth grain, buckwheat (all types), etc.), as listed in **Table 3-1**. All agricultural uses are limited to one use per year. Broflanilide end-use products are formulated as soluble concentrate (SC) and water-dispersible granules for agricultural spray uses. There is one end-use product for seed treatment, Teraxxa F4, which is broflanilide (1.55%) co-formulated with several fungicides (fluxapyroxad [0.78%], pyraclostrobin [1.55], triticonazole [1.55%] and metalaxyl [0.93%]). This assessment only addresses broflanilide.

In addition, several broflanilide products are proposed for control of termites, ants, and various other insects around homes, buildings, eating establishments, transportation facilities, *etc.* (**Table 3-2**). Proposed broflanilide non-agricultural, non-termiticide end-use products are formulated as soluble concentrates (SC), water-dispersible granules, granules, gels, foams, and ready-to-use formulations. Broflanilide is also proposed to be applied as a liquid into soil using trenching or soil excavation techniques for termite control. **Tables 3-1** and **3-2** summarize the proposed use patterns considered in this ecological risk assessment.

In addition, a formulated product, Terinda™ was proposed for termiticide use with HE and HP (high precision) technology for experimental use, which will not be included in this assessment since it would involve evaluating the efficacy of termiticide application efficiency. However, the application rate is similar to the localized (spot/partial) area treatment listed in **Table 3.2**.

Table 3-1. Proposed Agricultural Uses of Broflanilide

Uses	Formulation (% ai)	Maximum Single Application Rate (lb ai/A)	Timing	Equipment	Application Type	Comments
Corn	Soluble concentrate (SC) (26%)	0.045	Pre-emergence; once per year	Ground-boom Sprayer	Furrow	None
Tuberous and corm vegetables (Crop Group 1C)[A]		0.045	Pre-emergence; once per year	Ground-boom Sprayer	Furrow	
Cereal Grain Seed Treatments[B]	Seed treatment (26%)	0.0068[C]	Pre-emergence	Seeding equipment	Ground	Geographic restriction: Nassau and Suffolk counties of NY

[A] Crop Group 1C: potato, arracacha, arrowroot, artichoke (Chinese, Jerusalem), canna (edible), cassava (bitter, sweet), chayote (root), chufa, dasheen (taro), ginger, leren, sweet potato, tanier, turmeric, yam bean, yam (true).
[B] Cereal grains except rice and corn: wheat (all types), barley, oats, rye, triticale, amaranth grain, buckwheat (all types), cañihua, chia, cram-cram, huauzontle, quinoa, and spelt
[C] Application rate was calculated based on 0.005 lbs ai/100 lbs seed x 135 lbs seed /Acre for wheat.

Table 3-2. Proposed Non-agricultural Uses of Broflanilide

Uses	Formulation (% ai)	Maximum Single Application Rate	Timing	Application Method	Application Type	Comments
General insect control in commercial and residential settings	Gel baits (0.25 % ai)	10-20 beads/100 ft^2	Not Specified	Spot treatment	Injection into cracks and crevices	Concentrated bead placements of cockroach traffic and harborage; Geographic restriction: CA
	Gel bait (0.02 % ai)	Pea-sized beads and refillable bait stations	Suspected ant activity	Spot treatment	Directly into cracks and crevices	Ants; Geographic restriction: CA
	Granular bait (0.005 % ai)	0.04 lbs ai/A	Not Specified	Broadcast application	Sprinkle or spot application	Ants
	Granular bait (0.025 % ai)	0.04 lbs ai/A	Not Specified	Spot treatment	Spot or band application	Flies; Geographic restriction: CA
	Pressurized bait (0.125 % ai)	Not Specified	Not Specified	Spot treatment	Spray on congregation sites	Flies; Geographic restriction: CA
	Pressurized insecticide (0.20 % ai)	Not Specified	Not Specified	Spot treatment	Hand-held spray on cracks and crevices	Ants; Geographic restriction: CA
Termite and other wood-destroying insect applications in commercial and residential settings	SC	0.00065 lbs ai/Linear ft^A	Not Specified	Localized spot or partial area	Hand-held liquid spray	Trenching or soil excavation
	Foam	Unspecified	Not Specified	Spot treatment	Hand-held foam spray on cracks and crevices	Small spot treatment allowed for outdoor use

[A] Applicate rate (lbs a.i./linear ft) = (0.835 lbs a.i./128 fl oz) * (0.5 fl oz/1 gallon) * (2 gallon/10 linear ft) * = 0.00065 lbs a.i./linear ft.

3.2.1 Label Uncertainties

There are no salient uncertainties for this assessment resulting from the use directions in the most recently updated proposed labels.

4 Residues of Concern

In this risk assessment, the stressors are those chemicals that may exert adverse effects on non-target organisms. Collectively, the stressors of concern are known as the Residues of Concern (ROC). The ROC usually includes the active ingredient, or parent chemical (*i.e.*, broflanilide). Degradates may be included in, or excluded from, the ROC based on submitted toxicity data, the level of formation relative to the application rate of the parent compound in laboratory studies, modeled exposure estimates, and quantitative structure-activity relationships (QSARs). Structure-activity analysis may be qualitative, based on retention of functional groups in the degradate, or it may be quantitative, using programs such as the Ecological Structure Activity Relationship (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model), the Organization for Economic Cooperation and Development (OECD) QSAR Toolbox (http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm), the EPA Assessment Tools for the Evaluation of Risk (ASTER; https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=&dirEntryID=2804), or others.

The ROC for the aquatic exposure assessment includes the parent compound (broflanilide) alone based on the potential for exposure to each degradate as indicated by their presence and magnitude (as a percentage of the applied broflanilide) in the laboratory and field studies. Major degradates ($\geq$10% of the applied parent) include DC-8007, AB-Oxa, S(Br-OH)-8007, MFBA benzoic acid, and carbon dioxide in some of the laboratory and field studies (**Appendix B**). Degradate DC-8007 is the only major, organic transformation product in environmentally relevant matrices, having formed in aerobic and anaerobic aquatic environments. Other major organic degradates (AB-Oxa, S(Br-OH)-8007, MFBA and benzoic acid) were identified in acidic and alkaline conditions of the aqueous photolysis study. These degradates may not be relevant under a neutral aquatic environment. In addition to their low exposure potential compared to broflanilide, aquatic and terrestrial animal toxicity data submitted to the agency show that these degradates are orders of magnitude less toxic than broflanilide.

5 Environmental Fate and Transport Characterization

Physical and chemical properties for broflanilide are presented in **Table 5-1**. Broflanilide has a low solubility in water (0.71 mg/L at 20°C). Its vapor pressure of 2.4×10^{-11} torr and Henry's law Constant of 3.0×10^{-14} atm-m^3/mol (20°C) suggest volatilization is not a major dissipation pathway from dry or moist soils. Soil adsorption coefficient (K_F) values of 113 to 248 mL/g indicate low mobility in soil. The mean K_F values of 48 L/kg for DM-8007 and 17 L/kg for DC-DM-8007 **(Table 5-2)** suggest that the degradates are more mobile than broflanilide. The coefficients of variation suggest that K_F values are a better descriptor of broflanilide sorption to soil than K_{FOC} **(Table 5.1)**. The Log Kow of 5.2 at pH 4 and 7 suggests broflanilide has the potential for bioaccumulation. The bioconcentration factors in rainbow trout whole fish tissues are 266-364X. If contaminated fish reach uncontaminated water, depuration is gradual, with >95% of the total residues accumulated during 28 days of exposure eliminated in 10 days (MRID

50211451). The degradate (DM-8007) of broflanilide was observed in the edible and non-edible tissues in the BCF study indicating that metabolism may be contributing to the depuration rate in the BCF study. However, no radioactivity was detected in the tank water during the depuration phase.

Table 5-1. Summary of Physical-Chemical, Sorption, and Bioconcentration Properties of Broflanilide

Parameter	Value[A]				Source/ Study Classification/ Comment
Molecular Weight (g/mol)	663.29				MRID 50211316 In Review
Water Solubility at 20°C (mg/L)	0.71				
Vapor Pressure (torr)	2.4×10^{-11} (20°C) 6.6×10^{-11} (25°C)				
Henry's Law constant at 20°C (atm-m^3/mol)	3.0×10^{-14}				
Log Dissociation Constant (pKa)	8.8				MRID 50211316 In Review Expected to partially ionize under alkaline pH
Octanol-water partition coefficient (K_{ow}) at 25°C (unitless)	5.2 @ pH 4 and 7 4.4 @ pH 10				MRID 50211316 In Review
Air-water Partition Coefficient (log K_{AW}) (unitless)	log K_{AW} = -6.44				EPIWEB 4.1 (estimated value)[C]. non-volatile from water
Freundlich Soil-Water Distribution Coefficients (K_F in L/kg-soil or sediment) Organic carbon normalized Freundlich distribution coefficients (K_{Foc} in L/kg-organic carbon)	**Soil/Sediment**	**K_F**	**K_{FOC}**	**1/N**	MRID 50211432 Acceptable. Slightly to Hardly Mobile (FAO classification system); K_F better predictor of sorption based on lower CV.
	ND Loam	246	6474	1.0	
	CA sandy loam	113	20204	0.99	
	NB loam	116	5797	0.92	
	UK silt loam	181	4643	0.90	
	ND loam	248	3596	0.93	
	Goose River Sediment	158	4924	0.86	
	Mean	177	7606	--	
	CV[B]	0.34	0.82	--	
	Japan Sandy[D] loam	*89*	*2952*	*0.98*	
Steady State Bioconcentration Factor (BCF) L/kg-wet weight fish or L/kg wet weight lipid	**Species**	**BCF**		**Depuration**	MRID 50211562 Acceptable. BCF values were based on a low dose of 1.0 µg/L and a high dose of 10 µg/L. BCF values for the higher dose are slightly lower than those for the lower dose.
	Rainbow trout (*Oncorhynchus mykiss*)	Edible 175-240X Nonedible 344-468X Whole fish 266-364X		>95% in 10 days	

Parameter	Value[A]	Source/ Study Classification/ Comment
[A] All estimated values were calculated according to "*Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in Problem Formulations for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*" (USEPA, 2010). [B] CV=Coefficient of Variation [D] Due to the volcanic parent material of the Japanese soil that is not comparable to most US soils, these K_F and K_{FOC} values were not included to calculate mean and CV values. -- = Not Applicable		

Table 5-2. Summary of Soil Sorption Coefficients of Broflanilide Degradates

Parameter	Soil/Sediment	Degradates						Source/ Study Classification/ Comment
		DC-8007			DC-DM-8007			
		K_F	K_{FOC}	1/N	K_F	K_{FOC}	1/N	
Soil adsorption coefficients K_F and K_{FOC} (L/kg)	ND loam	85	1984	1.10	29	681	0.91	MRIDs 50211433 & 50211434 Acceptable.
	NB loam	31	1496	0.97	14	668	0.94	
	TX sand	15	5097	0.96	4	1489	0.99	
	TX clay loam	72	2333	1.03	22	707	0.88	
	CA sandy loam	36	4504	0.99	14	1746	0.81	
Mean	All soils	48	3083	--	17	1058	--	
CV	All soils	0.62	0.52	--	0.57	0.49	--	
-- = Not applicable								

The environmental fate properties of broflanilide are listed in **Table 5-3**. Broflanilide is stable to hydrolysis and soil photolysis and persists in soil and water bodies under aerobic and anaerobic conditions with half-lives of 157 to 5,700 days. Aqueous photolysis may be the main route of degradation, and is pH dependent, with half-lives of 18 days at pH 5, 80 days at pH 7, and 4 days at pH 9. The major photodegradation products at pH 5 were S(Br-OH)-8007 (up to 14% of the applied), MFBA (up to 20% of the applied), and benzoic acid (up to 26% of the applied). At pH 9, the major photodegradation products were MFBA (up to 26% AR), benzoic acid (up to 44% of AR), and AB-oxa (up to 38% of AR). There were no major photodegradation products at pH 7. Several minor degradates (S(PFP-OH)-8007, S(F-OH)-8007, and DBr-8007) were also identified in the aqueous photolysis study. Photodegradation in basic or acidic aquatic environments could be a more important route of degradation as compared to photolysis in neutral conditions.

Table 5-3. Summary of Environmental Fate Properties of Broflanilide

Study	System Details	Half-life (days)[A,B]	Classification/Comment
Abiotic Hydrolysis	pH 5, 7, and 9, 50°C	Stable	MRID 50211328, Acceptable
Aqueous Photolysis	pH 7, 20°C 40°N sunlight	80 (SFO) @ pH 7	MRID 50211329, Acceptable
	pH 5 and 9, 20°C 40°N sunlight	18 (SFO) @ pH 5 4 (SFO) @ pH 9	MRID 50211330, Acceptable
Soil Photolysis	IL Silt Loam, 20°C, pH 5.9 40°N sunlight	Stable	MRID 50211429, Acceptable.
Photolysis in Air	Hydroxyl Radicals Reaction (1.5E6 OH/cm3	2.5	EPIWEB 4.1 (estimated value)[C]. non-volatile from water
Aerobic Soil Metabolism	CA Centerville Clay, 20°C	1173 (SFO) (*829 @ 25°C*)[C]	MRID 50211427, Acceptable.
	IL Drummer Silty clay loam, 25°C	2220 (SFO)	MRID 50211430, Acceptable. Reported half-lives were based on 365 days sampling data.
	NC Norfolk sandy loam 25°C	1485 (SFO)	
	TN Falaya Silt loam, 25ºC	2135 (SFO)	
Anaerobic Soil Metabolism	CA Centerville Clay, 20°C	1117 (SFO)	MRID 50211430, Acceptable.
	IL Drummer Silty clay loam, 20°C	157 (SFO)	
	NC Norfolk sandy loam 20°C	2354 (SFO)	
	TN Falaya Silt loam, 25ºC	1113 (SFO)	
Aerobic Aquatic Metabolism	Brandywine Creek Sediment from PA, 20°C	1430 (DFOP)	MRID 50211437, Acceptable
	Choptank River Sediment from MD, 20°C	945 (SFO)	
Anaerobic Aquatic Metabolism	Brandywine Creek Sediment from PA, 20°C	871 (SFO)	MRID 50211438, Acceptable
	Choptank River Sediment from MD, 20°C	1411 (SFO)	

[A] The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the DFOP slow DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media* (NAFTA, 2012).
[B] SFO=single first order; DFOP=double first order in parallel; IORE=indeterminate order (IORE); SFO DT_{50}=single first order half-life; T_{IORE}=the half-life of a SFO model that passes through a hypothetical DT_{90} of the IORE fit; DFOP slow DT_{50}=slow rate half-life of the DFOP fit.
[C] Since all the reported DT_{50} values were based on 20°C for aerobic soil metabolism except for this soil, the reported half-life value was adjusted to 25°C based on a Q_{10} of 2.0.

Broflanilide persists in terrestrial and aquatic environments. In aerobic soil, the DT_{50} values of broflanilide were calculated to be 829, 1485, 2135 and 2220 days for CA, NC, TN and IL soils, respectively. There were no major (>10% of applied radioactivity (AR) degradation products but several minor transformation products were detected in soil. Very little mineralization in soil was observed with levels of CO_2 reaching a maximum of 1.2% AR after 365 days of incubation. The estimated half-life values of broflanilide in anaerobic soil were 157, 1113, 1117 and 2354 days for the IL, TN, CA and NC soils, respectively, indicating that broflanilide is persistent in soil under both aerobic and anaerobic conditions. There was only one major transformation product observed, DC-8007, at a maximum amount of 74% AR in the anaerobic soil metabolism study. Several minor degradates (S(PFP-OH)-8007, DM-8007, and DC-DM-8007) were identified in soil/sediment metabolism studies. Percent formation of transformation products from broflanilide studies is provided in **Table B-1 (Appendix B)**.

Broflanilide is also persistent (DT_{50}s of 945 and 1430 days) under stratified redox test conditions in sediment samples from Choptank River, MD and Brandywine Creek, PA under aerobic aquatic conditions. Similar DT_{50}s of 871 to 1411 days were observed under anaerobic aquatic conditions. The only major transformation product under both aerobic and anaerobic aquatic conditions was DC-8007, detected at 12% to 18% in a Brandywine Creek sediment.

Several other unidentified minor transformation products (Unidentified Extracted Residues [UER]) in **Table B-1 (Appendix B)** were detected at maximum individual concentrations of <10% of AR in various environmental fate studies; however, the maximum total concentrations of unidentified transformation products reached very high levels of 45% AR at pH 5 and 65% AR at pH 9 in the aqueous photolysis study.

Unextracted residues (UR) accounted for 5% to 14% of the applied in the environmental fate metabolism studies. Soil samples with high amounts of URs from an aerobic soil metabolism study (MRID 50211427) were used to determine the residue extractability using methanol:water (high dielectric constant), followed by ethyl acetate (polar with low dielectric constant), then hexane (non-polar) and lastly dioxane (non-polar) as extraction solvents. The extraction procedure with multiple solvents of different dielectric constants did not significantly reduce the amounts of URs. The additional solvents did not extract more than 1.4% of the applied (<LOQ to 1.4% of applied was extracted), which indicates that the majority of URs were strongly bound with the soil or sediment.

Terrestrial field dissipation (TFD) of broflanilide was studied using bare ground plots at five sites in the U.S.A., including sites in North Carolina, Florida, California, Washington, and North Dakota. A summary of TFD data is provided in **Table 5-4**. Dissipation half-lives values ranged from 13 to 188 days across the five sites in the United States. Based on the results observed in the TFD studies, broflanilide dissipated in all locations with the formation of low levels of degradates [DM-8007, S(PFP-OH)-8007, DC-DM-8007 and DC-8007]. None of the residues appeared inherently prone to leaching and remained almost exclusively in the topsoil (0-6 inches), which is consistent with the relatively high soil adsorption coefficients of broflanilide and its degradates.

Overall, these terrestrial field dissipation results indicate that the persistence is highly dependent on the environmental conditions. While most residues in terrestrial field dissipation studies remained in the top soil layer, residues were detected in the lowest depth of 6 inches

(15 cm) sampled. This indicates that broflanilide has low potential to leach to groundwater in most but not all environments. While field dissipation studies are designed to capture a range of loss processes; laboratory studies are designed to capture loss from one process (*e.g.*, hydrolysis or aerobic metabolism). In additon, a non-guideline outdoor aerobic soil metabolism study (MRID 50211560) was conducted on bare soil under field conditions at two sites in California and Georgia. Most of the applied material and resulting degradation products were confined to the uppermost 0-5 cm horizon throughout the study resulting in no significant losses via leaching to lower depths. Dissipation/degradation half-lives values ranged from 57 days for California site and 182 days for Georgia site, are similar to TFD half-lives. Thus, the degradation half-lives from the laboratory studies (DT_{50}s of 829 to 2220 days) are not directly comparable to the dissipation half-lives from the field studies (38 to 188 days); however, it is informative to have some understanding of how the laboratory data compares to the loss rates in the field dissipation studies.

Table 5-4. Summary of Field Dissipation Data for Broflanilide

Study	System Details	Broflanilide Half-life (days)[1,2]	Max Leaching Soil Core Depth (cm)	Source, Classification
Terrestrial Field Dissipation (DT_{50})	Southern Coastal Plain, NC	38 (IORE)	0-15	MRID 50211431, Acceptable
	Southern Florida Flatwoods, FL	57 (IORE)	0-15	
	Sacramento and San Joaquin Valleys, CA	118 (IORE)	0-15	
	Columbia Basin, WA	13 (IORE)	0-15	
	Red River Valley of the North, ND	188 (IORE)	0-15	

[1] The value used to estimate a half-life value is the calculated SFO DT_{50}, T_{IORE}, or the DFOP slow DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media* (NAFTA, 2012).
[2] IORE=indeterminate order (IORE); T_{IORE}=the half-life of a SFO model that passes through a hypothetical DT_{90} of the IORE fit.

6 Ecotoxicity Summary

Ecological effects data are used to estimate the toxicity of broflanilide to animals and plants. Ecotoxicity data for broflanilide and its associated degradates (including DC-DM-8007, DC-8007, DM-8007, AB-Oxa, S(Br-OH)-8007, and MFBA) have been submitted in support of this ecological risk assessment. The most sensitive endpoints from the data package are summarized in **Section 6.1** and **Section 6.2**, and the remainder of the data are presented in **Appendix D**.

Because the aquatic and terrestrial toxicity data for the degradates are orders of magnitude less toxic than broflanilide, their discussion is limited to **Appendix D.**

Table 6-1 and **Table 6-2** summarize the most sensitive measured toxicity endpoints available across taxa. These endpoints may not capture the most sensitive toxicity endpoint for a particular taxon but capture the most sensitive endpoint across tested species for each taxon for which data were submitted. All studies in this table are classified as acceptable or supplemental. Non-definitive endpoints are designated with a greater than (>) or less than (<) value.

6.1 Aquatic Toxicity

Table 6-1 summarizes the most sensitive toxicity endpoints for aquatic organisms; a more comprehensive list of toxicity data for aquatic organisms is presented in **Appendix D.** In instances where the most sensitive endpoint was derived with typical end-use product (TEP), data are included along with the most sensitive endpoint derived with technical grade active ingredient (TGAI).

Fish

Several acute freshwater fish studies were submitted to the agency. The most sensitive of these was a test on the bluegill (*Lepomis macrochirus*) which resulted in an LC_{50} of 251 µg a.i./L. There was a steep dose response with 3% mortality at 158 µg a.i./L and 100% mortality at 290 µg a.i./L, contributing to uncertainty in the estimated LC_{50}. Similarly, in a study with rainbow trout (*Oncorhynchus mykiss*) the LC_{50} = 359 µg a.i./L with a steep dose response (<260 µg a.i./L no mortality, and doses 260 µg a.i./L with 15% and 649 µg a.i./L with 100% mortality). These responses contribute to the uncertainty in the estimated acute endpoints for these studies. The other two studies testing fathead minnow (*Pimphales promelas*) and Carp (*Cyprinus carpio*) each had few mortalities at their highest tested concentrations so estimated LC_{50}s were non-definitive (>508 and >498 µg a.i./L respectively). The only estuarine marine acute fish study, tested sheepshead minnow (*Cyprinodon variegatus*) also had limited mortality 10% mortality and an LC_{50} > 1300 µg a.i./L.

Two early life-stage chronic fish toxicity studies testing the sensitivity of fathead minnow (*Pimphales promelas*) and sheepshead minnow (*Cyprinodon variegatus*) were submitted. In the fathead minnow study, there were statistically significant 9% and 85% reductions in larval survival at 147 and 475 µg a.i./L. respectively; therefore, the NOAEC was established at 51 µg a.i./L. The 475 µg a.i./L test concentration also showed significant effects to weight (68 - 72 % reduction) and length (33% reduction). Given the apparent difference in sensitivity among fish test species, it is unknown if bluegill or rainbow trout would result in more sensitive endpoints that those provided in the fathead minnow test. Typically, an acute to chronic ratio would be used to estimate the NOAECs for these taxa, however in this case the acute fathead minnow study did not result in a definitive LC50 and had little mortality. So, this remains an uncertainty for freshwater fish. In the sheepshead minnow study, the NOAEC was established at 11 µg a.i./L., based on reduced length (4%), dry weight (10-13%), wet weight (10%), and time to hatch (16%) at 25.2 µg a.i./L. Additionally, significant reduction in survival (91%) was observed at 159 µg a.i./L.

Water Column Invertebrates

Acute freshwater invertebrate data testing daphnia (*Daphnia magna*) showed no effects up to the highest tested concentration, 322 µg a.i./L, therefore the LC_{50} is >322 µg a.i./L. Acute studies on the eastern oyster (*Crassostrea virginica*) and mysid (*Americamysis bahia*) were also submitted. The oyster study showed no effects up to the highest tested concentration (LC_{50} > 440 µg a.i./L). The mysid was sensitive to broflanilide under the conditions of the test, with an LC_{50} of 0.0215 µg a.i./L. There was a steep dose response with 35%, 95% and 100% mortality at 0.0202, 0.0284, and 0.0428 µg a.i./L respectively. Mysids in the 0.0107 µg a.i./L test concentration showed no signs of chemical stress.

Chronic *Daphnia* and mysid toxicity studies showed sensitivity to broflanilide. The available daphnia study resulted in a NOAEC of 5.93 µg a.i./L based upon 6-8% reductions in length, total offspring, birth rate, and time to first brood at 11.6 µg a.i./L. The submitted mysid chronic toxicity study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female.

Benthic Invertebrates

Three sub-chronic (10-day) toxicity studies on benthic invertebrates were submitted. In a static renewal sediment test with *Chironomus dilutus* the LC_{50} was 9.99 µg ai/kg dry sediment (0.211 µg ai/L pore water, 454 µg ai/kg-OC (organic carbon normalized sediment)) based on mean-measured concentrations. The NOAEC for survival was 1.5 µg/kg dry sediment (0.032 µg/L pore water, 68 µg ai/kg OC) based on 9% reduction in survival at the LOAEC (4.8 µg/kg dry sediment). In a static renewal sediment test with *Hyalella azteca* the LC_{50} was 13.5 µg ai/kg dry sediment (0.461 µg ai/L pore water, 752 µg ai/kg OC) based on mean measured concentrations. The NOAEC for survival was 4.9 µg ai/kg dry sediment (0.16 µg ai/L pore water, 270 µg ai/kg OC) based on 12% reduced survival at the LOAEC (9.5 µg ai/kg dry sediment). In a study testing the estuarine/marine invertebrate *Leptocheirus plumulosus,* the LC_{50} was determined as 14 µg ai/kg dry sediment (0.079 µg ai/L pore water[1], 410 µg ai/kg-organic carbon) based on mean-measured concentrations. The NOAEC for survival was 9.6 µg ai/kg dry sediment (0.054 µg ai/L pore water, 0.29 µg ai/kg OC) based on 100% reduced survival at the LOAEC (20 µg ai/kg dry sediment).

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[1] Measured pore water concentrations were not provided in the study. As described above the sorption of broflanilide to sediments is best described by K_f. Therefore, the K_F was determined more appropriate for estimating pore water concentrations from the measured bulk sediment concentrationsPore Water Concentration (µg a.i./L pore water) = Endpoint (µg ai/kg-sediment)/(K_F); K_F= 177 L/kg-sediment

Three chronic toxicity studies on benthic invertebrates were also submitted. In a 60-day static-renewal sediment test with *Chironomus dilutus*, the overall NOAEC was 1.5 µg ai/kg dry sediment (0.024 µg ai/L pore water; 67 µg ai/kg OC) based on 20% reduced survival and 36% reduced percent emergence. No other endpoints were significantly affected by exposure to the test material. There was significant solvent interference in the study which was considered when selecting the NOAEC from among the responses for these endpoints. In a 42-day reproduction study on *Hyalella azteca,* significant solvent effects were observed for several endpoints, confounding the interpretation of the chemical response. This was considered when determining the NOAECs and LOAECs for the measured endpoints. The overall NOAEC was non-definitive (< 1.7 µg ai/kg dry sediment; <0.039 µg ai/L pore water; < 91 µg ai/kg OC) based on a 46% reduction in male to female ratio. NOAECs were also determined for survival (6.7 µg ai/kg dry sediment; >20% reductions) and reproduction (3.3 µg ai/kg dry sediment; >45% reductions). In a 28-day spiked sediment test with *Leptocheirus plumulosus*, the NOAEC was determined to be 3.8 µg ai/kg dry sediment (0.021 µg ai/L pore water; 130 µg ai/kg OC) based on 12% reduced survival at the LOAEC (8.4 µg a.i./kg dry sediment). No effects to growth or reproduction were observed.

Aquatic Plants

The most sensitive aquatic non-vascular plant toxicity study with technical grade broflanilide was a static toxicity study (MRID 50211458) with *Skeletonema costatum*, in which there were significant ($p<0.05$) reductions in cell density. The 96-hour IC_{50} is 570 µg a.i./L and a NOAEC of 160 µg a.i./L. No other tested species showed effects.

In a static toxicity study of broflanilide (MRID 50211464) with the freshwater vascular plant duckweed (*Lemna gibba*), there were no observed chemical effects (IC_{50} > 630 µg a.i./L; NOAEC > 630 µg a.i./L)

Table 6-1. Aquatic Toxicity Endpoints Selected for Risk Quotient Calculations for Broflanilide

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)[1]	MRID/ Classification	Comments
Freshwater Fish (surrogates for vertebrates)					
Acute	TGAI 99% ai	Bluegill *Lepomis macrochirus*	96-h LC_{50} = 251	50211452 Acceptable	Static renewal test Since the dose response is so steep, there is uncertainty in the estimated LC_{50}; the true LC_{50} falls above 158 µg a.i./L (3% mortality) and below 290 µg a.i./L (100% mortality).
Chronic	TGAI 99% ai	Fathead Minnow *Pimphales promelas*	34-Day NOAEC = 51 LOAEC = 147	50211449 Acceptable	based on reduced larval survival (9%) at LOAEC

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)[1]	MRID/ Classification	Comments
Estuarine/marine Fish (Surrogates for vertebrates)					
Acute	TGAI 99% ai	Sheepshead Minnow *Cyprinodon variegatus*	96-h LC_{50} = >1300	50211490 Acceptable	10% mortality at 1300 µg a.i./L
Chronic	TGAI 99% ai	Sheepshead Minnow *Cyprinodon variegatus*	34-Day NOAEC = 11 LOAEC = 25	50211450 Acceptable	based on reduced length (4%), dry weight (10-13%), wet weight (10%), time to hatch (16%).
Freshwater Invertebrates					
Acute	TGAI 99% ai	Water Flea *Daphnia magna*	48-h LC_{50} > 322	50211452 Acceptable	No effects at highest test concentration
Chronic	TGAI 99% ai	Water Flea *Daphnia magna*	21-Day NOAEC = 5.93 LOAEC = 11.6	50211566 Acceptable	LOAEC based on 6-8% reductions in length, total offspring, birth rate, and time to first brood
Estuarine/marine Invertebrates					
Acute	TGAI 99% ai	Mysid *Americamysis bahia*	96-h LC_{50} = 0.0215	50211485 Acceptable	none
Chronic	TGAI 99% ai	Mysid *Americamysis bahia*	28-Day NOAEC < 0.0018 LOAEC = 0.0018	50211488 Supplemental	LOAEC based on F1 survival 18% reduced survival and 22% less offspring per female. Classification based on lack of a definitive NOAEC.
Freshwater Invertebrate (sediment)					
Sub-chronic	TGAI 99% ai	Midge *Chironomus dilutus*	10-day NOAEC = 1.5 µg/kg dry sediment (0.032 µg/L pore water, 68 µg ai/kg OC) based on 9% reduction in survival at the LOAEC (4.8 µg/kg dry sediment).	50211459 Acceptable	LC_{50} = 9.99 µg ai/kg dry sediment LC_{50} = 454 µg a.i./kg- OC LC_{50} = 0.211 µg a.i./L-pore water
Sub-chronic	TGAI 99% ai	Amphipod *Hyalella azteca*	10-day NOAEC = 4.9 µg ai/kg dry sediment (0.16 µg ai/L pore water, 270 µg ai/kg OC) based on 12% reduced survival at the LOAEC (9.5 µg ai/kg dry sediment).	50211460 Acceptable	LC_{50} = 13.5 µg ai/kg dry sediment LC_{50} = 752 µg ai/kg OC LC_{50} = 0.461 µg ai/L pore water

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)[1]	MRID/ Classification	Comments
Chronic	TGAI 99% ai	Midge *Chironomus dilutus*	60-day NOAEC = 1.5 LOAEC = 4.7 µg ai/kg dry sediment NOAEC = 67 LOAEC = 213 µg ai/kg OC NOAEC = 0.024 LOAEC = 0.079 µg ai/L pore water	50211461 Acceptable	LOAEC Based on 36% reduction in percent emergence and 20% reduction in survival.
Chronic	TGAI 99% ai	Amphipod *Hyalella azteca*	42-day NOAEC < 1.7 LOAEC = 1.7 µg ai/kg dry sediment NOAEC < 91 LOAEC = 91 µg ai/kg OC NOAEC < 0.039 LOAEC = 0.039 µg ai/L pore water	50211462 Supplemental	Significant solvent effects were observed for several endpoints, confounding the interpretation of the chemical response. LOAEC based on 46% reduction in male to female ratio. Other NOAECs: Survival = 6.7 µg ai/kg dry sediment (>20% reductions) Reproduction & Number of Offspring/female = 3.3 µg ai/kg dry sediment (>45% reductions)
Saltwater invertebrate (sediment)					
Sub-chronic	TGAI 99% ai	Amphipod *Leptocheirus plumulosus*	10-day NOAEC = 9.6 µg ai/kg dry sediment (0.054 µg ai/L pore water, 290 µg ai/kg OC) based on 100% reduced survival at the LOAEC (20 µg ai/kg dry sediment).	50211487 Acceptable	Sediment Spiked Estimated pore water concentrations. LC_{50} = 14 µg ai/kg dry sediment LC_{50} = 410 µg ai/kg-OC LC_{50} = 0.079 µg ai/L pore water

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)[1]	MRID/ Classification	Comments
Chronic	TGAI 99% ai	Amphipod *Leptocheirus plumulosus*	28-day NOAEC = 3.8 LOAEC = 8.4 µg ai/kg dry sediment NOAEC = 130 LOAEC = 290 µg ai/kg OC NOAEC = 0.021 LOAEC = 0.048 µg ai/L pore water	50211463 Acceptable	Overlying water spiked (refreshed 12 times day) Estimated pore water concentrations. LOAEC Based on 36% reduction in percent emergence and 12% reduction in survival.
Aquatic plants and algae					
Vascular	TGAI 99% ai	Duckweed *Lemna gibba*	EC_{50} > 630 NOAEC = 630	50211464 Acceptable	No effects
Non-vascular	TGAI 99% ai	Marine Diatom *Skeletonema costatum*	9-d EC_{50} = 570 NOAEC = 160	50211458 Acceptable	Cell density

TGAI=Technical Grade Active Ingredient; TEP= Typical end-use product; a.i.=active ingredient
[1] NOAEC and LOAEC are reported in the same units.
>Greater than values designate non-definitive endpoints where no effects were observed at the highest level tested, or effects did not reach 50% at the highest concentration tested (USEPA, 2011).
< Less than values designate non-definitive endpoints where growth, reproductive, and/or mortality effects are observed at the lowest tested concentration.

6.2 Terrestrial Toxicity

Table 6-2 contains a summary of the most sensitive toxicity values for terrestrial organisms; a more comprehensive list of toxicity data for terrestrial organisms is presented in **Appendix D**. In instances where the most sensitive endpoint was derived with TEP, it is included along with the most sensitive endpoint derived with the TGAI. Available toxicity data for birds are used as a surrogate for toxicity to terrestrial-phase amphibians and reptiles.

Birds

An acute oral toxicity tests of TGAI with bobwhite quail (*Colinus virginianus*; MRID 50211439), mallard duck (*Anas platyrhynchos*; MRID 50211440), and canary (*Serinus canaria*; MRID 50211441) reported no effects in response broflanilide at 2000 mg a.i./kg-bw. Based on these data, broflanilide is classified as practically non-toxic to birds on an acute oral exposure basis.

No mortalities or sublethal effects were observed in subacute dietary toxicity studies with bobwhite quail (*Colinus virginianus*; MRID 5021143) or mallard duck (*Anas platyrhynchos*; MRID 50211442). The LC_{50s} are >5000 mg a.i./kg-diet. Based on these data, broflanilide is classified as practically non-toxic to birds on a subacute dietary exposure basis.

In an avian reproduction study with mallard ducks (MRID 50211561), growth and reproductive effects (reduced eggs laid and 14% reduction in surviving hatchlings) were observed at 87.4 mg a.i./kg-diet (NOAEC = 29.7 mg a.i./kg-diet). At the 276 mg ai/kg diet test concentration, there were slight reductions in egg production that were considered to have been related to treatment. Additionally, there were slight (5-6%), but significant dose-dependent reductions from control on survivor weights at the 87.4 and 276 mg ai/kg diet treatment levels. There were no other treatment-related effects observed. A reproduction study with bobwhite quail (MRID 50211445) showed significant inhibitions in 14-days survivors/hatchling at the mean-measured 506 and 1021 mg ai/kg diet treatment groups, and in 14-day survivor weight at the mean-measured 1021 mg ai/kg diet (NOAEC = 254 mg a.i./kg-diet).

Mammals

An acute oral toxicity study with rats (*Rattus norvegicus*; MRID 50211349) reported no chemical related effects at the highest tested concentration (LD_{50} > 5000 mg a.i./kg-bw). Therefore, broflanilide is considered practically non-toxic to mammals on an acute oral exposure basis.

In a two-generation reproduction study (MRID 49575319) with rats (*R. norvegicus*), there were no observed effects related to growth or survival of adults, however decreased pup weights were observed in both male and female F1 pups (5-7%) and this increased in F2 pups (6-10%) at 1500 and 15000 ppm. The study NOAEC based on the pup weight effects is 300 mg a.i./kg-diet (26 mg a.i./kg-bw/day).

Terrestrial Invertebrates (Bees)

Broflanilide is highly toxic to honey bees and bumble bees on both an acute contact and oral exposure basis. In an acute (single dose) contact and acute oral combined toxicity study with adult honey bees (*Apis mellifera*; MRID 50211466), technical grade active ingredient (≥98% ai) was used. The study provided the most sensitive 48-hr contact LD_{50} = 0.0088 µg a.i./bee as well as the most sensitive acute oral LD_{50} = 0.0149 µg a.i./bee. Two additional acute oral and acute contact toxicity studies on adult honey bees with TGAI (98% a.i.; MRID 50124717) and TEP (9.6% a.i.; MRID 50325607) were submitted. Acute contact LD_{50s} estimated from these studies ranged from 0.012 to 0.017 µg a.i./bee and acute oral LD_{50}s ranging from 0.045 to 0.0693 µg a.i./bee (details in **Appendix D**). Additional broflanilide toxicity studies were conducted using TGAI (98% a.i; MRID 50211466) and TEP (9.6% a.i.; MRID 50325608) with the social non-*Apis* bumblebee *Bombus terrestris*. In the contact toxicity tests, the 48 hr LD_{50s} were >0.120 and 0.122 µg a.i./bee respectively. These studies also tested the acute oral toxicity of the compounds with bumblebees; 48-hour acute oral LD_{50s} were 0.0195 and 0.0139 µg a.i./bee respectively. An acute (1-day) exposure toxicity test with larval honey bees conducted with TGAI (98% a.i.; MRID 50211471) was submitted. This resulted in an 8-day LD_{50} of >0.029 µg a.i./larva/day. Significant mortality (36%) was observed at the highest tested concentration 0.029 µg a.i./larva/day. Based on these results, broflanilide is considered highly toxic to adult and larval bees.

A 10-day chronic (repeat dose) toxicity test with adult honeybees (MRID 50211469) conducted with broflanilide technical (98% a.i.) resulted in NOAEL of 0.00062 µg a.i./bee/day and LOAEL of 0.0011 µg a.i./bee/day based on 30% mortality. Surviving bees at the LOAEL were reported to show uncoordinated movements. The next two doses 0.00237 and 0.0049 µg a.i./bee/day resulted in 93 and 100% mortality.

A 22-day chronic (repeat dose) toxicity test with larval honeybees (MRID 50211472) conducted with TGAI (98% a.i) resulted in a NOAEL of 0.000080 µg a.i./larva/day based on 18% larval mortality at 0.00027 µg a.i./larva/day. This result was not statistically significant; however mortality followed a dose response and this level of response was considered to be biologically significant. Pupal mortality and percent emergence were also significantly affected by exposure with NOAELs of 0.0008 µg a.i./larva/day.

Terrestrial Plants

Submitted terrestrial plant seedling emergence (MRID 50325617) and vegetative vigor (MRID 50325616) studies were conducted on *Allium cepa* (onion), *Lolium perenne* (ryegrass), *Triticum aestivum* (wheat), *Zea mays* (corn), *Beta vulgaris* (sugar beet), *Brassica napus* (rape), *Brassica oleracea* (cabbage), *Glycine max* (soybean), *Lactuca sativa* (lettuce), *and Lycopersicon esculentum* (tomato) with a TEP (9.6% a.i.). In the vegetative vigor study, the most sensitive dicots were sugar beet (NOAEC < 0.0023 lb a.i./A) and cabbage (NOAEC = 0.014 lb a.i./A); however, the observations did not manifest in a dose response manner and regression-based toxicity endpoints (IC_{25s}) were highly uncertain. No other plants tested in the vegetative vigor or seedling emergence studies responded to the formulations; therefore, the IC_{25}s for monocots and dicots for both studies were determined to be >0.091 lbs a.i./A.

Table 6-2. Terrestrial Toxicity Endpoints Selected for Risk Estimation for Broflanilide.

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Birds (surrogates for terrestrial amphibians and reptiles)					
Acute Oral	TGAI (98.67%)	Mallard duck (*Anas platyrhynchos*)	LD_{50} > 2000 mg a.i./kg-bw	50211440 (Acceptable)	Practically Non-Toxic No effects
Sub-acute dietary	TGAI (98.67%)	Mallard duck (*Anas platyrhynchos*)	LC50 > 5000 mg a.i./kg-diet LD50 > 1364 mg a.i./kg-bw	50211443 (Acceptable)	Practically non-toxic. No effects
Chronic	TGAI (98.67%)	Mallard duck (*Anas platyrhynchos*)	NOAEC = 29.7 mg LOAEC = 87.4 Mg a.i./kg-diet;	50211561 (Acceptable)	decreased eggs laid, and %14-day survivors of hatchlings

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Mammals					
Acute Oral	TGAI (98.67%)	Rat (*Rattus norvegicus*)	LD_{50}: > 5000 mg/kg	50211349 (Acceptable)	Practically non-toxic
Chronic (2-generation reproduction)	TGAI (98.67%)	Rat (*Rattus norvegicus*)	NOAEL = 26 LOAEL = 127 mg a.i./kg-bw/day (both sexes) NOAEC/LOAEC 300/1500 mg a.i./kg-diet	50211379 (Acceptable)	Decreased pup weights observed in both male and female F1 pups (5-7%) and F2 pups (6-10%) at 1500 and 15000 ppm.
Terrestrial invertebrates					
Acute contact (adult)	TGAI (98.67%)	Honey bee (*Apis mellifera* L.)	LD_{50} = 0.0088 µg a.i./bee	50211465 (Acceptable)	Highly toxic
Acute contact (adult)	TGAI (98.67%)	Bumblebee (*Bombus terrestris*)	LD_{50} > 0.120 µg a.i./bee	50211466 (Acceptable)	37% mortality at highest dose, impairment and slow movement at 0.03 ug a.i./bee and greater; no other effects were observed in study
Acute contact (adult)	TEP (9.6%)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.122 µg a.i./bee	50325608 (Acceptable)	Highly toxic
Acute oral (adult)	TGAI (98.67%)	Honey bee (*Apis mellifera* L.)	LD_{50} = 0.0149 µg a.i./bee	50211465 (Acceptable)	Highly toxic
Acute oral (adult)	TGAI (98.67%)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.0195 µg a.i./bee	50211466 (Acceptable)	Highly toxic
Acute oral (adult)	TEP (9.6%)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.0139 µg a.i./bee	50325608 (Acceptable)	Highly toxic
Chronic oral (adult)	TGAI (98.67%)	Honey bee (*Apis mellifera* L.)	10-day NOAEL = 0.00062 µg a.i./bee/day (0.018 mg a.i./kg-diet) LOAEL = 0.0010 µg a.i./bee/day (0.034 mg ai/kg-diet)	50211469 (Supplemental)	30% mortality at the LOAEC Supplemental because the study did not analytically measure concentrations
Acute oral (larval)	TGAI (98.67%)	Honey bee (*Apis mellifera* L.)	8-day LC_{50} > 0.88 mg a.i./kg-diet LD_{50} > 0.029 µg a.i./larva/day	50211471 (Acceptable)	28% mortality at highest dose compared to controls

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Chronic oral (larval)	TGAI (98.67%)	Honey bee (*Apis mellifera L.*)	22-day NOAEC = 0.00229 mg a.i./kg-diet (0.00008 µg a.i./larva/day) LOAEC = 0.00696 mg a.i./kg-diet (0.00027 µg a.i./larva/day)	50211472 (Acceptable)	Pupal Mortality Test Termination Mortality and Adult Emergence NOAEL = 0.0008 ug a.i./larva/day LOAEL = 0.0022 ug a.i./larva/day Based on 18% increased mortality (reduced emergence) relative to the negative control
Terrestrial and wetland plants					
Vegetative Vigor	TEP (9.6%)	Monocots: *Zea mays* (corn), *Triticum aestivum* (wheat), *Allium cepa* (onion), *Lolium perenne* (ryegrass) Dicots: *Beta vulgaris* (sugar beet), *Lactuca sativa* (lettuce); *Brassica napus* (oilseed rape), *Brassica oleracea* (cabbage), Glycine *max* (soybean), *Lycopersicon esculentum* (tomato)	21-day Dicots (cabbage and sugar beet): EC_{25} = Not Reliable Sugar beet Survival NOAEC < 0.0023 lb a.i./acre Cabbage Survival NOAEC = 0.014 lb a.i./acre Monocots No Effects: EC_{25} > 0.091 lb a.i./acre; NOAEC = 0.091 lb a.i./acre)	50325617 (Acceptable; Supplemental for cabbage and sugar beet)	The most sensitive dicots were sugar beet and cabbage based on survival. The observations did not manifest in a dose response manner and are highly uncertain. No other dicots or monocots showed effects.
Seedling Emergence	TEP (9.6%)		21-day No observed effects to any species: EC_{25} > 0.091 lb a.i./acre; NOAEC = 0.091 lb a.i./acre)	50325616 (Acceptable)	--

TGAI=Technical Grade Active Ingredient; TEP= Typical end-use product; a.i.=active ingredient

[1] NOAEC and LOAEC are reported in the same units.

>Greater than values designate non-definitive endpoints where no effects were observed at the highest level tested, or effects did not reach 50% (for terrestrial plants 25%) at the highest concentration tested (USEPA, 2011).

< Less than values designate non-definitive endpoints where growth, reproductive, and/or mortality effects are observed at the lowest tested concentration.

7 Analysis Plan

7.1 Overall Process

This assessment uses a weight-of-evidence approach that relies heavily, but not exclusively, on a risk quotient (RQ) method. The RQs are calculated by dividing an estimated environmental concentration (EEC) by a toxicity endpoint (*i.e.*, EEC/toxicity endpoint). This is a way to determine if an estimated concentration is expected to be above or below the concentration associated with the effects endpoint. The RQs are compared to regulatory Levels of Concern (LOCs). For acute and chronic risk to non-listed vertebrates, the LOCs are 0.5 and 1.0, respectively, and for non-listed plants, the LOC is 1.0. The acute and chronic risk LOCs for bees are 0.4 and 1.0, respectively. In addition to RQs, other available data can be used to help characterize the potential risks associated with the proposed use of the pesticide. Broflanilide is a new active ingredient and therefore, all the proposed uses on the label were modeled (see **Tables 3-1 and 3-2** of **Section 3**).

7.2 Modeling

Various models are used to calculate aquatic and terrestrial EECs (see **Table 7-1**). The specific models used in this assessment are discussed further below.

Table 7-1. List of the Models Used to Assess Risk

Environment	Taxa of Concern	Exposure Media	Exposure Pathway	Model(s) or Pathway
Aquatic	Vertebrates/ Invertebrates (including sediment dwelling)	Surface water and sediment	Runoff and spray drift to water and sediment	PWC version 1.52[2]
	Aquatic Plants (vascular and nonvascular)			
Terrestrial	Vertebrate	Dietary items	- Dietary residues from liquid sprays (includes residues on foliage, seeds/pods, arthropods, and soil) - Ingestion of seeds	T-REX version 1.5.2[4] -Kenaga nomogram (for liquid foliar sprays) Refinements for Treated Seed (USEPA, 2016)
		Consumption of aquatic organisms	Residues taken up by aquatic organisms	KABAM version 1.0[5]
	Plants	Spray drift/runoff	Runoff and spray drift to plants	TERRPLANT version 1.2.2
	Bees and other terrestrial invertebrates	Contact Dietary items	Spray contact and ingestion of residues in/on dietary items	BeeREX version 1.0

Environment	Taxa of Concern	Exposure Media	Exposure Pathway	Model(s) or Pathway
			as a result of direct application	
All Environments	All	Movement through air to aquatic and terrestrial media	Spray drift	AgDRIFT version 2.1.1 (Spray drift)

[1] Sediment analysis is recommended when the soil-water distribution coefficient (K_F) ≥50-L/kg-soil; the log K_{OW}≥3; or the K_{OC} ≥ 1000 L/kg-organic carbon. Analysis of risk in sediment from exposure in pore water may also occur if aquatic invertebrates are particularly sensitive, as it is expected that RQs will exceed LOCs even if the sediment is not the primary exposure media.
[2] The Pesticide in Water Calculator (PWC) is a Graphic User Interface (GUI) that estimates pesticide concentration in water using the Pesticide Root Zone Model (PRZM) and the Variable Volume Water Model (VVWM). PRZM-VVWM.
[3] Pesticides in Flooded Applications Model (PFAM) is used to simulate EECs when pesticides are applied to flooded or intermittently flooded areas.
[4] The Terrestrial Residue Exposure (T-REX) Model is used to estimate pesticide concentration on avian and mammalian food items.
[5] The K_{OW} based Aquatic Bioaccumulation Model (KABAM) is used to estimate exposure to terrestrial animals that may consume aquatic organisms when a chemical has the potential to bioconcentrate or bioaccumulate. The general triggers for running this model is that: the pesticide is a non-ionic, organic chemical; the Log K_{OW} value is between 3 and 8; and the pesticide has the potential to reach aquatic habitats.

8 Aquatic Organisms Risk Assessment

8.1 Aquatic Exposure Assessment

The non-agricultural uses such as baits, spots and localized termiticide treatments in commercial and residential areas are expected not to be a significant contributor to aquatic exposure based on their application rate and limited spatial extent of use in a given 10-hectare area as compared to agricultural uses (USEPA, 2018). Agricultural uses of broflanilide, on the other hand, are expected to produce substantial exposure in surface water and are, therefore, modeled in this assessment. Exposure modeling was performed using the PWC model (version 1.52) to estimate surface water EECs. The information concerning the model can be found on the EPA Water Models web-page[2].

8.1.1 Model Inputs

Proposed broflanilide labels present numerous possible variations of application rates, application methods, and formulations for modeled agricultural and non-agricultural scenarios. The rates, methods and formulations (**Tables 3-1 and 3-2**) that would likely result in the highest

[2] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

EECs in the PWC model were modeled. **Table 8-1** provides the PWC model input parameters, which were based on the maximum annual application rates and application intervals for corn potato and wheat uses. It also includes PWC scenarios, environmental fate properties and spray drift factors used in the PWC modeling. Environmental fate input parameter values for broflanilide are presented in **Table 8-1**. A revised 90th percentile aerobic soil half-life was used to estimate aquatic exposure (see details in section F-1 in **Appendix F**). Input parameters were selected in accordance with EFED's "Guidance for *Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*," Version 2.1 (USEPA, 2009).

Table 8-1. PC Input Parameters for Broflanilide

Parameter	Input Value and Unit	Comment	Source
Scenario	Corn 10 Corn standard scenarios from IA, IL, IN, KS, MN, MS, NC, NE, OH, and PA Tuberous & corm MEpotatoSTD IDpotatoSTD Seed treatment ND WheatSTD	All standard available scenarios for PWC	PWC Model
Maximum Single Application Rate lbs a.i./A *(Kg a.i./ha)*	Corn, tuberous & corm 0.045*(0.05)* – liquid application Cereal crops 0.0068 (0.0076)	Label directions	Proposed labels
Applications per Year	1 (crops treatment)	Label directions	Tables 3-1 & 3-2
Initial Application Date	Pre-emergence: -7E[A]	Assumed for crop uses based on label directions	Label directions
Application Interval (days)	Not Applicable	Single application	Label directions
Application Method	Crop Uses: Furrow liquid spray	Label directions	Proposed label
Spray drift and application efficiency	**Crops Uses:** Spray Drift Fraction Ground liquid spray: 0 Application Efficiency Ground liquid spray: 1.0	Direct spray into open seed furrow	Assumed [B]
Depth of Incorporation	1 (inch) for corn 4 (inches) for potato	Assumed for crops	Incorporation depths were not specified in labels
Hydrolysis ($t_{1/2}$)	0 (stable)	stable	MRID 00131100
Aerobic soil metabolism ($t_{1/2}$) @25°C	2198 days	Represents the 90th %ile upper confidence limit on the mean of four half-lives (Table 5.3)	Input Guidance[C] MRID 50211427[D] MRID 50211430

Parameter	Input Value and Unit	Comment	Source
Aerobic aquatic metabolism ($t_{1/2}$) @ 20°C	**Total Water/Sediment System** 1934 days	Represents the 90th %ile upper confidence limit on the mean of two half-lives (Table 5.3)	Input Guidance[C] MRID 50211437
Anaerobic aquatic metabolism ($t_{1/2}$) @20°C	**Total Water/Sediment System** 1972 days	Represents the 90th %ile upper confidence limit on the mean of two half-lives (Table 5.3)	Input Guidance[C] MRID 50211438
Aquatic photolysis ($t_{1/2}$) @ 40°N	80.0 days @ pH 7.0	---	MRID 50211329
Vapor pressure @ 25°C	6.6×10^{-11} torr	---	50211316
Solubility in water	0.71 mg/L	---	
Henry's Law constant	3.32×10^{-9} (Unitless)	---	Estiamted: PWC model
Molecular weight	663.29	Parent compound value	MRID 50211316
Partition coefficient K_F (mL/g)	177 mL/g (parent)	The average K_F of 6 values for broflanilide (246, 113, 116, 181, 248, 158 mL/g).	MRID 50211432

[A] 7 days before crop emergence
[B] Spray drift is expected to be negligible from, and the application efficiency is expected to be 100% for, this use because the spray occurs within the open furrow below the surface of the surrounding field.
[C] USEPA, 2009. http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm
[D] Since the reported DT50 was based on 20°C for this study, the half-life value was adjusted to 25°C based on a Q10 of 2.0 before calculating the upper-bound 90th percentile on the mean of all soils.

Recently, the registrant revised the proposed labels for corn and potato to include a vegetative filter strip (VFS) of at least 10 feet between the field and down-gradient aquatic habitat to reduce broflanilide loading into surface water bodies. Currently, the Agency does not quantitatively assess the effectiveness of these practices in reducing pesticide concentrations in runoff. In addition, the current surface water model used by the Agency does not have the capability to account for prescribed setbacks or vegetative buffer distances. While a well-maintained vegetative buffer could potentially intercept broflanilide-laden runoff (both soluble and sediment bound) prior to reaching surface waters, there is still a great deal of uncertainty regarding the performance of buffers, which includes but is not limited to proper design and placement and the duration of their efficacy. In addition, EFED assumed no drift for furrow applications for corn and potato applications, therefore the 10 ft buffer does not impact the spary drift fraction for these proposed uses.

8.1.2 Model Outputs

Estimated broflanilide concentrations in surface water are summarized in **Table 8-2**. The maximum 1-in-10-year EECs of **0.46 µg/L** for the 1-day mean, **0.41 µg/L** for the 21-d mean, and **0.41 µg/L** for the 60-d mean concentration in surface water were estimated based on the maximum annual use rate for corn of 0.045 lbs/A using furrow application. The maximum 1-10-year 1-day and 21-day mean pore water and bulk sediment EECs are both **0.39 µg/L** in pore water **70 µg/kg** for dry sediment and **1743 µg/kg-OC** in organic carbon adjusted sediment**.**

These concentrations were based on PRBEN 0.5. EFED also explored PRBEN 0.75 and concluded that the PRBEN parameter has a minimal impact on water column peak EECs, while daily average, chronic and benthic EECs are not impacted. **(Section F3 of Appendix F).** Example outputs from the model runs are provided in **Appendix C**.

Table 8-2. Surface Water EECs for Proposed Broflanilide Uses

Use	PWC Scenario	Annual App Rate lbs a.i./A,	1-in-10 year mean EEC						
			Water Column (µg/L)			Pore-Water (µg/L)		Bulk Sediment (µg/kg-organic carbon)[1]	
			1-day	21-day	60-day	1-day	21-day	1-day	21-day
Ground Furrow Application									
Corn	IAcornstd	0.045	0.20	0.18	0.17	0.17	0.17	743	743
	ILCornSTD		0.32	0.30	0.29	0.29	0.29	1261	1261
	INCornStd		0.28	0.27	0.25	0.24	0.24	1062	1062
	KSCornStd		0.41	0.39	0.38	0.37	0.37	1615	1615
	MNCornStd		0.28	0.26	0.24	0.24	0.24	1075	1075
	MScornSTD		**0.46**	**0.41**	**0.41**	**0.39**	**0.39**	**1743**	**1743**
	NCcornESTD		0.22	0.20	0.20	0.19	0.19	845	845
	NECornStd		0.40	0.38	0.36	0.35	0.35	1558	1558
	OHCornSTD		0.27	0.25	0.24	0.24	0.24	1040	1040
	PAcornSTD		0.23	0.22	0.21	0.20	0.20	894	894
Tuberous & Corm	IDNpotato_WirrigSTD	0.045	0.01	0.01	0.01	0.01	0.01	25	25
	MEpotatoSTD		0.02	0.02	0.02	0.02	0.02	74	74
Seed Treatment	NDwheatSTD	0.0068	0.11	0.10	0.10	0.09	0.09	412	412

Maximum EECs are shown in **bold**.

[1]The benthic conversion factor is 177 and the fraction organic carbon (foc) is 0.04 in the EPA pond.

8.1.3 Monitoring (Non-targeted Sampling)

Since broflanilide is a proposed new pesticide that is not yet registered in the United States, there are no water monitoring data to report.

8.2 Aquatic Organisms Risk Characterization

As noted earlier, RQs are calculated by dividing acute and chronic EECs by their respective most sensitive toxicity endpoint (*i.e.*, EEC/toxicity endpoint). For evaluating risk to aquatic animals, the 1-day average EEC is used as the acute EEC; for aquatic vertebrates, the 60-day average EEC is used for the chronic EEC while the 21-day average EEC is used as the chronic EEC for aquatic invertebrates.

8.2.1 Aquatic Vertebrates

Table 8-3 summarizes the highest acute and chronic RQ values for freshwater and estuarine/marine fish based on the use with the highest EECs, *i.e*., MS corn, at the maximum proposed application rate of 0.045 lbs ai/A. Based on the available data, RQs do not exceed the acute risk to non-listed species LOC (0.5) nor the chronic risk LOC (1.0) for freshwater and estuarine/marine fish. Also, for acute estuarine marine fish, the EECs are orders of magnitude below the highest tested concentration tested in the study which did not result in 50% or greater mortality. Therefore, the potential for adverse effects to fish and aquatic-phase amphibians, for which fish serve as surrogates, from exposure as a result of the proposed uses of broflanilide is expected to be low.

Table 8-3. Acute and Chronic Vertebrate Risk Quotients (RQs) for Freshwater and Estuarine/Marine Non-listed Species Based on Broflanilide Residues from Proposed Uses

Use Sites (Use Scenario)	1-in-10 Yr EEC µg/L		Risk Quotient			
			Freshwater		Estuarine/Marine	
	Daily Mean	60-day Mean	Acute[1]	Chronic[2]	Acute[1, 3]	Chronic[2]
			LC_{50} = 251 µg a.i./L	NOAEC = 51 µg a.i./L	LC_{50} > 1300 µg a.i./L	NOAEC = 11 µg a.i./L
Furrow Corn (MSCornSTD, 0.045 lb a.i./A, 1 app)	0.46	0.41	<0.01	0.01	NC	0.04

The endpoints listed in the table are the endpoint used to calculate the RQ.
[1] The EECs used to calculate these RQs are based on the 1-in-10-year peak 1-day average value from **Table 8-2.**
[2] The EECs used to calculate these RQs are based on the 1-in-10-year 60-day average value from **Table 8-2**.
[3] RQs were not calculated because the acute endpoint is non-definitive.

8.2.2 Aquatic Invertebrates

Invertebrates in the Water Column

Table 8-4 summarizes acute and chronic RQ values for freshwater and estuarine/marine water column invertebrates based on comparisons to EECs in overlying water. Freshwater invertebrate RQs based on the available chronic *Daphnia* study did not result in chronic LOC exceedances. Acute endpoint for Daphnia were non-definitive so RQs were not calculated; however acute risk is presumed to be low for these taxa because the highest tested concentrations are orders of magnitude greater than the EECs and did not result in 50% or greater mortality in the studies. The estuarine/marine invertebrate acute RQs (range 9.3 to 21.4) and chronic RQs (range >101 to >239) based on the mysid studies exceed the non-listed species acute risk LOC (0.5) and the chronic risk LOC (1.0) for all uses and modeled scenarios.

While the PWC modeling and subsequently the RQs consider 30 years of annual use, it is important to note that after a single application, the first year of modeling results in acute and chronic EECs that exceeded the estuarine/marine endpoints. These results reflect that a single use of broflanilide has the potential to result in risk to water column estuarine/marine invertebrates, and that repeated use can considerably increase these risks over time due to the persistence of broflanilide.

Table 8-4. Acute and Chronic Freshwater and Estuarine/Marine Invertebrate Risk Quotients (RQs) Based on Broflanilide Residues from Proposed Uses

Use Site (Use Scenario)		1-in-10 Yr EEC µg/L		Risk Quotient			
				Freshwater		Estuarine/Marine Non-Mollusk	
				Acute[3]	Chronic[2]	Acute[1]	Chronic[2]
		Daily Ave	21-day Ave	LC_{50} > 322 µg a.i./L	NOAEC = 5.93 µg a.i./L	LC_{50} = 0.0215 µg a.i./L	NOAEC <0.0018 µg a.i./L[3]
Ground Furrow Application @ 0.045 lbs a.i./A							
Corn	IAcornstd	0.20	0.18	NC	<0.1	**9.30**	**>101**
	ILCornSTD	0.32	0.30	NC	<0.1	**14.88**	**>172**
	INCornStd	0.28	0.27	NC	<0.1	**13.02**	**>154**
	KSCornStd	0.41	0.39	NC	<0.1	**19.07**	**>229**
	MNCornStd	0.28	0.26	NC	<0.1	**13.02**	**>154**
	MScornSTD	**0.46**	**0.41**	NC	<0.1	**21.40**	**>239**
	NCcornESTD	0.22	0.20	NC	<0.1	**10.23**	**>116**
	NECornStd	0.40	0.38	NC	<0.1	**18.60**	**>223**
	OHCornSTD	0.27	0.25	NC	<0.1	**12.56**	**>147**
	PAcornSTD	0.23	0.22	NC	<0.1	**10.70**	**>125**

The endpoints listed in the table are the endpoint used to calculate the RQ.
[1] The EECs used to calculate this RQ are based on the 1-in-10-year peak 1-day average value from **Table 8-2**.
[2] The EECs used to calculate this RQ are based on the 1-in-10-year 21-day average value from **Table 8-2**.
[3] RQs were not calculated because the acute endpoint is non-definitive.

Invertebrates in Benthic Sediment and Pore Water

Several acute and chronic benthic invertebrate toxicity studies are used to evaluate the potential risks of broflanilide to sediment dwelling invertebrates. These include freshwater (*Chironomus* and *Hyalella*) and estuarine marine (*Leptocheirus*) taxa. These data were evaluated against measures of exposure in terms of the mass of broflanilide in bulk sediment, organic carbon, and pore water as estimated by the PWC modeling for ground furrow uses described above. When endpoints in the available studies could not be calculated based on measured concentrations in pore water, estimated pore water concentrations were derived using the measured bulk sediment (µg a.i./kg-sediment) in the study and the mean K_F for broflanilide (177 L/kg-sediment). The K_F was selected over the K_{FOC} because the fate characteristics indicate that broflanilide sorption to sediment is best characterized by the K_F, which accounts for sorption to the silts, clays and organic matter.

Risk quotients exceed both acute (0.5) and chronic (1.0) LOCs for all proposed uses (**Table 8-5**) for all sediment and pore water based assessed EECs. Similar to the water column risks discussed above, the PWC modeling and subsequently the RQs consider 30 years of annual use. It is important to note that after a single application the first year of modeling results in acute and chronic EECs that exceed the acute and chronic benthic freshwater and estuarine/marine endpoints. These results reflect that a single use of broflanilide has the potential to result in risk to benthic invertebrates in freshwater and estuarine/marine invertebrates, and that repeated use can considerably increase these risks over time due to the persistence of broflanilide.

Table 8-5. Maximum Acute and Chronic Freshwater and Estuarine/Marine Benthic Invertebrate Risk Quotients (RQs).

Exposure Basis		Test Species	*Acute LC50 based RQs*[1]			*Chronic NOAEC based RQs*[2]		
			Chironomus Freshwater	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*	*Chironomus Freshwater*	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*
Benthic Invertebrate comparisons to Pore Water Based EECs		**Endpoints (µg a.i./L)**	0.211	0.461	0.079[3]	0.024	< 0.039	0.021[3]
Scenario	**Maximum 1-day mean EECs (ug a.i./L-pore water)**	**Maximum 21-day mean EECs (ug a.i./L-pore water)**						
Ground Furrow @ 0.045 lbs a.i./A	0.46	0.39	**2.2**	**1.0**	**5.8**	**16.3**	**>10.0**	**18.3**
Benthic Invertebrate comparisons to Bulk Sediment Based EECs		**Test Species**	*Acute LC50 based RQs*[1]			*Chronic NOAEC based RQs*[2]		
			Chironomus Freshwater	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*	*Chironomus Freshwater*	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*
		Endpoints (µg a.i./kg-sediment)	9.99	13.5	14	1.5	< 1.7	3.8
Scenario	**Maximum 1-day mean EECs (ug a.i./kg-sediment)**	**Maximum 21-day mean EECs (ug a.i./kg-sediment)**						
Ground Furrow @ 0.045 lbs a.i./A	70	70	**7.0**	**5.2**	**5.0**	**46.7**	**>41.4**	**1.4**
Benthic Invertebrate comparisons to Organic Carbon-Based EECs		**Test Species**	*Acute LC50 based RQs*[1]			*Chronic NOAEC based RQs*[2]		
			Chironomus Freshwater	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*	*Chironomus Freshwater*	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*
		Endpoints (µg a.i./kg-organic carbon)	454	752	410	67	< 91	130
Scenario	**Maximum 1-day mean EECs (ug a.i./kg-organic carbon)**	**Maximum 21-day mean EECs (ug a.i./kg-organic carbon)**						
Ground Furrow @ 0.045 lbs a.i./A	1743	1743	**3.8**	**2.3**	**4.3**	**26.0**	**>19.2**	**13.4**

Water Column Invertebrates comparisons to Pore Water EECs			***Acute LC50 based RQs*[1]**			***Chronic NOAEC based RQs*[2]**		
		Test Species	***Daphnia Freshwater***	***Mysid Estuarine/ Marine***		***Daphnia Freshwater***	***Mysid Estuarine/ Marine***	
		Endpoints (µg a.i./L-pore water)	>322[4]	0.0215		5.93	< 0.0018	
Scenario	**Maximum 1-day mean EECs (µg a.i./L-pore water)**	**Maximum 21-day mean EECs (µg a.i./L-pore water)**						
Ground Furrow @ 0.045 lbs a.i./A	0.46	0.47	NC	**21.4**		0.1	**>261.1**	

The endpoints listed in the table are the endpoint used to calculate the RQ.

[1] The EECs used to calculate this RQ are based on the 1-in-10-year peak 1-day average value from **Table 8-2**.

[2] The EECs used to calculate this RQ are based on the 1-in-10-year 21-day average value from **Table 8-2**.

[3] Pore water endpoint estimated based on K_F and measured bulk sediment-based endpoint.

[4] RQs were not calculated because the acute endpoint is non-definitive.

8.2.3 Aquatic Plants

Potential risks to aquatic non-vascular plants are estimated using the 1-in-10 year daily average concentration based on exposure from runoff and drift. For evaluating risks to non-listed plants, the EEC is compared to the most sensitive IC_{50} value and the resulting RQ is then compared to the LOC of 1.0. **Table 8-6** summarizes RQ values for non-vascular aquatic plants. Across all of the proposed uses, RQ values for vascular and non-vascular plants were below the LOCs and indicate that potential risk to non-listed species is low.

Table 8-6. Maximum Aquatic Plant Risk Quotients (RQs) for Non-listed Species Based on Broflanilide Residues from Proposed Uses.

Use Sites (Use Scenario)	1-in-10 Yr EEC µg/L	Risk Quotient[1]	
		Vascular Plants	Non-Vascular Plants
	Maximum Daily Ave	EC_{50} > 630 µg a.i./L	EC_{50} = 570 µg a.i./L
Ground Furrow (MSCornSTD, 0.045 lb a.i./A, 1 app)	0.46	<0.01	<0.01

[1] The level of concern (LOC) for risk to non-listed plants is 1. The endpoints listed in the table are the endpoint used to calculate the RQ.

9 Terrestrial Vertebrates Risk Assessment

9.1 Terrestrial Vertebrate Exposure Assessment

9.1.1 Dietary Items on the Treated Field

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals by emphasizing the dietary exposure pathway. Broflanilide is applied through ground application methods, which includes banded spray, and directed spray into furrows or trenches that will be refilled after application. Additionally, broflanilide may be applied through coating cereal grain seeds prior to planting. Therefore, potential dietary exposure for terrestrial wildlife in this assessment is based on consumption of broflanilide residues on food items following spray (soil), or from the direct consumption of treated seed. The EECs for birds[3] and mammals from consumption of dietary items on the treated field were calculated using T-REX v.1.5.2. Modeling was done assuming a broadcast application at 0.043 lbs a.i./A and the default foliar dissipation half-life of 35 days.

For ground applications of broflanilide, upper-bound Kenaga nomogram values are used to derive EECs for broflanilide exposures to terrestrial mammals and birds on the field of application based on a 1-year time period. Consideration is given to different types of feeding

[3] Birds are also used as a proxy for reptiles and terrestrial-phase amphibians.

strategies for mammals, including herbivores, insectivores, and granivores. Dose-based exposures are estimated for three weight classes of birds (*i.e*., 20 g, 100 g, and 1,000 g) and three weight classes of mammals (*i.e*., 15 g, 35 g, and 1,000 g). Dietary-based EECs on terrestrial food items range from 22.5 to 360 mg/kg-diet based on upper-bound Kenaga values (1.5 lb a.i./A, 1 application). Dose-based EECs, adjusted for body weight, range from 1.45 to 410 mg a.i./kg bw for birds and 0.76 to 343 mg a.i./kg bw for mammals. A summary of EECs is found in **Table 9-1**.

Table 9-1. Summary of Dietary (mg a.i./kg-diet) and Dose-based Estimated Environmental Concentrations (EEC; mg a.i./kg-bw) as Food Residues for Birds, Reptiles, Terrestrial-Phase Amphibians and Mammals from Proposed Uses of Broflanilide (T-REX v. 1.5.2, Upper-Bound Kenaga; based on assumed broadcast spray application at the proposed broflanilide maximum application rate of 0.043 lbs ai/A)

Food Type	Dietary-Based EEC (mg/kg-diet)	Dose-Based EEC (mg/kg-body weight)					
		Birds, Reptiles & Terrestrial-Phase Amphibians			Mammals		
		Small (20 g)	Medium (100 g)	Large (1000 g)	Small (15 g)	Medium (35 g)	Large (1000 g)
Assumed single 0.045 lb a.i./acre broadcast application							
Short grass	10.80	12.30	7.01	3.14	10.30	7.12	1.65
Tall grass	4.95	5.64	3.21	1.44	4.72	3.26	0.76
Broadleaf plants/small insects	6.08	6.92	3.95	1.77	5.79	4.00	0.93
Fruits/pods/seeds, dietary only	0.68	0.77	0.44	0.20	0.64	0.44	0.10
Arthropods	4.23	4.82	2.75	1.23	4.03	2.79	0.65
Seeds (granivore)	N/A	0.17	0.10	0.04	0.14	0.10	0.02

9.2 Terrestrial Vertebrates Risk Characterization

In- Furrow Use

RQ values for birds and mammals, are generated based on the upper-bound EECs discussed above. The RQs for acute-based exposure to birds and mammals were not quantifiable as available data are non-definitive and indicate that broflanilide is practically non-toxic **(see Section 6.2)**. Comparisons of maximum EECs to body weight and diet adjusted endpoints show that EECs are orders magnitude below the highest tested concentrations in the studies which showed no effects to the text organisms. Therefore, based on the available data, the potential acute dose or dietary risk to birds and mammals foraging on the application site is considered low.

Chronic RQs, based on upper-bound Kenaga values at the proposed maximum single application rate of 0.045 lbs a.i./A and conservatively assuming a broadcast spray application, range from < 0.01 – 0.35; therefore, RQs are below the chronic risk LOC at this proposed rate. Based on the available data, the potential for direct adverse effects on birds and mammals on a chronic exposure basis through diet from the proposed use of broflanilide is expected to be low.

Treated Seed Uses

Broflanilide is proposed for use as a seed treatment to cereal crops. Therefore, potential dietary exposure for terrestrial wildlife also includes direct consumption of broflanilide residues on treated seeds. The proposed label states the application rate as 0.005 lbs a.i./100 lbs of seed (0.0068 lbs a.i./A; **see Table 3-1**).

Characterization of the risk posed by seed treatments followed the methodology of USEPA, 2016 with the following modifications: a) calculation of the number of seeds to reach an acute threshold of concern was modified to reflect the LOC (0.5), b) foraging time equations were modified to reflect the equations originally presented in Benkman and Pulliam (1988) with modifications to accurately represent passerine consumption rates for known dietary items (*e.g.* removal of chipping sparrow data that gave unrealistically large foraging times for known seed dietary items under the original equations) and c) minimum and maximum bounds around the foraging area and foraging time of concern were used, replacing the previous mean estimates.

As expected, based on the lack of acute toxicity, the number of seeds a mammal or bird would need to eat per day to reach the acute LOC is very large. Therefore, there is low risk concern from the consumption of treated seeds on an acute basis. However, on a chronic basis, the numbers of seeds to reach the LOCs are reasonably achievable for small and medium sized birds (28 to 170) and mammals (416 to 786). Because the treated seeds are cereal grains, the availability of seed would be high, with at most a light covering of soils. Therefore, risk from consumption of broflanilide treated seeds is possible.

Table 9.2. Number of seeds needed to consume to reach chronic LOCs for birds and mammals.

Crop (estimated mass a.i./seed)	Birds			Mammals		
	Small	Medium	Large	Small	Medium	Large
Wheat/Sorghum (11000 seeds/lb; 0.00206 mg a.i./seed)						
Minimum # of seeds to reach Chronic LOC	34	170	1701	416	786	9708
Barley (9000 seeds/lb; 0.00252 mg a.i./seed)						
Minimum # of seeds to reach Chronic LOC	28	139	1391	340	642	7936

Residues in Aquatic Food Items For Terrestrial Vertebrates:

The KABAM model (K_{OW} (based) Aquatic BioAccumulation Model) version 1.0[4] was used to evaluate the potential exposure and risk of direct effects to birds and mammals via bioaccumulation and biomagnification in aquatic food webs. KABAM is used to estimate potential bioaccumulation of hydrophobic organic pesticides in freshwater aquatic ecosystems and risks to mammals and birds consuming aquatic organisms which have bioaccumulated these pesticides. The bioaccumulation portion of KABAM is based upon work by Arnot and Gobas (2004) who parameterized a bioaccumulation model based on PCBs and some pesticides (*e.g*., lindane, DDT) in freshwater aquatic ecosystems (Arnot and Gobas, 2004). KABAM relies on a chemical's octanol-water partition coefficient (K_{OW}) to estimate uptake and elimination constants through respiration and diet of organisms in different trophic levels. Pesticide tissue residues are calculated for organisms at different levels of an aquatic food web. The model then uses pesticide tissue concentrations in aquatic animals to estimate dose- and dietary-based exposures and associated risks to mammals and birds (surrogate for amphibians and reptiles) consuming aquatic organisms. Seven different trophic levels including phytoplankton, zooplankton, benthic invertebrates, filter feeders, small-sized (juvenile) forage fish, medium-sized forage fish, and larger piscivorous fish, are used to represent an aquatic food web. Input scenarios and parameters were chosen to maximum exposures from and are presented in **Table 9-3**.

Table 9-3. Bioaccumulation Model Input Values for Broflanilide

Characteristic	Value	Comments/Guidance
Pesticide Name	Broflanilide	
Log Kow	5.2	MRID 50211316
Koc (L/kg OC)	7606	Mean Koc MRID 50211432
Time to steady state (TS; days)	45	No input necessary. This value is calculated automatically from the Log Kow value entered above.
Pore water EEC (µg/L)	0.39	See **Table 8-2**

[4] KABAM User Guide and Model are available at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Characteristic	Value	Comments/Guidance
Water Column EEC (µg/L)	0.46	See **Table 8-2**
Broflanilide Most sensitive Effects Endpoints		
Avian	LD50 (mg/kg-bw)	>2000[1]
	LC50 (mg/kg-diet)	>5000[1]
	NOAEC (mg/kg-diet)	29.7
Mammalian	LD50 (mg/kg-bw)	>5000[1]
	LC50 (mg/kg-diet)	NA
	NOAEC (mg/kg-bw)	300

[1]Non-definitive endpoint

9.2.1 Bioaccumulation in Birds and Mammals

The bioaccumulation modeling did not evaluate each individual use but was conducted in a way to represent the maximum pore and overlying water EECs and the refined elimination rate constant. Model input EECs were first selected from PWC scenarios which produced the maximum EECs for water column and pore water applications of broflanilide. At the maximum EECs, there were no acute or chronic LOC exceedances (birds and mammals) (**Table 9-4**).

Table 9-4. KABAM Modeling Results for Birds and Mammals[1]

Organisms	**Crop**	**Application Rate, Method, and Interval**	**PWC Scenario/ Concentration**	**RQ[1]**	
				Acute	**Chronic**
Birds	Corn	0.045 lbs a.i./A, Ground Furrow Application (single application)	Max Overlying Water Column Concentration (0.46 µg/L)	NC	≤0.32
Mammals			Max Pore Water Concentration (0.39 µg/L)	0.25	≤0.032

[1]Acute LOC = 0.5; Chronic LOC=1.0; **Bold**=LOC exceedance[1]

10 Terrestrial Invertebrate Risk Characterization

10.1 Honeybee Risk Assessment

Broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests. Nakao and Banba (2016) suggested that broflanilide is metabolized to desmethyl-broflanilide within the insect, which acts as a noncompetitive resistant-to-dieldrin (RDL) γ-aminobutyric acid (GABA) receptor antagonist. Because of its mode of action, risks to bees is anticipated. The following section discusses the potential exposure routes and extent of potential risks to adult and larval bees.

10.1.1 Bee Exposure Assessment

Broflanilide's fate characteristics (log Kow; Koc) and the propensity to sorb to sediments suggest that it is not likely systemic in plants and therefore exposure to bees through pollen and nectar contamination is likely to primarily occur through spray drift deposition on flowering attractive vegetation. This conclusion is supported by submitted plant residue studies on corn, rape and canola (MRIDs 50211477, 50211478, 50211643) which showed no detections of broflanilide in plant tissues, pollen and nectar. In the rape study, one replicate of three had a single unexplained detection of broflanilide at 0.0015 mg/kg, but did not fit a pattern suggesting systemic transport. The proposed uses include several crops and vegetation that may be attractive to bees. However, the uses are labeled as either at plant/in-furrow or treated seed therefore systemic transport would be required to achieve exposures. The proposed uses that include spray application to the furrow may result in spray drift to bee attractive vegetation adjacent to the furrow, these are considered further for comparison to the available toxicity data.

Bee Tier I Exposure Estimates

Contact and dietary exposure are estimated separately using different approaches specific for different application methods. The BeeREX model (Version 1.0) was used to calculate default (*i.e*., high end, yet reasonably conservative) estimated environmental concentrations (EECs) for dietary and contact exposure from spray applications (due to spray drift onto areas adjacent to treated areas). Additional information on bee-related exposure estimates and the calculation of risk estimates in BeeREX can be found in the *Guidance for Assessing Risk to Bees* (USEPA *et al.*, 2014). Further information about the BeeREX model, including a summary of the methods used for deriving the default Tier I EECs can be found in the BeeREX User Guide[5].

10.1.2 Bee Risk Characterization

Since an exposure potential for bees is identified, the next step in the risk assessment process is to conduct a Tier 1 risk assessment. By design, the Tier 1 assessment begins with (high-end) model-generated (spray) estimates of exposure via contact and oral (dietary) routes. These EECs are then divided by acute (LD_{50}) and chronic (NOAEL) toxicity endpoints to derive RQs. Acute RQs are compared to an acute risk level of concern (LOC) of 0.4, where if the RQ is above 0.4, there is a risk concern (for mortality). For chronic exposure, the LOC is 1.0. Residue data for pollen or nectar data are available for broflanilide to refine estimated Tier I exposure concentrations. These data and their relevance to the assessment are considered below.

The proposed labels have application methods that should not result in direct spray of flowering attractive vegetation, so direct contamination of nectar or pollen, and the direct

[5] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#terrestrial

spray of foraging bees, is not considered a major pathway of exposure. The physiochemical properties of broflanilide (e.g., propensity to bind to sediment) suggests that it is not likely a systemic compound that would enter through the roots and travel to pollen and nectar. Therfore, the exposure potential to bees is highly limited. Based on these considerations, there is not a risk concern for honey bees for the currently proposed uses.

11 Terrestrial Plant Risk Assessment

The available seedling emergence and vegetative vigor studies did not result in definitive EC/IC_{25} endpoints, therefore RQs are not generated for this assessment. The agricultural uses (ground furrow) have application rates that are below the highest tested concentrations in the available studies. Because the rates are below the concentrations that did not achieve a 25% effect level, risk is presumed low for terrestrial plants.

12 Conclusions

This Ecological Risk Assessment (ERA) examines the environmental fate of broflanilide and the potential for adverse effects on non-listed species from exposure associated with proposed uses of broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests. Given the proposed uses of broflanilide and its environmental fate properties, exposure of non-target terrestrial and/or aquatic organisms is possible. Based on estimated exposure concentrations for the parent compound alone and currently available toxicity data, there is a potential for direct adverse effects to terrestrial and aquatic invertebrates, and because of the persistence of broflanilide in sediments these risks are likely to increase with annual reapplication. For spray applications, contact and dietary exposure to bees may occur if attractive vegetation is adjacent to the application area, but considering these proposed uses are in-furrow or crack and crevice applications, the exposure potential for foraging bees is considered low. Available data suggests a low risk potential to birds and mammals, including following the potential dietary exposure through bioaccumulation. However, there are potential growth effects to mammals, and therefore risk, through the consumption of broflanilide treated seeds. Risks to plants, birds, and fish are considered low for the proposed uses.

13 Literature Cited

Benkman, C.W. and H.R. Pulliam. 1988. Comparative Feeding Ecology of North American Sparrows and Finches. *Ecology*. 69: 1195—1199.

FAO. 2000. Appendix 2. Parameters of pesticides that influence processes in the soil. Pesticide Disposal Series 8. Assessing Soil Contamination. A Reference Manual. FAO Information Division Editorial Group. Rome, Food & Agriculture Organization of the United Nations (FAO).

Goring, C. A. I., Laskowski, D. A., Hamaker, J. H., & Meikle, R. W. 1975. Principles of pesticide degradation in soil. In R. Haque & V. H. Freed (Eds.), *Environmental dynamics of pesticides*. NY: Plenum Press.

NAFTA. 2012. *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*. December 2012. NAFTA Technical Working Group on Pesticides. Available at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-calculate-representative-half-life-values.

Nakao, T. and S Banba. 2016. Broflanilide: A meta-diamide insecticide with novel mode of action. Bioorganic & Medicinal Chemistry, Vol. 24:372-377.

Reichenberger, S. M. Bach, A. Skitschak, and H. Frede, 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness; A Review. Science of the Total Environment 384:1-35.

USDA-NRCS, 2000. Conservation Buffers to Reduce Pesticide Losses. U.S. Department of Agriculture–Natural Resource Conservation Service.

USEPA. 2004. *Government Printing Office. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency.

USEPA. 2009. *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version 2.1*. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. Available at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-selecting-input-parameters-modeling.

USEPA. 2010. *Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in the Problem Formulation for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*. January 25, 2010. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. Available at http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_reporting_fate.htm.

USEPA. 2011. *Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species*. Memorandum From D. J. Brady to E. F. a. E. Division. May 10, 2011. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. United States Environmental Protection Agency. Available at http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_non_definitive_endpoints.htm.

USEPA. 2012. *Standard Operating Procedure for Using the NAFTA Guidance to Calculate Representative Half-life Values and Characterizing Pesticide Degradation*. November 30, 2012. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. Available at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-calculate-representative-half-life-values.

USEPA. 2013. *Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessment*. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. Available at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676.

USEPA. 2014. *Guidance for Addressing Unextracted Residues in Laboratory Studies*. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues.

USEPA, 2016. Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance. Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs, Environmental Fate and Effects Division. March 31, 2016.

USEPA *et al*. 2016. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs, U.S. EPA, Washington DC; Health Canada Pest Management Regulatory Agency, Ottawa, ON, Canada; California Department of Pesticide Regulation, Sacramento, CA. Available on-line at: https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

USEPA, 2018. PRD and EFED Efforts to Meet Registration Review Goals by Ensuring Effective Planning Dialogue and Collaboration. Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs, Environmental Fate and Effects Division. MArch 09, 2018.

USEPA, 2019. Broflanilide**:** Section 3 New Chemical Drinking Water Exposure Assessment. Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs, Environmental Fate and Effects Division. August 20, 2019.

14 Referenced and Submitted MRIDs

14.1 Environmental Fate Studies

50211433 Kitamura, K. (2017) Soil Adsorption Coefficient of DM-8007: Final Report. Project Number: 2017/7008905, 522/15/K/1611, 652/15/P/4491. Unpublished study prepared by Chemicals Evaluation and Research Institute. 9p.

50211434 Kitamura, K. (2017) Soil Adsorption Coefficient of S(PEP-OH)-8007: Final Report. Project Number: 2017/7008906, 522/15/K/1612, 652/15/P/4494. Unpublished study prepared by Chemicals Evaluation and Research Institute. 9p.

50211435 Miner, P. (2017) Adsorption/Desorption of Carbon-14 DC-DM-8007 in US Soils. Project Number: 034583/1, 034583, 2017/7008697. Unpublished study prepared by Ricerca Biosciences, LLC. 137p.

50211436 Miner, P. (2017) Adsorption/Desorption of Carbon-14 DC-8007 in US Soils. Project Number: 034809, 034809/1, 2017/7016121. Unpublished study prepared by Ricerca Biosciences, LLC. 149p.

50211328 Schick, M. (2016) Hydrolysis of [Carbon 14]MCI-8007 at pH 4, 7 and 9. Project Number: 2499W, 2499W/1, 2016/7012757. Unpublished study prepared by PTRL West, Inc. 54p.

50211329 Ponte, M. (2017) Direct Aqueous Photodegradation of [Carbon 14]MCI-8007: Final Report. Project Number: 2579W, 2579W/2, 2017/7016803. Unpublished study prepared by EAG Laboratories. 215p.

50211330 Ponte, V. (2017) Direct Aqueous Photodegradation of [Carbon 14]Broflanilide in pH 5 and pH 9 Buffer. Project Number: 2914W, 2914W/1, 2017/7016650. Unpublished study prepared by EAG Laboratories. 359p.

50211640 Warren, R. (2017) Atmospheric Degradation of Broflanilide (BAS 450 I or MCI-8007) by Reaction with the Hydroxyl Radicals and Ozone: Structure-Activity Relationship Calculations Using AOPWIN v1.92: Final Report. Project Number: 439540, 2017/7015636. Unpublished study prepared by BASF Corporation. 13p.

50211427 Strobush, A. ; Ta, C. (2017) Aerobic Soil Metaabolism of Carbon-14 Brolanilide (MCI-8007 or BAS 450 I): Final Report. Project Number: 2017/7008279, 818049. Unpublished study prepared by BASF Crop Protection, Agvise Laboratories, Inc. 179p.

50211430 Ta, C. ; Strobush, A. (2017) Aerobic Soil Metabolism of Carbon-14 Broflanilide (MCI-8007 or BAS 450 I) in Intact Soil Cores and Processed Soils: Final Report. Project Number: 780122, 2017/7000457, 2015/7001365. Unpublished study prepared by BASF Corporation. 313p.

50211560 Talken, C. (2017) 450 I (Broflanilide): Outdoor Aerobic Soil Metabolism of Carbon-14-BAS 450 I on Bare Soil in California and Georgia, USA: Final Report. Project Number: 2015/7001365, 725271, 81084. Unpublished study prepared by ABC Laboratories, Inc., Research for Hire, Eurofins Agrosciences, Inc., AGVISE Laboratories. 380p.

50211428 Ta, C.; Alicea, A. ; Graves, C. (2017) Anaerobic Soil Metabolism of Carbon-14 Broflanilide (MCI-8007 or BAS 450 I): Final Report. Project Number: 818051, 2017/7008280, SANCO/10058/2005. Unpublished study prepared by BASF Corporation, Agvise Laboratories, Inc. 201p.

50680701 Ta, C. (2018) Responses of BASF to PMRA on the Identification and Quantification of Broflanilide and Transformation Products from the Chromatograms Provided in PMRA # 2828282, "Anaerobic Soil Metabolism of [Carbon 14] Broflanilide (MCI-8007 or BAS 450 I)". Project Number: 2018/7006697. Unpublished study prepared by BASF Corporation. 30p.

50211437 Stenzel, J.; Schaefer, E. (2017) Aerobic Aquatic Metabolism of Carbon-14 Broflanilide, Also known as Carbon-14 MCI-8007 and Carbon-14 BAS 450 I, in Two Test Systems: Final Report. Project Number: 236E/102, 2017/7016172. Unpublished study prepared by EAG Laboratories. 261p.

50211431 Warren, R.; Gordon, B.; Mitchell, J.; et al. (2017) Terrestrial Field Dissipation of the Insecticide Broflanilide (BAS 450 I or MCI-8007) Following Broadcast Applications of BAS 450 00 I (SC): Final Report. Project Number: 227/32, 710464, 2017/7008695. Unpublished study prepared by BASF Corporation, Ag Systems Associates, Florida Pesticide Research, Inc., California Agricultural Research, Inc., Qualls Agricultural Laboratory, Northern Plains Ag Research, Inc., Agvise Laboratories, Inc., Primera Analytical Solutions Corp. 1141p.

50211559 Gordon, B. (2017) Freezer Storage Stability of BAS 450 I and its Relevant Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil. Project Number: 414635, 2017/7012475, 710464. Unpublished study prepared by BASF Corporation. 339p.

50211560 Talken, C. (2017) 450 I (Broflanilide): Outdoor Aerobic Soil Metabolism of Carbon-14-BAS 450 I on Bare Soil in California and Georgia, USA: Final Report. Project Number: 2015/7001365, 725271, 81084. Unpublished study prepared by ABC Laboratories, Inc., Research for Hire, Eurofins Agrosciences, Inc., AGVISE Laboratories. 380p.

50124721 Altenburg, M. (2017) Potential effects of BAS 450 01 I on the reproduction of the soil mites Hypoaspis aculeifer in artificial soil with 5% peat: Final Report. Project Number: 788193, 2017/1000741. Unpublished study prepared by BASF SE. 33p.

50211451 Dodd, E. (2016) Mel-8007 (BAS 450 I, Broflanilide): Bioconcentration study in the Rainbow Trout (Oncorhynchus mykiss): Final Report. Project Number: MUY0012, 2017/7008732. Unpublished study prepared by Envigo CRS Limited. 135p.

50211562 Kendall, T.; Krueger, H.; Thomas, S. (2012) A Flow-Through Bioconcentration Screening Test with the Rainbow Trout (Oncorhynchus mykiss) Using Carbon-14-MLP-9595 and Carbon-14-MLP-8607: Final Report. Project Number: 236A/137, 2012/7008465, NP153819. Unpublished study prepared by Wildlife International Ltd. 41p.

50211340 Delinsky, D. (2017) Validation of Method D1603/01: Method for the Determination of Residues of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC-MS/MS (at LOQ of 1 ppb): Final Report. Project Number: 815843, 2017/7001823. Unpublished study prepared by BASF Corporation. 184p.

50211341 Delinsky, D. (2017) Validation of Method D1608/01: Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007 and S(PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS: Final Report. Project Number: 725931, 2017/7000331. Unpublished study prepared by BASF Corporation. 198p.

50211477 Mack, P. (2017) Determination of Residues of BAS 450 00 I in Pollen of Corn after One In-Furrow Soil Application in a Filed Residue Study in Germany 2016: Final Report. Project Number: 773951/1, S16/02197, 2016/1222128. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH. 177p.

50211478 Mack, P. (2017) Determination of Residues in Pollen and Nectar of Oilseed Rape Grown as a Succeeding Crop in Corn Field Previously Treated Once with BAS 450 00 I as a Soil In-Furrow Application: Final Report. Project Number: 773951/2, S16/00561, 2016/1222129. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH. 217p.

50211556 Delinsky, D. (2017) Validation of Method D1705/01: Method for the Determination of S(Br-OH)-8007 (Reg, No. 5959595), AB-Oxa (Reg. No. 5959600), and MFBA (Reg. No. 6088668) in Surface and Drinking Water by LC-MS/MS: Final Report. Project Number: 838397, 2017/7012333. Unpublished study prepared by BASF Crop Protecion. 141p.

50211645 Delinsky, D. (2017) Evaluation of the Limit Detection (LOD) for Method D1603/01, "Method for the Determination of Residue of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC-MS/MS (at LOQ of 1ppb): Final Report. Project Number: 834706, 2017/7008794. Unpublished study prepared by BASF Corporation. 42p.

50211646 Neeley, M. (2017) Independent Laboratory Validation of the following Method Entitled: BASF Analytical Method D1603/01: "Method for the Determination of Residues of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC-MS/MS (at LOQ of 1ppb)": Amended Final Report. Project Number: 776691, 16/CPS/052, 2017/7016080. Unpublished study prepared by Critical Path Services, LLC (CPS). 135p.

50211647 Horowitz, M. (2017) Evaluation of the Limit of Detection (LOD) for Method D1608/01: "Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS": Final Report. Project Number: 834707, 2017/7008773. Unpublished study prepared by BASF Corporation. 48p.

50211648 Xu, A. (2017) Independent Laboratory Validation of Method D1608/01: "Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S9PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS: Amended Final Report. Project Number: 776692, 053/1651, PASC/REP/0986. Unpublished study prepared by Primera Analytical Solutions Corporation. 161p.

50211649 Delinsky, D. (2017) Evaluation of Limit of Detection (LOD) for Method D1705/01, "Method for the Determination of S(BR-OH)-8007, AB-Oxa, and MFBA in Surface and Drinking Water by LC-MS/MS": Final Report. Project Number: 838399, 2017/7008790. Unpublished study prepared by BASF Corporation. 37p.

50211650 Xu, A. (2017) Independent Laboratory Validation of "Method for the Determination of S(Br-OH)-8007, AB-Oxa, and MFBA in Surface and Drinking Water by LC-MS/MS". Project Number: 2017/7012334. Unpublished study prepared by Primera Analytical Solutions Corporation. 159p.

14.2 Ecological Effects Studies

50211452 Brougher, D.; Oliver, D.; Gallagher, S. (2016) MCI-8007 (BAS 450 I): A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report. Project Number: 236A/171, 706453, 2016/7011589. Unpublished study prepared by EAG Laboratories. 57p.

50211514 Yamaguchi, N. (2016) Acute Immobilization Test of MFBA with Daphnia magna. Project Number: A160093, 2016/7012502. Unpublished study prepared by LSI Medience Corporation. 38p.

50211563 Yoshimura, N. (2016) Reproduction Test of MFBA with Daphnia magna. Project Number: A160094, 2016/7012501. Unpublished study prepared by LSI Medience Corporation. 59p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211486 Mason, J. (2017) BAS 450 I - Acute Toxicity Test with Eastern Oyster (Crassostrea virginica) Under Flow-Through Conditions: Final Report. Project Number: 986/6304, 838874, 2017/7008755. Unpublished study prepared by Smithers Viscient Laboratories. 60p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211566 Brougher, D.; Lockard, L.; Martin, K.; et al. (2017) BAS 450 I METABOLITE (S(Br-OH)-8007): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/333C, 838289, 2017/7016554. Unpublished study prepared by EAG, Inc. 65p.

50211567 Brougher, D.; Oliver, D.; VanHoven, R.; et al. (2017) BAS 450 I METABOLITE (AB-oxa): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/334A, 838290, 2017/7016553. Unpublished study prepared by EAG, Inc. 65p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211446 Milligan, A.; Oliver, D.; Gallagher, S. (2016) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Final Report. Project Number: 236A/168, 2016/7011895, 236/04201/RBT/96H3/OECD/OPPTS/100P/628. Unpublished study prepared by EAG Laboratories. 62p.

50211447 Milligan, A.; Oliver, D.; Gallagher, S. (2016) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Bluegill (Lepomis macrochirus): Final Report. Project Number: 236A/167, 2016/7011894, 236/042016A/BLU/96H3/OECD/OPPTS/100P/616. Unpublished study prepared by EAG Laboratories. 62p.

50211448 Minderhout, T.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Toxicity Test with the Fathead Minnow (Pimephales promelas). Project Number: 147A/326, 706458, 2016/7010896. Unpublished study prepared by EAG Laboratories. 59p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211490 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus). Project Number: 147A/307, 706460, 2016/7004280. Unpublished study prepared by EAG Laboratories. 60p.

50211512 Milligan, A.; Oliver, D.; Gallagher, S. (2017) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Common Carp (Cyprinus carpio): Final Report. Project Number: 236A/169, 2017/7016189, 236/042016/CC/96H3/OECD/OPPTS/100P/641. Unpublished study prepared by EAG Laboratories. 65p.

50211453 Vlechev, S.; Janson, G. (2017) Chronic Toxicity of BAS 450 I (MCI-8007) to Daphnia magna STRAUS in a 21 Days Semi-Static Test: Final Report. Project Number: 706454, 2015/1003902. Unpublished study prepared by BASF SE. 68p.

50211488 Claude, M.; Okiver, D.; Gallagher, S. (2017) BAS 450 I: A Flow-Through Life-Cycle Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/309A, 706462, 2017/7012232. Unpublished study prepared by EGA Laboratories. 139p.

50211449 Minderhout, T.; Oliver, D.; Gallagher, S. (2017) BAS 450 I: An Early Life-Stage Toxicity Test with the Fathead Minnow (Pimephales promelas). Project Number: 147A/330, 706459, 2017/7008344. Unpublshed study prepared by EAG Laboratories. 107p.

50211450 Minderhout, T.; Oliver, D.; Gallagher, S. (2017) BAS 450 I: An Early Life-Stage Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus). Project Number: 147A/310B, 741406, 2017/7000425. Unpublished study prepared by EAG Laboratoreis. 103p.

50211439 Taylor, K. (2016) Northern Bobwhite (Colinus virginianus) Acute Oral Toxicity Test (LD50) with BAS 450 I. Project Number: 706466, 2016/7004181, 986/4122. Unpublished study prepared by Smithers Viscient. 70p.

50211440 Keller, J.; Groters, S.; Ravenzwaay, B. (2015) BAS 450I: Acute Toxicity in the Mallard Duck (Anas platyrhynchos) after Single Oral Administration (LD50). Project Number: 13W0219/10W019, 706469, 2015/1099658. Unpublished study prepared by BASF SE. 66p.

50211441 Keller, J.; Groeters, S.; Ravenzwaay, B. (2015) BAS 450I: Acute Toxicity in the Canary (Serinus canaria) after Single Oral Administration (LD50). Project Number: 15W0219/10W018, 738719, 2015/1095047. Unpublished study prepared by BASF SE. 68p.

50211442 Martin, K.; Temple, D.; Keller, K.; et al. (2017) BAS 450 I (MCI-8007): A Dietary LC50 Study with the Mallard. Project Number: 147B/312, 706470, 2017/7007306. Unpublished study prepared by EAG Laboratories. 68p.

50211443 Hubbard, P.; Temple, D.; Keller, K.; et al. (2017) BAS 450 I (MCI-8007): A Dietary LC50 Study with the Northern Bobwhite. Project Number: 147B/311, 706467, 2017/7007305. Unpublished study prepared by EAG Laboratories. 70p.

50211444 Wikander, M.; Temple, D.; Martin, K.; et al. (2017) BAS 450 I (MCI-8007): A Reproduction Study with the Mallard: Final Report. Project Number: 147B/285, 706471, 2017/7012416. Unpublished study prepared by EAG, Inc. 291p.

50211445 Martin, K.; Bryden, M.; Lockard, L.; et al. (2016) BAS 450 I (MCI-8007): A Reproduction Study with the Northern Bobwhite. Project Number: 147B/281, 744218, 2016/7001783. Unpublished study prepared by Wildlife International Ltd. 254p.

50211561 Martin, K.; Elliott, S.; Temple, D.; et al. (2017) BAS 450 I (MCI-8007): A Reproduction Study with the Mallard: Final Report. Project Number: 147B/327, 823204, 2017/7012417. Unpublished study prepared by EAG, Inc. 300p.

49722101 Ruhland, S. (2015) Chronic Toxicity of BAS 450 I (MCI-8007) to the Honeybee (Apis mellifera L.) under Laboratory Conditions. Project Number: 2015/1243703, 728743, 15/10/48/035/B. Unpublished study prepared by BioChem agrar Labor fuer biologische und chemische Analytik GmbH. 15p.

49722102 Kleebaum, K. (2015) Chronic Toxicity of BAS 450 I (MCI-8007) to Honeybee Larvae Apis mellifera L. under Laboratory Conditions (in vitro). Project Number: 728744, 2015/1243704, 15/10/48/098/B. Unpublished study prepared by BioChem agrar Labor fuer biologische und chemische Analytik GmbH. 18p.

50124717 Franke, M. (2016) Acute toxicity of BAS 450 01 I to the honeybee Apis mellifera L. under laboratory conditions: Final Report. Project Number: 803700, 16/10/48/151/B, 2016/1193024. Unpublished study prepared by Biochem Agrar, Labor fuer Biologische und Chemische. 42p.

50211465 Franke, M. (2015) Acute Toxicity of MCI-8700 (BAS 450 I) to the Honeybee Apis mellifera L. under Laboratory conditions: Final Report. Project Number: 706472, 15/10/48/096/B, 2015/7008312. Unpublished study prepared by Biochem Agrar, Labor fuer Biologische und Chemische. 45p.

50211565 Kling, A. (2017) Metabolite of BAS 450 I - Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions: Final Report. Project Number: 809888, S17/02982, 2017/1064904. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH/Ecotox GmbH. 37p.

50325607 Franke, M. (2017) Acute Toxicity of BAS 450 00 I to the Honeybee Apis melifera L. under Laboratory Conditions (Including Amendment No. 1): Final Report. Project Number: 706784, 15/10/48/095/B, 2017/7016518. Unpublished study prepared by Biochem Agrar. 46p.

50211470 Bergfiled, A. (2015) BAS 450 00 I (a.i. Reg. No. 5672774): Toxicity of Residues on Foliage to the Honey Bee, Apis mellifera. Project Number: 81147, 727107, 2014/7003659. Unpublished study prepared by ABC Laboratories, Inc. 87p.

50325617 McKelvey, R.; Porch, J.; Siddiqui, A. (2017) BAS 450 00 I: A Toxicity Test to Determine the Effects on Seedling Emergence and Seedling Growth of Ten Species of Plants: Final Report. Project Number: 147P/116, 706781, 2017/7000508. Unpublished study prepared by EAG Laboratories-Easton. 114p.

50325616 Orvos, A.; Porch, J.; Elliott, S. (2016) BAS 450 00 I: A Toxicity Test to Determine the Effects on Vegetative Vigor of Ten Species of Plants. Project Number: 147P/117, 706782, 2016/7006296. Unpublished study prepared by Wildlife International, Ltd. 118p.

50325617 McKelvey, R.; Porch, J.; Siddiqui, A. (2017) BAS 450 00 I: A Toxicity Test to Determine the Effects on Seedling Emergence and Seedling Growth of Ten Species of Plants: Final Report. Project Number: 147P/116, 706781, 2017/7000508. Unpublished study prepared by EAG Laboratories-Easton. 114p.

50325616 Orvos, A.; Porch, J.; Elliott, S. (2016) BAS 450 00 I: A Toxicity Test to Determine the Effects on Vegetative Vigor of Ten Species of Plants. Project Number: 147P/117, 706782, 2016/7006296. Unpublished study prepared by Wildlife International, Ltd. 118p.

50211464 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 7-Day Static-Renewal Toxicity Test with Duckweed (Lemna gibba G3). Project Number: 147P/120A, 706452, 2016/7009370. Unpublished study prepared by Wildlife International, Ltd. 72p.

50211455 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 96-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/108, 2017/7015494, 236/101716B/RAPHIDO/96/OECD/OCSPP/100P/621. Unpublished study prepared by EAG Laboratories. 73p.

50211456 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Cyanobacteria (Anabaena flos-aquae). Project Number: 147P/118A/BASF/STUDY, 706451, 2016/7005685. Unpublished study prepared by Wildlife International, Ltd. 69p.

50211457 Arnie, J.; Oliver, D.; Proch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Freshwater Diatom (Navicula pelliculosa). Project Number: 147P/119A, 706479, 2016/7005686. Unpublished study prepared by Wildlife International, Ltd. 74p.

50211458 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Marine Diatom (Skeletonema costatum). Project Number: 147P/114B/BASF, 706464, 2016/7005684. Unpublished study prepared by EAG Laboratories. 75p.

50905101 Arnie, J.; Paz, T.; Tull, C.; et al. (2019) Broflanilide Metabolite DC-8007: A 96 -Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/111, 2019/2045045. Unpublished study prepared by EAG Laboratories. 74p.

50211454 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 72-Hour Toxicity Test with the Freshwater Alga (Pseudokirchneriella subcapitata): Final Report. Project Number: 236P/105, 2017/7012409, 236/042016A/PSEUDO72/OECD/SUB236. Unpublished study preapred by EAG Laboratories. 63p.

50211455 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 96-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/108, 2017/7015494, 236/101716B/RAPHIDO/96/OECD/OCSPP/100P/621. Unpublished study prepared by EAG Laboratories. 73p.

50211456 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Cyanobacteria (Anabaena flos-aquae). Project Number: 147P/118A/BASF/STUDY, 706451, 2016/7005685. Unpublished study prepared by Wildlife International, Ltd. 69p.

50211457 Arnie, J.; Oliver, D.; Proch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Freshwater Diatom (Navicula pelliculosa). Project Number: 147P/119A, 706479, 2016/7005686. Unpublished study prepared by Wildlife International, Ltd. 74p.

50211564 Yamaguchi, N. (2016) Growth Inhibition Test of MFBA with Green Algae (Pseudokirchneriella subcapitata). Project Number: A160092, 2016/7012524. Unpublished study prepared by LSI Medience Corporation. 41p.

50973901 (50211568) Brougher, D.; Lockard, L.; Gallagher, S.; et al. (2017) BAS 450 I Metabolite (MFBA): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/335, 839217, 2017/7016207. Unpublished study prepared by EAG, Inc. 59p.

Appendix A: Risk Conclusions Based on Initial Label/Package Submission

Table A-1 summarizes potential risks associated with the use of broflanilide. For aquatic organisms, there are no level of concern (LOC) exceedances for freshwater or estuarine/marine fish, nor for aquatic plants. LOCs for water column freshwater invertebrates are not exceeded, based on water column or pore water comparisons to the available acute and chronic *Daphnia* endpoints. Estuarine mollusk (eastern oyster) acute data suggest risk to mollusks when compared to modeled EECs. Acute and chronic water column estuarine/marine invertebrate endpoints from the mysid studies result in RQs that exceed acute and chronic LOCs based on modeled water column and pore water EECs. Similarly, all sub-acute and chronic endpoints for three species of freshwater and estuarine benthic invertebrates are exceeded by modeled EECs, therefore there are risks identified for all invertebrates that interact with sediments in aquatic habitats. Aquatic risk quotients (RQs) are based upon the 1 in 10 year concentration from 30-years of weather data and use. Because the modeling suggests that broflanilide will accumulate in the sediments over this period of time these RQs reflect the risks associated with that accumulation (*i.e.,* the last few years of the modeling simulations yield the highest EECs). While the PWC modeling and subsequently the RQs consider 30-years of annual use. , it is important to note that after a single application the first year of some model simulations result in acute and chronic EEC that exceed the estuarine/marine endpoints (for t-band application to MS corn at 0.043 lbs a.i./A first year acute RQ = 7 and chronic RQ = 68). These results reflect that a single application of broflanilide has the potential to result in risk to water column estuarine/marine invertebrates. Due to the persistence of broflanilide, repeated use can considerably increase these risks over time.

Based on the available data, there is low potential for effects on birds and mammals on a chronic exposure basis through diet from the proposed use of broflanilide as a spray or injection, or from the consumption of treated seeds on an acute basis. However, on a chronic basis, the numbers of treated seeds to reach the avian and mammalian chronic LOCs are reasonably achievable for small and medium sized birds (28 to 170 seeds/day) and mammals (416 to 786 seeds/day). Because the treated seeds are cereal grains, the availability of seed would be high, with at most a light covering of soils. Therefore, chronic risk from consumption of broflanilide treated seeds is within reason. Given the conservatism of the KABAM estimated BCFs as compared to the empirically based BCFs (discussed in section 9.2), the results suggest that bioaccumulation is not a concern for broflanilide.

Broflanilide's propensity to sorb to lipids and sediments suggest that it is not likely systemic in plants and therefore exposure to bees through pollen and nectar contamination would only occur through direct spray of flowering attractive vegetation. This assumption is supported by empirical data generated to provide measured residues in pollen and nectar following in-furrow and seed treatment uses. The studies resulted in only one detection in pollen, which when compared to toxicity endpoints for honey bees or bumble bees, does not result in risk concerns. Acute and chronic risks to individual bees were identified following potential spray drift to flowering vegetation for ground furrow proposed uses. Additionally, any non-target terrestrial invertebrates, including bees that come into contact with or consume terrestrial sediments (*e.g.*, ground dwelling/nesting bees), are at risk from the proposed uses. Because of the persistence of broflanilide in sediments, the risks to sediment dwelling/interacting invertebrates would increase with every subsequent use of broflanilide.

Risks to terrestrial plants are considered low. The proposed furrow application rates for corn, tuberous and corm vegetables are below the concentrations that did not achieve a 25% effect level. So risks for these uses are low. This use may result in spray drift that would exceed the concentrations tested in the available studies. Because the endpoints are not definitive, and EECs exceed the highest tested concentrations, risk to plants that intercept the drift at the time of application for the termite furrow use cannot be precluded. However, these applications are proposed by hand held sprayer and likely do not represent a large spatial extent of potential exposure.

Table A-1. Summary of Risk Quotients (RQ) for Taxonomic Groups Based on Proposed Uses of Broflanilide.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Freshwater Fish	Acute	0.01	No	--
	Chronic	<0.1	No	--
Estuarine/ Marine Fish	Acute	NC	NA	Endpoint was non-definitive, EECs orders of magnitude lower than highest tested concentration
	Chronic	0.1-0.2	No	--
Freshwater Invertebrates (Water-Column Exposure)	Acute	NC	NA	Endpoint was non-definitive, EECs orders of magnitude lower than highest tested concentration
	Chronic	<0.1-0.3	No	--
Estuarine/ Marine Invertebrates (Water-Column Exposure)	Acute	12-83	Yes	RQs exceed LOC based on mysid data. No risks to mollusks based on eastern oyster data.
	Chronic	>122 to >950	Yes	RQs exceed LOC for water-column species for all uses. NOAEC was not established in available study so RQs based on LOAEC of 0.0018 µg a.i./L, where there was 17% reduced survival for offspring and 22% reduced reproduction.
Freshwater Invertebrates (Sediment Exposure)	Acute[2]	1 - 30	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.
	Chronic	12 to 174	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Estuarine/ Marine Invertebrates (Sediment Exposure)	Acute[2]	5.1 – 79.1	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates.
	Chronic	20 to >944	Yes	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates. Non-definitive mysid endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female.
Mammals	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint – no effects in study
	Chronic	<0.4	No	Potential chronic risk from consumption of treated seed; 416-786 seeds/day to reach LOC
Birds	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint – no effects in study
	Chronic	<0.4	No	Potential chronic risk from consumption of treated seed; 28-170 seeds/day to reach LOC
Terrestrial Invertebrates[3]	Acute Adult	0.4 – 92.7	Yes	Acute and chronic risk concerns for bees is limited to foraging nectar and/or pollen contaminated by spray drift. Broflanilide is not likely systemic and submitted residues in pollen and nectar studies support low risk from systemic transport.
	Chronic Adult	9.7 – 2228	Yes	
	Acute Larval	0.1 – 20.2	Yes	
	Chronic Larval	31.9 - 7308	Yes	All non-target invertebrates that interact with soils for foraging diet, nesting, reproduction etc. are at risk. These risks follow a single application and because of broflanilide' s persistence in soils, will likely increase with each annual application.
Aquatic Plants	Not Applicable	<0.01	No	--
Terrestrial Plants	Not Applicable	<0.01	No	Uncertainty regarding the potential for effects following termite use rate at 0.29 lbs a.i./A, as this exceeds the highest tested concentrations in the studies (0.091 lbs a.i./A).

Level of Concern (LOC) Definitions:
Terrestrial Animals: Acute=0.5; Chronic=1.0; Terrestrial invertebrates=0.4
Aquatic Animals: Acute=0.5; Chronic=1.0
Plants: 1.0

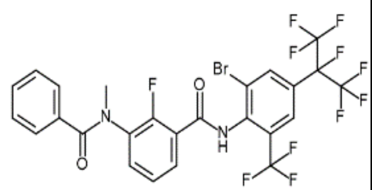
[1] RQs reflect exposure estimates for parent and maximum application rates allowed on labels.

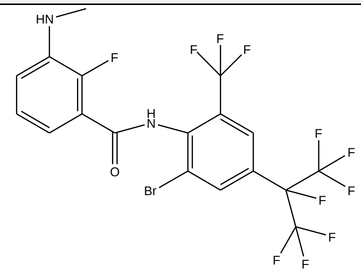
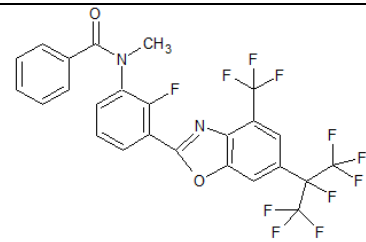
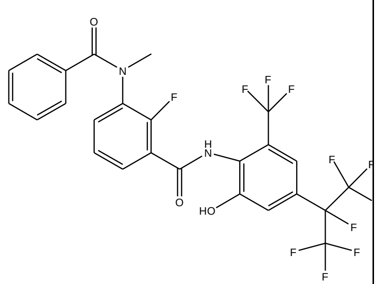
[2] Based on water-column toxicity data compared to pore-water concentration.

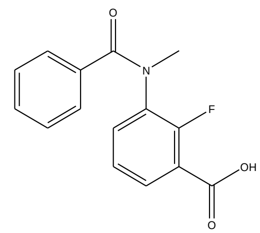
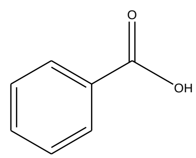
[3] RQs for terrestrial invertebrates are applicable to honey bees, which are also a surrogate for other species of bees. Risks to other terrestrial invertebrates (*e.g.*, earthworms, beneficial arthropods) are only characterized when toxicity data are available.

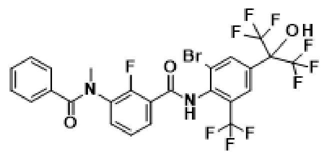
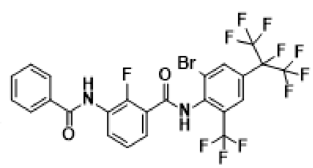
Appendix B. Chemical Names and Structures

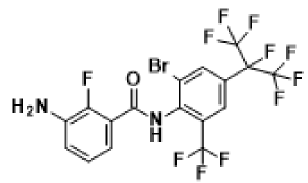
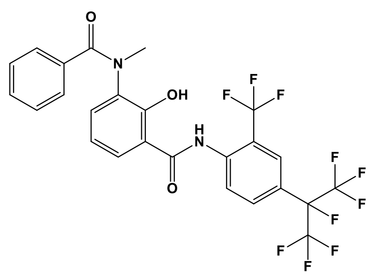
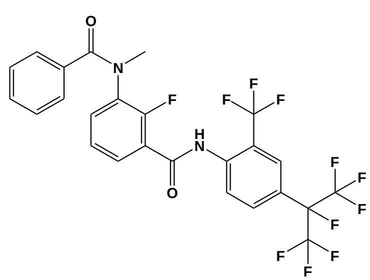
Table B-1. Names and chemical structures of the environmental transformation products of broflanilide

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
PARENT COMPOUND							
Broflanilide MCI-8007 BAS 450 I BASF Reg. No. 5672774	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide **CAS#:** 1207727-04-5 **Formula:** $C_{25}H_{14}BrF_{11}N_2O_2$ **MW:** 663.28 g/mol **SMILES Code:** CN(C1=CC=CC(=C1F)C(=O)NC2=C(C=C(C=C2Br)C(C(F)(F)F)(C(F)(F)F)F)C(F)(F)F)C(=O)C3=CC=CC=C3		Hydrolysis	50111328	pH 4, 7 and 9 @ 50°C	-	-
			Aqueous photolysis	50111329	pH 7 @ 25°C	-	-
				50111330	pH 5,7 & 9 @ 25°C	-	-
			Soil photolysis	50211429	Silt Loam	-	-
			Aerobic aquatic	50211437	Brandywine Creek Sediment	-	-
					Choptank River Sediment	-	-
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	-	-
					Choptank River Sediment	-	-
			Aerobic soil	50211427	Centerville Clay, CA	-	-
				50211430	Drummer silty clay loam, IL		
					Norfolk sandy loam, NC		
					Falaya Silt loam, TN		
			Anaerobic soil	50211428	Centerville Clay, CA	-	-
					Drummer silty clay loam, IL		
					Norfolk sandy loam, NC		
					Falaya Silt loam, TN		
MAJOR TRANSFORMATION PRODUCTS							
DC-8007 BASF Reg. No. 5936907	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(methylamino)benzamide **CAS#:** N/A **Formula:** $C_{18}H_{10}BrF_{11}N_2O$		Aqueous photolysis		pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	1.0 (1) ND [1] 1.3 (0)	ND (16) ND ND (16)
			Aerobic aquatic	50211437	Brandywine Creek Sediment	**11.8 (273)**	9.9 (365)
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	**18.2 (365)**	**18.2 (365)**

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
	MW: 559.17 g/mol **SMILES Code:** CNc1cccc(C(=O)Nc2c(Br)cc(cc2C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c1F		Anaerobic soil	50211438	Drummer silty clay loam, IL	**71.7 (363)**	**71.7 (363)**
AB-oxa BASF Reg. No. 5959600	*N*-{2-fluoro-3-[6-(perfluoropropan-2-yl)-4-(trifluoromethyl)-1,3-benzooxazol-2-yl]phenyl}-*N*-methylbenzamide **CAS#:** N/A **Formula:** $C_{25}H_{13}F_{11}N_2O_2$ **MW:** 582.37 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(c2F)c3oc4cc(cc(c4n3)C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	6.9 (6) 6.1 (12) **37.6 (3)**	2.1 (16) 4.7 (16) 1.3 (16)
S(Br-OH)-8007 BASF Reg. No. 5959595	2-fluoro-*N*-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-hydroxy-6-(trifluoromethyl)phenyl]-3-(*N*-methylbenzamido) benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}F_{11}N_2O_3$ **MW:** 600.38 g/mol **SMILES Code:**		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**14.3(9)** ND 5.5 (9)	**11.4 (16)** ND 1.0 (16)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
	CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3c(O)cc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2F						
MFBA	2-fluoro-3-(N-methylbenzamido)benzoic acid **CAS#:** N/A **Formula:** $C_{15}H_{12}FNO_3$ **MW:** 273.26 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)O)c2F	 	Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**19.7 (16)** ND **25.6 (16)**	**19.7 (16)** ND **25.6 (16)**
Benzoic acid BASF Reg. No. 4005129	**CAS#:** 65-85-0 **Formula:** $C_7H_6O_2$ **MW:** 122.1 g/mol **SMILES Code:** OC(=O)c1ccccc1	 	Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**25.7 (13)** ND **43.5 (9)**	**25.6 (16)** ND **42.9 (16)**
Carbon dioxide	**CAS#**: 124-38-9 **Formula**: CO_2 **MW:** 44.0 g/mol **SMILE Code:** **SMILES:** C(=O)=O	O=C=O	Aqueous photolysis	50111329 50111330	pH 5-9 @ 25°C	<10.0 (16)	<10.0 (16)
			Aerobic aquatic	50211437	Brandywine Creek Sediment	**15.4 (365)**	**15.4 (365)**
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<5.0 (365)	<1.0 (365)
			Aerobic soil	50211430	Norfolk sandy loam, NC	1.2 (365)	1.2 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	<2.0 (365)	<2.0 (365)
Unextracted Residues	N/A	N/A	Soil photolysis	50211429	Silt Loam	<5.0 (14)	<5.0 (14)
			Aerobic aquatic	50211437	Choptank River Sediment	**14.2 (365)**	**14.2 (365)**
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<10.0 (365)	<10.0 (365)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
			Aerobic soil	50211430	Norfolk sandy loam, NC	**12.9 (365)**	**12.9 (365)**
			Anaerobic soil	50211438	All soil samples	<10 (365)	<10 (365)
MINOR TRANSFORMATION PRODUCTS							
S(PFP-OH)-8007 BASF Reg. No. 5959598	*N*-[2-bromo-4-(1,1,1,3,3,3-hexafluoro-2-hydroxypropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}BrF_{10}N_2O_3$ **MW:** 661.29 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3c(Br)cc(cc3C(F)(F)F)C(O)(C(F)(F)F)C(F)(F)F)c2F		Aqueous photolysis	50111329 50111330	pH 5-9 @ 25°C	8.3 (6)	5.5 (16)
			Aerobic soil	50211427	Centerville Clay, CA	1.1 (0)	ND (365)
				50211430	Norfolk sandy loam, NC	1.0 (15)	0.5 (365)
			Anaerobic soil	50211438	Centerville Clay, CA	3.9 (14)	ND[1] (363)
DM-8007 BASF Reg. No. 5856361	3-benzamido-*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide **CAS#:** N/A **Formula:** $C_{24}H_{12}BrF_{11}N_2O_2$ **MW:** 649.25 g/mol **SMILES Code:** N(C(=O)C1=CC=CC=C1)(C2=C(C(=CC=C2)C(=O)NC3=C(C=C(C=C3Br)C(O)(C(F)(F)F)C(F)(F)F)C(F)(F)F)[H]		Soil photolysis	50211429	Silt Loam	4.2 (6)	2.6 (14)
			Aerobic soil	50211427	Centerville Clay, CA	1.6 (91)	1.1 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	1.5 (30)	ND (363)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
DC-DM-8007 BASF Reg. No. 5936906	3-amino-*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide **CAS#:** N/A **Formula:** $C_{17}H_8BrF_{11}N_2O$ **MW:** 545.15 g/mol **SMILES Code:** CNc1cccc(C(=O)Nc2c(Br)cc(cc2C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c1F		Aerobic soil	50211430	Norfolk sandy loam, NC	0.9 (259)	ND (365)
S(F-OH)-8007 BASF Reg. No. 5959597	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-hydroxy-3-(*N*-Methylbenzamido)benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}BrF_{10}N_2O_3$ **MW:** 661.29 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3ccc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2O		Aqueous photolysis	50111330	pH 9 @ 25°C	3.8 (6)	1.7 (16)
DBr-8007 BASF Reg. No. 5959596	2-fluoro-3-(N-methylbenzamido)-N-[4-(perfluoropropan-2-yl)-2-(trifluoromethyl)phenyl]benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}F_{11}N_2O_2$ **MW:** 584.4 g/mol **SMILES Code:**		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	3.8 (2) ND 3.8 (6)	0.2 (16) ND 0.7 (16)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
	CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3ccc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2F						
UNIDENTIFIED RESIDUES							
Total Unidentified Extracted Residues (UER) [2]	N/A	N/A	Hydrolysis	50111328	pH 4, 7 and 9 @ 50°C	<10.0 (5)	<10.0 (5)
			Aqueous photolysis	50111330	pH 5 @ 25°C pH 9 @ 25°C	**45.4 (16)** **64.8 (16)**	**45.4 (16)** **64.8 (16)**
			Aerobic aquatic	50211437	Choptank River Sediment	<10.0 (365)	<10.0 (365)
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<5.0 (365)	<5.0 (365)
			Aerobic soil	50211427	Centerville Clay, CA	1.9 (365)	1.9 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	<5.0 (365)	<5.0 (365)

Bolded when appearing at >10%

- = Not applicable

[1] ND = Not Detected

[2] UER consisted of minor degradates, each of which were <10% of the applied.

Appendix C. Sample Outputs for PWC

Summary of Water Modeling of Broflanilide and the USEPA Standard Pond

Estimated Environmental Concentrations for Broflanilide are presented in **Table C-1** for the USEPA standard pond with the MScornSTD field scenario. A graphical presentation of the year-to-year peaks is presented in **Figure C-1**. These values were generated with the Pesticide Water Calculator (PWC), Version 1.52. Critical input values for the model are summarized in **Tables C-2** and **C-3**.

This model estimates that about 1.2% of Broflanilide applied to the field eventually reaches the water body. The main mechanism of transport from the field to the water body is by runoff (91.2% of the total transport) followed by erosion (8.82%).

In the water body, pesticide dissipates with an effective water column half-life of 1577.4 days. (This value does not include dissipation by transport to the benthic region; it includes only processes that result in removal of pesticide from the complete system.) The main source of dissipation in the water column is metabolism (effective average half-life = 2011.6 days) followed by photolysis (7318.3 days) and volatilization (4953371 days).

In the benthic region, pesticide dissipation is negligible (2051.1 days). The main source of dissipation in the benthic region is metabolism (effective average half-life = 2051.1 days). The vast majority of the pesticide in the benthic region (99.79%) is sorbed to sediment rather than in the pore water.

Table C-1. Estimated Environmental Concentrations (ppb) for Broflanilide.

Peak (1-in-10 yr)	0.462
4-day Avg (1-in-10 yr)	0.440
21-day Avg (1-in-10 yr)	0.414
60-day Avg (1-in-10 yr)	0.412
365-day Avg (1-in-10 yr)	0.386
Entire Simulation Mean	0.262

Table C-2. Summary of Model Inputs for Broflanilide.

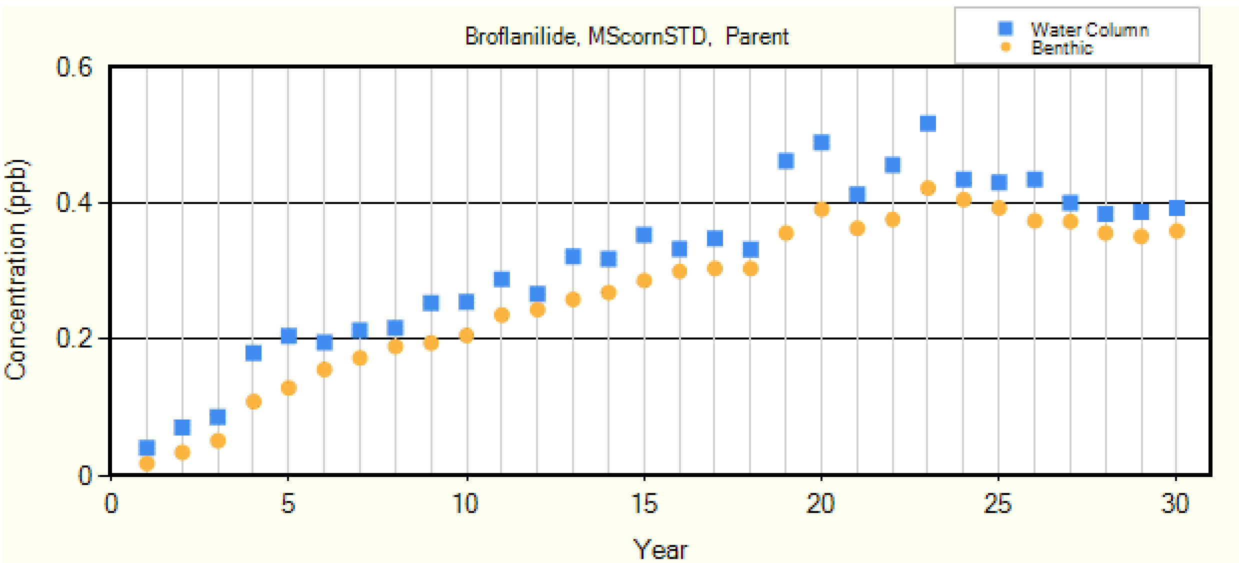
Scenario	MScornSTD
Cropped Area Fraction	1
Kd (ml/g)	177
Water Half-Life (days) @ 20 °C	1934
Benthic Half-Life (days) @ 20 °C	1972
Photolysis Half-Life (days) @ 40 °Lat	80
Hydrolysis Half-Life (days)	0
Soil Half-Life (days) @ 25 °C	2198
Foliar Half-Life (days)	
Molecular Weight	663.29

Vapor Pressure (torr)	6.6E-11
Solubility (mg/l)	0.71
Henry's Constant	3.32E-09

Table C-3. Application Schedule for Broflanilide.

Date (Days Since Emergence)	Type	Amount (kg/ha)	Eff.	Drift
-7	Linearly increasing to 2.54 cm	0.05	1	0

Figure C-1. Yearly Peak Concentrations



Appendix D: Summary of Available Toxicity Data

Table D-1. Summary of Available Aquatic and Terrestrial Toxicity Studies and Endpoints

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
Aquatic Animals - Invertebrates			
850.101 TGAI (MCI-8007, 98.67%, Broflanilide)	*Daphnia magna*	LC 50 > 0.332 mg a.i./L	50211452 Acceptable
850.101 TGAI (MFBA, 99.3%, Metabolite of Broflanilide)	*Daphnia magna*	LC50 > 100 mg a.i./L	50211514 Acceptable
850.1025 TGAI (MCI-8007, 98.67%, Broflanilide)	*Crassostrea virginica*	LC > 0.44 mg a.i./L; NOAEC = 0.44 mg a.i./L	50211486 Acceptable
850.1035 TGAI (AB-oxa, 98.64%, Metabolite of Broflanilide)	*Americamysis bahia*	LC50 = 0.0302 mg a.i./L; NOAEC < 0.0026 mg a.i./L	50211567 Acceptable
850.1035 TGAI (MCI-8007, 98.67%, Broflanilide)	*Americamysis bahia*	lC50 = 0.0000215 mg a.i./L; NOAEC = 0.0000107 mg a.i./L visually determined based on 35% mortality at 0.0000202 mg a.i./L	50211485 Acceptable
850.1035 TGAI (MFBA, 99.87%, Metabolite of Broflanilide)	*Americamysis bahia*	LC50 > 0.112 mg a.i./L; NOAEC = 0.059 mg a.i./L; LOAEC = 0.112 mg a.i./L based on lethargy	50973901 (50211568) Acceptable
850.1035 TGAI (S(Br-OH), 98.86%, Metabolite of Broflanilide)	*Americamysis bahia*	LC50 = 0.0406 mg a.i./L; NOAEC < 0.00449 mg a.i./L; steep dose response and uncertainty of LC50 (10, 30, 0, 0, 100% mortality across test groups).	50211566 Acceptable
850.13 TGAI (MCI-8007, 98.67%, Broflanilide)	*Daphnia magna*	NOAEC = 0.00593 mg a.i./L; LOAEC = 0.0116 mg a.i./L; based on 6-8% reductions in length, total offspring, birth rate, and time to first brood.	50211453 Acceptable
850.13 TGAI (MFBA, 99.3%, Metabolite of Broflanilide)	*Daphnia magna*	NOAEC = 98.0 mg a.i./L; no effects	50211563 Acceptable
850.135 TGAI (MCI-8007, 98.67%, Broflanilide)	*Americamysis bahia*	NOAEC < 0.0000018 mg a.i./L; LOAEC = 0.0000018 mg a.i./L based on F1 survival 18% reduced survival and 22% less offspring per female.	50211488 Supplemental

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
850.1735 TGAI (BAS 450 I, 99.9%, Broflanilide)	*Chironomus dilutus*	LC50 = 0.454 mg a.i./kg-sediment OC; Mortality: NOAEC = 0.068 mg a.i./kg-sediment OC; LC50 = 0.00181 mg a.i./L pore water; Mortality: NOAEC = 0.000384 ug a.i./L pore water;	50211459 Acceptable
850.1735 TGAI (DC-8007, 99.60%, Metabolite of Broflanilide)	*Chironomus dilutus*	LC50 > 3.5 mg a.i./kg-sediment; NOAEC = 3.5 mg a.i./kg-sediment;	50211513 Acceptable
850.1735 TGAI (MCI-8007, 98.67%, Broflanilide)	*Hyalella azteca*	LC50 = 0.752 mg a.i./kg-sediment OC; NOAEC = 0.27 mg a.i./kg-sediment OC; LC50 = 0.461 ug a.i./L pore water; NOAEC = 0.16 ug a.i./L pore water. Survival	50211460 Acceptable
850.174 TGAI (MCI-8007, 98.67%, Broflanilide)	*Leptocheirus plumulosus*	LC50 = 0.410 mg a.i./kg-sediment OC; NOAEC = 0.29 mg a.i./kg-sediment OC based on survival	50211487 Acceptable
EPA 100.4 (WS-CT) TGAI (MCI-8007, 98.67%, Broflanilide)	*Hyalella azteca*	NOAEC < 0.000039 mg a.i./L pore; <0.091 mg a.i./kg-sediment OC based on male-female ratio; NOAEC = 0.000039 mg a.i./L pore; = 0.091 mg a.i./kg-sediment OC based on survival (solvent control comparison due to significant interaction);	50211462 Supplemental
EPA 100.5 (WS-CT) TGAI (BAS 450 I, 99.9%, Broflanilide)	*Chironomus dilutus*	NOAEC = 0.067 mg a.i./kg-sediment OC; 0.000024 mg a.i./L pore; 0.0015 mg a.i./kg-sediment based on percent emergence (36% reduction) and survival (20% reduction).	50211461 Supplemental
NG (WS-CT) TGAI (MCI-8007, 98.67%, Broflanilide)	*Leptocheirus plumulosus*	NOAEC = 0.130 mg a.i./kg-sediment OC; based on survival, and growth rate	50211463 Supplemental
Aquatic Animals - Fish			
850.1075 TGAI (MCI-8007, 98.67%, Broflanilide)	*Cyprinodon variegatus*	LC50 > 1.3 mg a.i./L; NOAEC = 0.15 mg a.i./L	50211490 Acceptable
850.1075 TGAI (MCI-8007, 98.67%, Broflanilide)	*Cyprinus carpio*	LC50 > 0.498 mg a.i./L; NOAEC =0.241 mg a.i./L	50211512 Acceptable
850.1075 TGAI (MCI-8007, 98.67%, Broflanilide)	*Lepomis macrochirus*	LC50 = 0.251 mg a.i./L; NOAEC = 0.158 mg a.i./L; Since the dose response is so steep, there is uncertainty in the estimated LC50; the true LC50 falls above 158 µg a.i./L and below 290 µg a.i./L.	50211447 Acceptable

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
850.1075 TGAI (MCI-8007, 98.67%, Broflanilide)	*Oncorhynchus mykiss*	LC50 = 0.359 mg a.i./L; NOAEC = 0.132 mg a.i./L; Since the dose response is so steep, there is uncertainty in the estimated LC50; the true LC50 falls above 260 µg a.i./L and below 649 µg a.i./L	50211446 Acceptable
850.1075 TGAI (MCI-8007, 98.67%, Broflanilide)	*Pimephales promelas*	LC50 > 0.508 mg a.i./L; NOAEC = 0.508 mg a.i./L; no effects	50211448 Acceptable
850.14 TGAI (MCI-8007, 98.67%, Broflanilide)	*Cyprinodon variegatus*	NOAEC = 0.011 mg a.i./L; LOAEC = 0.025 mg a.i./L; based on reduced length (4%), dry weight (10-13%), wet weight (10%), time to hatch (16%). Note: 91% reduced survival at 0.159 mg a.i./L	50211450 Acceptable
850.14 TGAI (MCI-8007, 98.67%, Broflanilide)	*Pimephales promelas*	NOAEC = 0.051 mg a.i./L; LOAEC 0.147 mg a.i./L; based on 9% reduction in larval survival.	50211449 Acceptable
Aquatic Plants			
850.44 TGAI (MCI-8007, 98.67%, Broflanilide)	*Lemna gibba*	EC50 > 0.63 mg a.i./L; NOAEC = 0.63 mg a.i./L	50211464 Acceptable
850.45 TGAI (MCI-8007, 98.67%, Broflanilide)	*Anabaena flos-aquae*	EC50 > 0.916 mg a.i./L; NOAEC = 0.916 mg a.i./L	50211456 Acceptable
850.45 TGAI (MCI-8007, 98.67%, Broflanilide)	*Navicula pelliculosa*	EC50 > 0.522 mg a.i./L; NOAEC = 0.0852 mg a.i./L	50211457 Acceptable
850.45 TGAI (MCI-8007, 98.67%, Broflanilide)	*Pseudokirchneriella subcapitata*	EC50 > 0.6 mg a.i./L; NOAEC = 0.6 mg a.i./L	50211454 Acceptable
850.45 TGAI (MCI-8007, 98.67%, Broflanilide)	*Raphidocelis subcapitata*	EC50 > 0.71 mg a.i./L; NOAEC = 0.12 mg a.i./L	50211455 Acceptable
850.45 TGAI (MCI-8007, 98.67%, Broflanilide)	*Skeletonema costatum*	EC50 = 0.57 mg a.i./L; NOAEC = 0.16 mg a.i./L	50211458 Acceptable
850.45 TGAI (DC-8007, 99.60%, Metabolite of Broflanilide)	*Raphidocelis subcapitata*	EC50 = 1.08 mg a.i./L; NOAEC = 0.0486 mg a.i./L	50211455 Supplemental
850.54 TGAI (MFBA, 99.3%, Metabolite of Broflanilide)	*Pseudokirchneriella subcapitata*	EC50 > 96.8 mg a.i./L	50211564 Acceptable

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
Terrestrial Animals - Birds			
850.21 TGAI (BAS 450 I, 98.67%, Broflanilide)	*Anas platyrhynchos*	LD/LC 50 >2000 mg a.i./kg-bw; no effects	50211440 Acceptable
850.21 TGAI (BAS 450 I, 98.67%, Broflanilide)	*Colinus virginianus*	LD/LC 50 >2000 mg a.i./kg-bw; no effects	50211439 Acceptable
850.21 TGAI (BAS 450 I, 98.67%, Broflanilide)	*Serinus canaria*	LD/LC 50 >2000 mg a.i./kg-bw; no effects	50211441 Acceptable
850.22 TGAI (BAS 450 I/MCI-8007, 98.67%, Broflanilide)	*Anas platyrhynchos*	LC50 > 5000 mg a.i./kg-diet; LD50 > 2081 mg a.i/kg-bw;	50211442 Acceptable
850.22 TGAI (BAS 450 I/MCI-8007, 98.67%, Broflanilide)	*Colinus virginianus*	LC50 > 5000 mg a.i./kg-diet; LD50 > 1364 mg a.i./kg-bw; no effects	50211443 Acceptable
850.23 TGAI (BAS 450 I/MCI-8007, 98.67%, Broflanilide)	*Anas platyrhynchos*	NOAEC < 250 mg a.i./kg-diet; < 32.8 mg a.i./kg-bwt; effects to both % 14-day hatchling survival (high & low doses) and mean eggshell thickness (all conc), and 14-day survivor body weights (not statistical)	50211444 Supplemental
850.23 TGAI (BAS 450 I/MCI-8007, 98.67%, Broflanilide)	*Colinus virginianus*	NOAEC = 254 mg a.i./kg-diet; significant inhibitions in 14-days survivors/hatchling at the mean-measured 506 and 1021 mg ai/kg diet treatment groups, and in 14-day survivor weight at the mean-measured 1021 mg ai/kg diet	50211445 Acceptable
850.23 TGAI (MCI-8007, 98.67%, Broflanilide)	*Anas platyrhynchos*	NOAEC = 29.7 mg a.i./kg-diet; 1 decreased eggs laid, and %14-day survivors of hatchlings	50211561 Acceptable
Terrestrial Animals - Pollinators			
850.3020 & NG (oral) TEP (BAS 450 00 I, 9.6%, Broflanilide)	*Apis mellifera*	Oral = 45 ng a.i./bee; Contact = 17 ng a.i./bee	50325607 acceptable
850.3020 & NG (oral) TEP (BAS 450 00 I, 9.6%, Broflanilide)	*Bombus terrestris*	oral = 13.9 ng a.i./bumblebee; contact = 122 ng a.i./bumblebee	50325608 acceptable
850.3020 & NG (oral) TEP (BAS 450 01 I, 26.5%, Broflanilide)	*Apis mellifera*	oral = 69.3 ng a.i./bee; contact = 12.4 ng a.i./bee	50124717 acceptable

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
850.3020 & NG (oral) TGAI (DC-DM-8007, 99.67%, Metabolite of Broflanilide)	*Apis mellifera*	oral > 20270 ng a.i./bee; contact >100000 ng a.i./bee	50211524 acceptable
850.3020 & NG (oral) TGAI (MCI-8007, 98.67%, Broflanilide)	*Apis mellifera*	oral = 14.9 ng a.i./bee; contact = 8.8 ng a.i./bee	50211465 acceptable
850.3020 & NG (oral) TGAI (MCI-8007, 98.67%, Broflanilide)	*Bombus terrestris*	oral = 19.5 ng a.i./bumblebee; contact > 120 ng a.i./bumblebee	50211466 acceptable
850.3020 & NG (oral) TGAI (Reg No. 5856361, DM-8007, 98.84%, Metabolite of Broflanilide)	*Apis mellifera*	oral = 1920 ng a.i./bee; contact = 190 ng a.i./bee	50211516 acceptable
850.3020 & NG (oral) TGAI (Reg No. 5936907, DC-8007, 99.60%, Metabolite of Broflanilide)	*Apis mellifera*	oral > 100000 ng a.i./bee; contact = 33200 ng a.i./bee	50211521 acceptable
850.3020 & NG (oral) TGAI (Reg No. 5959598, S(PFP-OH)-8007), 99.02%, Metabolite of Broflanilide)	*Apis mellifera*	oral > 5600 ng a.i./bee; contact > 5000 ng a.i./bee	50211519 acceptable
850.3020 & NG (oral) TGAI (Reg No. 6065386, B-urea, 99.19%, Metabolite of Broflanilide)	*Apis mellifera*	oral > 100000 ng a.i./bee; contact > 20000 ng a.i./bee	50211523 acceptable
850.3020 & NG (oral) TGAI (Reg No. 6066332, B-oxam-acid, 99.86%, Metabolite of Broflanilide)	*Apis mellifera*	oral > 23550 ng a.i./bee; contact > 100000 ng a.i./bee	50211565 acceptable
NG (ACO) TGAI (MCI-8007, 98.67%, Broflanilide)	*Apis mellifera*	LD50 = 1.29 ng a.i./bee/day; LC50 = 0.03 mg a.i./kg-food; NOAEL = 0.620 ng a.i./bee/day; NOAEC = 0.018 mg a.i./kg-food	50211469 supplemental
NG (LAO) TGAI (MCI-8007, 98.67%, Broflanilide)	*Apis mellifera*	LD50 > 29 ng a.i./larva; LC50 > 0.88 mg a.i./kg-food; NOAEL = 11 ng a.i./larva; NOAEC = 0.34 mg a.i./kg-food	50211471 acceptable

OCSPP Guideline, Study Type & TGAI/TEP/% ai	Test Species	Toxicity Endpoints, Effects	MRID Classification
NG (LCO) TGAI (MCI-8007, 98.67%, Broflanilide)	*Apis mellifera*	Larval stage: LD50 = 7.5 ng a.i./larva, LC50 = 0.196 mg a.i./kg-food, NOAEL = 0.08 ng a.i./larva, NOAEC = 0.00229 mg a.i./kg-food; Pupal stage: LD50 = 2.1 ng a.i./larva, LC50 = 0.0557 mg a.i./kg-food, NOAEL = 0.8 ng a.i./larva, NOAEC = 0.02218 mg a.i./kg-food; Emergence: ED50 = 1.3 ng a.i./larva, EC50 = 0.0348 mg a.i./kg-food, NOAEL 0.8 ng a.i./larva, NOAEC 0.0218 mg a.i./kg-food	50211472 acceptable
850.303 TEP (BAS 450 00 I (100 SC), 9.5%, Broflanilide)	*Apis mellifera*	RT25 < 3 hrs	50211470 acceptable
Terrestrial Plants			
850.4100-1 and 850.4100-2 TEP (BAS 450 00 I, 9.6%, Broflanilide)	*Allium cepa, Lolium perenne, Triticum aestivum, Zea mays, Beta vulgaris, Brassica napus, Brassica oleracea, Glycine max, Lactuca sativa, Lycopersicon esculentum*	NOAECs = 0.091 lb a.i./A, EC25s >0.091 lb a.i./A::Monocots Tier I: No observed effects, NOAEC = 0.091 lbs a.i./A; Dicots Tier I significant for Lettuce and Cabbage: Cabbage Tier II Survival: NOAEC = 0.09, EC25=0.01, EC50=0.48 lbs a.i./A; Sugarbeet survival NOAEC < 0.0023 but not dose response; No significant effects to any other taxa in Tier II.	50211478
850.4150-1 and 850.4150-2 TEP (BAS 450 00 I, 9.6%, Broflanilide)	*Allium cepa, Lolium perenne, Triticum aestivum, Zea mays, Beta vulgaris, Brassica napus, Brassica oleracea, Glycine max, Lactuca sativa, Lycopersicon esculentum*	No effects: Monocot and Dicot NOAECs = 0.091 lb a.i./A, EC25s >0.091 lb a.i./A	50211643

Appendix E. Terrestral Modeling Input/Output for a Single Application to Corn

E- 1. Example TREX Inputs

Chemical Identity and Application Information

Chemical Name:	broflanilide
Seed Treatment? (Check if yes)	FALSE
Use:	
Product name and form:	
% A.I. (leading zero must be entered for formulations <1% a.i.):	100.00%
Application Rate (lb ai/acre)	0.045
Half-life (days):	35
Application Interval (days):	
Number of Applications:	1
Are you assessing applications with variable rates or intervals?	no

Avian

Endpoint	Toxicity value	Indicate test species
LD50 (mg/kg-bw)	2000.00	Bobwhite quail
LC50 (mg/kg-diet)	5000.00	Mallard duck
NOAEL (mg/kg-bw)		Bobwhite quail
NOAEC (mg/kg-diet)	29.70	Mallard duck

Enter the Mineau et al. Scaling Factor 1.15

Mammalian

	Acute Study	Chronic Study
Size (g) of mammal used in toxicity study Default rat body weight is 350 grams	350	350

Endpoint	Toxicity value		Reference (MRID)
LD50 (mg/kg-bw)	5000.00		
LC50 (mg/kg-diet)			
Reported Chronic Endpoint	26.00	mg/kg-bw	
Is dietary concentration (mg/kg-diet) reported from the available chronic mammal study? (yes or no)	yes		
Enter dietary concentration (mg/kg-diet)	300.00		

E-2. KABAM Inputs and Outputs

Table 1. Chemical characteristics of brofalnilide.		
Characteristic	**Value**	**Comments/Guidance**
Pesticide Name	**brofalnilide**	**Required input**
Log K_{OW}	**5.2**	**Required input** Enter value from acceptable or supplemental study submitted by registrant or available in scientific literature.
K_{OW}	**158489**	No input necessary. This value is calculated automatically from the Log K_{OW} value entered above.
K_{OC} (L/kg OC)	**7606**	**Required input** Input value used in PRZM/EXAMS to derive EECs. Follow input parameter guidance for deriving this parameter value (USEPA 2002).
Time to steady state (T_S; days)	**45**	No input necessary. This value is calculated automatically from the Log K_{OW} value entered above.
Pore water EEC (µg/L)	**0.39**	**Required input** Enter value generated by PRZM/EXAMS benthic file. PRZM/EXAMS EEC represents the freely dissolved concentration of the pesticide in the pore water of the sediment. The appropriate averaging period of the EEC is dependent on the specific pesticide being modeled and is based on the time it takes for the chemical to reach steady state. Select the EEC generated by PRZM/EXAMS which has an averaging period closest to the time to steady state calculated above. In cases where the time to steady state exceeds 365 days, the user should select the EEC representing the average of yearly averages. The peak EEC should not be used.
Water Column EEC (µg/L)	**0.46**	**Required input** Enter value generated by PRZM/EXAMS water column file. PRZM/EXAMS EEC represents the freely dissolved concentration of the pesticide in the water column. The appropriate averaging period of the EEC is dependent on the specific pesticide being modeled and is based on the time it takes for the chemical to reach steady state. The averaging period used for the water column EEC should be the same as the one selected for the pore water EEC (discussed above).

Table 2. Input parameters for rate constants. "calculated" indicates that model will calculate rate constant.					
Trophic level	**k_1 (L/kg*d)**	**k_2 (d^{-1})**	**k_D (kg-food/kg-org/d)**	**k_E (d^{-1})**	**k_M* (d^{-1})**
phytoplankton	calculated	calculated	0*	0*	0
zooplankton	calculated	calculated	calculated	calculated	0

benthic invertebrates	calculated	calculated	calculated	calculated	0
filter feeders	calculated	calculated	calculated	calculated	0
small fish	calculated	calculated	calculated	calculated	0.26
medium fish	calculated	calculated	calculated	calculated	0.26
large fish	calculated	calculated	calculated	calculated	0.26

* Default value is 0.
k_1 and k_2 represent the uptake and elimination constants respectively, through respiration.

k_D and k_E represent the uptake and elimination constants, respectively, through diet.

k_M represents the metabolism rate constant.

Table 3. Mammalian and avian toxicity data for brofalnilide. These are required inputs.

Animal	Measure of effect (units)	Value	Species	If selected species is "other," enter body weight (in kg) here.
Avian	LD_{50} (mg/kg-bw)	2000	Northern bobwhite quail	
	LC_{50} (mg/kg-diet)	5000	mallard duck	
	NOAEC (mg/kg-diet)	29.7	mallard duck	
	Mineau Scaling Factor	1.15	Default value for all species is 1.15 (for chemical specific values, see Mineau et al. 1996).	
Mammalian	LD_{50} (mg/kg-bw)	5000	laboratory rat	
	LC_{50} (mg/kg-diet)	N/A	other	
	Chronic Endpoint	300	laboratory rat	
	units of chronic endpoint*	ppm		

*ppm = mg/kg-diet

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by brofalnilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	0.000	N/A	0.055	0.010
rice rat/star-nosed mole	0.000	N/A	0.072	0.011

small mink	0.000	N/A	0.124	0.020
large mink	0.000	N/A	0.137	0.020
small river otter	0.000	N/A	0.147	0.020
large river otter	0.001	N/A	0.254	0.032
Avian				
sandpipers	0.002	0.001	N/A	0.107
cranes	0.000	0.001	N/A	0.122
rails	0.001	0.001	N/A	0.128
herons	0.000	0.001	N/A	0.150
small osprey	0.000	0.001	N/A	0.200
white pelican	0.000	0.002	N/A	0.320

E-3. Example TerrPlant Input and Output

TerrPlant v. 1.2.2

Green values signify user inputs (Tables 1, 2 and 4).

Input and output guidance is in popups indicated by red arrows.

Table 1. Chemical Identity.

Parameter	User Inputs
Chemical Name	**Broflanilide**
PC code	
Use	
Application Method	**ground**
Application Form	**liquid**
Solubility in Water (ppm)	**0.71**

Table 2. Input parameters used to derive EECs.

Input Parameter	Symbol	Value (user inputs)	Units
Application Rate	A	**0.043**	**lbs ai/A**
Incorporation	I	**1**	none
Runoff Fraction	R	**0.01**	none
Drift Fraction	D	**0.01**	none

Table 3. EECs for Broflanilide. Units in lbs ai/A.

Description	Equation	EEC
Runoff to dry areas	(A/I)*R	0.00043
Runoff to semi-aquatic areas	(A/I)*R*10	0.0043
Spray drift	**A*D**	**0.00043**
Total for dry areas	**((A/I)*R)+(A*D)**	**0.00086**
Total for semi-aquatic areas	**((A/I)*R*10)+(A*D)**	**0.00473**

Table 4. Plant survival and growth data used for RQ derivation. Units are in lbs ai/A. All values are user inputs

Plant type	Seedling Emergence		Vegetative Vigor	
	EC_{25}	NOAEC	EC_{25}	NOAEC
Monocot	**x**	**0.091**	**x**	**0.0023**
Dicot	**x**	**0.091**	**x**	**0.0023**

Table 5. RQ values for plants in dry and semi-aquatic areas exposed to Broflanilide through runoff and/or spray drift.*

Plant Type	Listed Status	Dry	Semi-Aquatic	Spray Drift
Monocot	non-listed	#VALUE!	#VALUE!	#DIV/0!
Monocot	listed	<0.1	<0.1	0.19
Dicot	non-listed	#VALUE!	#VALUE!	#DIV/0!
Dicot	listed	<0.1	<0.1	0.19

*If RQ > 1.0, the LOC is exceeded, resulting in potential for risk to that plant group.

Appendix F: Responses to BASF Suggested Revisions for Aquatic Modeling and Mysid Chronic Endpoint

BASF shared several PWC modeling options on 6/11/2020 as well as revised labels (via email on 6/30/2020 from Jennifer Gains, RD) to refine RQs. The modeling options included proposed spray drift, soil half-life, PRBEN, and sediment burial model input modifications. EFED explored the following modifications to revise and characterize chronic risk to estuarine/marine invertebrates.

Revisions

- Revised aerobic soil metabolism half-life

Characterizations

- Non-guideline aerobic soil half-life characterization
  - Unprocessed intact soil core
  - Outdoor aerobic soil metabolism
- Use of revised PRBEN PWC input
- Use of PWC burial function
- Proposed 10-ft vegetative buffer
- Proposal to retract T-band application for corn and potato uses
- Use of coarse droplets to reduce spray drift
- An alternative mysid endpoint

F.1. Revised aerobic soil metabolism half-life

EFED agrees with the registrant in revising the 90th percentile aerobic soil half-life model input to be derived from half-lives based on processed soils and sampling intervals across the 365-day study durations. Aerobic soil metabolism half-lives were estimated for both 120-day and 365-day study durations in the data evaluation record (DER). In the draft/initial ecological risk assessment (ERA), the 90th percentile soil half-life of 4168 days was based on PMRA- and EFED-harmonized endpoints that were used in the PWC model for aquatic exposure. This 90th percentile soil half-life value was derived from three half-lives based on the initial 120 days of study duration from IL, NC, and TN soil studies and one half-life based on the 365-day study duration from the CA soil study. The half-life values for broflanilide for the first 120-day data from the processed soils were 5742, 804, and 1546 days for the IL, NC and TN soils, respectively (MRID 50211430). However, in this study, degradation of parent compound, and formation of minor unidentified transformation products, CO_2, and non-extracted residues, continued to increase from the 120- through 365-day sampling intervals. The half-life values for broflanilide from the processed soils were 2220, 1485, and 2295 days for the IL, NC and TN soils, respectively based on the full 365-day test durations. An additional half-life of 1173 days from the CA soil study was also based on the full 365-day test duration (MRID 50211429). Therefore, the 90th percentile soil half-life value was revised based on the four half-lives based on the full

365-day test durations. The revised 90th percentile half-life value of 2198 days was used in revising 21-day pore water EECs, which resulted in a 5 to 15% reduction from the EEC values formerly generated. However, revised chronic mysid RQ values (>94 to >217) using the 90th percentile value of 2198 days (vs. 4168 days) continue to exceed the LOC (**Table F-1**).

F.2. Non-guideline aerobic soil half-life characterization

F.2.1. Non-processed intact soil core

As a part of characterization, the registrant used non-guideline aerobic soil metabolism half-lives from unprocessed soil cores. EFED does not agree with the registrant on the use of half-lives derived from unprocessed soil cores. Per the guideline requirement, soil samples should be processed as soon as possible after sampling. Plant residues, macro soil fauna and stones should be removed prior to passing the soil through a 2 mm sieve which removes small stones, fauna and plant debris. The unprocessed soil results indicate that the levels of extracted broflanilide remaining in soil with time generally decreased faster in intact soil cores as compared to processed soils. In addition, the levels of transformation products formed and CO_2 evolved from unprocessed soil cores were slightly higher than those in processed soils. The half-life values for broflanilide for the unprocessed intact soil cores were calculated to be 1293, 392, and 616 days for the IL, NC and TN soils, respectively based on the 365-day test durations. The results suggest that processing (homogenizing and sieving) of soil may have impacted the rate of degradation of broflanilide. It was also observed that levels of non-extracted residues were consistently higher in the unprocessed intact soil cores (12.1-40.6%) as compared to the processed soils (8.0-12.9%), suggesting that degradation of broflanilide in the unprocessed soil cores was due partly to sorption of chemical into soil matrix including plant and fauna residues. However, these conclusions were made with caution considering that the application rates were eight times lower in unprocessed soil cores compared with processed samples. Thus, EFED considers half-lives generated from unprocessed intact soil (which includes plant and fauna residues) not analogous to those of processed soil and not applicable to determine aquatic exposure due to the presence of biological, non-soil components that may overestimate degradation due to sorption.

F.2.2. Outdoor aerobic soil metabolism

For characterization, the registrant also explored non-guideline outdoor aerobic soil metabolism half-lives from two field studies. EFED does not agree with the registrant on the use of half-lives derived from outdoor aerobic soil metabolism studies. EFED considers outdoor aerobic soil metabolism half-lives are inappropriate for PWC model inputs because they may represent multiple dissipation routes, while PWC relies upon specific, distinct degradation or sorption parameters. The half-life values for broflanilide ranged from 16.2 days for CA to 182 days for GA. Overall, these results indicate that persistence is highly dependent on the environmental conditions. Since there was no apparent loss of the applied material via leaching, and a physical barrier around the treated plots prevented any residue loss from off-site movement via runoff, residue decline in this study can be primarily attributed to binding to the soil compartment and degradation of the parent molecule. While outdoor field studies were designed to capture in-situ degradation processes, it is difficult to control other loss processes, such as wind erosion. Laboratory studies are designed to capture loss from one process (hydrolysis, aerobic metabolism, *etc*.). Thus, the values from laboratory studies are not directly comparable to the values from the field studies. Thus, EFED considers outdoor aerobic soil metabolism half-lives are not appropriate for PWC model inputs. However, it is informative to have some understanding of how the laboratory data compares to the loss rates in the field studies.

F.3. Use of revised PRBEN PWC model parameter

The PRBEN parameter has a minimal impact on water column peak EECs, while daily average, chronic and benthic EECs are not impacted. The reason for this is that PRBEN controls the instantaneous distribution of incoming pesticide mass and the peak water column concentrations based on the instantaneous amount of mass in the water column. Water column and benthic acute (daily average) EECs are less affected than peak water column EECs because water column and benthic daily average EEC are based on a daily average rather than an instantaneous concentration. For high K_{OC} compounds, PRBEN has little impact on concentrations averaged over a day or longer; it only dramatically impacts short-term concentrations like the instantaneous peak. This is because equilibration is rapid for high K_{OC} compounds, and the longer-term equilibrium-oriented concentrations (*i.e.*, 1 day or longer) are the same regardless of how mass is initially distributed (as controlled by PRBEN). EFED explored a PRBEN of 0.75 based on pyrethroids (EPA-HQ-OPP-2008-0331-0078) to compare to the default 0.5 value. However, registrant proposed a PRBEN value of 0.90. The results suggest no impact on chronic estimates of aquatic exposure (**Table F-1**).

F.4. Use of burial function of PWC model parameter

Sediment burial is a refinement option available in PWC that can be included in risk characterization, particularly for persistent chemicals with high sorption in soil. Currently, sediment burial is not proposed to replace PWC values (*i.e.*, without burial), but can be useful for characterization purposes. Sediment dynamics (including the sediment burial option) were taken to a Scientific Advisory Panel in 2008 (Docket # EPA-HQ-OPP-2008-0550) to evaluate the appropriateness of this model approach for estimating burial. The Panel concluded that sediment burial is an important consideration, though there were questions regarding the rate of burial (*i.e.*, especially under high erosion conditions) and the permanence of burial (*i.e.*, persistent chemicals have not actually disappeared but are temporarily unavailable). Further, the EPA pond model is intended to represent static waterbodies as well as small first and second order streams where sediment burial may not be as likely (or permanent).

Table F-1 presents pore water EECs and RQs for invertebrates (mysid) using the PWC IA and MS corn scenarios for ground applications, with and without the PWC burial refinement option and using the revised 90th percentile aerobic soil metabolism half-life value. For broflanilide, using sediment burial as a modeling process reduces EECs up to 71-90%;

however, chronic mysid RQs (>22 to >28) continue to exceed the LOC (**Table F-1**).

Table F-1. Revised EECs and RQ Calculations

Model Inputs	21-day Pore Water EECs (ug/L)[1]	% EEC Reduction	Chronic Mysid NOAEC based RQs[2]	% RQ Reduction	Comments
Harmonized 90th%ile soil half-life (4186 days)	0.20- 0.41	--	>111->228	--	PWC Inputs based on PMRA-EFED harmonized fate endpoints
Revised EPA 90th%ile soil half-life (2198 days)	0.17-0.39	15-5	>94->217	15-5	PWC Inputs based on 365 days study period
PWC PRBEN	0.17-0.39	No impact on EECs and RQs			PRBEN has no impact on chronic EECs
PWC Burial function	0.05-0.04	71-90	>28->22	71-90	% of RQs reduction based on revised 90th%ile half-life value (i.e., 2198 days)[3]

[1] Draft risk assessment reported pore water EECs for in-furrow corn as 0.20-0.41 ug a.i./L-pw.

[2] Chronic mysid NOAEC <0.0018 ug a.i./L-pw and since the endpoint is non-definitive the RQs are understood estimates with true RQs greater than these estimates.

[3] Percent RQ reduction compared to original assessment 80-90%

F.5. Implication of a recently proposed 10 ft vegetative buffer

The registrant proposed via email (6-11-2020) a vegetative filter strip (VFS) of at least 10 feet between the field and down-gradient aquatic habitat to reduce broflanilide loading into surface water bodies. The maintenance and effectiveness of VFS can vary. Reichenberger *et al*. (2007) reviewed 180 publications and evaluated many aspects related to the effectiveness of VFS in reducing pesticide loads into adjacent water bodies. They concluded that the effectiveness of VFS to reduce pesticide loading into an adjacent surface water body depends on many factors, such as topography, field conditions, soil types, soil antecedent moisture condition, rainfall intensity, properties of pesticides, application methods, the width of the VFS, and types of vegetation within the buffer strip. On average VFS efficiencies are roughly a 50% reduction for a 5-meter (m) width, 90% for a 10-m width, and 97.5% for a 20-m width. However, VFS maintenance is critical for their continuing effectiveness in intercepting runoff loads to mitigate pesticide loadings from runoff into water bodies. Reviews of above articles suggest that VFS could also serve as a sink for sediment-laden pesticide. Long-term effectiveness of VFS requires regular maintenance including excavation to remove overburdens of sediments (especially for persistent chemicals like broflanilide), repairing vegetation damage, and removing over-mature vegetation or invasion of noxious weeds (USDA, 2000).

Currently, the Agency does not quantitatively assess the effectiveness of these practices in reducing pesticide concentrations in runoff. In addition, the current surface water model used by the Agency does not have the capability to account for prescribed setbacks or vegetative buffer distances. While a well-maintained vegetative buffer could potentially intercept broflanilide-laden runoff (both soluble and sediment bound) prior to reaching surface waters, there is still a great deal of uncertainty regarding the performance of buffers, which includes but is not limited to proper design and placement and the duration of their efficacy.

F.6. Implication of registration's proposal to retract T-band application for corn and potato uses

In the draft ecological risk assessment, the highest RQs were derived from T-band application for corn and potato. Offsite spray drift fractions may have contributed to aquatic exposure from T-band applications. Due to the registrant's proposed retracting of T-band applications from corn and potato uses (via email 6/11/20202) and subsequesnt revised label submission, any references related to T-band application were removed in this RA.

F.7. Using coarse droplets to reduce spray drift

EFED assumed no drift for furrow applications for corn and potato applications. Therefore, as T-band applications are not proposed in the revised labels, use of coarse droplets to mitigate offside drift is a moot point.

F.8. Consideration of alternative mysid chronic endpoint

The submitted mysid chronic toxicity (MRID 50211488) study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female. EFED recognizes that there were uncertainties regarding this study and the observed effect across increasing dose concentrations. The registrant proposed an alternative NOAEC endpoint of 0.0063 ug a.i./L. Based on comparisons of the refined EECs in **Table F-1**, the RQs would range between 22 and 60 for the reduced half-life-based estimates and would be as low as 6 assuming sediment burial.

While not discussed by the registrant in the meeting, there are several other benthic invertebrate chronic endpoints relied to determine risk in the assessment. Comparison of the pore-water based endpoints to the refined EECs in **Table F-1** indicates that RQs (1-16) exceed the chronic invertebrate LOC. Therefore, despite the reduced EECs related to the revised half-life estimate and the compounded refinement considering sediment burial, a conclusion of risk would remain because RQs remain above the chronic LOC for aquatic invertebrates.

F.9. Conclusions

EFED explored several modifications (revised aerobic soil metabolism half-lives, spray drift, soil half-life, PRBEN, sediment burial, and an alternative mysid endpoint) to revise and characterize chronic risk to estuarine/marine water column invertebrates. The 90th percentile soil half-life value was revised based on the four half-lives based on a 365-day test duration and the revised EECs resulted in a 5 to 15% reduction in the RQs values. Non-guideline aerobic soil metabolism half-lives are not analogous to those from guideline studies with processed soil and are not applicable to determine aquatic exposure due to the presence of biological, non-soil components that may overestimate degradation due to sorption.

Since the registrant has withdrawn T-band applications for corn and potato uses, the use of coarse droplets to mitigate offside drift is a moot point.

The PWC model results indicate the PRBEN input has no impact on chronic aquatic exposure. Sediment burial and revised 90th%ile aerobic soil metabolism half-life values were used for characterization purposes and resulted in reducing EECs up to 71-89%; however, RQs (>22 to >28) continue to exceed LOCs.

The Agency does not quantitatively assess VFS effectiveness in reducing pesticide concentrations in runoff. While there is good evidence that buffers can reduce pesticide movement into water bodies to some extent, there is still a great deal of uncertainty regarding the performance of VFS.

Lastly, EFED considered the registrant's comments regarding the mysid chronic endpoint. The use of their alternative endpoint results in an exceedance of the chronic LOC (RQ 6) when also considering the reduced EECs with the adjusted half-life and sediment burial. While this characterization was considered, EFED will not be revising the current determination of the mysid NOAEC (<0.0018 ug a.i./L) based on the review of the science. Furthermore, comparison of other benthic invertebrate chronic endpoints to the reduced EECs continues to result in RQs exceeding the LOC. Therefore, a determination of risk to aquatic invertebrates remains.