



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

MEMORANDUM

DATE: April 17, 2024

SUBJECT: **Saflufenacil.** Occupational and Residential Exposure Assessment for Registration Review

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The conclusions conveyed in this assessment were developed in full compliance with *EPA Scientific Integrity Policy for Transparent and Objective Science*, and EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions*. The full text of *EPA Scientific Integrity Policy for Transparent and Objective Science*, as updated and approved by the Scientific Integrity Committee and EPA Science Advisor can be found here: https://www.epa.gov/system/files/documents/2023-12/scientific_integrity_policy_2012_accessible.pdf. The full text of the EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions* can be found here: <https://www.epa.gov/scientific-integrity/approaches-expressing-and-resolving-differing-scientific-opinions>.

Introduction

As part of Registration Review, the Pesticide-Reevaluation Division (PRD) of the Office of Pesticide Programs (OPP) has requested that the Health Effects Division (HED) conduct an occupational and residential exposure assessment, as needed, to estimate the risk to human health that will result from the currently registered use of saflufenacil. This memorandum serves as HED's assessment of the occupational and residential exposure and risk from existing uses of saflufenacil.

It is HED policy to use the best available data to assess exposure. Several sources of generic data were used in this assessment as surrogate data in the absence of chemical-specific data, including studies from the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1); the Agricultural Handler Exposure Task Force (AHETF) database; the Outdoor Residential Exposure Task Force (ORETF) database; the Agricultural Reentry Task Force (ARTF) database; and other registrant-submitted exposure monitoring studies (MRID 44339801). Some of these data are proprietary, and subject to the data protection provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on 4/15/2021. Since the 2021 occupational assessment, updated occupational handler exposure spreadsheet tools became available. Therefore, this occupational assessment reflects the following updates:

- The occupational handler assessment was updated, and the 2021 spreadsheet was used.

A summary of the findings and an assessment of occupational risk resulting from the registered uses of saflufenacil are provided in this document, which supersedes the 2021 occupational assessment.

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1.0 Executive Summary

Background

Saflufenacil is a broad-spectrum herbicide in mode-of-action Group 14 (cell membrane disruptors). It acts through the inhibition of protoporphyrinogen oxidase (PPO), resulting in cell membrane damage and subsequent plant death. This document assesses exposure and risk from the registered uses of saflufenacil required during Registration Review. The most recent saflufenacil exposure assessment was conducted for a Section 3 registration for uses on caneberry, fig, and chia (C. Severini, D456302, 07-AUG-2020). An Occupational and Residential Exposure Assessment for Registration Review was completed in 2021 (L. Venkateshwara, D462362, 21-SEP-2021). This assessment is being updated with new 2021 occupational handler spreadsheet.

Use Profile

Saflufenacil is a pre- and post-emergence herbicide that acts by inhibiting PPO, which leads to chlorophyll destruction by photooxidation and causes bleaching of emerging foliar tissue. Saflufenacil is currently registered in the U.S. for use on several raw agricultural commodities including legume vegetables, citrus fruit, pome fruit, stone fruit, tree nuts, cereal grains, cotton, oilseeds, grapes, grass forage/hay/grass grown for seed, olives, soybean, pomegranate, caneberry, fig, and chia. Saflufenacil is currently formulated as a water dispersible granule (WDG), emulsifiable concentrate (EC), and soluble concentrate (SC). Applications are made by air, groundboom, chemigation, and hand-held equipment at application rates ranging from 0.0167 to 0.356 lb ai/A. The labels require handlers to wear "baseline" attire (i.e., long-sleeved shirt, long pants, shoes and socks), as well as personal protective equipment (PPE) including protective eyewear, and chemical resistant gloves. The restricted entry interval (REI) is 12 hours listed on all labels.

Exposure Profile

Based on the registered uses of saflufenacil, it is expected that short- and intermediate-term dermal and inhalation occupational handler and occupational post-application exposures will occur. Chronic exposure is not expected for the registered use patterns. There are currently no uses in residential settings that would result in residential handler and post application exposure; however, there is the potential for non-occupational exposure (dermal and incidental oral) as a result of spray drift.

Hazard Characterization

For all occupational and non-occupational risks, the point of departure (POD) for short-term adult oral, short- and intermediate-term dermal and inhalation exposure/risk assessment is a no-observed adverse-effect level (NOAEL) of 5 mg/kg/day based on decreased fetal body weights and increased skeletal variations at the lowest-observed adverse-effect level (LOAEL) of 20 mg/kg/day in the developmental study in rats. For the short- and intermediate-term incidental oral exposure scenarios, the POD was derived the offspring NOAEL from the two-generation reproductive study which is 15 mg/kg/day. The LOAEL is 50 mg/kg/day based upon decreased viability and lactation indices, decreased pre-weaning body weight, and changes in hematological parameters. Since an oral study was used for the dermal POD, a dermal absorption factor (DAF) of 6% was used for the dermal risk assessment

derived from a dermal penetration study (MRID 47128214). Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure. A 69 kg body weight was used for all adult exposure calculations because the endpoint was observed in fetuses. Saflufenacil was classified as “not likely to be carcinogenic to humans” based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity. The total uncertainty factor (UF) that was applied to occupational and non-occupational risk assessments is 100 for short- and intermediate-term risks (10x interspecies factor, 10x intraspecies factor). Since the POD for the dermal and inhalation routes of exposure are based on the same effect, the exposures from these routes can be combined to estimate total risk. The short- and intermediate-term dermal level of concern (LOC) are the same (LOC = 100). Due to the lack of an available subchronic inhalation toxicity study (the HASPOC decision described below), the inhalation LOC is for MOEs less than 1000 based on a combined UF to account for interspecies variability (10X), intraspecies extrapolation (10X), and 10x database UF for the lack of a subchronic inhalation toxicity study. Some occupational inhalation scenarios currently result in MOEs <1000.

Residential Exposure and Risk

There are currently no registered residential uses or use sites for saflufenacil. As such, no residential handler or post-application exposures/risks were assessed.

Non-Occupational Spray Drift Exposure and Risk

A quantitative non-occupational spray drift assessment was conducted for the registered uses of saflufenacil to evaluate potential exposure to people who live adjacent to treated fields. Adult dermal and children’s (1 to < 2 year old) dermal and incidental oral risk estimates from indirect exposure related to spray drift are not of concern (margins of exposure (MOEs) $\geq$ LOC of 100 for adult dermal and MOEs $\geq$ LOC of 100 for children’s incidental oral and dermal) at the edge of the field.

Occupational Exposure and Risk

Except for six occupational scenarios as discussed below, there are no risks of concern from all other exposure routes from the registered uses of saflufenacil. Tolerance recommendations are discussed in Section 2.1 and recommended label modifications are discussed in Section 2.2.

The combined dermal and inhalation occupational risk estimate MOEs range from 61 to 390,000. MOEs greater than the LOC of 100 are not of concern. Most occupational handler combined dermal and inhalation MOEs are greater than 100 at labeled PPE (long-sleeved shirt, long pants, shoes and socks, protective eyewear, and chemical-resistant gloves). The addition of PPE (e.g., double-layer clothing or PF10 respirator, as applicable) for the six scenarios described below would yield MOEs above the LOC (i.e., not of concern). A summary of occupational handler exposure risk estimates can be found in Table 11.1.

The following scenarios resulted in MOEs below the LOC at labeled PPE; however, they would not be of concern with the addition of a double layer of clothing. The dermal exposure route was the risk driver for these scenarios:

- Applying broadcast spray (all starting formulations) to rights of way (e.g., utilities, railroad, roadways) at 0.0285 lb active ingredient (ai)/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to Christmas tree farms, at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to field crop, typical acreage at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to industrial/commercial areas at 0.0285 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].

The following scenarios reached MOEs above the LOC of 1000 with the addition of a PF10 and/or PF50 respirator. The aggregate risk index (ARI) approach was used to present risk estimates for these scenarios since the LOCs for inhalation (LOC=1000) and dermal (LOC= 100) exposures are different. In the ARI approach, ARIs of less than 1 are risk estimates of concern. Due to the lack of an available subchronic inhalation study, the inhalation LOC is 1000; the two scenarios below resulted in inhalation MOEs below the LOC of 1000. The inhalation exposure route was the risk driver for these scenarios:

- Mixing/loading/applying foliar liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0067 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 380 (with PF10 respirator, MOE = 3800); total ARI = 0.34 (with PF10 respirator, total ARI = 2.6)].

Mixing/loading/applying soil-directed liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0285 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 90 (with PF10 respirator, MOE = 900; with a with PF50 respirator, MOE = 1,400); total ARI = 0.086 (with PF10 respirator, total ARI = 0.61 and with PF 50 respirator, total ARI = 1.3)]. Most of the occupational handler combined dermal and inhalation risk estimates resulted in MOEs greater than the LOC of 100 at label PPE. There were four scenarios that, with the inclusion of additional personal protective equipment (PPE), would no longer result in MOEs of concern (see Table 8.1). See Section 2.1 to see a list of scenarios that require additional PPE and what PPE is needed.

A quantitative post-application dermal exposure assessment has not been conducted for most of the registered uses since the use directions indicate that the product is to be applied to the base of the plant, and is not to contact the foliage. Currently, HED has no transfer coefficients or other data to assess post-application dermal exposures to soil by occupational workers. In general, such exposures are considered to be negligible. Therefore, for the soil-directed uses, post-application exposures and risks to occupational workers were not assessed. Saflufenacil is used as a harvest aid/desiccation aid on chia and this use was assessed for post-application dermal exposure. A quantitative post-application dermal exposure assessment was conducted for the registered use on chia and resulted in no risks of

concern on the day of application (MOE = 5,300). The 12-hour REI, which currently appears on the labels, is adequate for the registered uses.

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

Human Studies Review

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from PHED 1.1, the AHETF database, ORETF database, the ARTF database, and other registrant-submitted exposure monitoring studies (44339801) are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website¹.

2.0 Risk Assessment Conclusions and Recommendations

2.1 Summary of Risk Estimates

Most of the occupational handler combined dermal and inhalation risk estimates resulted in MOEs greater than 100 at label PPE or with additional PPE, and therefore, are not of concern.

Except for six occupational scenarios as discussed above, there are no risks of concern from all other exposure routes from the registered uses of saflufenacil.

The combined dermal and inhalation occupational risk estimate MOEs range from 61 to 390,000. MOEs greater than the LOC of 100 are not of concern. Most occupational handler combined dermal and inhalation MOEs are greater than 100 at labeled PPE (long-sleeved shirt, long pants, shoes and socks, protective eyewear, and chemical-resistant gloves). The addition of PPE (e.g., double-layer clothing or PF10 and or PF50 respirator, as applicable) for the six scenarios described below would yield MOEs above the LOC (i.e., not of concern). A summary of occupational handler exposure risk estimates can be found in Table 11.1.

The following scenarios resulted in MOEs below the LOC at labeled PPE; however, they would not be of concern with the addition of a double layer of clothing. The dermal exposure route was the risk driver for these scenarios:

- Applying broadcast spray (all starting formulations) to rights of way (e.g., utilities, railroad, roadways) at 0.0285 lb active ingredient (ai)/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].

¹ Available online: [Occupational Pesticide Handler Exposure Data | US EPA](#) and [Occupational Pesticide Post-application Exposure Data | US EPA](#)

- Mixing/loading/applying broadcast liquid formulation to Christmas tree farms, at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to field crop, typical acreage at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to industrial/commercial areas at 0.0285 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].

The following scenarios reached MOEs above the LOC with the addition of a PF10 and/or PF50 respirator. The aggregate risk index (ARI) approach was used to present risk estimates for these scenarios since the LOCs for inhalation (LOC=1000) and dermal (LOC= 100) exposures are different. In the ARI approach, ARIs of less than 1 are risk estimates of concern. Due to the lack of an available subchronic inhalation study, the inhalation LOC is 1000; the two scenarios below resulted in inhalation MOEs below the LOC of 1000. The inhalation exposure route was the risk driver for these scenarios:

- Mixing/loading/applying foliar liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0067 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 380 (with PF10 respirator, MOE = 3800); total ARI = 0.34 (with PF10 respirator, total ARI = 2.6)].
- Mixing/loading/applying soil-directed liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0285 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 90 (with PF10 respirator, MOE = 900; with a with PF50 respirator, MOE = 1,400); total ARI = 0.086 (with PF10 respirator, total ARI = 0.61 and with PF 50 respirator, total ARI = 1.3)].

2.2 Label Recommendations

HED's HASPOC used a weight-of-evidence approach to determine that a subchronic inhalation toxicity study is not required at this time (A. Dunbar, TXR 0056720, 02-AUG-2013; and V. Kurker, TXR 0058170, 20-APR-2021), provided that a PF10 and PF 50 respirator at application rates of 0.0067 lb ai/gallon and 0.0285 lb ai/gallon, are added to the product labels for these nursery uses. In the absence of modified labels or submission of a subchronic inhalation toxicity study, a 10X database UF will continue to be applied to the inhalation scenarios where occupational scenarios result in inhalation MOEs less than 1000.

2.3 Data Deficiencies and Requirements

There are no data deficiencies based on the currently registered uses.

3.0 Hazard Characterization

Acute Toxicity

Saflufenacil is classified as Toxicity Category III for acute oral and acute dermal toxicity. It is classified as Toxicity Category IV for acute inhalation, acute eye irritation and acute dermal irritation. It is not a dermal sensitizer. Table 3.1 presents a summary of the acute toxicity information for saflufenacil:

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute Oral (rat)	47128101 (93.8% a.i.)	LD ₅₀ > 2000 mg/kg (F)	III
870.1200	Acute Dermal (rat)	47128102 (93.8% a.i.)	LD ₅₀ > 2000 mg/kg (M & F)	III
870.1300	Acute Inhalation (rat)	47128103 (93.8% a.i.)	LC ₅₀ > 5.3 mg/L (M & F)	IV
870.2400	Primary Eye Irritation (rabbit)	47128104 (93.9% a.i.)	Minimally irritating	IV
		47128105 (93.8% a.i.)	Minimally irritating	IV
870.2500	Primary Skin Irritation (rabbit)	47128106 (93.9% a.i.)	Non-irritating	IV
870.2600	Dermal Sensitization (guinea pig)	47128107 (93.8% a.i.)	Not a dermal sensitizer (Maximization)	N/A

Subchronic and chronic toxicity studies for saflufenacil in rats, mice, and dogs identified the hematopoietic system as the primary systemic target. Decreased hematological parameters were seen at about the same dose level across species, except dogs, where the effects were seen at a slightly higher dose. These effects occurred around the same dose level from short- through long-term exposures without increasing in severity. Effects were also seen in the liver in mice, the spleen in rats, and in both of these organs in dogs. These effects occurred around the same dose level from short-through long-term exposures without increasing in severity.

Increased fetal susceptibility was observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects such as decreased fetal body weights and increased skeletal variations occurred at doses that were not maternally toxic in the developmental study in rats, indicating increased quantitative susceptibility. In rabbits, developmental effects such as increased liver porphyrins were observed at doses that were not maternally toxic, also indicating increased quantitative susceptibility. In the 2-generation reproductive toxicity study in rats, the reported offspring effects were more severe than the maternal effects at the same dose level, indicating evidence for increased qualitative susceptibility.

In a 28-day dermal toxicity study in rats, saflufenacil did not induce any type of dermal or systemic toxicity up to the limit dose of 1,000 mg/kg/day. The Hazard and Science Policy Council (HASPOC) met on July 18, 2013 to discuss the need for a subchronic inhalation toxicity study for saflufenacil (A. Dunbar, TXR 0056720, 02-AUG-2013;). Based on a weight-of-evidence approach, the HASPOC recommended that a subchronic inhalation toxicity study is not required for saflufenacil at this time for

the following reasons: (1) the physical/chemical properties of saflufenacil including its low volatility (3.4×10^{-17} mmHg, 20°C); (2) its low acute inhalation toxicity (Toxicity Category IV); and (3) the use of an oral POD resulting in inhalation MOEs that are 10x greater than the Agency's level of concern (inhalation MOEs > 1,000). HED's Hazard Science and Policy Council (HASPOC) used a weight-of-evidence approach to determine that a subchronic inhalation toxicity study is recommended to be waived at this time (V. Kurker, TXR 0058170, 20-APR-2021), provided that a PF10 and PF50 respirators at application rates of 0.0067 lb ai/gallon and 0.0285 lb ai/gallon, respectively, be added to the product label for these nursery uses given that inhalation MOEs were below the LOC of 1000. In the absence of modified labels or submission of a subchronic inhalation toxicity study, a 10X database UF will continue to be applied to the inhalation scenarios where occupational scenarios result in inhalation MOEs less than 1000.

The short- and intermediate-term incidental oral PODs were selected from the two-generation reproductive study. The offspring NOAEL is 15 mg/kg/day and the LOAEL is 50 mg/kg/day, based on decreased viability and lactation indices, decreased pre-weaning body weight, and changes in hematological parameters. A 6% dermal-absorption factor (DAF) was used for oral to dermal route-to-route extrapolations, and inhalation is assumed to be equivalent to oral. A 100X uncertainty factor (UF) (10X for interspecies extrapolation and 10X for intraspecies variation) was incorporated into the acute and chronic reference doses. Saflufenacil is classified as "Not Likely Carcinogenic to Humans"; therefore, cancer risk assessments are not required.

Toxicological PODs Used for Risk Assessment

The toxicity endpoints and the PODs for various exposure scenarios are presented in Tables 3.2.1 and 3.2.2. For all occupational and non-occupational risks, the POD for short-term adult oral, short- and intermediate-term dermal and inhalation exposure/risk assessment has a NOAEL of 5 mg/kg/day based on decreased fetal body weights and increased skeletal variations at 20 mg/kg/day (LOAEL) in the developmental study in rats. For the short- and intermediate-term incidental oral exposure scenarios, the POD was derived the offspring NOAEL from the two-generation reproductive study which is 15 mg/kg/day. The LOAEL is 50 mg/kg/day based upon decreased viability and lactation indices, decreased pre-weaning body weight, and changes in hematological parameters. For overall risk, the dermal and inhalation exposures were combined and compared to the same NOAEL. Chronic exposures are not expected.

Table 3.2.1. Summary of Toxicological Doses and Endpoints for Saflufenacil for Use in Dietary and Non-Occupational Human Health Risk Assessments.				
Exposure Scenario	Point of Departure	UFs/ FQPA SF	RfD, PAD,	Study and Toxicological Effects
Incidental Oral Short- and Intermediate-Term (1-30 days and 1-6 months, respectively)	NOAEL = 15 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF = 1X	Non-Occupational LOC for MOE = 100	Reproduction and fertility effects (rat) Offspring LOAEL = 50 mg/kg/day based on decreased viability and lactation indices, decreased pre-weaning body weight, and changes in hematological parameters.

Table 3.2.1. Summary of Toxicological Doses and Endpoints for Saflufenacil for Use in Dietary and Non-Occupational Human Health Risk Assessments.

Exposure Scenario	Point of Departure	UFs/ FQPA SF	RfD, PAD,	Study and Toxicological Effects
Adult Oral Short-Term (1-30 days)	NOAEL = 5 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF = 1X	Non-Occupational LOC for MOE = 100	Developmental study (rat) LOAEL = 20 mg/kg bw/day based on decreased fetal bodyweight and increased skeletal variations.
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months, respectively)	NOAEL = 5 mg/kg/day Dermal-absorption factor = 6% ¹	UF _A = 10X UF _H = 10X FQPA SF = 1X	Non-Occupational LOC for MOE <100	Developmental study (rat) LOAEL = 20 mg/kg bw/day based on decreased fetal bodyweight and increased skeletal variations.
Inhalation Short- and Intermediate-Term (1-30 days and 1-6 months, respectively)	NOAEL = 5 mg/kg/day Inhalation assumed to be equivalent with oral	UF _A = 10X UF _H = 10X FQPA SF = 1X	Non-Occupational LOC for MOE <100	Developmental study (rat) LOAEL = 20 mg/kg bw/day based on decreased fetal bodyweight and increased skeletal variations.
Cancer (oral, dermal, inhalation)	Classification: Not Likely to be Carcinogenic to Humans based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity.			

1- The dermal absorption fact was derived from a rat dermal absorption study (MRID 47128214). NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). LOC = level of concern. FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose.

Table 3.2.2. Summary of Toxicological Doses and Endpoints for Saflufenacil for Use in Occupational Human Health Risk Assessment.

Exposure/ Scenario	POD	UFs/ FQPA SF	LOC for Risk Assessment	Study and Toxicological Effects
Dermal Short-Intermediate-Term (1-30 days and 1-6 months, respectively)	NOAEL=5 mg/kg/day	UF _A = 10X UF _H = 10X <i>Dermal absorption Factor = 6%</i>	Occupational/ LOC for MOE = 100	Prenatal developmental in (rat) Developmental NOAEL= 5 mg/kg/day LOAEL = 20 mg/kg/day based on based on decreased fetal body weights and increase skeletal variations.
Inhalation Short-Intermediate-Term (1-30 days and 1-6 months, respectively)	NOAEL=5 mg/kg/day	UF _A = 10X UF _H = 10X UF _{DB} = 10X <i>Inhalation-absorption assumed equivalent to oral</i>	Occupational LOC for MOE = 100	Prenatal developmental in (rat) Developmental NOAEL= 5 mg/kg/day LOAEL = 20 mg/kg/day based on based on decreased fetal body weights and increase skeletal variations.
Cancer (oral, dermal, inhalation)	Classification: Classification: Not carcinogenic based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity.			

1 The dermal absorption fact was derived from a rat dermal absorption study (MRID 47128214). Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). $UF_{DB} = 10X$ database UF is still applied to inhalation scenarios with MOEs <1000, pending submission of route-specific inhalation study or addition of respirator to labels (TXR #0058170). FQPA SF = FQPA safety factor MOE = margin of exposure. LOC = level of concern.

Absorption

A DAF of 6% was estimated for saflufenacil based on the highest degree of skin penetration at the lowest dose tested in a rat dermal absorption study. Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure.

Body Weight

Since the dermal and inhalation PODs are based on developmental and/or fetal effects, the adult body weight appropriate for dermal and inhalation assessments is 69 kg. A body weight of 11 kg was used for children 1 to <2 years of age for dermal and incidental oral assessments for the spray drift assessment.

4.0 Use Profile

Saflufenacil is currently registered for use on legume vegetables, citrus fruit, pome fruit, stone fruit, tree nuts, cereal grains, cotton, grapes, grass forage/hay/grass grown for seed, olives, soybean, pomegranate, caneberry, fig, and chia. There are no registered residential uses. All the labels have consistent PPE requirements. The labels require handlers to wear "baseline" attire (i.e., long-sleeved shirt, long pants, shoes and socks), as well as personal protective equipment (PPE) including protective eyewear, and chemical resistant gloves. The restricted entry interval (REI) is 12 hours listed on all labels.

Based on the uses, short- and intermediate-term occupational exposures are expected (handler and post-application). The maximum single application rates range from 0.0167 – 0.134 lb ai/A, and a summary of directions for the uses are detailed below in Table 4.1.

Table 4.1. Summary of Representative Registered Occupational /Commercial Products and Use Directions for Saflufenacil

Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
Ground, Aerial, Hand Held Equipment	Soluble Concentrate (SC), KIXOR HERBICIDE EPA Reg # 7969-324	Christmas Tree Farm	Christmas tree plantations	0.134 (0.0268 lb ai/gal)	Not Specified (NS)	NS	REI ^f = 12 hours MRI ^f : 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply as an over-the-top spray	• Long-sleeved shirt and long pants • Shoes plus socks • Chemical-resistant gloves • Protective eyewear such as face shield, goggles, or safety glasses
		Field crop, high acreage ^a	Field Corn (grain, seed, silage)	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days. PHI ^f = 80 days (forage and silage)	
			Popcorn	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days. PHI = 80 days (forage and silage)	
			Small grains ¹	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days.	
			Sorghum, grain	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days. PHI = 70 days (forage)	
			Sorghum, sweet	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days. PHI = 70 days (forage)	
		Field crop, typical ^b	Sweet Corn	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days. PHI = 80 days (forage and silage)	
		Orchard/ Vineyard ^c	Citrus Fruits ⁶	0.0445 (0.00890 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 21 days. PHI = 0 days	
			Pome Fruits ⁸	0.0445 (0.00890 lb ai/gal)	NS	0.134		
			Stone Fruits ⁹	0.0445 (0.00890 lb ai/gal)	NS	0.134		
			Tree Nuts ⁷	0.0445 (0.00890 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 21 days. PHI = 7 days	
		Noncrop	Fallow and Postharvest	0.134 (0.0268 lb ai/gal)	NS	0.134	REI= 12 hours MRI: 14 days.	
			Noncropland Areas – Bareground, Pine Control	0.134 (0.0268 lb ai/gal)	NS	NS	REI= 12 hours MRI: 14 days. Max. annual use rate: 0.134 lb ai/A	

Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
	SC, HEAT Powered by KIXOR Herbicide EPA Reg # 7969-297	Conifer Plantation	Conifer and Hardwood Plantations	0.134 (0.00536 lb ai/gal)	NS	NS	REI = 12 hours MRI = 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply through any type of irrigation system (e.g. chemigation). Do not apply as an over-the-top spray	• Long-sleeved shirt and long pants • Shoes plus socks • Waterproof gloves • Protective eyewear including face shield, goggles, or safety glasses
		Field grown ornamentals/ Nursery	Field-grown Tree Nurseries	0.134 (0.00670 lb ai/gal)	NS	NS	REI= 12 hours MRI: 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply through any type of irrigation system (e.g. chemigation). - Do not make over-the-top application to any desirable plant or tree. - Do not apply more than 0.0891 lb ai/A to tree stock 1-year old or less.	
Groundboom, Airblast	SC, HEAT Powered by KIXOR Herbicide EPA Reg # 7969-297	Christmas Tree Farms	Christmas tree plantations	0.0285 lb ai/gal (spot treatment)	NS	NS	REI = 12 hours MRI = 14 days. Max. annual use rate: 0.134 lb ai/A	• Long-sleeved shirt and long pants • Shoes plus socks • Waterproof gloves • Protective eyewear including face shield, goggles, or safety glasses
		Conifer Plantation	Conifer and Hardwood Plantations	0.0285 lb ai/gal (spot treatment)	NS	NS	- Do not apply through any type of irrigation system (e.g. chemigation). - Do not apply as an over-the-top spray	
		Field grown ornamentals/ Nursery	Field-grown Tree Nurseries	0.0285 lb ai/gal (spot treatment)	NS	NS	REI = 12 hours MRI = 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply through any type of irrigation system (e.g. chemigation). - Do not make over-the-top application to any desirable plant or tree. - Do not apply more than 0.0891 lb ai/A to tree stock 1-year old or less.	
		Noncrop	Industrial Landscaping	0.0285 lb ai/gal (spot treatment)	NS	NS	REI = 12 hours MRI = 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply through any type of irrigation system (e.g. chemigation).	

Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
							- Do not make over-the-top application to any desirable industrial landscape vegetation	
Chemigation	EC, VERDICT POWERED BY KIXOR HERBICIDE EPA Reg # 7969-279	Field crop, high acreage ^d	Field Corn (grain, seed, silage)	0.111	NS	0.111	REI = 12 hours MRI = 14 day PHI = 0 (grain); 80 (forage and silage)	- Long-sleeved shirt and long pants - Shoes plus socks - Chemical-resistant gloves - Protective eyewear (face shield, goggles, or safety glasses)
		Field crop, typical	Sweet Corn	0.0891	NS	0.111		
		Noncrop	Fallow	0.111	NS	0.111	REI = 12 hours MRI = 14 day	
Manually Pressurized Handgun	SC, SHARPEN POWERED BY KIXOR HERBICIDE EPA Reg # 7969-278	Noncrop	Noncropland Areas ² (fence rows, nonirrigation ditchbanks, dry irrigation ditchbanks, and on farmstead areas (barnyards, lanes, driveways, machinery or implement yards, windbreaks))	0.000445 lb ai/gal	NS	NS	REI= 12 hours MRI: 14 days. Max. annual use rate: 0.134 lb ai/A - Do not apply through any type of irrigation system (e.g. chemigation). - Do not apply spot treatments using high-pressure hand wands.	- Long-sleeved shirt and long pants - Shoes plus socks - Waterproof gloves - Protective eyewear including face shield, goggles, or safety glasses
Groundboom, Aerial			Chia	2 oz/A = 0.044 lb ai/A 0.01 oz/gal = 0.0044 lb ai/gal	Max. of 2 applications/season on (max. cumulative amount of 2 oz/A/season; single application rate ranges from 1-2 oz/A)	0.044 lb ai/A/season	Ground application spray volume = 10 gal/A; aerial application spray volume = 5 gal/A Max. seasonal application rate applies only to harvest aid/desiccation use Make harvest aid/desiccation applications when crops have reached physiological maturity No applications using chemigation equipment allowed PHI: 3 days; allow up to 10 days for optimum desiccation effect Not for use in California	

Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
Backpack; Mechanically Pressurized Handgun	SC, HEAT Powered by KIXOR Herbicide EPA Reg # 7969-297		Forestry Use – Pine Control (Selective Stem Appl)	0.356 (0.0178 lb ai/gal)	NS	NS	REI= 12 hours MRI: 14 days. Max. annual use rate: 0.134 lb ai/A	- Long-sleeved shirt and long pants - Shoes plus socks - Waterproof gloves - Protective eyewear including face shield, goggles, or safety glasses
			Noncropland Areas ² - Pine Control (Selective Stem Appl)	0.0285 lb ai/gal	NS	NS	- Do not apply through any type of irrigation system (e.g. chemigation).	
Groundboom, Aerial	Water-dispersible Granule, OPTILL POWERED BY KIXOR HERBICIDE EPA Reg. # 7969-280	Field crop, high acreage	Clearfield® Corn	0.0223 (0.00446 lb ai/gal)	NS	0.0223	REI= 12 hours - Do not apply through any type of irrigation system (e.g. chemigation). - Use only in Clearfield corn.	- Protective eyewear such as face shield, goggles, or safety glasses - Long-sleeved shirt and long pants - Chemical-resistant gloves - Shoes plus socks
			Soybean	0.0223 (0.00446 lb ai/gal)	NS	0.0223	REI= 12 hours PHI = 85 days (grain) - Do not apply through any type of irrigation system (e.g. chemigation).	
		Field crop, typical	Chickpea (garbanzo bean)	0.0167 (0.00334 lb ai/gal)	1	0.0167	REI= 12 hours PHI = 65 days (forage and hay)	
			English (garden, green) peas	0.0167 (0.00334 lb ai/gal)	1	0.0167	- Do not apply through any type of irrigation system (e.g. chemigation).	
Groundboom	Water-dispersible Granule, TREEVIX POWERED BY KIXOR HERBICIDE EPA Reg # 7969-276	Orchard/ Vineyard ⁶	Citrus Fruits ⁶	0.0875 (0.00875 lb ai/gal)	3-4	0.175	REI= 12 hours MRI: 21/42 days. Max. annual use rate: 0.175 lb ai/A PHI = 0 days (for applications at 0.0438 lb ai/A); 42 days (for applications at 0.0875 lb ai/A) - Do not apply by air. - Do not apply through any type of irrigation system (e.g. chemigation). - Apply to the base of tree trunks while targeting emerged broad leaf weeds.	- Protective eyewear such as face shield, goggles, or safety glasses - Long-sleeved shirt and long pants - Shoes plus socks - Chemical-resistant gloves

Table 4.1. Summary of Representative Registered Occupational /Commercial Products and Use Directions for Saflufenacil								
Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
			Tree Nuts ⁷	0.0875 (0.00875 lb ai/gal)	3-4	0.175	REI= 12 hours MRI: 21/42 days. Max. annual use rate: 0.175 lb ai/A PHI = 7 days (for applications at 0.0438 lb ai/A); 42 days (for applications at 0.0875 lb ai/A) - Do not apply by air. - Do not apply through any type of irrigation system (e.g. chemigation).	
Groundboom, backpack			Caneberry and Fig	0.044 lb ai/A (0.0044 lb ai/A)	Max. of 4 applications/year (max. cumulative amount of 4 oz/A/season or year)	0.176 lb ai/A/season or year (i.e., all yearly applications can be made during same season)	Do not apply via aerial, chemigation or high pressure hand wand equipment 10 gal/A rate requirement for ground applications REI: 12 hours RTI: 21 days PHI: 0 days (caneberry); 21 days (fig)	
ATV-mounted or tractor-mounted sprayer equipped for low-pressure hand wand application		Orchard/ Vineyard	Citrus Fruits ⁶	0.000438 lb ai/gal (spot treatment)	3-4	0.175	REI= 12 hours MRI: 21/42 days. Max. annual use rate: 0.175 lb ai/A PHI = 0 days (for applications at rates of 0.0438 lb ai/A); 42 days (for applications at 0.0875 lb ai/A) - Do not apply by air. - Do not apply through any type of irrigation system (e.g. chemigation). - Do not apply spot treatments using high pressure hand wands.	
			Pome Fruits ⁸	0.000438 lb ai/gal (spot treatment)	3-4	0.175	REI= 12 hours MRI: 21 days Max. annual use rate: 0.175 lb ai/A PHI = 0 days	
			Stone Fruits ⁹	0.000438 lb ai/gal (spot treatment)	3-4	0.175	- Do not apply by air. - Do not apply through any type of irrigation system (e.g. chemigation). - Do not apply spot treatments using high pressure hand wands.	

Table 4.1. Summary of Representative Registered Occupational /Commercial Products and Use Directions for Saflufenacil

Method of Application	Product and Formulation (Reg. No.)	Crop Category	Use Site	Maximum Application Rate (lb ai/A – unless specified)	Maximum No. Applications per season	Maximum Application Rate per season (lb ai/A)	Use Directions, Application Timing, Type and Limitations	PPE
			Tree Nuts ⁷	0.000438 lb ai/gal (spot treatment)	3-4	0.175	REI= 12 hours MRI: 21/42 days. Max. annual use rate: 0.175 lb ai/A PHI = 7 days (for applications at rates of 0.0438 lb ai/A); 42 days (for applications at 0.0875 lb ai/A) - Do not apply by air. - Do not apply through any type of irrigation system (e.g., chemigation). - Do not apply spot treatments using high pressure hand wands.	
			Olive, Pomegranate	0.000438 lb ai/gal (spot treatment)	3-4	0.175	REI= 12 hours MRI: 21 days. Max. annual use rate: 0.175 lb ai/A PHI = 0 days - Do not apply by air. - Do not apply through any type of irrigation system (e.g., chemigation) - Do not apply spot treatments using high pressure hand wands.	
			Grapes (Bearing and nonbearing vineyards)	0.000438 lb ai/gal	NS	0.0656	REI= 12 hours MRI: 21 days. PHI = 0 days - Do not apply by air. - Do not apply through any type of irrigation system (e.g., chemigation). - Do not use in nurseries - Do not apply spot treatments using high pressure hand wands.	

¹ **Small grains** include barley, canaryseed, millet, oats, rye, triticale, and wheat

² **Noncropland Areas – Bareground, Pine Control** includes fence rows, non-irrigation ditchbanks, petroleum tank farms, pumping installations, railroads, rights-of-way (utility, pipeline, highway), storage areas, and utility plant sites; wildlife management areas, wildlife openings, and wildlife habitats

³ **Industrial Landscaping** includes industrial landscapes and landscaped highway medians, interchanges, embankments, and buffer areas where perennial plants are established.

⁴ **Native Grass Areas** – applications to establishment and maintenance of native grass and natural areas (including wildlife management areas, wildlife openings, wildlife food plots, and wildlife habitats).

⁵ **Noncropland Areas** includes fence rows, non-irrigation ditchbanks, dry irrigation ditchbanks, and on farmstead areas (barnyards, lanes, driveways, machinery or implement yards, windbreaks).

⁶ **Citrus Fruits** includes calamondin, citrus citron, clementine, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin (satsuma), orange (sweet and sour), pummelo, tangelo, tangerine.

⁷ **Tree Nuts** includes almond, beechnut, brazil nut, butternut, cashew, chestnut, chinquapin, filbert (hazelnut), hickory nut, Macadamia nut, pecan, pistachio, walnut.

⁸ **Pome Fruits** includes apple, crabapple, loquat, mayhaw, pear, pear, oriental, quince

⁹ **Stone Fruits** includes apricot, aprium, cherry, sweet, cherry, tart, nectarine, peach, plum, plum, chicksaw, plum, damson, plum, Japanese, plumcot, pluot, prune

a These crops have the highest single application rate among the high-acreage field crops listed in the KIXOR HERBICIDE (EPA Reg # 7969-324). Other high-acreage field crops listed include field peas (dry field peas), soybean, lentils, cotton, and sunflower.

- b These crops have the highest single application rate among the typical field crops listed in the KIXOR HERBICIDE (EPA Reg # 7969-324). Other typical field crops listed include chickpea (garbanzo bean), edible beans, and edible peas.
- c These crops have the highest single application rate among the orchard crops listed in the KIXOR HERBICIDE (EPA Reg # 7969-324). Other orchard crops listed include grapes.
- d This crop has the highest single application rate among the high-acreage field crops listed in the VERDICT POWERED BY KIXOR HERBICIDE (EPA Reg # 7969-279). Other high-acreage field crops listed include popcorn, grain sorghum, and soybean.
- e These crops have the highest single application rate among the orchard crops listed in the TREEVIX POWERED BY KIXOR HERBICIDE (EPA Reg # 7969-276). Other orchard crops listed include pome and stone fruits, olive, pomegranate, grapes,
- f PHI – Preharvest interval; REI – Reentry interval; MRI – Minimum retreatment interval

5.0 Residential Exposure and Risk Estimates

There are currently no registered or proposed new uses expected to result in residential exposure for saflufenacil. As such, a quantitative residential handler and post-application exposure/risk assessment was not necessary.

6.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (e.g., children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling onto 50 feet wide lawns coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessment is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them.² Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here are thought to occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis analogous to how exposures to turf products are considered in risk assessment.

In order to evaluate the drift potential and associated risks, an approach based on drift modeling coupled with techniques used to evaluate residential uses of pesticides was utilized. Essentially, a residential turf assessment based on exposure to deposited residues has been completed to address drift from the agricultural applications of saflufenacil. In the spray drift scenario, the deposited residue value was determined based on the amount of spray drift that may occur at varying distances from the edge of the treated field using the AgDrift (v2.1.1) model and the *Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift Policy*. Once the deposited residue values were determined, the remainder of the spray drift assessment was based on the algorithms and input values specified in the recently revised (2012) *Standard Operating Procedures for Residential Risk Assessment (SOPs)*.

A screening approach was developed based on the use of the AgDrift model in situations where specific label guidance that defines application parameters is not available.³ AgDrift is appropriate for use only when applications are made by aircraft, airblast orchard sprayers, and groundboom sprayers. When AgDrift was developed, a series of screening values (i.e., the Tier 1 option) were incorporated into the model and represent each equipment type and use under varied conditions. The screening options specifically recommended in this methodology were selected because they are plausible and

² This approach is consistent with the requirements of the EPA's Worker Protection Standard.

³ <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#AgDrift>

represent a reasonable upper bound level of drift for common application methods in agriculture. These screening options are consistent with how spray drift is considered in a number of ecological risk assessments and in the process used to develop drinking water concentrations used for risk assessment. In all cases, each scenario is to be evaluated unless it is not plausible based on the anticipated use pattern (e.g., herbicides are not typically applied to tree canopies) or specific label prohibitions (e.g., aerial applications are not allowed). Section 6.1 provides the screening level drift related risk estimates.

6.1 Combined Risk Estimates from Lawn Deposition Adjacent to Applications

The spray drift risk estimates are based on an estimated deposited residue concentration as a result of the screening level agricultural application scenarios. Saflufenacil is a broad-spectrum herbicide in mode-of-action Group 14 (cell membrane disruptors) and can be applied via aerial, chemigation and groundboom equipment. The recommended drift scenario screening level options are listed below using the highest possible application rates per registered labels as a worst-case scenario conservative approach:

- **Groundboom applications** are based on the AgDrift option for high boom height and using very fine to fine spray type using the 90th percentile results.
- **Aerial applications** are based on the use of AgDrift Tier 1 aerial option for a fine to medium spray type and a series of other parameters which will be described in more detail below (e.g., wind vector assumed to be 10 mph in a downwind direction for entire application/drift event).⁴

For saflufenacil, chemical-specific turf transferable residue (TTR) data are not available, therefore, the estimated TTR is based on a default assumption from the 2012 Residential SOPs that the transferable residue available for exposure from a liquid formulation is 1% of the total deposited residue of the maximum application rate for each use category.

Adult dermal and children's (1 to < 2-year-old) dermal and incidental oral combined risk estimates from indirect exposure related to spray drift are not of concern (MOEs ≥ LOC of 100 for adult dermal and for children combined incidental oral and dermal) at the edge of the field. Results are presented in Table 6.1.1 and 6.1.2 below and Appendix B.

Table 6.1.1 Spray Drift Risk Estimates for Adult Dermal from Saflufenacil				
Crop/Rate Group	Spray Type/ Nozzle Configuration	Application Rate (lb ai/A)	Estimated TTR _t ^a (ug/cm ²)	At Edge
				Dermal MOE LOC = 100 ^b
Field crop (typical and high acreage)				
Aerial	<i>Fine to Medium</i>	0.134	0.01489	5,600
Groundboom	<i>High Boom Very fine to Fine</i>			7,600

a. Estimated TTR (ug/cm²) = Application Rate × F × (1-D)^t × 4.54E8 μg/lb × 2.47E-8 acre/cm², where F = fraction of ai as transferable residue following application (0.01), D = fraction of residue that dissipates daily (0.1).

⁴ AgDrift allows for consideration of even finer spray patterns characterized as very fine to fine. However, this spray pattern was not selected as the common screening basis since it is used less commonly for most agriculture.

- b. MOEs at various distances from field edge = dermal POD (5 mg/kg/day) ÷ Dose (mg/kg/day), where the dermal dose is calculated using the algorithms provided in the Turf Residential SOPs (<http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>), and the TTR used in the calculations is the estimated TTR * drift fraction of spray drift that deposits on lawns at various distances from the field edge (see Appendix B).
- c. Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled (A or gal/day) × DAF (6%) ÷ BW (69 kg).

Table 6.1.2 Spray Drift Risk Estimates for Children (1 to <2 years old) Dermal + Incidental Oral Exposure from Saflufenacil				
Crop/Rate Group	Spray Type/ Nozzle Configuration	Application Rate (lb ai/A)	Estimated TTR _t (ug/cm ²)	At Edge
				Combined MOE LOC = 100
Field crop (typical and high acreage)				
Aerial	<i>Fine to Medium</i>	0.134	0.01489	2,900
Groundboom	<i>High Boom Very fine to Fine</i>			4,000

- a. Estimated TTR (ug/cm²) = Application Rate × F × (1-D)^t × 4.54E8 µg/lb × 2.47E-8 acre/cm², where F = fraction of ai as transferable residue following application (0.01), D = fraction of residue that dissipates daily (0.1).
- b. MOEs at various distances from field edge = dermal POD (5 mg/kg/day) ÷ Dose (mg/kg/day), where the dermal dose is calculated using the algorithms provided in the Turf Residential SOPs (<http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>), and the TTR used in the calculations is the estimated TTR * drift fraction of spray drift that deposits on lawns at various distances from the field edge (see Appendix B).
- c. Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled (A or gal/day) × DAF (6%) ÷ BW (69 kg).

7.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037>). The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (<http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219>). During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for saflufenacil.

8.0 Occupational Exposure and Risk Estimates

8.1 Occupational Handler Exposure/Risk Estimates

HED uses the term handlers to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the registered uses. The quantitative inhalation exposure/risk assessment developed for occupational handlers is based on the scenarios presented in Tables 8.1.1.

Occupational Handler Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor is detailed below on an individual basis.

Application Rate: The application rates used in this assessment can be found in Table 4.1. The labels with the highest rates were selected for the crops.

Unit Exposures: It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include PHED 1.1, the AHETF database, the Outdoor Residential Exposure Task Force (ORETF) database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as “unit exposures”, are outlined in the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table⁵”, which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at the Agency website⁶.

Area Treated or Amount Handled: The inputs for area treated or amount handled were based on information in ExpoSAC Policy 9.1 and are provided in Table 8.1.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational handlers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (e.g., completing multiple applications for multiple clients within a region).

For saflufenacil, based on the registered uses, short- and intermediate-term exposures are expected; however, the PODs for short- and intermediate-term exposures are the same therefore, short-term exposure and risk estimates are protective of longer-term durations.

Personal Protective Equipment: Estimates of dermal and inhalation exposure were calculated for various levels of PPE. Results are presented for “baseline,” defined as a single layer of clothing consisting of a long-sleeved shirt, long pants, shoes plus socks, no protective gloves, and no respirator, as well as baseline with various levels of PPE as necessary (e.g., gloves, respirator, etc). The saflufenacil

⁵ Available online: [Occupational Pesticide Handler Unit Exposure Surrogate Reference Table 2021 \(epa.gov\)](https://www.epa.gov/pesticide-handling/occupational-pesticide-handler-unit-exposure-surrogate-reference-table-2021)

⁶ Available online: [Occupational Pesticide Handler Exposure Data | US EPA](https://www.epa.gov/pesticide-handling/occupational-pesticide-handler-exposure-data)

product labels direct mixers, loaders, applicators, and other handlers to wear - protective eyewear (face shield, goggles, or safety glasses), long-sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves and or waterproof gloves.

Occupational Handler Non-Cancer Exposure and Risk Estimate Equations

The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in Appendix A.

Combining Exposures/Risk Estimates:

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for these exposure routes were similar. Dermal and inhalation risk estimates were combined using the following formula:

$$\text{Total MOE} = \text{Point of Departure (mg/kg/day)} \div \text{Combined dermal + inhalation dose (mg/kg/day)}$$

A total aggregated risk index (ARI) was used for two of the scenarios since the LOC values for dermal exposure (100) and inhalation exposure (1000) are different. The target ARI is 1; therefore, ARIs of less than 1 are risk estimates of concern. The aggregate risk index (ARI) was calculated as follows.

$$\text{Aggregate Risk Index (ARI)} = 1 \div [(\text{Dermal LOC} \div \text{Dermal MOE}) + (\text{Inhalation LOC} \div \text{Inhalation MOE})]$$

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

Except for six occupational scenarios as discussed above, there are no risks of concern from all other exposure routes from the registered uses of saflufenacil. Tolerance recommendations are discussed in Section 2.1 and recommended label modifications are discussed in Section 2.2.

The combined dermal and inhalation occupational risk estimate MOEs range from 61 to 390,000. MOEs greater than the LOC of 100 are not of concern. Most occupational handler combined dermal and inhalation MOEs are greater than 100 at labeled PPE (long-sleeved shirt, long pants, shoes and socks, protective eyewear, and chemical-resistant gloves). The addition of PPE (e.g., double-layer clothing or PF10 respirator, as applicable) for the six scenarios described below would yield MOEs above the LOC (i.e., not of concern). A summary of occupational handler exposure risk estimates can be found in Table 11.1.

The following scenarios resulted in MOEs below the LOC at labeled PPE; however, they would not be of concern with the addition of a double layer of clothing. The dermal exposure route was the risk driver for these scenarios:

- Applying broadcast spray (all starting formulations) to rights of way (e.g., utilities, railroad, roadways) at 0.0285 lb active ingredient (ai)/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].

- Mixing/loading/applying broadcast liquid formulation to Christmas tree farms, at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to field crop, typical acreage at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, total MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to industrial/commercial areas at 0.0285 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, total MOE = 140)].

The following scenarios reached MOEs above the LOC with the addition of a PF10 and/or PF50 respirator. The aggregate risk index (ARI) approach was used to present risk estimates for these scenarios since the LOCs for inhalation (LOC=1000) and dermal (LOC= 100) exposures are different. In the ARI approach, ARIs of less than 1 are risk estimates of concern. Due to the lack of an available subchronic inhalation study, the inhalation LOC is 1000; the two scenarios below resulted in inhalation MOEs below the LOC of 1000. The inhalation exposure route was the risk driver for these scenarios:

- Mixing/loading/applying foliar liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0067 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 380 (with PF10 respirator, MOE = 3800); total ARI = 0.34 (with PF10 respirator, total ARI = 2.6)].
- Mixing/loading/applying soil-directed liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0285 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 90 (with PF10 respirator, MOE = 900; with a with PF50 respirator, MOE = 1,400); total ARI = 0.086 (with PF10 respirator, total ARI = 0.61 and with PF 50 respirator, total ARI = 1.3)].

The combined dermal and inhalation occupational risk estimate MOEs range from 61 to 390,000. MOEs greater than the LOC of 100 are not of concern. Most occupational handler combined dermal and inhalation MOEs are greater than 100 at label PPE (long-sleeved shirt, long pants, shoes and socks, protective eyewear, and chemical-resistant gloves). The four scenarios described below require additional PPE to yield MOEs above 100 (i.e., not of concern). A summary of occupational handler exposure risk estimates can be found in Table 8.1.1.

The following scenarios resulted in risks of concern at label PPE, however, they would not be of concern with the addition of a double layer of clothing and gloves. The dermal exposure route was the risk driver for these scenarios:

- Applying broadcast spray (all starting formulations) to rights of way (e.g., utilities, railroad, roadways) at 0.0285 lb active ingredient (ai)/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, MOE = 140)].

- Mixing/loading/applying broadcast liquid formulation to Christmas tree farms and field crop, typical acreage at 0.0268 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 100; total MOE = 94 (with double-layer clothing, MOE = 140)].
- Mixing/loading/applying broadcast liquid formulation to industrial/commercial areas at 0.0285 lb ai/gallon solution using mechanically pressurized handgun [dermal MOE = 98; total MOE = 92 (with double-layer clothing, MOE = 140)].

The following scenarios reached MOEs not of concern with the addition of a PF 10 respirator. The inhalation exposure route was the risk driver for these scenarios:

- Mixing/loading/applying foliar liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0285 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 90 (with PF10 respirator, MOE = 900); total MOE = 61 (with PF10 respirator, MOE = 160)].
- Mixing/loading/applying soil-directed liquid formulations to nursery crops (ornamentals, vegetables, trees, container stock) at 0.0067 lb ai/gallon solution with mechanically pressurized handgun [inhalation MOE = 380 (with PF10 respirator, MOE = 380); total MOE = 61 (with PF10 respirator, MOE = 160)].

HED's Hazard Science and Policy Council (HASPOC) used a weight-of-evidence approach to determine that a subchronic inhalation toxicity study is not required at this time (A. Dunbar, TXR 0056720, 02-AUG-2013 and V. Kurker, TXR 0058170, 20-APR-2021). However, these two scenarios did not have inhalation MOEs ten times greater than the LOC. Therefore, a PF10 respirator requirement should be added to the product labels for these nursery uses. In the absence of modified labels, a 10X database uncertainty factor will be applied to inhalations scenarios and an inhalation study will be required.

The Agency matches quantitative occupational exposure assessment with appropriate characterization of exposure potential. While HED presents quantitative risk estimates for human flaggers where appropriate, agricultural aviation has changed dramatically over the past two decades. According the 2012 National Agricultural Aviation Association (NAAA) survey of their membership, the use of GPS for swath guidance in agricultural aviation has grown steadily from the mid 1990's. Over the same time period, the use of human flaggers for aerial pesticide applications has decreased steadily from ~15% in the late 1990's to only 1% in the most recent (2012) NAAA survey. The Agency will continue to monitor all available information sources to best assess and characterize the exposure potential for human flaggers in agricultural aerial applications.

HED has no data to assess exposures to pilots using open cockpits. The only data available is for exposure during aerial applications (covering both airplanes and helicopters) of liquid formulations to pilots in enclosed cockpits (data from AHETF) and of granule formulations in enclosed cockpits (data from PHED). Therefore, risks to pilots are assessed using the engineering control (enclosed cockpits) and baseline attire (long-sleeve shirt, long pants, shoes, and socks); use of the data in this fashion is consistent with the Agency's Worker Protection Standard (WPS) stipulations for engineering controls, which says label-required PPE for applicators can be reduced when using an enclosed cockpit (40 CFR

170.240(d)(6)(iii)) as well as a provision regarding use of gloves for aerial applications (40 CFR 170.240(d)(6)(i)), which says pilots are not required to wear protective gloves for the duration of the application. With this level of protection, there are no risk estimates of concern for applicators.

Note on flagger scenarios: The Agency matches quantitative occupational exposure assessment with appropriate characterization of exposure potential. While HED presents quantitative risk estimates for human flaggers where appropriate, agricultural aviation has changed dramatically over the past two decades. According the 2012 National Agricultural Aviation Association (NAAA) survey of their membership, the use of GPS for swath guidance in agricultural aviation has grown steadily from the mid 1990's. Over the same time period, the use of human flaggers for aerial pesticide applications has decreased steadily from ~15% in the late 1990's to only 1% in the most recent (2012) NAAA survey. The Agency will continue to monitor all available information sources to best assess and characterize the exposure potential for human flaggers in agricultural aerial applications.

Note on aerial applicator scenario: HED has no data to assess exposures to pilots using open cockpits. The only data available is for exposure during aerial applications (covering both airplanes and helicopters) of liquid formulations to pilots in enclosed cockpits (data from AHETF) and of granule formulations in enclosed cockpits (data from PHED). Therefore, risks to pilots are assessed using the engineering control (enclosed cockpits) and baseline attire (long-sleeve shirt, long pants, shoes, and socks); use of the data in this fashion is consistent with the Agency's Worker Protection Standard (WPS) stipulations for engineering controls, which says label-required PPE for applicators can be reduced when using an enclosed cockpit (40 CFR 170.607(f)(3)) as well as a provision regarding use of gloves for aerial applications (40 CFR 170.607(f)(1)), which says pilots are not required to wear protective gloves for the duration of the application, unless gloves are otherwise required for pilots on the pesticide product labeling. With this level of protection, there are no risk estimates of concern for applicators.

Note on mixing/loading liquid formulation scenarios: A 2019 study by the AHETF measured dermal and inhalation exposure for workers who loaded liquid pesticides using closed systems such as gravity feed, container breach, and suction/extraction systems. After analyzing the exposure monitoring data, the AHETF observed that exposures were higher than expected and subsequently identified that, when using suction/extraction systems, removing and handling chemical extraction probes without rinsing them prior to removal from the pesticide container had the potential to result in high exposures via direct exposure to the liquid concentrate. The AHETF therefore submitted to the Agency a dataset that excludes monitoring of those workers who handled unrinsed chemical extraction probes and recommended that the Agency take additional regulatory actions to ensure workers do not remove and handle chemical extraction probes still coated with the concentrated liquid formulation.

The Agency agreed with the AHETF proposal, recognizing that handling of unrinsed chemical extraction probes is inconsistent with the exposure reduction principles of closed systems. Closed loading systems are an engineering control designed to prevent direct contact between users and the pesticide formulation, thereby reducing exposures. According to EPA's Worker Protection Standard (WPS), a closed system must remove the pesticide from its original container and transfer the pesticide product through connecting hoses, pipes and couplings that are sufficiently tight to prevent exposure of handlers to the pesticide product, except for the negligible escape associated with normal operation of the system [40 CFR § 170.607(d)(2)(i)]. However, in addition to considerations regarding closed

systems, given the high exposure potential from this activity, the Agency is requiring revisions to applicable product label instructions to restrict handling un-rinsed extraction probes and conducting stakeholder outreach and revising worker training modules to ensure that users of suction/extraction systems rinse the chemical extraction probes within the pesticide container prior to their removal so that they are not exposed to the concentrated liquid formulation.

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Mixer/Loader														
Dry Flowable, Aerial, Broadcast	Field crop, typical	51.6	SL/G	8.96	No-R	0.0167	lb ai/acre	350	acres	0.000263	19000	0.000759	6600	4900
Liquid, Backpack, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	37.6	SL/G	0.219	No-R	0.0285	lb ai/gallon solution	1000	gallons solution	0.00093	5400	0.0000904	55000	4900
Liquid, Mechanically-pressurized Handgun, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	37.6	SL/G	0.219	No-R	0.0285	lb ai/gallon solution	1000	gallons solution	0.00093	5400	0.0000904	55000	4900
Dry Flowable, Aerial, Broadcast	Field crop, high-acreage	51.6	SL/G	8.96	No-R	0.0223	lb ai/acre	1200	acres	0.0012	4200	0.00348	1400	1100
Dry Flowable, Airblast, Broadcast	Orchard/Vineyard	51.6	SL/G	8.96	No-R	0.0875	lb ai/acre	40	acres	0.000157	32000	0.000455	11000	8200
Dry Flowable, Groundboom, Broadcast	Orchard/Vineyard	51.6	SL/G	8.96	No-R	0.0875	lb ai/acre	40	acres	0.000157	32000	0.000455	11000	8200
Dry Flowable, Groundboom, Broadcast	Field crop, typical	51.6	SL/G	8.96	No-R	0.0167	lb ai/acre	80	acres	0.0000599	83000	0.000174	29000	21000
Dry Flowable, Groundboom, Broadcast	Field crop, high-acreage	51.6	SL/G	8.96	No-R	0.0223	lb ai/acre	200	acres	0.0002	25000	0.00058	8600	6400
Liquid, Aerial, Broadcast	Roads, parking lots, etc. (pre-paving)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	60	acres	0.000263	19000	0.0000255	200000	17000
Liquid, Aerial, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	60	acres	0.000263	19000	0.0000255	200000	17000
Liquid, Aerial, Broadcast	Orchard/Vineyard	37.6	SL/G	0.219	No-R	0.0445	lb ai/acre	350	acres	0.00051	9800	0.0000494	100000	8900
Liquid, Aerial, Broadcast	Field crop, typical	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	350	acres	0.00153	3300	0.000149	34000	3000
Liquid, Aerial, Broadcast	Field crop, high-acreage	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	1200	acres	0.00526	950	0.00051	9800	870

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Liquid, Aerial, Broadcast	Conifer plantation	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	1200	acres	0.00526	950	0.00051	9800	870
Liquid, Airblast, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	20	acres	0.0000878	57000	0.00000851	590000	52000
Liquid, Airblast, Broadcast	Orchard/Vineyard	37.6	SL/G	0.219	No-R	0.0445	lb ai/acre	40	acres	0.0000582	86000	0.00000565	880000	78000
Liquid, Chemigation, Broadcast	Field crop, typical	37.6	SL/G	0.219	No-R	0.0891	lb ai/acre	350	acres	0.00102	4900	0.000099	51000	4500
Liquid, Chemigation, Broadcast	Field crop, high-acreage	37.6	SL/G	0.219	No-R	0.111	lb ai/acre	350	acres	0.00127	3900	0.000123	41000	3600
Liquid, Groundboom, Broadcast	Roads, parking lots, etc. (pre-paving)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	5	acres	0.0000219	230000	0.00000213	2300000	210000
Liquid, Groundboom, Broadcast	Golf course (tees and greens only)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	5	acres	0.0000219	230000	0.00000213	2300000	210000
Liquid, Groundboom, Broadcast	Golf course (fairways, tees, greens)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	40	acres	0.000176	28000	0.000017	290000	26000
Liquid, Groundboom, Broadcast	Field-grown ornamental crops	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	40	acres	0.000176	28000	0.000017	290000	26000
Liquid, Groundboom, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	60	acres	0.000263	19000	0.0000255	200000	17000
Liquid, Groundboom, Broadcast	Orchard/Vineyard	37.6	SL/G	0.219	No-R	0.0445	lb ai/acre	40	acres	0.0000582	86000	0.00000565	880000	78000
Liquid, Groundboom, Broadcast	Field crop, typical	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	80	acres	0.00035	14000	0.0000341	150000	13000
Liquid, Groundboom, Broadcast	Field crop, high-acreage	37.6	SL/G	0.219	No-R	0.134	lb ai/acre	200	acres	0.000878	5700	0.0000851	59000	5200

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Applicator														
Spray (all starting formulations), Aerial, Broadcast	Roads, parking lots, etc. (pre-paving)	2.08	EC	0.0049	EC	0.134	lb ai/acre	60	acres	0.0000145	340000	0.000000571	8800000	330000
Spray (all starting formulations), Aerial, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	2.08	EC	0.0049	EC	0.134	lb ai/acre	60	acres	0.0000145	340000	0.000000571	8800000	330000
Spray (all starting formulations), Aerial, Broadcast	Orchard/Vineyard	2.08	EC	0.0049	EC	0.0445	lb ai/acre	350	acres	0.0000282	180000	0.00000111	4500000	170000
Spray (all starting formulations), Aerial, Broadcast	Field crop, typical	2.08	EC	0.0049	EC	0.134	lb ai/acre	350	acres	0.0000849	59000	0.00000333	1500000	57000
Spray (all starting formulations), Aerial, Broadcast	Field crop, high-acreage	2.08	EC	0.0049	EC	0.134	lb ai/acre	1200	acres	0.00029	17000	0.0000114	440000	16000
Spray (all starting formulations), Aerial, Broadcast	Conifer plantation	2.08	EC	0.0049	EC	0.134	lb ai/acre	1200	acres	0.00029	17000	0.0000114	440000	16000
Spray (all starting formulations), Airblast, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	1590	SL/G	4.71	No-R	0.134	lb ai/acre	20	acres	0.0037	1400	0.000183	27000	1300
Spray (all starting formulations), Airblast, Broadcast	Orchard/Vineyard	1590	SL/G	4.71	No-R	0.0875	lb ai/acre	40	acres	0.00484	1000	0.000239	21000	950

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Spray (all starting formulations), Groundboom, Broadcast	Roads, parking lots, etc. (pre-paving)	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	5	acres	0.00000939	530000	0.0000033	1500000	390000
Spray (all starting formulations), Groundboom, Broadcast	Golf course (tees and greens only)	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	5	acres	0.00000939	530000	0.0000033	1500000	390000
Spray (all starting formulations), Groundboom, Broadcast	Golf course (fairways, tees, greens)	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	40	acres	0.000075	67000	0.0000264	190000	50000
Spray (all starting formulations), Groundboom, Broadcast	Field-grown ornamental crops	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	40	acres	0.000075	67000	0.0000264	190000	50000
Spray (all starting formulations), Groundboom, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	60	acres	0.000112	45000	0.0000396	130000	33000
Spray (all starting formulations), Groundboom, Broadcast	Orchard/Vineyard	16.1	SL/G	0.34	No-R	0.0875	lb ai/acre	40	acres	0.000049	100000	0.0000172	290000	74000
Spray (all starting formulations), Groundboom, Broadcast	Field crop, typical	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	80	acres	0.00015	33000	0.0000528	95000	24000
Spray (all starting formulations), Groundboom, Broadcast	Field crop, high-acreage	16.1	SL/G	0.34	No-R	0.134	lb ai/acre	200	acres	0.000375	13000	0.000132	38000	9700

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Spray (all starting formulations), Mechanically-pressurized Handgun, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	2050	SL/G	8.68	No-R	0.0285	lb ai/gallon solution	1000	gallons solution	0.0508	98	0.00358	1400	92
		1360	DL/G							0.0337	150			140
Flagger														
Spray (all starting formulations), Aerial, Broadcast	Nursery (ornamentals, vegetables, trees, container stock)	12	SL/G	0.202	No-R	0.134	lb ai/acre	60	acres	0.0000839	60000	0.0000235	210000	47000
Spray (all starting formulations), Aerial, Broadcast	Orchard/Vineyard	12	SL/G	0.202	No-R	0.0445	lb ai/acre	350	acres	0.000163	31000	0.0000457	110000	24000
Spray (all starting formulations), Aerial, Broadcast	Field crop, typical	12	SL/G	0.202	No-R	0.134	lb ai/acre	350	acres	0.00049	10000	0.000137	36000	7800
Spray (all starting formulations), Aerial, Broadcast	Field crop, high-acreage	12	SL/G	0.202	No-R	0.134	lb ai/acre	350	acres	0.00049	10000	0.000137	36000	7800
Mixer/Loader/Applicator														
Dry Flowable, Backpack, Ground/soil-directed	Orchard/Vineyard	8260	SL/G	2.58	No-R	0.000438	lb ai/gallon solution	40	gallons solution	0.000126	40000	0.000000655	7600000	40000
Dry Flowable, Mechanically-pressurized Handgun, Broadcast (foliar)	Orchard/Vineyard	2050	SL/G	8.68	No-R	0.00875	lb ai/gallon solution	1000	gallons solution	0.0156	320	0.0011	4500	300

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Dry Flowable, Mechanically-pressurized Handgun, Drench/Soil-/Ground-directed	Orchard/Vineyard	2050	SL/G	8.68	No-R	0.000438	lb ai/gallon solution	1000	gallons solution	0.000781	6400	0.0000551	91000	6000
Dry Flowable, Mechanically-pressurized Handgun, Broadcast (foliar)	Field crop, typical	2050	SL/G	8.68	No-R	0.00334	lb ai/gallon solution	1000	gallons solution	0.00596	840	0.00042	12000	790
Dry Flowable, Mechanically-pressurized Handgun, Drench/Soil-/Ground-directed	Field crop, typical	2050	SL/G	8.68	No-R	0.00334	lb ai/gallon solution	1000	gallons solution	0.00596	840	0.00042	12000	790
Liquid, Backpack, Ground/soil-directed	Orchard/Vineyard	8260	SL/G	2.58	No-R	0.0089	lb ai/gallon solution	40	gallons solution	0.00256	2000	0.0000133	380000	2000
Liquid, Backpack, Broadcast (foliar)	Christmas Tree farm	30500	SL/G	69.1	No-R	0.0268	lb ai/gallon solution	40	gallons solution	0.0284	180	0.00107	4700	170
Liquid, Backpack, Ground/soil-directed	Christmas Tree farm	8260	SL/G	2.58	No-R	0.0285	lb ai/gallon solution	40	gallons solution	0.00819	610	0.0000426	120000	610
Liquid, Backpack, Ground/soil-directed	Conifer plantation	8260	SL/G	2.58	No-R	0.0285	lb ai/gallon solution	40	gallons solution	0.00819	610	0.0000426	120000	610

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Liquid, Backpack, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	30500	SL/G	69.1	No-R	0.00536	lb ai/gallon solution	40	gallons solution	0.00569	880	0.000214	23000	850
Liquid, Backpack, Broadcast (foliar)	Nursery (ornamentals, vegetables, trees, container stock)	30500	SL/G	69.1	No-R	0.0067	lb ai/gallon solution	15	gallons solution	0.00267	1900	0.000101	50000	1800
Liquid, Backpack, Ground/soil-directed	Nursery (ornamentals, vegetables, trees, container stock)	8260	SL/G	2.58	No-R	0.0285	lb ai/gallon solution	15	gallons solution	0.00307	1600	0.0000159	310000	1600
Liquid, Backpack, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	2500	SL/G	27.6	No-R	0.0285	lb ai/gallon solution	40	gallons solution	0.00248	2000	0.000457	11000	1700
Liquid, Manually-pressurized Handwand, Broadcast (foliar)	Christmas Tree farm	430	SL/G	23.6	No-R	0.0268	lb ai/gallon solution	40	gallons solution	0.000401	12000	0.000367	14000	6500
Liquid, Manually-pressurized Handwand, Broadcast (foliar)	Nursery (ornamentals, vegetables, trees, container stock)	430	SL/G	23.6	No-R	0.0067	lb ai/gallon solution	15	gallons solution	0.0000376	130000	0.0000343	150000	70000
Liquid, Manually-pressurized Handwand, Broadcast	Industrial/commercial (tires, rail yards, junk yards, etc.)	430	SL/G	23.6	No-R	0.0285	lb ai/gallon solution	40	gallons solution	0.000426	12000	0.00039	13000	6200

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar)	Orchard/Vineyard	2050	SL/G	8.68	No-R	0.0089	lb ai/gallon solution	1000	gallons solution	0.0158	320	0.00112	4500	300
Liquid, Mechanically-pressurized Handgun, Drench/Soil-/Ground-directed	Orchard/Vineyard	2050	SL/G	8.68	No-R	0.0089	lb ai/gallon solution	1000	gallons solution	0.0158	320	0.00112	4500	300
Liquid, Mechanically-pressurized Handgun, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	880	SL/G	1.9	No-R	0.134	lb ai/acre	5	acres	0.000513	9700	0.0000184	270000	9400
Liquid, Mechanically-pressurized Handgun, Broadcast	Golf course (tees and greens only)	880	SL/G	1.9	No-R	0.134	lb ai/acre	5	acres	0.000513	9700	0.0000184	270000	9400
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar)	Christmas Tree farm	2050	SL/G	8.68	No-R	0.0268	lb ai/gallon solution	1000	gallons solution	0.0477	100	0.00338	1500	94
		1360	DL/G							0.0317	160			140
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar)	Nursery (ornamentals, vegetables, trees, container stock)	3610	SL/G	448	No-R	0.0067	lb ai/gallon solution	300	gallons solution	0.00631	790	0.013	380	ARI = 0.34 ^{9a}
				44.8	PF10 R							0.0013	3800	ARI = 2.6 ⁹

Table 8.1. Occupational Handler Non-Cancer Exposure and Risk Estimates for Saflufenacil.

Exposure Scenario	Crop or Target	Dermal Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Inhalation Unit Exposure ¹ (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate ²	App Rate Unit	Area Treated or Amount Handled Daily ³	Area Treated/ Amount Handled Unit	Dermal		Inhalation		Total
										Dose ⁴ (mg/kg/day)	MOE ⁵ (LOC = 100)	Dose ⁶ (mg/kg/day)	MOE ⁷ (LOC = 100)	MOE ⁸ (LOC = 100)
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar)	Nursery (ornamentals, vegetables, trees, container stock)	3610	SL/G	448	No-R	0.0285				0.0269	190	0.0556	90	ARI= 0.086 ⁹
				44.8	PF10 R							0.00556	3800	ARI = 2.6 ⁹
				8.96	PF50 R							0.00111	4500	ARI =1.3 ⁹
Liquid, Mechanically-pressurized Handgun, Broadcast	Industrial/commercial (tires, rail yards, junk yards, etc.)	2050	SL/G	8.68	No-R	0.0285	lb ai/gallon solution	1000	gallons solution	0.0508	98	0.00358	1400	92
		1360	DL/G							0.0337	150			140
Liquid, Mechanically-pressurized Handgun, Broadcast	Field crop, typical	2050	SL/G	8.68	No-R	0.0268	lb ai/gallon solution	1000	gallons solution	0.0477	100	0.00338	1500	94
		1360	DL/G							0.0317	160			140
Loader/Applicator														
Liquid, Backpack, Broadcast	Rights-of-way (e.g., utilities, railroad, roadways)	30500	SL/G	69.1	No-R	0.0285	lb ai/gallon solution	40	gallons solution	0.0303	170	0.00114	4400	160

1 Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>);

Level of PPE: Baseline, PPE, Eng. Controls.

2 Based on registered labels (see Table 4.1).

3 Exposure Science Advisory Council Policy #9.1.

4 Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled (A or gal/day) × DAF (6%) ÷ BW (69 kg).

5 Dermal MOE = Dermal NOAEL (5 mg/kg/day) ÷ Dermal Dose (mg/kg/day).

6 Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled (A or gal/day) ÷ BW (69 kg).

7 Inhalation MOE = Inhalation NOAEL (5 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

8 Total MOE = NOAEL (5 mg/kg/day) ÷ Dermal Dose + Inhalation Dose OR Total MOE = 1 ÷ (1/Dermal MOE + 1/Inhalation MOE)

8.2 Occupational Post-application Exposure/Risk Estimates

HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

8.2.1 Occupational Post-application Inhalation Exposure/Risk Estimates

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037>). The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (<https://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219>). During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for saflufenacil.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the agency's risk assessments.

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers. Handler exposure resulting from application of pesticides outdoors is likely to result in higher exposure than post-application exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of most occupational post-application inhalation exposure scenarios.

8.2.2 Occupational Post-application Dermal Exposure/Risk Estimates

Occupational Post-application Dermal Exposure Data and Assumptions

Most of the registered uses for saflufenacil are soil-directed preplant or preemergent uses where no crop foliage is present. Currently, HED has no transfer coefficients or other data to assess post-application dermal exposures from soil by occupational workers. In general, such exposures are considered to be negligible. Therefore, for the registered soil-directed uses, post-application dermal exposures and risks to occupational workers were not assessed.

Most of the labels indicate that crop injury will result if the products are applied post-emergent (over the top) to any crop. Saflufenacil is used as a harvest aid/desiccation aid on chia and this use was assessed for post-application dermal. A quantitative post-application dermal exposure assessment was conducted for the registered use on chia and resulted in no risks of concern on the day of application (MOE = 5,300).

A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessments. Each assumption and factor is detailed below on an individual basis.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Based on the registered uses for saflufenacil, both short- and intermediate-term exposures are expected for occupational post-application workers.

Transfer Coefficients: It is the policy of HED to use the best available data to assess post-application exposure. Sources of generic post-application data, used as surrogate data in the absence of chemical-specific data, are derived from ARTF exposure monitoring studies, and, as proprietary data, are subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting post-application exposure that are used in this assessment, known as “transfer coefficients”, are presented in the ExpoSAC Policy 3⁷ which, along with additional information about the ARTF data, can be found at the Agency website⁸. Table 8.2.2.1. provides a summary of the post-application activities and associated transfer coefficients for the registered crops/use sites. As no “transfer coefficients” specific to the registered crop (chia) were available for use, data from similar crops were used so barley was used as a surrogate. Since the registered use for chia is limited to harvest aid/desiccation, “scouting” (defined as the process of monitoring crop development in the field to evaluate crop concerns) is the only post-application activity relevant to this assessment.

Crops	Policy Crop Group Category	Crop Height	Foliage Density	Transfer Coefficients (cm ² /hr)	Activities
Barley, wheat (spring), wheat (winter)	15	LOW	MIN	1100	Scouting

Application Rate: The application rates used in this assessment can be found in Table 4.1.

Exposure Time: The average occupational workday is assumed to be 8 hours.

Dislodgeable Foliar Residues: Chemical-specific dislodgeable foliar residue (DFR) data have not been submitted for saflufenacil. Therefore, this assessment uses HED’s default assumption that 25% of the application is available for transfer on day 0 following the application and the residues dissipate at a

⁷ Available: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

⁸ Available: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

rate of 10% each following day. Since the highest estimated occupational post-application exposure using default DFR values for saflufenacil is minimal in comparison to the level of concern (i.e., the calculated MOE is greater than 2 times higher than the level of concern, MOE = 5,300 compared to the LOC of 100); EPA is waiving the 40CFR DFR data requirement. In this instance, it is unlikely that chemical-specific DFR data would be needed to further refine exposure assessments or would add appreciably to our overall understanding of the availability of dislodgeable foliar pesticide residues for saflufenacil.

Occupational Post-application Non-Cancer Dermal Exposure and Risk Estimate Equations

The algorithms used to estimate non-cancer exposure and dose for occupational post-application workers can be found in Appendix A.

Occupational Post-application Non-Cancer Dermal Risk Estimates

The post-application dermal risk estimate can be found in Table 8.2.2.2.

Table 8.2.2.2. Occupational Post-application Non-Cancer Exposure and Risk Estimates for Saflufenacil.					
Crop/Site	Activities	Transfer Coefficient (cm ² /hr)	DFR ¹	Dermal Dose (mg/kg/day) ²	MOE ³
Short- and intermediate-term					
Barley, wheat (spring), wheat (winter)	Scouting	1100	0.12	0.001	5,300

1 DFR = 0.044 lb ai/A × F × (1-D)^t × 4.54E8 µg/lb × 2.47E-8 acre/cm²; where F = 0.25 and D = 0.10 per day

2 Daily Dermal Dose = [DFR (µg/cm²) × Transfer Coefficient × 0.001 mg/µg × 8 hrs/day × 0.06] , BW (69 kg).

3 MOE = 5 mg/kg/day / Daily Dermal Dose.

Restricted Entry Interval

Saflufenacil is classified as Toxicity Category III via the dermal route and Toxicity Category IV for skin irritation potential. It is not a skin sensitizer. Short- and intermediate-term post-application risk estimates were not a concern on day 0 (12 hours following application) for all post-application activities. Under 40 CFR 156.208 (c) (2), is classified as Acute III or IV for acute dermal, eye irritation and primary skin irritation are assigned a 12-hour REI. Therefore, the [156 subpart K] Worker Protection Statement interim REI of 12 hours is adequate to protect agricultural workers from post-application exposures to saflufenacil. HED would recommend a REI of 12 hours. This is the REI listed on the registered labels, and is considered protective of post-application exposure.

Appendix A. Summary of Occupational and Residential Non-cancer Algorithms

Occupational Non-cancer Handler Algorithms

Potential daily exposures for occupational handlers are calculated using the following formulas:

$$E = UE * AR * A * 0.001 \text{ mg/ug}$$

where:

- E = exposure (mg ai/day),
- UE = unit exposure (µg ai/lb ai),
- AR = maximum application rate according to registered label (lb ai A or lb ai/gal), and
- A = area treated or amount handled (e.g., A/day, gal/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

- ADD = average daily dose absorbed in a given scenario (mg ai/kg/day),
- E = exposure (mg ai/day),
- AF = absorption factor (dermal and/or inhalation), and
- BW = body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal and inhalation dose received by occupational handlers are compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

- MOE = margin of exposure: value used by HED to represent risk estimates (unitless),
- POD = point of departure (mg/kg/day), and
- ADD = average daily dose absorbed in a given scenario (mg ai/kg/day).

Occupational Non-cancer Post-application Algorithms

Potential daily exposures for occupational post-application workers are calculated using the following formulas:

$$DFR_t = AR * F * (1-D)^t * \left(4.54E8 \frac{ug}{lb}\right) * \left(2.47E-8 \frac{A}{cm^2}\right)$$

where:

DFR_t = dislodgeable foliage residue on day "t" ($\mu\text{g}/\text{cm}^2$),
 AR = application rate (lb ai/acre),
 F = fraction of ai retained on foliage or 25% (unitless),
 D = fraction of residue that dissipates daily or 10% (unitless), and
 t = number of days after application day (days).

$$E = TC * DFR_t * ET * 0.001 \frac{mg}{ug}$$

where:

E = exposure (mg ai/day),
 TC = transfer coefficient (cm^2/hr),
 DFR_t = dislodgeable foliar residue on day "t" ($\mu\text{g}/\text{cm}^2$), and
 ET = exposure time (hours/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

ADD = average daily dose absorbed in a given scenario (mg ai/kg/day),
 E = exposure (mg ai/day),
 AF = absorption factor (dermal and/or inhalation), and
 BW = body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal dose received by occupational post-application workers is compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational post-application workers. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

MOE = margin of exposure: value used by HED to represent risk estimates (unitless),
POD = point of departure (mg/kg/day), and
ADD = average daily dose absorbed in a given scenario (mg ai/kg/day).

Appendix B. Summary of Spray Drift Algorithms

Modified TTR Equation to Account for Spray Drift

The equation presented below, should be used to evaluate potential risks from spray drift. This equation is similar to the standard TTR equation, except that an additional term has been included (DF or Drift Fraction) that provides an adjustment for the amount of drift that moves into and deposits in a non-target area, such as a lawn. This equation applies to situations where TTR data are not available.

$$\text{TTR} = \text{AR} * \text{DF} * \text{F} * (1-\text{D})^{\text{t}} * \text{CF2} * \text{CF3}$$

where:

TTR	=	turf transferable residue ($\mu\text{g}/\text{cm}^2$)
DF	=	drift fraction of spray drift that deposits on lawns (unitless)
AR	=	application rate (lbs ai/ft ² or lb ai/acre)
F	=	fraction of ai as transferable residue following application (unitless)
D	=	fraction of residue that dissipates daily (unitless)
T	=	post-application day on which exposure is being assessed (Day 0 in this SOP)
CF2	=	weight unit conversion factor ($4.54 \times 10^8 \mu\text{g}/\text{lb}$)
CF3	=	area unit conversion factor ($1.08 \times 10^{-3} \text{ ft}^2/\text{cm}^2$ or $2.47 \times 10^{-8} \text{ acre}/\text{cm}^2$)

If chemical specific TTR data are available, the residue on Day 0 is used after it is adjusted based on the ratio of the applicable application rate for risk assessment (i.e., based on the crop of concern) and the application rate for the TTR study followed by an additional adjustment for the drift fraction factor as illustrated above.