OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

MEMORANDUM

DATE: June 17, 2024

SUBJECT: **Saflufenacil**. Petition for Proposed New Uses on Mint (Peppermint and Spearmint) and Crop Group Conversions and Expansions. **Revised Summary of Analytical Chemistry and Residue Data.**

PC Code: 118203
CAS No.: 372137-35-4
Petition No.: 2E9045
Risk Assessment Type: NA
TXR No.: NA
MRID No.: see below

Task Group No.: 00484712
Parent Case No.: 00478596
Registration No.: 7969-275, 7969-278, 7969-276
Regulatory Action: Section 3
Reg Review Case No.: NA
40 CFR: §180.649

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OCSPP Guideline	REFERENCE
860.1500	MRID 52065001. Moore, P. (2022) Saflufenacil: Magnitude of the Residue on Mint. Project Number: 11921. Unpublished study prepared by University of Idaho, University of Wisconsin and Washington State University. 494p.

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.

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1.0 Executive Summary

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. Saflufenacil is currently registered in the U.S. for use on several raw agricultural commodities with tolerances ranging from 0.01 ppm to 50 ppm (40 CFR §180.649). It is currently registered for use on 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. Tolerances for plant commodities are expressed in terms of combined residues of saflufenacil and its metabolites calculated as the stoichiometric equivalent of saflufenacil, in or on the commodities. Tolerances for milk, fish-freshwater finfish, fish-shellfish, crustacean and the fat, liver, meat, and meat byproducts (excluding liver) of cattle, goat, hog, horse, and sheep are listed in 40 CFR §180.566(a)(2) and are expressed in terms of only saflufenacil. Since the completion of the previous review of this petition, the applicant withdrew their initial request to support certain crop group expansions for 6-22A through 6-22F, 7-22, 15-22A through 15-22F, and 16-22, and is reflected in this updated version. Additionally, the mint term definition (Table 2.2.2) was clarified that the proposed mint tolerance would cover *Mentha* species, broadly; otherwise, all other information remains the same as prior analysis completed April 17, 2024.

Proposed Use: Interregional Research Project Number 4 (IR-4) has petitioned for the establishment of permanent tolerances under 40 CFR §180.649(a)(1) for residues of saflufenacil, including its metabolites in/on mint (new use on mint, fresh leaves and mint, dried leaves); crop group conversions in citrus fruit (crop group 10-10), pome fruit (crop group 11-10), stone fruit (crop group 12-12), tree nuts (crop group 14-12. Table 3.2.1 is a summary of the proposed end-use product and Table 3.2.2 is a summary of the proposed application instructions. The use directions are adequate and are supported by the submitted magnitude of the residue data.

Nature of the Residue - Primary Crops, Livestock, and Rotational Crops: The HED Residues of Concern Knowledgebase Subcommittee (ROCKS) determined that residues of concern for the tolerance expression and risk assessment consist of saflufenacil, M800H11, and M800H35 (Memo, B. Daiss, D359645, 06-JAN-2009). An additional major metabolite (M800H02) that is not included in the tolerance expression was observed in soybean seed following post-emergence application. As the structure of M800H02 is closely related to the parent compound and it is the precursor of the regulated metabolite M800H11, HED concludes that M800H02 is a residue of concern for risk-assessment purposes in seed crops following post-emergence treatment. The residues of concern for risk assessment are as defined in Table 4.0.

Magnitude of the Residue - Primary Crops: HED concludes that the available residue data are adequate to support the proposed uses and the tolerances recommended in Table 2.2.2. There are adequate storage stability data to validate the storage conditions and intervals of samples collected from the field trials. No additional residue data are required.

Magnitude of the Residue - Livestock: HED concludes that the currently established tolerances for residues in/on livestock commodities are adequate to cover all registered uses.

Magnitude of the Residue - Rotational Crops: Based on the available rotational crop data, the currently established rotational crop restrictions are acceptable.

Magnitude of the Residue – Processed Commodities: The mint processing study is considered scientifically acceptable. Following a single foliar application at 3x the rate used in the corresponding field trials, residues of saflufenacil in mint oil were below the LOQ (<0.010 ppm). Processing factors could not be calculated for saflufenacil and its metabolites as residues were below the LOQ in/on the RAC and each of the commodities. The observed processing factors did not exceed the maximum theoretical concentration factor for mint of 330x (peppermint and spearmint).

2.0 Recommendations

Provided a revised Section F is submitted, HED concludes that the residue chemistry database is adequate to support the proposed application scenarios and establishment of the tolerances listed in Section 2.2.2. A human health risk assessment will be prepared as a separate document (O. Gbemigun, Task Group No. 00484712, 2024-06-17)

2.1 Data Deficiencies/Data Needs

None

2.2 Tolerance Considerations

2.2.1 Enforcement Analytical Method

Samples were analyzed for residues of saflufenacil, M800H11, M800H35, and M800H02 using Method D0603/04, a high-performance liquid chromatography method with tandem mass spectrometry detection (LC-MS/MS). Method D0603/04 is an updated version of the enforcement method (Method D0603/02) for determination of residues of saflufenacil and its metabolites in plant matrices that has been revised to add instructions for determination of M800H02.

Briefly, samples were extracted with methanol:water (70:30, v:v) by shaking for 10 minutes and then isolated by two consecutive centrifugation steps. An aliquot of the supernatant was concentrated under nitrogen to remove methanol, then acidified with 0.1% trifluoroacetic acid, and partitioned with ethyl acetate:cyclohexane (70:30, v:v) and centrifuged. An aliquot of the organic phase was evaporated to dryness under nitrogen and reconstituted in methanol:water (50:50, v:v) for LC/MS/MS analysis.

The limit of quantitation (LOQ), based on lowest level of method validation (LLMV), was 0.01 ppm. The limit of detection (LOD) is defined as 10% below the smallest concentration within the standard curve were 0.1 ppm. Residues of the metabolites M800H11 and M800H35 were converted to parent equivalents by using MWCFs of 1.06 and 1.42, respectively; residues of M800H02 were not converted to parent equivalents.

2.2.2 Recommended Tolerances

HED reviewed the submitted residue data and determined the appropriate tolerance levels for residues of mint (Table 2.2.2). A summary of proposed and recommended tolerances for saflufenacil are summarized below.

Table 2.2.2. Tolerance Summary for Saflufenacil (40 CFR §180.649).

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Proposed Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments
40 CFR 180.649 (a) General. (1) Tolerances are established for residues of saflufenacil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*′-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil, in or on the plant commodities.				
Fruit, citrus, group 10-10	-	0.03	0.03	Tolerance based on Fruit, citrus, group 10 tolerance at 0.03 ppm.
Fruit, citrus, group 10	0.03	-	remove	
Fruit, pome, group 11-10	-	0.03	0.03	Tolerance based on Fruit, pome, group 11 tolerance at 0.03 ppm.
Fruit, pome, group 11	0.03	-	remove	
Fruit, stone, group 12-12	-	0.03	0.03	Tolerance based on Fruit, stone, group 12 tolerance at 0.03 ppm.
Fruit, stone, group 12	0.03	-	remove	
Mint, dried leaves*	-	0.04	0.03	Tolerance based on mint, dried leaves residue data.
Mint, fresh leaves*	-	0.04	0.03	Tolerance based on mint, fresh leaves residue data.
Nut, tree, group 14-12	-	0.03	0.03	Tolerance based on Nut, tree, group 14 tolerance at 0.03 ppm.
Nut, tree, group 14	0.03	-	remove	
Pistachio	0.03	-	remove	

* The term "mint" is an umbrella term for the *Mentha* plant family that includes spearmint, peppermint, orange mint, apple mint, etc. See 40 CFR 180.1(g). As spearmint and peppermint are the main varieties utilized in commercial production, HED considers the residue data to cover all *Mentha* species.

2.2.3 Revisions to Petitioned-For Tolerances

A revised Section F is requested with the revised tolerance levels and/or commodity definitions as recommended by HED. For mint, fresh and dried leaves, the proposed and recommended tolerance values differ due to combined residues being expressed in terms of saflufenacil and metabolites, M800H02, M800H11, and M800H35 by the study author versus HED excluded residues of M800H02 as the Residues of Concern Knowledgebase Subcommittee (ROCKS) determined that the residues of concern for the tolerance expression and risk assessment consist of saflufenacil, M800H11, and M800H35.

2.2.4 International Harmonization

The Codex has established MRLs for saflufenacil in or on Fruit, citrus, group 10-10 at 0.01 ppm; Fruit, pome, group 11-10 at 0.01 ppm; Fruit, stone, group 12-12 at 0.01 ppm; and Nut, tree, group 14-12 at

0.01 ppm. These MRLs are different than the HED-recommended tolerance levels (all 0.03 ppm) for saflufenacil. Based on available residue data, use by U.S. growers consistent with approved label instructions would result in residues that exceed the Codex MRL. Harmonizing with these Codex MRLs could put U.S. growers at risk of violative residues despite legal use of saflufenacil according to the label. Refer to Appendix 1 for the international residue limit table.

2.3 Label Recommendations

The proposed labels are adequate; no revisions are necessary.

3.0 Introduction

3.1 Chemical Identity

Table 3.1 is a summary of the nomenclature and chemical structure for saflufenacil and its metabolites. See Attachments A and B for structures of the metabolites and the physiochemical properties of technical grade saflufenacil, respectively.

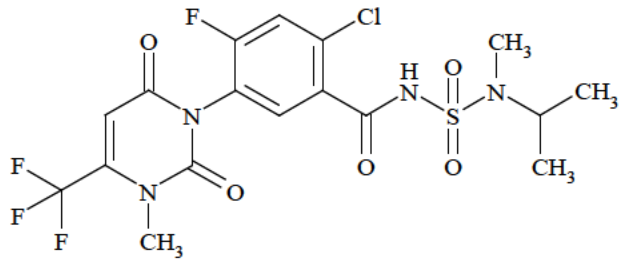
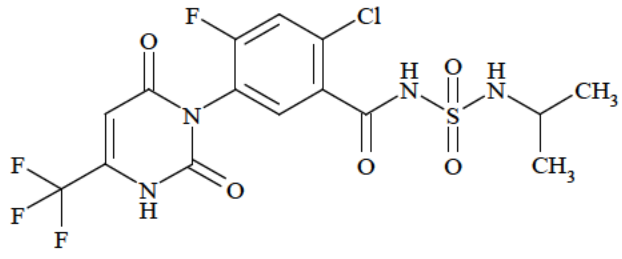
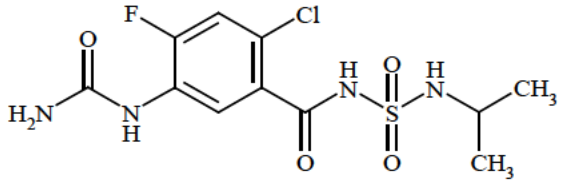
Table 3.1. Saflufenacil and Metabolite Nomenclature.	
Chemical Structure	
Common name	Saflufenacil
Company experimental name	BAS 800 H (synonyms: AC 433 379, BASF Reg. No. 4054449)
IUPAC name	*N*'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)benzoyl]-*N*-isopropyl-*N*-methylsulfamide
CAS name	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide
CAS registry number	372137-35-4
End-use product (EP)	Sharpen® Powered by Kixor® Herbicide (EPA Reg. No. 7969-278) (2.85 lb ai/gal SC formulation) Saflufenacil CS Herbicide (7969-xxx)
Chemical Structure	
Common name	M800H11
Chemical name	*N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*'-isopropylsulfamide

Table 3.1. Saflufenacil and Metabolite Nomenclature.	
Chemical Structure	
Common name	M800H35
Chemical name	*N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea

3.2. Physical/Chemical Characteristics

Saflufenacil is an uracil herbicide that is expected to be mobile to highly mobile. Its major routes of degradation are alkaline hydrolysis and biodegradation in aerobic soil. The compound is expected to degrade with a half-life of 1 to 5 weeks in aerobic soil environments and a half-life of 7 to 15 weeks (2 to 4 months) in aerobic aquatic environments. Its vapor pressure is 4.5 x 10^{-15} Pa at 20 ºC. Because it is a low-volatile herbicide, saflufenacil could be less prone to atmospheric transport than more-volatile herbicides. A summary of the physicochemical properties can be found in Appendix III.

3.3 Pesticide Use Pattern/Directions for Use (860.1200)

IR-4 has submitted a supplemental label for Treevix by Kixor Herbicide (EPA Reg. No 7969-276) and Sharpen® Powered by Kixor® Herbicide (EPA Reg. No. 7969-278). Information pertaining to proposed end-use product are listed in Table 3.3.1. The summary of the proposed use patterns is detailed in Table 3.3.2.

Table 3.3.1. Summary of Proposed End-Use Product.						
Trade Name	Reg. No.	ai (% of formulation)	Formulation Type	Target Site	Target Pests	Label Date
Sharpen® Powered by Kixor® Herbicide	7969-278	29.74	SC	Soil	Broadleaf weeds	Expires 2026
Treevix by Kixor Herbicide	7969-276	70	WG	Soil	Postemergence broadleaf weeds	Not specified

WG = water-dispersible granule.
SC = suspension Concentrate.

Table 3.3.2. Summary of Directions for Use of Saflufenacil.							
Formulation	Applic. Timing, Type, and Equip.	Max Single App. Rate (lb ai/A)	Max. # Apps per year	Max Seasonal App. Rate (lb ai/A)	RTI (days)	PHI (days)	Use Directions and Limitations
Mint (New Use - Postemergence)							
Treevix® by Kixor® Herbicide (7969-276) Sharpen®P powered by Kixor® Herbicide. (7969-278)	Broadcast spray Groundboom sprayer, Fixed wing, Helicopter	0.044	2	0.044	-	0	Do not apply to mint that has broken dormancy. Do apply to mint in the first year of growth and establishment. Do not apply to mint stands that have been weakened by age, disease, cold weather, excessive moisture, or other factors that reduce crop vigor.

PHI = preharvest interval; RTI = retreatment interval; NOTE: Sharpen® is already registered for burn-down use on grass at a rate of 0.134 lb ai/A with a 0-day PHI.

Crop rotation restriction: If any labeled crop treated with Treevix® herbicide is lost to adverse weather or for other reasons, the area treated may be replanted to citrus fruit trees 1 month after treatment and to caneberry, fig trees, nut trees, olive trees, pomegranate trees, pome fruit trees, and stone fruit trees 3 months after treatment.. Wait 9 months before planting any other crop.

Conclusion: The submitted use directions for Treevix by Kixor Herbicide (EPA Reg. No 7969-276) and Sharpen® Powered by Kixor® Herbicide are adequate to allow evaluation of the residue data relative to the proposed use.

4.0 Metabolism/Degradate Residue Profile

Nature of the Residue

Reference List:
ROCKS Memo – B. Daiss, D359645, 06-JAN-2009
Risk Assessment Memo – G. Kramer, D426933, 05-NOV-2015
Residue Chemistry Memo, G. Kramer, D414003, 24-JUN-2014

Table 4.0 and the following paragraphs are summaries of the residues of concern in plants and livestock.

Plants (Primary Crops): The previously submitted metabolism data for corn, soybean, and tomato; and a confined rotational crop study are adequate to elucidate the nature of the residue in plants resulting from preplant/preemergence application, a postemergence-directed at the base of plants underneath the leaf canopy application, and a pre-harvest/desiccant application. An additional nature of residue study with a postemergence application in rice as a representative monocot (grass) species showed metabolism similar to the metabolism of Saflufenacil in plants following a preplant/preemergence application. The HED ROCKS determined that residues of concern for the tolerance expression and risk assessment consist of saflufenacil, M800H11, and M800H35 (Memo, B. Daiss, D359645, 06-JAN-2009).

Livestock: The nature of the residue in livestock is adequately understood based on acceptable metabolism studies conducted on lactating goats and laying hens. Mint is not a livestock feeding item.

Table 4.0. Summary of Metabolites and Degradates to be Included in the Risk Assessment.			
Matrix		Residues Included in Risk Assessment	Residues Included in Tolerance Expression
Plants	Primary Crops (preplant application)*	Saflufenacil + M800H11, M800H35	Saflufenacil + M800H11, M800H35
	Primary Crops (foliar application)	Saflufenacil + M800H11, M800H02, M800H35	
	Rotational Crops	Saflufenacil + M800H11, M800H35	
Livestock	Ruminants	Saflufenacil	Saflufenacil
	Poultry		
Drinking Water		Saflufenacil + M800H01, M800H02, M800H07, M800H08, M800H15, M800H22, Product 8	N/A

* Plus post-emergence foliar application to cereal grains and grasses and to weeds in fruit/nut orchards/groves.

5.0 Residue Profile

5.1 Residue Analytical Methods (860.1340)

Reference List: Memo, G. Kramer, D414003, 24-JUN-2014.

Method D0603/02 is the current enforcement method for determination of residues of saflufenacil and its metabolites M800H11 and M800H35 in different plant matrices. Residues of saflufenacil and its metabolites M800H11 and M800H35 were extracted with methanol:water (70:30; v:v). The methanol extract was evaporated and reconstituted in methanol:water (50:50; v:v) for LC-MS/MS analysis. Two transitions per analyte were monitored for the quantitation and confirmation of saflufenacil, M800H11 and M800H35. The residues of each analyte were expressed as parent equivalents using a molecular weight conversion factor (MWCF; 1.0 for saflufenacil, 1.06 for M800H11, and 1.42 for M800H35). The LOQ was 0.01 ppm for each analyte. The LOD was reported to be 3X the standard deviation (SD) at the LOQ for each analyte (0.002-0.003 ppm).

A revised version (Method D0603/04) of the current enforcement method was used for the crop field trials. Method D0603/04 has been revised from the established enforcement method, Method D0603/02, to add instructions for determination of metabolite M800H02. Method D0603/04 is adequate for data collection in the submitted field trials based on acceptable concurrent recovery data. Recoveries were majorly within the acceptable range of 70-120% except lower M800H11 recoveries in dried mint tops and mint oil, both at the 0.01 ppm level. As the data acquisition method is essentially identical to the enforcement method with regards to the residues of concern and it was successfully validated, HED concludes that an adequate enforcement method is available to enforce a tolerance for residues of saflufenacil in mint commodities.

5.1.1 Data-Collection Methods

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Samples were analyzed for residues of saflufenacil, M800H11, M800H35, and M800H02 using LC-MS/MS Method D0603/04. Method D0603/04 is an updated version of the enforcement method (Method D0603/02) for determination of residues of saflufenacil and its metabolites in plant matrices

that has been revised to add instructions for determination of M800H02. A complete description of the method was included in the submission.

Briefly, samples were extracted with methanol:water (70:30, v:v) by shaking for 10 minutes and then isolated by two consecutive centrifugation steps. An aliquot of the supernatant was concentrated under nitrogen to remove methanol, then acidified with 0.1% trifluoroacetic acid, and partitioned with ethyl acetate:cyclohexane (70:30, v:v) and centrifuged. An aliquot of the organic phase was evaporated to dryness under nitrogen and reconstituted in methanol:water (50:50, v:v) for LC/MS/MS analysis. The following ion transitions were monitored:

MRID	Analyte	Quantitation Ion Transition	Confirmation Ion Transition
52065001	Saflufenacil	*m/z* 501.0 → 142.0	*m/z* 501.0 → 349.0
	M800H11	*m/z* 473.0 → 197.9	*m/z* 473.0 → 335.0
	M800H35	*m/z* 370.1 → 198.0	*m/z* 353.1 → 215.0

The LOQ, based on the LLMV, was 0.01 ppm. The LOD is defined as 10% below the smallest concentration within the standard curve were 0.1 ppm. Residues of the metabolites M800H11 and M800H35 were converted to parent equivalents by using MWCFs of 1.06 and 1.42, respectively; residues of M800H02 were not converted to parent equivalents.

The combined LOQs for saflufenacil, M800H11, and M800H35 were 0.03 ppm for mint and mint commodities. Acceptable concurrent recoveries were obtained from samples of mint matrices fortified with saflufenacil, M800H11, M800H35, and M800H02, at 0.010 ppm. The fortification levels adequately represented measured residue levels.

5.1.2 Multi-Residue Methods (860.1360)

Saflufenacil and its metabolites M800H11 and M800H35 were screened through the multi-residue methods described in the United States Food and Drug Administration (FDA) Pesticide Analytical Manual, Vol. I (PAM I). Saflufenacil and the metabolites were tested using procedures outlined in Protocols B, C, D, E, and F of the MRM. All Protocols B, C, D, E, and F were found to be unsuitable for determination of residues of saflufenacil and its metabolites M800H11 and M800H35. Since the analytes are not *N*-methyl-carbamates, naturally fluorescent or substituted urea derivatives, the tests using Protocol A and G were not performed.

5.1.3 Tolerance Enforcement Methods

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See Section 2.2.1

5.1.4 Submittal of Analytical Reference Standards (860.1650)

Analytical standards of saflufenacil (expiration date: 01/01/2026), M800H11 (metabolite 5303307; expiration date: 03/01/2032), and M800H35 (metabolite 5303308; expiration date: 04/01/2027) are currently available in the National Pesticide Standards Repository [source: personal communication with C. Vigo of Analytical Chemistry Laboratory, 04/03/2023].

5.2 Storage Stability (860.1380)

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Storage stability samples were fortified with saflufenacil and its metabolites at 0.1 ppm soon after the receipt of the samples by the analytical laboratory. Analysis of the storage stability samples was not conducted because acceptable storage stability data are available indicating that residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage for at least 18.0 months in various crop commodities including corn grain, forage, and stover; soybean seed, forage, and hay; orange fruit and pulp; radish root; raisin; and garbanzo bean seed (D349938, G. Kramer, 22-JUL-2009). The available data are acceptable to support the storage conditions and durations of the samples from the submitted field trials.

Table 5.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Mint, fresh or dried	Generally <-17[2]	268-323 days (8.8-10.6 months)	Residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage (≤-5 °C) for at least 18.0 months in various crop commodities.[3]

[1] Interval from harvest to extraction. Samples were analyzed within 0-1 days of extraction.

[2] Samples from the 2015 trials CA41 and CA42 were received at the intermediate facility partially thawed.

[3] D349938, G. Kramer, 22-JUL-2009.

5.3 Residue Data

5.3.1 Crop Field Trials (860.1500)

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IR-4 has submitted field trial data for saflufenacil on mint from 5 field trials conducted in the United States during the 2021 growing seasons. All trials were conducted in North American Free Trade Agreement (NAFTA) Growing Regions 5 and 11. Five mint field trials (four peppermint trials and one spearmint trial) were conducted at field sites located in Endeavor WI (Region 5), Parma ID (Region 11), Prosser WA (Region 11), Randolph WI (Region 5), and Moxee WA (Region 11).

At each trial, during mint dormancy and after weed emergence, one foliar application of the test substance was made to the treated plots. In the TRT02 treatment plots, the application rates ranged from 0.042 to 0.045 lbs ai/A (see Table B.1.2). In addition, two field trials included mint oil processing treatment plots (3X rate; TRT03). In the TRT03 treatment plots, the application rates were 0.132 and 0.134 lbs ai/A. All applications included methylated seed oil (MSO) and ammonium sulfate (AMS) or ammonium nitrate and urea (UAN-32) adjuvants, were made using appropriate spray equipment, and the spray volume was sufficient to provide adequate dispersal of the test substance.

At commercial maturity, samples of fresh mint tops were collected from the untreated control plots (TRT01) and the TRT02 treatment plots. Additional fresh mint tops were harvested from the TRT01 and TRT02 plots and dried for approximately one day in a forced air drier or food dehydrator to produce dried mint top samples. Fresh and dried mint tops were harvested between 101- and 125-day PHIs (preharvest intervals). In two field trials, mint hay was harvested by cutting the untreated control plot and the TRT03 treatment plot with a sickle bar mower or hedge trimmer, and allowing the hay to dry in the field. Once the mint hay reached approximately 50-60% moisture in one trial and 15-19% moisture

in the other trial (see protocol change 4), grab samples and samples for oil processing were collected. The mint hay for oil processing was distilled via a mint still, at the field sites, to product mint oil samples. Mint hay samples and mint hay for distilling into mint oil were harvested at 103- and 124-day PHIs. Residue decline was not investigated.

Storage stability samples were fortified with saflufenacil and its metabolites at 0.1 ppm soon after the receipt of the samples by the analytical laboratory. Analysis of the storage stability samples was not conducted because acceptable storage stability data are available indicating that residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage for at least 18.0 months in various crop commodities including corn grain, forage, and stover; soybean seed, forage, and hay; orange fruit and pulp; radish root; raisin; and garbanzo bean seed (DP# 349938, 7/22/09, G. Kramer). These data are acceptable to support the storage conditions and durations of the samples from the submitted field trials.

Samples were analyzed for residues of saflufenacil, M800H11, M800H35, and M800H02 using Method D0603/04, a LC-MS/MS method. Method D0603/04 is an updated version of the enforcement method (Method D0603/02) for determination of residues of saflufenacil and its metabolites in plant matrices that has been revised to add instructions for determination of M800H02. Residues of the metabolites were converted to parent equivalents using MWCFs of 1.06 for M800H11 and 1.420 for M800H35. The LOQ (determined as the LLMV) for each analyte was 0.010 ppm. The LOD is defined as 10% below the smallest concentration within the standard curve. The LOQ (determined as the LLMV) for each analyte was 0.010 ppm in mint and all processed commodities. Acceptable method validation and concurrent recoveries were obtained from samples of fresh and dried mint fortified with saflufenacil, M800H11, and M800H35 each at 0.01 ppm. The fortification levels adequately represented measured residue levels.

Following soil and ground applications of saflufenacil at a total rate of 0.042 – 0.045 lb ai/A (TRT02) or 0.132 – 0.134 lb ai/A (TRT03), residues of saflufenacil and its metabolites were each <LOQs in/on all mint samples harvested at a PHI of 101-125 days. To calculate total residue, a value of 0.01 ppm was used for residues below LLMV of 0.010 ppm. Combined residues of saflufenacil and its metabolites, M800H11, and M800H35 were 0.03 ppm in all treated samples.

Residues were below the LOQ in the RAC and processed fraction therefore, processing factors could not be calculated. The observed processing factors did not exceed the maximum theoretical concentration factor for mint of 330x (spearmint and peppermint). A summary of the residue data is provided in Table 5.3.1.

Table 5.3.1. Summary of Residues from Mint Field Trials with Saflufenacil.												
Crop Matrix	Total Application Rate (lb ai/A)	PHI (days)	n[1]	Analyte	Residues (ppm parent equivalents)						
					Min.[2]	Max.[2]	LAFT[3]	HAFT[3]	Median[3]	Mean[3]	SD[3]
Mint, fresh, tops	0.042 - 0.045	101 - 125	10	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A
Mint, dried tops	0.042 - 0.045	103 - 125	10	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A
Mint, hay Mint, oil	0.132 – 0.134	103 - 124	2	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A

[1] n = number of independent field trials.

[2] Values based on residues in individual samples.

[3] Values based on per-trial averages. LAFT = lowest average field trial, HAFT = highest average field trial, SD = standard deviation. For computation of the LAFT, HAFT, median, mean, and standard deviation, values <LOQ are assumed to be at the LOQ (0.010 ppm for saflufenacil, M800H11, and M800H35). N/A = Not applicable.

[4] Combined residues of saflufenacil, M800H11, and M800H35.

5.3.2 Field Rotational Crops

The previously submitted field rotational crop data are adequate to satisfy data requirements for application rates up to 0.137 lb ai/A (1X). The available data indicate that residues of saflufenacil and its metabolites M800H11 and M800H35 (residues of concern in rotational crops) were each <LOQ in/on all rotational crop matrices at a 120-day PBI. These data support the labeled rotational crop restriction of 4 months for all non-labeled crops. Unless the petitioner requests PBIs shorter than 120 days, no additional data are required, and tolerances for inadvertent residues in/on rotational crops need not be established in conjunction with the currently proposed uses.

6.0 Tolerance Derivation

The recommended tolerance for the combined residues of saflufenacil and its metabolites M800H11 and M800H35, expressed as parent equivalents, is 0.03 ppm in/on mint. As no quantifiable saflufenacil residues were found in the RAC 3X sample above LOQ, processing factors could not be calculated. There are no Codex, Canadian, or Mexican MRLs established for mint; therefore, there are no international harmonization issues associated with mint.

Appendix I. International Residue Limits Table
Appendix II. Geographical Distribution of Mint Trial Data
Appendix III. Physical/Chemical Properties

Appendix I: International Residue Limits Table

Saflufenacil (118203)

Summary of U.S. and International Tolerances and Maximum Residue Limits				
Residue Definition:				
U.S.	Canada		Mexico[2]	Codex
40 CFR 180.649: Plant: saflufenacil, including its metabolites and degradates, sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*'-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, including the metabolites *N'*-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl}-*N*-isopropyl sulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea Livestock: 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide		Saflufenacil The residue is not fat soluble. Residue definition does not include metabolites.
Commodity[1]	*Tolerance (ppm)/Maximum Residue Limit (mg/kg)*			
	U.S.	Canada	Mexico[2]	Codex
Fruit, citrus, group 10-10	0.03	0.03	0.03	0.01
Fruit, pome, group 11-10	0.03	0.03	0.03	0.01
Fruit, stone, group 12-12	0.03	0.03	0.03	0.01
Mint, dried leaves	0.03	-	-	-
Mint, fresh leaves	0.03	-	-	-
Nut, tree, group 14-12	0.03	0.03	0.03	0.01
From the Global MRL Database. Completed: O. Gbemigun (July 25, 2023)				

[1] Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.

[2] Mexico adopts U.S. tolerances and/or Codex MRLs for its export purposes.

Appendix II: Geographical Distribution of Sweet and Field Mint Trial Data

Table A.1. Trial Numbers and Geographical Locations.

Crop	No. Trials	Growing Zone												Total
		1	2	3	4	5	6	7	8	9	10	11	12	
Mint	Sub.					2						3		5
	Req.[1]					2						3		5

[1] As per Table 1 of 860.1500 for mint.

Appendix III. Physical/Chemical Properties

Table B.1. Physicochemical Properties of Technical Grade Saflufenacil.	
Parameter	Value
Melting point	Average = 189.9 °C, peak max = 193.4 °C
pH	4.43 of 1% solution at 25 °C
Bulk Density (ambient temp.)	0.661 kg/L (free fall), 0.736 kg/L (packed)
Water solubility (20 °C)	in g/100 mL: 0.0025 in water (pH = 5); 0.0014 in pH 4 buffer; 0.21 in pH 7 buffer; not determined due to degradation in pH 9 buffer
Solvent solubility (20 °C)	in g/100 mL: 19.4 acetonitrile; 24.4 dichloromethane; 55.4 *N,N*-dimethylformamide; 27.5 acetone; 6.55 ethyl acetate; 36.2 tetrahydrofuran; 35.0 butyrolactone; 2.98 methanol; 0.25 isopropyl alcohol; 0.23 toluene; <0.01 1-octanol; <0.005 n-heptane
Vapor pressure at 20/25 °C	20 °C = 4.5×10^{-15} Pa 25 °C = 2.0×10^{-15} Pa
Dissociation constant (pK_a)	4.41
Octanol/water partition coefficient	Mean Log P_{ow} = 2.6 (P_{ow} = 368.3)
UV/visible absorption spectrum	wavelength maximum: λ_{max} = 271.6 nm extinction coefficient: ε = 9709 L/mol-cm

Reference: BASF Registration Document Number (DocID) 2005/1026464.

B.7.6 Residues Resulting from Supervised Trials (Annex IIA 6.3; Annex IIIA 8.3)

B.7.6.1 Residues in Target Crops

B.7.6.1.2 Mint

Document ID: MRID No. 52065001

Report: Moore, P. (2022) Saflufenacil: Magnitude of the Residue on Mint. Project Number: 11921. Unpublished study prepared by University of Idaho, University of Wisconsin and Washington State University. 494p.

Guidelines: EPA OCSPP Harmonized Test Guideline 860.1500 Crop Field Trials and 860.1520 Processed Food, Feed (August 1996)
PMRA Regulatory Directive DIR98-02 – Residue Chemistry Guidelines, Section 9 – Crop Field Trials
PMRA Regulatory Directive DIR2010-05 – Revisions to the Residue Chemistry Crop Field Trial Requirements
OECD Guideline 509 Crop Field Trial (September 2009)

GLP Compliance: No deviations from U.S. EPA regulatory requirements were reported which would have an impact on the validity of the study.

Acceptability: The study is considered scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, Task Group No. 00484712.

Scientific Integrity: 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.pdff. 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.

Primary Reviewer: Oluwaseun Gbemigun, Ph.D., Biologist, RAB1/HED (7509T) Oluwaseun Gbemigun

EXECUTIVE SUMMARY

Interregional Research Project Number 4 (IR-4) has submitted field trial data for saflufenacil on mint from 5 field trials conducted in the United States during the 2021 growing season. All trials were conducted in North American Free Trade Agreement (NAFTA) Growing Regions 5 and 11.

At each trial, during mint dormancy and after weed emergence, one foliar application of the test substance was made to the treated plots. In the TRT02 treatment plots, the application rates ranged from 0.042 to 0.045 lb ai/A (see Table B.1.2). In addition, two field trials included mint oil processing treatment plots (3X rate; TRT03). In the TRT03 treatment plots, the application rates were 0.132 and

0.134 lb ai/A. All applications included methylated-seed oil (MSO) and ammonium sulfate (AMS) or ammonium nitrate and urea (UAN-32) adjuvants, were made using appropriate spray equipment, and the spray volume was sufficient to provide adequate dispersal of the test substance.

At commercial maturity, samples of fresh mint tops were collected from the untreated control plots (TRT01) and the TRT02 treatment plots. Additional fresh mint tops were harvested from the TRT01 and TRT02 plots and dried for approximately one day in a forced air drier or food dehydrator to produce dried mint top samples. Fresh and dried mint tops were harvested between 101 and 125 days PHI (post-harvest interval). In two field trials, mint hay was harvested by cutting the untreated control plot and the TRT03 treatment plot with a sickle bar mower or hedge trimmer, and allowing the hay to dry in the field. Once the mint hay reached approximately 50-60% moisture in one trial and 15-19% moisture in the other trial (see protocol change 4), grab samples and samples for oil processing were collected. The mint hay for oil processing was distilled via a mint still, at the field sites, to product mint oil samples. Mint hay samples and mint hay for distilling into mint oil were harvested at 103 and 124 days PHI, respectively. Residue decline was not investigated.

Storage stability samples were fortified with saflufenacil and its metabolites at 0.1 ppm soon after the receipt of the samples by the analytical laboratory. Analysis of the storage stability samples was not conducted because acceptable storage stability data are available indicating that residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage for at least 18.0 months in various crop commodities including corn grain, forage, and stover; soybean seed, forage, and hay; orange fruit and pulp; radish root; raisin; and garbanzo bean seed (D349938, G. Kramer, 07/22/2009). These data are acceptable to support the storage conditions and durations of the samples from the submitted field trials.

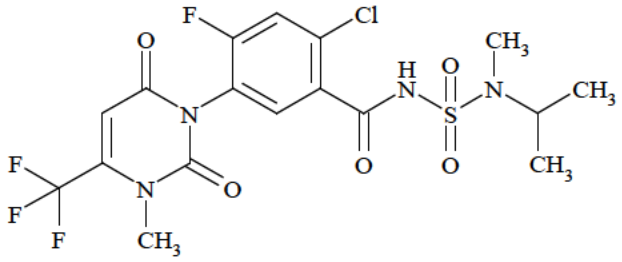
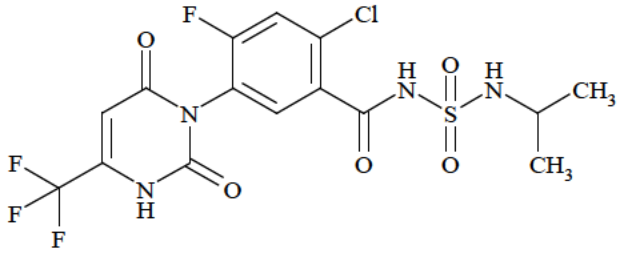
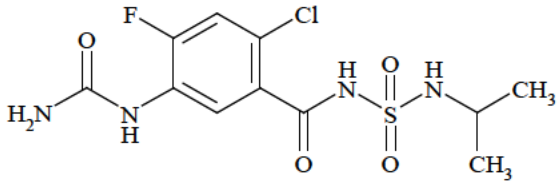
Samples were analyzed for residues of saflufenacil, M800H11, M800H35, and M800H02 using BASF Method D0603/04, a high-performance liquid chromatography method with tandem mass spectrometry detection (LC-MS/MS). Method D0603/04 is an updated version of the enforcement method (Method D0603/02) for determination of residues of saflufenacil and its metabolites in plant matrices that has been revised to add instructions for determination of M800H02. Residues of the metabolites were converted to parent equivalents using molecular weight conversion factors (MWCFs) of 1.06 for M800H11 and 1.420 for M800H35. The limit of quantitation (LOQ; determined as the lowest level of method validation, LLMV) for each analyte was 0.010 ppm. The limit of detection (LOD) is defined as 10% below the smallest concentration within the standard curve. The limit of quantitation (LOQ; determined as the lowest level of method validation, LLMV) for each analyte was 0.010 ppm in mint and all processed commodities. Acceptable method validation and concurrent recoveries were obtained from samples of fresh and dried mint fortified with saflufenacil, M800H11, and M800H35 each at 0.01- 0.1 ppm. The fortification levels adequately represented measured residue levels.

Following soil and ground applications of saflufenacil at a total rate of 0.042 – 0.045 lb ai/A (TRT02) or 0.132 – 0.134 lb ai/A (TRT03), residues of saflufenacil and its metabolites were each below the LOQs in/on all mint samples harvested at a PHI of 101-125 days. To calculate total residue, a value of 0.01 ppm was used for residues below LLMV of 0.010 ppm. Combined residue of saflufenacil and its metabolites, M800H11, and M800H35 was 0.03 ppm in all treated samples.

Residues were below the LOQ in the RAC and processed fraction; therefore, processing factors could not be calculated. The observed processing factors did not exceed the maximum theoretical concentration factor for mint of 330x (spearmint and peppermint).

I. MATERIALS AND METHODS

A. MATERIALS

Table B.7.6.1.2-1. Nomenclature for Saflufenacil and Metabolites.	
Common name	Saflufenacil
Identity	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide
CAS registry number	372137-35-4
Molecular weight	500.9 g/mol
Company experimental name	BAS 800 H
	
Metabolite name	M800H11
Identity	*N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*'-isopropylsulfamide
Molecular weight	472.8 g/mol
	
Metabolite name	M800H35
Identity	*N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea
Molecular weight	352.8 g/mol
	

B. Study Design

1. Test Procedure

Five field trials on mint were conducted with a WG formulation during the 2021 growing season. Field trial locations by United States growing zone are summarized in Table B.7.6.1.2-2.

All trials were separated by ≥20 miles and are therefore considered independent (568_Criteria for Independence of Trials 4/23/13 (EPA and PMRA)).

Table B.7.6.1.2-2. Trial Numbers and Geographical Locations.

Crop	No. Trials	Growing Zone												Total
		1	2	3	4	5	6	7	8	9	10	11	12	
Mint	Sub.					2						3		5
	Req.[1]					2						3		5

[1] As per Table 1 of 860.1500 for mint

Locations and detailed use patterns for the trials are provided in Table B.7.6.1.2-3. Broadcast applications were made to the ground/soil; the soil characteristics are presented in Appendix I.

Table B.7.6.1.2-3. Study Use Pattern.

Location: City, State; Year (Trial ID)	End-use Product[1]	Plot	Method of Application; Timing of Application	Volume (gal/A)	Rate per Application (lb ai/A)	Retreatment Interval (days)	Total Rate (lb ai/A)	Surfactant/ Adjuvant[2]
MRID 52065001								
Parma, ID; 2021 (ID161)	BAS 800 06 H	TRT02	Broadcast to the ground	18	0.043	--	0.043	MSO + AMS
Moxee, WA; 2021 (WA*329)	BAS 800 06 H	TRT02	Soil broadcast	17	0.045	--	0.045	MSO + AMS
		TRT03	Soil broadcast	17	0.132	--	0.132	MSO + AMS
Prosser, WA; 2021 (WA330)	Sharpen	TRT02	Soil broadcast	20	0.042	--	0.042	MSO + AMS
Endeavor, WI 2021 (WI188)	BAS 800 06 H	TRT02	Soil broadcast	19	0.043	--	0.043	MSO + AMS
Randolph, WI; 2021 (WI352)	BAS 800 06 H	TRT02	Soil broadcast	19	0.044	--	0.044	MSO + AMS
		TRT03	Soil broadcast	19	0.134	--	0.134	MSO + AMS

[1] End use formulated product is called Sharpen Powered by KIXOR Herbicide, which has a product code as BAS 800 06 H.
[2] MSO - methylated seed oil; AMS - ammonium sulfate.

Mint was grown and maintained using typical agricultural practices. Irrigation was used at all trials. Despite variations in weather conditions reported at some trial sites, no unusual weather conditions were reported to have adversely affected crop production or yield during the study.

Sample Handling and Preparation

At commercial maturity, samples of fresh mint tops were collected from the untreated control plots and the TRT02 treatment plots. Additional fresh mint tops were harvested and dried for approximately one day in a forced air drier or food dehydrator to produce dried mint top samples. Fresh and dried mint tops were harvested between 101- and 125-day PHIs (pre-harvest interval).

In two field trials, mint hay was harvested by cutting the untreated control plot and the TRT03 (3X rate) treatment plot with a sickle bar mower or hedge trimmer, and allowing the hay to dry in the field. Once the mint hay reached approximately 50-60 % moisture in one trial and 15-19% moisture in the other trial (see protocol change 4), grab samples were collected. The remaining mint hay was distilled via a mint still, at the field sites, to product mint oil samples. Mint hay samples and mint hay for distilling into mint oil were harvested at PHIs of 103 days and 124 days.

The samples were shipped to the analytical laboratory frozen by ACDS freezer truck. All samples arrived frozen and intact at the analytical laboratory. The samples were checked in, processed with dry ice (except oil samples), and then stored frozen until extraction and analysis. Mint oil samples were stored frozen and brought to room temperature before subsampling and/or analysis.

2. Description of Analytical Procedures

Samples were analyzed for residues of saflufenacil, M800H11, M800H35, and M800H02 using BASF Method D0603/04, LC-MS/MS method. Method D0603/04 is an updated version of the enforcement method (Method D0603/02) for determination of residues of saflufenacil and its metabolites in plant matrices that has been revised to add instructions for determination of M800H02. A complete description of the method was included in the submission.

Briefly, samples were extracted with methanol:water (70:30, v:v) by shaking for 10 minutes and then isolated by two consecutive centrifugation steps. An aliquot of the supernatant was concentrated under nitrogen to remove methanol, then acidified with 0.1% trifluoroacetic acid, and partitioned with ethyl acetate:cyclohexane (70:30, v:v) and centrifuged. An aliquot of the organic phase was evaporated to dryness under nitrogen and reconstituted in methanol:water (50:50, v:v) for LC/MS/MS analysis. The following ion transitions were monitored:

MRID	Analyte	Quantitation Ion Transition	Confirmation Ion Transition
52065001	Saflufenacil	*m/z* 501.0 → 142.0	*m/z* 501.0 → 349.0
	M800H11	*m/z* 473.0 → 197.9	*m/z* 473.0 → 335.0
	M800H35	*m/z* 370.1 → 198.0	*m/z* 353.1 → 215.0

The LOQs based on lowest level of method validation (LLMV) was 0.01 ppm. The limit of detection (LOD) is defined as 10% below the smallest concentration within the standard curve were 0.1 ppm. Residues of the metabolites M800H11 and M800H35 were converted to parent equivalents by using MWCFs of 1.06 and 1.42, respectively; residues of M800H02 were not converted to parent equivalents.

II. RESULTS AND DISCUSSION

Method performance was evaluated both prior to sample analysis and concurrently with sample analysis, except for mint hay, which was only evaluated concurrently. The method validation on mint hay was waived due to the similarity of this matrix with dried mint tops. Recoveries of saflufenacil were in the range 90-106% in fresh mint tops, 76- 103% in dried mint tops, 80-90% in mint hay, and 87-101% in mint oil. Recoveries of M800H11 were in the range 86-115% in fresh mint tops, 68-91% in

dried mint tops, 79-100% in mint hay, and 68-108% in mint oil (see Table C.1.3). Recoveries of M800H35 were in the range 86-107% in fresh mint tops, 79-106% in dried mint tops, 84-97% in mint hay, and 78-106% in mint oil (see (see Table B.7.6.1.2-4). Two recovery results were outside the acceptable range of 70-120%. Both were recoveries for M800H11. One was in dried mint tops and one in mint oil, both at the 0.01 ppm level. The reviewer approved of these low recovery results, because the remaining recoveries in the sets were acceptable. The fortification levels adequately represented the measured residues.

The detector response was linear (coefficient of determination, r^2 ≥0.999) within the range of 0.05-10.0 pg/µL. Representative chromatograms of control samples, fortified samples, and treated samples were provided. The control chromatograms generally had no peaks of interest above the chromatographic background. The fortified sample chromatograms contained only the analyte of interest, and peaks were symmetrical and well defined. Apparent residues were below the LOQ (<0.01 ppm as analyte) in/on all controls.

Table B.7.6.1.2-4. Summary of Method Validation and Concurrent Recoveries of Saflufenacil, M800H11, and M800H35 from Mint.

MRID	Matrix	Analyte	Fortification Level (ppm)	Sample Size (n)	Recoveries[1] (%)	Mean ± Std. Dev. (%)
Method Validation						
52065001	Fresh Mint Tops (Leaves & Stems)	Saflufenacil	0.01	3	91-94	93 ± 2
			0.1	3	92-98	96 ± 3
		M800H11	0.01	3	77-89	82 ± 6
			0.1	3	95-99	96 ± 2
		M800H35	0.01	3	99-105	101 ± 3
			0.1	3	101-106	103 ± 3
	Dried Mint Tops (Leaves & Stems)	Saflufenacil	0.01	3	77-89	82 ± 6
			0.1	3	82-87	82 ± 6
		M800H11	0.01	3	68-89	80 ± 11
			0.1	3	74-87	80 ± 7
		M800H35	0.01	3	87-106	96±10
			0.1	3	80-90	85±5
	Mint, oil	Saflufenacil	0.01	3	93-101	97 ± 4
			0.1	3	87 - 97	93 ± 6
		M800H11	0.01	3	92-103	99 ± 6
			0.1	3	91-102	97 ± 6
		M800H35	0.01	3	102-106	104 ± 2
			0.1	3	90-99	95±5
Concurrent Recovery						
52065001	Fresh Mint Tops (Leaves & Stems)	Saflufenacil	0.01	5	90-106	101 ± 6
		M800H11	0.01	5	94-115	102 ± 8
		M800H35	0.01	5	88-107	96 ± 9
	Dried Mint Tops (Leaves & Stems)	Saflufenacil	0.01	5	79-103	91 ± 9
			0.1	1	81	-
		M800H11	0.01	5	87-91	88 ± 1
			0.1	1	76	-
		M800H35	0.01	5	80-97	87±8
			0.1	1	79	-

Table B.7.6.1.2-4. Summary of Method Validation and Concurrent Recoveries of Saflufenacil, M800H11, and M800H35 from Mint.						
MRID	Matrix	Analyte	Fortification Level (ppm)	Sample Size (n)	Recoveries[1] (%)	Mean ± Std. Dev. (%)
	Mint, hay	Saflufenacil	0.01	2	82, 85	84 ± 2
			0.1	2	80, 90	85 ± 7
		M800H11	0.01	2	84, 89	87 ± 4
			0.1	2	79, 100	90 ±15
		M800H35	0.01	2	84, 92	88±6
			0.1	2	87, 97	92±7
	Mint, oil	Saflufenacil	0.01	4	90-95	93 ± 3
		M800H11	0.01	4	68-108	90 ± 17
		M800H35	0.01	4	78-103	87±11

In all treated samples, the residues of saflufenacil and each of its metabolites: M800H11, and M800H35 were <0.01 ppm (<LOQ). To calculate total residue, a value of 0.01 ppm was used for residues <LOQ. The total combined residue of saflufenacil and its metabolites M800H11, and M800H35 was 0.03 ppm in all treated samples.

Storage stability samples were fortified with saflufenacil and its metabolites at 0.1 ppm soon after the receipt of the samples by the analytical laboratory. Analysis of the storage stability samples was not conducted because acceptable storage stability data are available indicating that residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage for at least 18.0 months in various crop commodities including corn grain, forage, and stover; soybean seed, forage, and hay; orange fruit and pulp; radish root; raisin; and garbanzo bean seed (D349938, G. Kramer, 07/22/2009). These data are acceptable to support the storage conditions and durations of the samples from the submitted field trials.

Table B.7.6.1.2-5. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Mint, fresh or dried	Generally <-17[2]	268-323 days (8.8-10.6 months)	Residues of saflufenacil, M800H11, and M800H35 are stable during frozen storage (≤-5 °C) for at least 18.0 months in various crop commodities including corn grain, forage, and stover; soybean seed, forage, and hay; orange fruit and pulp; radish root; raisin; and garbanzo bean seed.[3]

[1] Interval from harvest to extraction. Samples were analyzed within 0-1 days of extraction.
[2] Samples from the 2015 trials CA41 and CA42 were received at the intermediate facility partially thawed.
[3] D349938, G. Kramer, 07/22/2009.

The results from the submitted field trials are presented in Table B.7.6.1.2-6 and summarized in Table B.7.6.1.2-7. Following soil and ground applications of saflufenacil at a total rate of 0.042 – 0,045 lb ai/A (TRT02) or 0.132 – 0.134 lb ai/A (TRT03), residues of saflufenacil and its metabolites were each below the LOQs in/on all mint samples harvested at a PHI of 101-125 days. Combined residues of all analytes were <0.03 ppm in/on fresh mint and mint processed commodities.

Table B.7.6.1.2-6. Residue Data from Mint Field Trials with Saflufenacil.[1]

Location: City, State; Year (Trial ID)	Zone	Crop,Variety	Plot[2]	Total Application Rate (lb ai/A)	Matrix	PHI (days)	Residues[3] (ppm parent equivalents) [Average]			
							Saflufenacil	M800H11	M800H35	Combined[4]
MRID 52065001										
Endeavor, WI; 2021 (WI188)	5	Peppermint, Black Mitcham	TRT02	0.043	Mint, fresh, tops	101	[<0.01]	[<0.01]	[<0.01]	[<0.03]
					Mint, dried, tops	103	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Parma, ID; 2021 (ID161)	11	Peppermint, Black Mitcham	TRT02	0.044	Mint, fresh, tops	125	[<0.01]	[<0.01]	[<0.01]	[<0.03]
					Mint, dried, tops	125	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Prosser, WA; 2021 (WA330)	11	Peppermint, Black Mitcham	TRT02	0.042	Mint, fresh, tops	118	[<0.01]	[<0.01]	[<0.01]	[<0.03]
					Mint, dried, tops	118	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Randolph, WI; 2021 (WI352)	5	Peppermint, Black Mitcham	TRT02	0.044	Mint, fresh, tops	103	[<0.01]	[<0.01]	[<0.01]	[<0.03]
					Mint, dried, tops	106	[<0.01]	[<0.01]	[<0.01]	[<0.03]
			TRT03	0.134	Mint, hay	103	[<0.01]	[<0.01]	[<0.01]	[<0.03]
					Mint, oil	103	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Moxee, WA; 2021 (WA329)	11	Spearmint, Native	TRT02	0.045	Mint, fresh, tops	125	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Moxee, WA; 2021 (WA329)	11	Spearmint, Native	TRT02	0.045	Mint, dried, tops	125	[<0.01]	[<0.01]	[<0.01]	[<0.03]
Moxee, WA; 2021	11	Spearmint, Native	TRT03	0.132	Mint, hay	124	[<0.01]	[<0.01]	[<0.01]	[<0.03]
			TRT03	0.132	Mint, oil	124	[<0.01]	[<0.01]	[<0.01]	[<0.03]

[1] Sharpen Powered byKIXOR Herbicide (BAS 800 06 H) was used.

[2] TRT02 plots received treatment at 1x the target rate and TRT03 plots received treatment at ~3x the target rate

[3] ND = Not detected (<LOD). The LOD was 0.1 ppm. Per-trial averages and combined residues and were calculated by the study reviewer using the LOQ for all residues reported as <LOQ.

[4] Combined residues of saflufenacil and metabolites M800H11 and M800H35; the combined LOQ was 0.03 ppm.

Table B.7.6.1.2-7. Summary of Residues from Mint Field Trials with Saflufenacil.												
Crop Matrix	Total Application Rate (lb ai/A)	PHI (days)	n[1]	Analyte	Residues (ppm parent equivalents)						
					Min.[2]	Max.[2]	LAFT[3]	HAFT[3]	Median[3]	Mean[3]	SD[3]
Mint, fresh, tops	0.042 - 0.045	101 - 125	10	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A
Mint, dried tops	0.042 - 0.045	103 - 125	10	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A
Mint, hay Mint, oil	0.132 – 0.134	103 - 124	2	Saflufenacil	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H11	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				M800H35	0.010	0.010	0.010	0.010	0.010	0.010	N/A
				Combined[4]	0.030	0.030	0.030	0.030	0.030	0.030	N/A

[1] n = number of independent field trials.
[2] Values based on residues in individual samples.
[3] Values based on per-trial averages. LAFT = lowest average field trial, HAFT = highest average field trial, SD = standard deviation. For computation of the LAFT, HAFT, median, mean, and standard deviation, values <LOQ are assumed to be at the LOQ (0.010 ppm for saflufenacil, M800H11, and M800H35). N/A = Not applicable.
[4] Combined residues of saflufenacil, M800H11, and M800H35.

III. CONCLUSIONS

The mint field trials are considered scientifically acceptable. Following soil and ground applications of saflufenacil at a total rate of 0.042 – 0,045 lb ai/A (TRT02) or 0.132 – 0.134 lb ai/A (TRT03), residues of saflufenacil and its metabolites were each below the LOQs in/on all mint samples harvested at a PHI of 101-125 days. Combined residues of all analytes were <0.03 ppm in/on fresh mint and mint processed commodities.

Residues were below the LOQ in the RAC and processed fraction therefore, processing factors could not be calculated.

An acceptable method was used for residue quantitation, and adequate storage stability data are available to support sample storage durations and conditions for all analytes.

REFERENCES

D349938, G. Kramer, 07/22/2009

Appendix I. Soil Characteristics for Mint Field Trials.

Trial ID	Trial Location (City, State)	Trial Start Year	Soil characteristics				Meteorological Comments	
			Type	%OM	pH	CEC (meq/100 g)	Rainfall	Temperatures
21-ID161	Parma ID	2021	Silt loam	1.08	7.6	17.5	Normal	Normal
21-WA329	Moxee WA	2021	Loam	0.88	7.7	14.1	Normal	Normal
21-WA330	Prosser WA	2021	Silt loam	1.53	7.9	14.4	Normal	Normal
21-WI188	Endeavor WI	2021	Sandy loam	60.2	5.0	60	Normal	Normal
21-WI352	Randolph WI	2021	Sandy loam	39.5	6.0	61	Normal	Normal