

Evaluation Report for Category B, Subcategories B.2.1, B.2.3, B.2.4, B.2.5, B.2.6, B.3.1, B.3.2, B.3.5, B.3.10, and B.3.11 Application

Application Number:	2023-0485
Application:	New End-use Product (Chemistry) – Guarantee, Identity of
	Formulants, Proportion of Formulants, Formulation Type, New
	Combination of Technical Grade Active Ingredients;
	New Product Label (Application Rate Increase or Decrease,
	Application Timing, Rotational Crops/Plantback Interval, New
	Pests, Tank Mixes)
Product:	Surtain Herbicide
Registration Number:	35212
Active ingredients (a.i.):	Pyroxasulfone and Saflufenacil
PMRA Document Number:	3590403

Purpose of Application

The purpose of this application was to register the end-use product, Surtain Herbicide, for residual control of un-emerged annual grasses and broadleaf weeds in field corn in Eastern Canada.

Chemistry Assessment

Surtain Herbicide is formulated as a microcapsule suspension containing saflufenacil at a concentration of 75 g/L and pyroxasulfone at a concentration of 120 g/L. This end-use product has a density of 1.08 - 1.12 g/mL and pH of 5.5 - 6.5. The required chemistry data for Surtain Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Surtain Herbicide is of low acute oral, dermal and inhalation toxicity. It is non-irritating to the eyes, mildly irritating to the skin and not a dermal sensitizer.

Chemical handler and postapplication worker exposure risk assessments on file were determined to be adequate to cover the registered use of Surtain Herbicide on field corn for all scenarios. No health risks of concern were identified for workers or bystanders, provided that appropriate personal protective equipment are worn and all label directions are followed.

No new residue data for pyroxasulfone in field corn were submitted or required to register Surtain Herbicide. The resulting residues in field corn from the use of Surtain Herbicide are expected to be covered under the Maximum Residue Limit (MRL) currently established for the active ingredient in/on field corn.



Furthermore, the resulting residues in animal commodities are expected to be covered under the MRLs currently established for the active ingredient in/on animal commodities. Residues in field corn and animal matrices at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Residue data from field trials conducted in Canada and the United States for saflufenacil were submitted to support the use of Surtain Herbicide on field corn. Saflufenacil was applied to field corn at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated field corn was reviewed to determine the potential for concentration of residues of saflufenacil into processed commodities.

Maximum Residue Limits

The recommendation for proposed MRLs for saflufenacil was based upon the submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. The MRLs to cover residues of saflufenacil and metabolites M800H11 and M800H35 in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 1Summary of Field Trial and Processing Data Used to Support Maximum
Residue Limits (MRLs)

Commodity	Application	PHI (days)	Residues (ppm)				
	Method/ Total Application Rate (g a.i./ha)		LAFT	HAFT	Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
Field corn grain	Early post- emergent foliar application/ 141-157	78- 137	<0.03	<0.03	-	0.03	None
Field corn grain	Harvest aid/desiccant/ 243-247	3	<0.031	<0.05	1.6x flour	None	0.04 (Field corn flour)
					3.9x bran	None	0.06 (Field corn bran)

g a.i./ha = grams of active ingredient per hectare; ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the dietary burden and residue data, the following MRLs to cover residues of saflufenacil in animal commodities are also proposed:

Food Commodity	Currently Established MRL (ppm)	Proposed MRL (ppm)	
	20		
Liver of cattle, goats, horses and sheep	(Meat byproducts of cattle, goats, horses and sheep)	40	
Liver of hogs	1.0	2.0	
Liver of nogs	(Meat byproducts of hogs)	5.0	
Most hyproducts (av cont liver) of	20	0.3	
cattle, goats, horses and sheep	(Meat byproducts of cattle, goats, horses and sheep)		
Fat of cattle, goats, horses and sheep	0.02	0.03	
Meat of cattle, goats, horses and sheep	0.01	0.015	
Most hyproducts (avaant liver) of hogs	1.0	0.01	
Meat byproducts (except liver) of llogs	(Meat byproducts of hogs)		

Table 2Summary of the Proposed Maximum Residue Limits (MRLs) in Animal
Commodities

ppm = parts per million

Following the review of all available data, the MRLs proposed in Tables 1 and 2 are recommended to cover residues of saflufenacil. Dietary risks from exposure to residues of saflufenacil in these crop/livestock commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, these foods that contain residues are considered safe to eat.

Environmental Assessment

The use of Surtain Herbicide on field corn is within the currently registered use patterns for saflufenacil and pyroxasulfone. However, in Surtain Herbicide, the saflufenacil component is encapsulated, which differs from the form in previously registered saflufenacil products. Terrestrial field dissipation of the capsule suspension and emulsifiable concentrate formulations of saflufenacil were compared, and it was concluded that the capsule suspension does not significantly affect the dissipation of saflufenacil in the environment. Therefore, the risk is acceptable when Surtain Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The registration of Surtain Herbicide provides users with the first product co-formulated with saflufenacil and pyroxasulfone to control both grasses and broadleaf weeds when it is applied pre-plant, pre-emergence, and early post-emergence to field corn. In addition, since saflufenacil and pyroxasulfone are from two herbicide mode of action groups, Surtain Herbicide provides users with a valuable tool that may help to manage the development of herbicide-resistant weed biotypes in field corn.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from both efficacy trials and dedicated crop tolerance trials conducted in Ontario, Manitoba, and Saskatchewan in 2022. This information collectively demonstrated that the performance, in terms of efficacy and crop tolerance, of Surtain Herbicide is acceptable when it is applied as per the label instructions. Based on the weight of evidence, the registration of Surtain Herbicide is considered to have acceptable value.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Surtain Herbicide.

References

PMRA	Reference
Document	
Number	
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3433408	2022, BAS 821 00 H Local Lymph Node Assay (LLNA), DACO: 4.6,4.6.6
3433409	2022, Terrestrial Field Dissipation of Saflufenacil Following Application of a Capsule Suspension Formulation, DACO: 8.1,8.3,8.3.1,8.3.2
3433412	2022, BAS 821 00 H Acute Eye Irritation in Rabbits, DACO: 4.6,4.6.4
3433413	2022, BAS 821 00 H Acute Dermal Irritation / Corrosion in Rabbits, DACO: 4.6,4.6.5
3433414	2022, BAS 821 00 H Acute Oral Toxicity Study in Rats, DACO: 4.6,4.6.1
3433415	2022, BAS 821 00 H Acute Dermal Toxicity Study in Rats, DACO: 4.6,4.6.2
3433416	2022, Magnitude and Decline of Residues of Saflufenacil and its Metabolites in/on Corn Following Postemergence Applications, DACO: 7.4,7.4.1,7.4.2
3433417	2022, Magnitude of Residues of Saflufenacil and its Metabolites in/on Corn Processed Fractions Following Post Emergence Applications, DACO: 7.4,7.4.5
3433418	2022, Comparison of Saflufenacil (BAS 800 H) Field Soil Dissipation Endpoints from North American Trials with Different Formulation Types, DACO: 8.1,8.6.2
3433419	2022, BAS 821 00 H Acute Inhalation Toxicity Study in Wistar Rats 4-hour Liquid Aerosol Exposure (Nose Only), DACO: 4.6,4.6.3
3433420	2022, Determination of Odor for BAS 821 00 H Before and After Accelerated Storage for 14 Days at 54C, DACO: 3.0,3.5.3 CBI
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3433422	2022, Surtain Herbicide Group A - Product Identity, Composition, and Analysis, DACO: 3.0,3.1,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.4 CBI
3433425	2023, Efficacy and Value Data Supporting the Registration of Surtain Herbicide in Canada, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3,1, 10.2.3.3,10.3.1,10.3.2,10.3.3,10.4,10.5.1,10.5.2,10.5.3,10.7.1,10.7.2
3433431	2023, Surtain Herbicide (BAS 821 00 H) Formulation Characteristics, Encapsulation Reaction and SPSF Documentation, DACO: 3.0,3.2,3.2.2, 3.5.4,3.7 CBI
3433433	2023, Description of Saflufenacil Capsule Biology a Component of Surtain Herbicide (BAS 821 00 H), DACO: 9.9
3433440	2023, Waiver of DACO 7.4.1, 7.4.2, 7.4.5, 7.4.4 Requirements for Pyroxasulfone a Component of Surtain Herbicide (BAS 821 00 H), DACO: 7.4,7.4.1,7.4.2,7.4.4,7.4.5

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	Liquid Chromatography, DACO: 3.4.1
3451536	2022, Validation of the Analytical Method AFL1062/01: Determination of the Active Ingredients Pyroxasulfone and Saflufenacil in BAS 821 00 H by Liquid Chromatography, DACO: 3.4.1
3451537	2023, Analysis of [CBI REMOVED] in Surtain Herbicide (BAS 821 00 H), DACO: 3.4.2
3451538	2016, Determination of [CBI REMOVED], DACO: 3.4.2
3451539	2016, Validation of the Method for Determination of [CBI REMOVED], DACO: 3.4.2
3451540	2017, Determination of [CBI REMOVED], DACO: 3.4.2
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3469427	2023, Phytotoxicity Reports, DACO: 10.3.2
3479125	2023, Surtain Herbicide : Process Description, DACO: 3.2 CBI
3479126	2023, DACO 3.2 and 3.3, DACO: 3.2,3.3.1 CBI
3576083	2024, DACO 4.6.8, DACO: 4.6.8

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