Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number:	2019-0997
Application:	Changes to Product Label- New Site or Host
Product:	Authority 480 Herbicide
Registration Number:	29012
Active ingredient (a.i.):	Sulfentrazone
PMRA Document Number :	3096642

Purpose of Application

The purpose of this application was to add spring and durum wheat to the label of Authority 480 Herbicide as host crops for control of kochia.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

Authority 480 Herbicide for use on wheat (spring and durum) to control kochia represents an expansion of use for sulfentrazone. A mixer/loader/applicator quantitative risk assessment was conducted. No health risks of concern were identified provided that workers wear the appropriate personal protective equipment and follow all label directions.

New residue data for sulfentrazone from wheat field trials conducted in Canada and the United States were submitted and reviewed to support the addition of spring and durum wheat as new host crops. Sulfentrazone was applied by ground equipment as a preplant or preemergent soil treatment to fields of wheat at two-fold the Canadian rate, and samples were harvested according to label directions. In addition, one trial from the submitted wheat study was conducted with an exaggerated application rate six-fold the rate to determine the potential for concentration of sulfentrazone residues into processed commodities; however, processing of the raw agricultural commodities (RAC) was not performed, nor required, given that residues in/on RAC samples were all below the limit of quantitation (LOQ) of the method.

Canada

Maximum Residue Limit (MRL)

The recommendation of an MRL for sulfentrazone is based upon a newly submitted field trial study conducted on wheat, as well as the guidance provided in the OECD MRL Calculator. As per the residue definition for enforcement purposes in plant matrices, an MRL of 0.03 ppm to cover combined residues of sulfentrazone and the metabolites DMS and HMS (expressed in sulfentrazone equivalents) in/on wheat is recommended as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial Data Used to Support the Maximum Residue Limit (MRL) for Sulfentrazone

Commodity	Application Method/Total Application Rate (g a.i./ha)	PHI[1] (days)	Residues[2] (ppm)		Mean Experimental Processing Factors	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT[3]	HAFT[3]			
Wheat grain	Soil broadcast application preplant or preemergent to wheat/ (CDN/US data) 201 – 224	87 – 311	<0.03	<0.03	Processing factors could not be calculated since residues in RAC were below the LOQ[2].	None	0.03 for wheat

[1] PHI = Preharvest Interval
[2] Residues expressed as the sum of sulfentrazone and the metabolites DMS and HMS (expressed as sulfentrazone equivalents); the limit of quantitation (LOQ) of the method was 0.01 ppm for each of the three analytes (i.e., 0.03 ppm for the sum) and was used for values below the LOQ.
[3] LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial.

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover combined residues of sulfentrazone and the metabolites DMS and HMS (expressed as sulfentrazone equivalents) in/on wheat RAC and processed commodities. Residues in these food commodities at the proposed MRL will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Authority 480 Herbicide application to spring wheat and durum wheat for control of kochia fits within the previously registered use pattern. No additional risk to the environment is expected from the application of Authority 480 Herbicide to spring and durum wheat. Existing label statements are sufficient for risk mitigation.

Value Assessment

The expansion of the use pattern of Authority 480 Herbicide to include spring and durum wheat as host crops, as well as rescue crops, will provide Canadian growers greater flexibility to employ Authority 480 Herbicide for early season weed management, especially in western Canada.

Value information submitted for review included data from replicated field research trials and large scale operational trials conducted in the Canadian Prairies over multiple years. The information demonstrated that spring and durum wheat as host crops, as well as rescue crops, can be expected to have an adequate margin of crop tolerance to Authority 480 Herbicide when applied in accordance with the label instructions.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to add spring and durum wheat to the label of Authority 480 Herbicide as host crops for control of kochia.

References

PMRA Document Number	Reference
2970802	2018, Magnitude and decline of the residues of sulfentrazone and metabolites in/on wheat and processed commodities following application of Spartan 4F, DACOs: 7.1,7.4.1,7.4.2,7.4.5
2970783	2016, Trial report, DACO: 10.3.2(A).
2970784	2013, Trial report, DACO: 10.3.2(A).
2970785	2013, Trial report, DACO: 10.3.2(A).
2970786	2012, Trial report, DACO: 10.3.2(A).
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2970795	2016, Trial report, DACO: 10.3.2(A).
2970796	2014, Trial report, DACO: 10.3.2(A).
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2970798	2013, Trial report, DACO: 10.3.2(A).

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