

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2019-1213
Application: B.3.12: Changes to Product Labels-New Site or Host
Product: Sefina Insecticide
Registration Number: 33265
Active ingredients (a.i.): Afidopyropen
PMRA Document Number: 3100883

Purpose of Application

The purpose of this application was to amend the label of Sefina Insecticide to add Crop Group 17 (grass forage, fodder and hay), Crop Group 18 (nongrass animal feeds) and Sorghum (Grain and Sweet).

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

Residue data from field trials conducted in the United States were submitted for afidopyropen to support the addition of Crop Group 17, Crop Group 18, and sorghum to the label for Sefina Insecticide. Afidopyropen was applied to the crops at the proposed rate and harvested according to label directions.

Maximum Residue Limit

The recommendation for maximum residue limits (MRL) for afidopyropen was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). An MRL to cover residues of afidopyropen in/on sorghum is proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodities (RACs).

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

Commodity	Application Method/ Total Application Rate (g a.i./ha/season)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Sorghum	Foliar/39.1-41.0	12-15	<0.01	0.104	Sweet sorghum syrup: 0.8 (median)	-	0.2

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the anticipated residues resulting from the updated dietary burden, MRLs of 0.01 ppm in milk (to replace the current MRL of 0.001 ppm) and 0.09 ppm in liver of cattle, goats, hogs, horses and sheep, to cover residues of afidopyropen are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 and for livestock commodities are recommended to cover residues of afidopyropen. Residues in these crop and livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use of the end-use product Sefina Insecticide on Crop Group 17 (grass forage, fodder and hay), Crop Group 18 (nongrass animal feeds), and sorghum is not expected to result in potential occupational or bystander exposure over the registered use of afidopyropen. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

The environmental risks associated with the use of Sefina Insecticide containing the active ingredient afidopyropen are acceptable when used according to the label directions.

Value Assessment

Results from field trials supported the use of Sefina Insecticide to control pea aphid and suppression of blue alfalfa aphid, spotted alfalfa aphid and potato leafhopper on Crop Group 18 (Non-grass animal feeds) and Crop Group 17 (Grass forage, fodder and hay), and suppression of sugarcane aphid on sorghum. Sefina Insecticide provides a new mode of action for these uses, which may aid in resistance management.

Conclusion

The PMRA reviewed the information in support of the application to amend the label of Sefina Insecticide to add Crop Group 17 (grass forage, fodder and hay), Crop Group 18 (nongrass animal feeds) and Sorghum (Grain and Sweet). Based on the results of this review, the addition of Crop Group 17 (grass forage, fodder and hay), Crop Group 18 (nongrass animal feeds) and Sorghum (Grain and Sweet) is acceptable.

References

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2993125 2019, Field trial report DEV-I-2016-CA-H71-A-01.0-CA-CA1-JR2, DACO: 10.2.3.3,10.3.2

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2975193	2018. Validation of BASF analytical method D1507/02: Method for the determination of residues of Afidopyropen (BAS 440 I - Reg No. 5599022) and its metabolites M440I001 (Reg No. 5741530), M440I003 (Reg No. 5741533), M440I005 (Reg No. 5824382), M440I017 (Reg No. 6045738) and CPCA Carnitine (M440I060, Reg No. 6009307) in animal matrices by LC-MS/MS. BASF Reg. Doc. No. 2018/7001846.
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2975203	2017. Magnitude of the residue of Afidopyropen (BAS 440 I) after applications of BAS 440 01 I to grain sorghum. BASF Reg. Doc. No. 2017/7016329.
2975207	2017. Magnitude of the residues of Afidopyropen (BAS 440 I) in sweet sorghum processed fractions following applications of BAS 440 01 I. BASF Reg. Doc. No. 2017/7016330.

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