

Evaluation Report for Category B, Subcategory 3.2, 3.6 Application

Application Number: 2010-2924
Application: B.3.2 (Product label – application timing)
B.3.6 (Product label – pre-harvest)
B.3.12 (Product label - new site or host)
Product: Eragon
Registration Number: 29372
Active ingredients (a.i.): Saflufenacil (SFF)
PMRA Document Number : 1968726

Purpose of Application

The purpose of this application was to amend the registration of Eragon to include an application as a harvest aid at rates of 25 to 50 g a.i./ha plus Merge Adjuvant at 1.0 L/ha or in tank mix with glyphosate herbicide at 900 g a.e./ha for desiccation of soybeans and dry common beans. This was a NAFTA joint review.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of Eragon as a harvest aid on dry common beans and soybeans is considered acceptable when workers follow label directions and precautions, including listed personal protective equipment.

Metabolism data for saflufenacil in soybeans, and residue data for saflufenacil in dry beans, dry peas and soybeans were submitted to support the use expansion of this active ingredient on the Eragon label. Residue data for saflufenacil on cotton were also submitted to support the establishment of maximum residue limits (MRLs) for saflufenacil on imported cotton commodities. In addition, processing studies on treated soybeans and cotton were assessed to determine the potential for concentration of residues of saflufenacil into processed commodities.

Maximum Residue Limits

Recommendations for MRLs for saflufenacil in/on dry beans, dry peas, soybeans and cotton were based on guidance provided in Regulatory Proposal PRO2005-04, Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data.

conducted according to label directions, MRLs to cover residues of saflufenacil in/on dry beans, dry peas, soybeans and cotton will be established as shown in Table 1. Residues of saflufenacil in processed commodities not listed in Table 1 are covered under the MRLs for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRLs) for Saflufenacil.

Commodity	Application Method/ Total Application Rate	PHI (days)	Saflufenacil Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Dry beans	Harvest aid/ 49-52 g a.i./ha	2	<0.0 3	<0.2 5	Not required	0.03* (for Crop Group 6)	0.3 (for Crop Group 6C)
Dry peas	Harvest aid/ 49-51 g a.i./ha	2-4	<0.0 3	<0.0 7	Not required		
Soybeans	Harvest aid/ 49-51 g a.i./ha	2-4	<0.0 3	<0.0 7	No concentration observed in soybean processed fractions		0.1
Cotton	Harvest aid/ 48-52 g a.e./ha	5	<0.0 3	<0.1 4	No concentration observed in cotton processed fractions	0.03**	0.2

* The recommended MRLs of 0.3 ppm in/on Crop Subgroup 6C and 0.1 ppm in/on dry soybeans will replace the current MRL of 0.03 ppm in/on these commodities due to the addition of a late-season application. Accordingly, the current MRL of 0.03 ppm on Crop Group 6 will be revised to specify MRLs of 0.03 ppm for Crop Subgroups 6A and 6B.

** The recommended MRL of 0.2 ppm in/on imported undelinted cotton seeds is to replace the established MRL of 0.03 ppm due to addition of the harvest aid use pattern.

Based on the anticipated dietary burden to livestock and the residue data provided, MRLs of 2.5 ppm in liver of cattle, goats, horses and sheep, and 0.05 ppm in meat byproducts except liver of cattle, goats, horses and sheep will be promulgated to cover residues of saflufenacil in these commodities.

Following the review of all available data, MRLs are recommended to cover residues of saflufenacil in/on dry beans, dry peas, soybeans, cotton and animal commodities. Residues of saflufenacil and metabolites in these commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental risk assessment was required as the proposed label changes will not result in higher risk.

The proposed application rate for harvest aid falls within the currently registered use pattern for pre-seed or pre-emergence application with other crops, with a single application per season allowed, either in the spring as a weed control treatment or in the fall as a harvest aid treatment.

Buffer zones were calculated for all registered crops based on the proposed application rates. As a result, the buffer zone values have remained identical to the one currently registered for Eragon. Minimal label amendments pertaining to environmental protection and container disposal are needed.

Value Assessment

The submitted data from 18 trials conducted in Alberta, Manitoba, and Ontario in 2008 and 2009 demonstrated that the efficacy of Eragon applied alone or in tank mix with a glyphosate herbicide as harvest aid in dry common beans / soybeans was acceptable. When the treatments were applied as directed, crop yield was not affected compared to the untreated control or the registered treatment of Reglone.

Conclusion

Following the review of all available data, the PMRA was able to support the amended registration of Eragon to include an application as a harvest aid at rates of 25 to 50 g a.i./ha plus Merge Adjuvant at 1.0 L/ha or in tank mix with glyphosate herbicide at 900 g a.e./ha for desiccation of soybeans and dry common beans.

References

PMRA

Document

Number

Reference

- | | |
|---------|--|
| 1924705 | 2010, Summaries Metabolism/ Toxicokinetics Studies, DACO: 6.1 |
| 1924710 | 2010, Metabolism of 14C-BAS 800 H in soybean following a postemergence application (Including amendment no. 1), DACO: 6.3 |
| 1924714 | 2010, Summaries Food, Feed and Tobacco Residue Studies, DACO: 7.1 |
| 1924718 | 2010, Residue Enforcement Method for Determination of BAS 800 H and Its Metabolites M800H11 and M800H35 Residues in Plant Matrices Using LC/MS/MS, DACO: 7.2.2 |
| 1924728 | 2010, Magnitude of the residue of Saflufenacil in soybeans after application of BAS 800 00 H (WG formulation) and BAS 800 04 H (SC formulation) used as a desiccant, DACO: 7.4.1,7.4.2 |
| 1924729 | 2010, The magnitude of residues of Saflufenacil in dry bean following a late season application of BAS 800 00 H used as a desiccant, DACO: 7.3,7.4.1,7.4.2 |
| 1924731 | 2010, Magnitude of residues of Saflufenacil in cotton raw agricultural |

- commodities and processed fractions after late season application with BAS 800 00 H used as a defoliant/desiccant, DACO: 7.4.1,7.4.2,7.4.5
- 1924732 2010, Magnitude of the residue of Saflufenacil in dry peas after application of BAS 800 00 H used as a desiccant, DACO: 7.3,7.4.1,7.4.2,7.4.6
- 1924737 2010, The magnitude of Saflufenacil residues in soybean aspirated grain and processed fractions, DACO: 7.3,7.4.5
- 1924683 Heat Herbicide and Eragon Herbicide: Addition of harvest aid use pattern in dry beans, lentils, field peas, soybeans, and sunflowers. BASF Canada Inc. April 30, 2010. DACO 10, Value. pp. 33.
- 1924685 Dry bean field trial reports. DACO 10.2.2.3. pp 89.
- 1924690 Soybean field trial reports. DACO 10.2.3.3. pp 33.

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2012

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.