



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-7083
Application: New or changes to product labels – new site or host
Product: Assure II Herbicide
Registration Number: 25462
Active ingredients (a.i.): Quizalofop-P-ethyl
PMRA Document Number : 2429518

Purpose of Application

The purpose of this application was to add Enlist corn (field and seed) to the Assure II Herbicide label.

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 Assure II Herbicide on Enlist corn to control annual and perennial grasses fits within the currently registered use pattern for quizalofop-P-ethyl. The potential exposure for mixers, loaders, and applicators, as well as post-application workers, is not expected to exceed the current exposure to registered products. No occupational exposure risks of concern are expected provided that all label statements, precautions and directions are followed.

Residue data including field trials conducted in Canada and the United States were submitted to support the domestic use of Assure II Herbicide on Enlist field and seed corn. Quizalofop-P-ethyl was applied to hybrid field corn containing the Aryloxyalkanoate Dioxygenase-1 (AAD-1) gene at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated AAD-1 corn was reviewed to determine the potential for concentration of residues of quizalofop-P-ethyl into processed commodities.

Maximum Residue Limit(s)

Residues of the resolved isomer quizalofop-P-ethyl are covered by maximum residue limits (MRLs) established for quizalofop-ethyl, the unresolved isomeric mixture. The recommendation for MRL for quizalofop-ethyl was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). The MRL to cover residues of quizalofop-ethyl including the acid metabolite in/on field corn 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 commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues ¹ (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Transgenic field corn grain	Postemergent application/86.2- 98.6	79- 144	<0.02	<0.02	Could not be determined as the combined residues of quizalofop- P-ethyl and the metabolite quizalofop acid were <0.02 ppm in/on corn grain and the processed commodities of refined oil, meal, grits and flour when treated at exaggerated rates	None	0.02

¹Combined residues of quizalofop-P-ethyl and the metabolite quizalofop acid, expressed as quizalofop-P-ethyl equivalents.

Based on the dietary burden and residue data, no changes are needed to the MRLs established in the Health Canada MRL database for residues of quizalofop-ethyl including the acid metabolite in/on livestock commodities (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>).

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of quizalofop-ethyl. Residues in Enlist corn commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional data are required to support the registration of the new host crop, Enlist corn.

Since there is no change to the existing use pattern, no increase in environmental risk is expected. The existing buffer zones and revised environmental precautionary statements on the label are expected to mitigate environmental risks.

Value Assessment

Data from 14 dedicated crop tolerance field trials and a rationale were provided for review. The trials were established between 2011 and 2012 in the northern USA (Illinois, Indiana, Iowa, Minnesota, New York, South Dakota and Wisconsin) to determine the tolerance of field corn that has been genetically modified to tolerate quizalofop-P-ethyl (i.e. Enlist corn) to a post-emergence application of Assure II Herbicide. The provided trial data demonstrated that Enlist field corn can be expected to exhibit an adequate margin of crop safety to an application of Assure II Herbicide when applied in accordance with the label. Furthermore, unacceptable injury to Enlist seed corn would not be expected given that seed corn hybrids will contain the same gene that provides tolerance to quizalofop-P-ethyl in field corn hybrids. Based on the provided data, amending the registration of Assure II Herbicide to include Enlist corn (field and seed) as a new host crop for post-emergence treatment was supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Assure II Herbicide, and has found the information sufficient to add a use on Enlist corn (field and seed) to the product label.

References

- 2385080 2013, 10.3.2A Quizalofop Field Corn Summary v10, DACO: 10.3.2(A).
- 2419871 2013, Frozen Storage Stability of Quizalofop and Quizalofop Ethyl Ester in Corn Commodities, DACO: 7.3
- 2419870 2010, A Nature of the Residue Study with [14C]-Quizalofop Applied to AAD-1 Corn (Event 278), DACO: 6.1, 6.3
- 2121031 2010, Magnitude of Residue of 2,4-D and Quizalofop-P-ethyl in/on Herbicide Tolerant Field Corn Containing the Aryloxyalkanoate Dioxygenase-1 (AAD-1) Gene, DACO: 7.2.1, 7.3, 7.4.1, 7.4.2

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