

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2011-0413
Application: B.3.12 (Product labels - new site or host)
Product: Touchdown Total Herbicide
Registration Number: 28072
Active ingredients (a.i.): Glyphosate (GPP)
PMRA Document Number: **2046582**

Purpose of Application

The purpose of this application was to add a new line of canola (*Brassica napus*), Optimum GLY Canola, to the use pattern of Touchdown Total Herbicide. Touchdown Total Herbicide is presently registered for use on glyphosate tolerant canola, and the use pattern (rates, pest claims, etc.) is unchanged.

Health Assessments

Plant metabolism and residue data for glyphosate in canola containing the transgenic event DP-Ø73496-4 (Optimum GLY canola) were submitted to support the use expansion to this crop on the Touchdown Total Herbicide label. In addition, a processing study in treated Optimum GLY canola was also provided and assessed to determine the potential for concentration of residues of glyphosate into processed commodities.

Maximum Residue Limit(s)

Based on the maximum residues observed in Optimum GLY canola generated according to the approved label use directions, a maximum residue limit (MRL) of 20 ppm to cover residues in/on canola will be established as shown in Table 1. Residues of glyphosate in processed commodities not listed in Table 1 are covered under established MRL for the raw agricultural commodity (RAC).

Commodity	Application Method/ Total Application Rate (g a.e./ha)	PHI (days)	Combined Residues* (ppm)		Experimental Processing Factor	Currently Established MRL**	Recommended MRL***
			Min	Max			
Optimum GLY Canola	Broadcast (pre- emergence + postemergence + preharvest) / 2231-2533	6-8	0.64	15.18	No concentration observed in canola processed fractions	10	20

* Glyphosate, *N*-acetylglyphosate, AMPA and *N*-acetyl AMPA.

** The current MRL for glyphosate on canola is established for glyphosate and the metabolite AMPA.

***The proposed MRL for glyphosate on canola is proposed for glyphosate and the metabolites *N*-acetylglyphosate, AMPA and *N*-acetyl AMPA, and will replace the existing MRL for canola.

Following the review of all available data, an MRL is recommended to cover residues of glyphosate and the metabolites in canola. Residues of glyphosate and metabolites in this commodity at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Chemistry and Environmental Assessment

Chemistry and environmental assessments were not required for this application.

Value Assessment

The data from 11 trials conducted in the United States and Canada were submitted for review in support of the use of Touchdown Total Herbicide on Optimum GLY Canola. Canola varieties designated as Optimum GLY Canola are tolerant to applications of glyphosate. The data submitted for review support the use of Touchdown Total Herbicide on Optimum GLY Canola.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of a new line of canola (*Brassica napus*), Optimum GLY Canola, to the use pattern of Touchdown Total Herbicide.

References

- 2006679 Trial reports and value review, DACO: 10.1, 10.2.3.1, 10.2.3.4(b), 10.3.1, 10.3.2
- 2013875 2010, The Metabolism of [14C]Glyphosate in 0827 Canola, DACO: 6.3
- 2006674 2010, Magnitude and Decline of Glyphosate Related Residues in Forage and Seed Genetically Modified Canola Event DP-073496-4 and Magnitude of Glyphosate Related Residues in Canola Event DP-073496-4 Seed Process Fractions Following Applications of Touchdown Total Herbicide – Locations in the United States and Canada, Season 2009. DACO: 7.1, 7.4.1, 7.4.2, 7.4.6
- 2006677 2010, Magnitude and Decline of Glyphosate Related Residues in Forage and Seed Genetically Modified Canola Event DP-073496-4 and Magnitude of Glyphosate Related Residues in Canola Event DP-073496-4 Seed Process Fractions Following Applications of Touchdown Total Herbicide – Locations in the United States and Canada, Season 2009. DACO: 7.1, 7.4.1, 7.4.2, 7.4.6

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