Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Numbers: 2008-0449
Application: New host
Products: Touchdown Total Liquid Herbicide
Registration Number: 28072
Active ingredients (a.i.): Glyphosate (present as mono-ammonium salt or diammonium salt)
PMRA Document Number: **1875853**

Purpose of Application

The purpose of this application was to expand the use of the end-use product, Touchdown Total Liquid Herbicide (Registration Number 28072), to include use in glyphosate tolerant soybeans that contain the GAT Optimum genetic event.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

The data received for plant metabolites of glyphosate in plants containing the GAT Optimum genetic event showed low acute oral toxicity in rats and the genotoxicity studies were all negative. A short-term oral toxicity study in rats with n-acetyl glyphosate also showed very low toxicity. These two plant metabolites are not more toxic than glyphosate or the common metabolite AMPA. Therefore, full risk assessments are not required for the plant metabolites.

The proposed use expansion is not expected to increase exposure for workers mixing/loading and applying the product or entering treated soybean fields from the currently registered use pattern for glyphosate.

Plant metabolism and residue data for glyphosate in glyphosate tolerant soybean containing the GAT Optimum genetic event were submitted to support the proposed use expansion. In addition, a processing study in treated glyphosate tolerant soybean containing the GAT Optimum genetic event was also provided and assessed to determine the potential for concentration of residues of glyphosate in processed commodities.

Based on the maximum residues observed in glyphosate tolerant soybeans that contain the GAT Optimum genetic event treated according to label directions, maximum residue limit (MRL) of 20 ppm to cover residues in/on soybeans 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).

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Table 1 Summary of field trial and processing data used to establish Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.e./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL*	Recommended MRL**
			Min	Max			
Glyphosate tolerant soybean containing GAT Optimum genetic event	Broadcast (pre-emergence + 2x postemergence + preharvest) / 6.66 – 6.98	14	0.33	8.64	No concentration observed in soybean processed fractions	20	20

*The current MRL for glyphosate on soybeans is established for the parent glyphosate and the metabolite AMPA.
**The proposed MRL for glyphosate on soybeans is proposed for the parent glyphosate and the metabolites N-acetylglyphosate, AMPA and N-acetyl AMPA, and will replace the existing MRL for soybeans.

Based on the dietary burden and residue data, MRLs of 2.0 ppm in kidney, 0.2 ppm in liver, 0.08 ppm in meat, eggs and milk, and 0.15 ppm in fat will be promulgated to cover the combined residues of glyphosate, *N*-acetylglyphosate and AMPA.

Following the review of all available data, MRLs are recommended to cover residues of glyphosate and the metabolites. Residues of glyphosate 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 studies were required to support the proposed use expansion. The rates of application, timing, and application methods for this use are identical to those for the currently registered use of Touchdown Total Liquid Herbicide on glyphosate tolerant soybeans without the GAT Optimum genetic event. Thus, no increased risk to the environment is expected.

Value Assessment

Data from 15 trials conducted in the United States and Canada were submitted for review in support of the use of Touchdown Total Liquid Herbicide on soybeans containing the GAT Optimum genetic event. The data indicate an acceptable level of crop safety, therefore the use pattern is acceptable.

Conclusion

The PMRA had conducted an evaluation of the subject application and found the information sufficient to support the use expansion of the end-use product, Touchdown Total Liquid Herbicide, to glyphosate tolerant soybeans that contain the GAT Optimum genetic event.

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