



Evaluation Report for Category B, Subcategory 3.12 Application

Application Numbers: 2008-2270
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: 1870053

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 corn that contains 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 corn fields from the currently registered use pattern for glyphosate.

Plant metabolism and residue data for glyphosate in glyphosate tolerant field corn containing the GAT Optimum genetic event were submitted to support the proposed use expansion. In addition, a processing study in treated glyphosate tolerant field corn 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 field corn that contain the GAT Optimum genetic event treated at $\sim 1.1\times$, a maximum residue limit (MRL) of 3.0 ppm to cover residues in/on field corn 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).

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 field corn containing GAT Optimum genetic event	Broadcast (pre-emergence + 2x postemergence + preharvest) / 6.59 – 7.22	7	0.20	0.67	No concentration observed in corn processed fractions	3.0	3.0

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

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

Following the review of all available data, an MRL is recommended to cover residues of glyphosate and the metabolites in field corn. 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.

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 corn 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 corn 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 corn that contains the GAT Optimum genetic event.

References

PMRA Document Number: 1552807

Reference: 2007, Analytical Method for the Determination of Glyphosate and Degradate Residues in Various Crop Matrices Using LC/MS/MS, DACO: 7.1,7.2.1,7.2.2,7.2.5

PMRA Document Number: 1552809

Reference: 2007, Analytical Method for the Determination of N-acetylglyphosate ands other Analytes in Various Animal Matrices Using LC/MS/MS, DACO: 7.1,7.2.1

PMRA Document Number: 1552811

Reference: 2007, Independent Labotatory Validation of DuPont-15444,"Analytical Method for the Determination of Glyphosate and Relevant Metabolite Residues in Various Crop Matrices Using LC/MS/MS", DACO: 7.1,7.2.3

PMRA Document Number: 1552814

Reference: 2007, Independent Labotatory Validation of DuPont-20009,"Analytical Method for the Determination of N-acetylglyphosate and Other Analytes In Various Animal Matrices Using LC/MS/MS", DACO: 7.1,7.2.3

PMRA Document Number: 1552816

Reference: 2007, Method Assessment and Validation of PAM Multi-Residue Method for the Determination of N-acetylglyphosate, DACO: 7.1,7.2.4

PMRA Document Number: 1552819

Reference: 2007, The Metabolism of [14 C]-N-Acetylglyphosate (IN-MCX20) in Laying Hens, DACO: 6.1,6.2

PMRA Document Number: 1552821

Reference: 2007, The Metabolism of [14 C]-N-Acetylglyphosate (IN-MCX20) in the Lactating Goat, DACO: 6.1,6.2

PMRA Document Number: 1552822

Reference: 2007, Magnitude of Residues of N-acetylglyphosate and Degradates in Laying Hen Tissues and Eggs, DACO: 7.1,7.5

PMRA Document Number: 1552825

Reference: 2007, Magnitude of Residues of N-acetylglyphosate and Degradates in Dairy Cow Tissues and Milk, DACO: 7.1,7.5

PMRA Document Number: 1552836

Reference: 2006, IN-MCX20: Mouse Bone Marrow Micronucleus Test, DACO: 4.1,4.5.7

PMRA Document Number: 1552837

Reference: 2007, IN-MCM20: Subchronic Toxicity 90-Day Feeding Study in Rats, DACO: 4.1,4.7.1

PMRA Document Number: 1552840

Reference: 2006, IN-MCX20: In Vitro Mammalian Cell Gene Mutation Test (CHO/HGPRT), DACO: 4.1,4.5.5

PMRA Document Number: 1552843

2007, IN-EY252: In Vitro Mammalian Chromosome Aberration Test in Human Peripheral Blood

Lymphocytes, Reference: DACO: 4.1, 4.5.4

PMRA Document Number: 1552845

Reference: 2007, IN-EY252: Mouse Bone Marrow Micronucleus Test, DACO: 4.1, 4.5.7

PMRA Document Number: 1552846

Reference: 2007, In Vitro Mammalian Cell Gene Mutation Test (CHO/HGPRT), DACO: 4.1, 4.5.5

PMRA Document Number: 1552847

Reference: 2007, IN-EY252: Acute Oral Toxicity Study in Rats-Up-and-Down Procedure, DACO: 4.1, 4.2.1

PMRA Document Number: 1608202

Reference: 2007, The Metabolism of [¹⁴C] glyphosate in Ptimum GAT (Event DP-098140-6) Field Corn, DACO: 6.1, 6.3

PMRA Document Number: 1608207

Reference: 2007, Magnitude of Residues if Glyphosate and Its Degradates in/on Field Corn forage, Grain, and Stover of Hybrid Corn Line 49712 containing the GAT Gene from Event DP-049712-7 Following Applications of Glyphosate Herbicides at Maximum Label Rates-United States Locations, Season 2005, DACO: 7.1,7.4.1,7.4.2,7.4.6

PMRA Document Number: 1608223

Reference: 2008, Tolerance of maize containing the GAT/HRA event DP-098140-6 to postemergence applications of glyphosate, DACO: 10.1, 10.2.3.1, 10.2.3.4(b), 10.3.1, 10.3.2

PMRA Document Number: 1608224

Reference: 2007, Magnitude of Residues of Glyphosate and Degradates in Aspirated Grain and Processed Fractions (Starch, Grits, Flour, Refined Oil (Wet Milling) Refined Oil (Dry milling) and Meal (Dry Milling) of a Field Corn Line Containing Event DP-098140-6 Following applications of glyphosate containing herbicides – United States and Canadian locations, Season 2006, DACO: 7.1, 7.5

PMRA Document Number: 1667738

Reference: 2004, Salmonella-Escherichia Coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay with N-acetyl-glyphosate, DACO: 4.5.4

PMRA Document Number: 1667739

Reference: 2004, Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells, DACO: 4.5.5

PMRA Document Number: 1667740

Reference: 2004, Acute Oral Toxicity Study In Rats with N-Acetyl-Glyphosate , Sodium Salt (Acute Toxic Class Method), DACO: 4.5.5

PMRA Document Number: 1667741

Reference: 2007, IN-EY252:Bacterial Reverse Mutation Assay, DACO: 4.5.4

PMRA Document Number: 1739972

Reference: 2007, Magnitude and Decline of Glyphosate and Its Degradates in/on Green Plant, Forage, Stover and Grain of Corn Line Containing Event DP-098140-6 GAT and ZM-HRA Genes Following a Variety of Tank Mix Applications of Two Glyphosate and Rimsulfuron, tribenuron methyl, chlorimuron ethyl, and metsulfuron methyl containing herbicides at maximum label rates – United States and Canadian locations, Season 2006, DACO 7.4.1

PMRA Document Number: 1739973

Reference: 2007, Magnitude and Decline of Glyphosate and Its Degradates in/on Green Plant, Forage, Stover and Grain of Corn Line Containing Event DP-098140-6 GAT and ZM-HRA Genes Following a Variety of Tank Mix Applications of Two Glyphosate and Rimsulfuron, tribenuron methyl, chlorimuron ethyl, and metsulfuron methyl containing herbicides at maximum label rates – United States and Canadian locations, Season 2006, DACO 7.4.1

PMRA Document Number: 1739974

Reference: 2007, Magnitude and Decline of Glyphosate and Its Degradates in/on Green Plant, Forage, Stover and Grain of Corn Line Containing Event DP-098140-6 GAT and ZM-HRA Genes Following a Variety of Tank Mix Applications of Two Glyphosate and Rimsulfuron, tribenuron methyl, chlorimuron ethyl, and metsulfuron methyl containing herbicides at maximum label rates – United States and Canadian locations, Season 2006, DACO 7.4.1

PMRA Document Number: 1799876

Reference: 2009, Stability of Glyphosate and Metabolites in Corn Green Plant, Forage, Grain and Stover Containing the GAT and ZM-HRA Genes During Frozen Storage, DACO: 7.3

ISBN : 1911-8082

Catalogue number: xxxxxxxxxxx (xxxxxxxxx)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2006

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.