Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.11, 3.12, 3.2, and 3.4 Application

Application Number: 2010-2912
Application: B.3.11-Changes to Product Labels-New Pests
B.3.12-Changes to Product Labels-New Site or Host
B.3.2-Changes to Product Labels-Application Timing
B.3.4-Changes to Product Labels-Application Method
Product: Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide
Registration Number: 27487
Active ingredients (a.i.): Glyphosate (present as potassium salt)
PMRA Document Number English PDF: 2035078

Purpose of Application

The purpose of this application was to support a new crop (hybrid corn seed production), new application timing (up to 13 leaf stage) and a new application method (high clearance ground equipment) to eliminate the need for hand or mechanical detasseling. This was a joint review with the United States.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

Residue data for glyphosate on seed corn were submitted to support the use expansion of this active ingredient on the Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide label. There were no food uses associated with seed corn. The maximum residue limits (MRLs) in livestock commodities are adequate to cover residues of glyphosate and metabolites resulting from feeding of treated corn commodities. 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.

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The use of glyphosate on glyphosate-tolerant field corn (varieties designated as containing Roundup Ready 2 Technology) using the Roundup Hybridization System (RHS) to eliminate manual detasseling did not fit within the registered use pattern of glyphosate. Thus, post application risk was assessed for the use of two additional applications on seed corn. Acceptable margins of exposure (MOEs) were calculated for workers re-entering treated fields. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

An environmental assessment was not conducted as no additional environmental data were required to support the use expansion of Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide for a new crop (hybrid corn seed production), new application timing (up to 13 leaf stage) and a new application method (high clearance ground equipment). Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Efficacy and non-safety adverse effects data were submitted from four replicated field trials conducted in the U.S.A in 2009 in which the efficacy of two applications of glyphosate (U.S.-registered Roundup PowerMax, EPA Registration Number 524-549) was evaluated for tassel control in RHS recipient lines, assessed as percent anther extrusion (AE) risk. In one treatment, an application of 1302 g a.e/ha (~1x maximum rate) at the corn eight leaf stage was followed by 632 g a.e./ha (0.7x minimum rate) applied at the ten leaf stage. In the other treatment, an application of 868 g a.e./ha (~1x minimum rate) at the eight leaf stage was followed by another at this same rate at the ten leaf stage.

The mean percent AE risk was less than 0.5% (the maximum allowable for the RHS to be commercially viable) when averaged over the 25 evaluated RHS inbreds over the four trial sites. There were some RHS inbreds whose AE risk was greater than 0.5; however, this may have been due in part to an application that was made at a suboptimal timing for that particular inbred (too early or more likely too late) since inbreds within a particular maturity group were all treated at the same time (i.e. timings were not inbred-specific within a maturity group). In practice, inbreds with AE risks over the 0.5% threshold would not be used in the production of hybrid seed using the RHS system.

In any one genetic background (e.g. inbred pair), the tolerance of the RHS inbred to late applications of glyphosate was compared to that of the non-RHS inbred. RHS inbreds appeared to be similarly tolerant of late applications of glyphosate as non-RHS inbreds when evaluated in terms of percent chlorosis, percent malformation, and height. Yield response appeared to be specific to genetic background (i.e. inbred pairs), in that for some inbred pairs, the RHS inbred treated with three applications of glyphosate, including one application at the crop three leaf stage for weed control and two late applications (at the 8 leaf stage and again at the ten leaf stage) for tassel control, was lower yielding than that of the non-RHS inbred treated with only one application of glyphosate at the crop three leaf stage.

While the tolerance of RHS inbreds to two late applications of the maximum rate was not evaluated, it is not anticipated that the tolerance of RHS inbreds would be substantially different from the two evaluated treatments. In practice, RHS inbreds with poor yield response would not be used in the production of hybrid seed using the RHS system.

Since the efficacy of Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide for post-emergence weed control in glyphosate-tolerant field corn (varieties designated as containing Roundup Ready 2 Technology) has been previously established, data are not required to support the use of Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide for weed control on seed corn inbreds that are also designated as containing Roundup Ready 2 Technology. This includes inbreds that are designated as RHS, since there is no change to efficacy claims or application rates and timings. Labelled tank mixes are supported for use on inbreds in RHS production fields provided that the tank mix partner herbicide is labelled for use in seed corn.

Conclusion

Following the assessment of the information provided in support of the product, Roundup Weathermax with Transorb 2 Technology Liquid Herbicide, the Pest Management Regulatory Agency has found the information sufficient to amend the registration of this end-use product to include the new crop, new application timing and application method.

References

PMRA Number	*Title*
1924473	2010, Daco 10 - Summary of Value of Roundup WeatherMAX with Transorb 2 Technology Liquid Herbicide for Hybrid Corn Seed Production using the RHS® system with Roundup Ready 2 Technology, DACO: 10.1,10.2.1,10.2.2,10.2.3,10.2.3.1,10.3.1,10.3.2,10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.6
1924477	2010, Use Description, DACO: 5.2
1924480	2009, Magnitude of Glyphosate Residues in corn Raw Agricultural Commodities Following Topical Application of a Glyphosate Based Formulation to Roundup Hybridization System (RHS) Seed Corn. US 2008 Trials, DACO: 7.2,7.4.1,7.4.2,7.4.6

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