



Evaluation Report for Category B, Subcategory 2.1, 2.3 and 2.6 Application

Application Number: 2015-0858
Application: New End-Use Product Chemistry: Guarantee, identity of formulants, new combination of technical grade active ingredients
Product: Roundup Xtend with VaporGrip Technology Herbicide
Registration Number: 32274
Active ingredients (a.i.): Glyphosate (present as the monoethanolamine salt) and Dicamba (present as the diglycolamine salt)
PMRA Document Number : 2526289

Purpose of Application

The purpose of this application was to register a new end-use product, Roundup Xtend with VaporGrip Technology Herbicide (guarantee 240 g /L glyphosate and 120 g/L dicamba), for non-selective control of annual and perennial weeds in Roundup Ready 2 Xtend soybeans and corn varieties.

Chemistry Assessment

Roundup Xtend with VaporGrip Technology Herbicide is formulated as a solution containing dicamba, present as diglycolamine salt at a nominal concentration of 120 g/L and glyphosate, present as ethanolamine salt at a nominal concentration of 240 g/L. This end-use product has a density of 1.23 g/mL and pH of 5.0 – 5.17. The required chemistry data for Roundup Xtend with VaporGrip Technology Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Roundup Xtend with VaporGrip Technology Herbicide is of low acute toxicity via the oral, dermal and inhalation routes of exposure in rats. It is minimally irritating to the eyes and skin of rabbits and is not a skin sensitizer in guinea pigs.

The occupational exposure and risk from the registration of the new commercial end-use product, Roundup Xtend with VaporGrip Technology Herbicide, containing glyphosate, present as the monoethanolamine salt (240 g a.e./L) and dicamba, present as the diglycolamine salt (120 g a.e./L) was assessed. The use is as a preplant, pre-emergent or postemergent (to the crop) ground application on Roundup Ready 2 Xtend soybeans and corn varieties with Roundup Ready 2 Technology to control a variety of annual broadleaf, grass and perennial weeds fits within the currently registered use pattern of the active ingredients. As such, no health risks of concern are expected from the new end-use product, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

The use directions including the application rate and timing are similar to the precedent end-use products. As such, exposure to residues of dicamba and glyphosate in/on treated corn and soybean commodities will not increase, and will be covered by the MRLs currently established in Health Canada's MRL Database (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>).

No increase to the dietary burden of livestock is anticipated when Roundup Xtend with VaporGrip Technology Herbicide is used according to the approved label directions. Residues of dicamba in livestock commodities are currently covered under Part B, Division 15, Subsection B.15.002(1) of the Food and Drugs Act and Regulations, FDA&R (≤ 0.1 ppm). The MRLs established for glyphosate in livestock commodities can be found in Health Canada's MRL Database (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>).

Residues of dicamba and glyphosate in/on soybean and corn commodities treated according to the approved label for Roundup Xtend with VaporGrip Technology Herbicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No increase in environmental exposure is expected from the use of this end-use product compared to registered uses of glyphosate and dicamba. Environmental concerns are mitigated through the use of buffer zones and label statements.

Value Assessment

This is the first herbicide co-formulated with glyphosate (Group 9) and dicamba (Group 4) for non-selective weed control in Roundup Ready 2 Xtend soybeans and corn varieties with Roundup Ready 2 Technology. The co-formulation of these active ingredients into a single product will be more easily handled and convenient to apply. The registration of Roundup Xtend with VaporGrip Technology Herbicide should contribute to weed resistance management by providing control of many glyphosate resistant broadleaf weeds and as well reducing the potential for the development of other glyphosate resistant weed species.

The value information submitted included data from 15 efficacy trials and five dedicated crop tolerance trials conducted in Manitoba, Ontario, and Quebec in 2013. Data from field trials demonstrated that efficacy and crop tolerance of Roundup Xtend with VaporGrip Technology Herbicide were acceptable and comparable to those of the registered tank mixture of Roundup WeatherMax (Registration Number 27487) + Banvel II (Registration Number 23957) at the same active rates per hectare. Furthermore, co-formulations and tank mixtures of glyphosate and dicamba have been registered in Canada for a number of years and antagonism between them has not been reported.

Based on the weight of evidence, the registration of Roundup Xtend with VaporGrip Technology Herbicide is deemed to have value and can be supported for non-selective weed management in corn varieties with Roundup Ready 2 Technology and Roundup Ready 2 Xtend soybeans.

Conclusion

The PMRA has completed a review of information provided in support of Roundup Xtend with VaporGrip Technology Herbicide and found it sufficient to support full registration.

References

PMRA Document Number	Reference
2507955	2013, MON 76832 Crop Tolerance sites, DACO: 10.7.1.
2507956	2013, MON 76832 Efficacy Sites, DACO: 10.7.1.
2507949	2013, 49195501 Product Chemistry MON76832 RD1769 Study, DACO: 3.5 CBI
2557164	2015, Storage Stability/Corrosion Study for MON 76832 Herbicide Formulation, DACO: 3.5.10 CBI
2564691	2015, MSDS [CBI removed], DACO: 0.9.1
2557165	2015, Chromatogram – Glyphosate, DACO: 3.4.1 CBI
2557166	2015, Chromatogram – Dicamba, DACO: 3.4.1 CBI
2507962	Coversheet Acute Oral MON76832 Monsanto36610AOTUDP, DACO: 4.2.1
2507963	Coversheet Acute Dermal MON76832 Monsanto36611ADT, DACO: 4.2.2
2507964	Coversheet Acute Inhalation MON76832 Monsanto36612AITNoliq, DACO: 4.2.3
2507965	Coversheet Skin Irritation MON76832 Monsanto36613PSI, DACO: 4.2.5
2507966	Coversheet Dermal Sensitization MON76832 Monsanto 33614DS, DACO: 4.2.6
2507967	Coversheet Acute Eye MON76832 Monsanto36018PEI, DACO: 4.2.4

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