

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number:	2018-1259
Application:	Submissions Subject to Protection of Proprietary Interest in
	Pesticide Data (PPIP) Policy-Equivalency/Data Compensation
	Assessment
Product:	Magna Herbicide
Registration Number:	33748
Active ingredients (a.i.):	S-metolachlor, Glyphosate and Mesotrione
PMRA Document Number	• : 3006334

Purpose of Application

The purpose of this application was to register the end use product Magna Herbicide based on a registered precedent product under the Protection of Proprietary Interest in Pesticide data (PPIP) program.

Chemistry Assessment

Magna Herbicide is formulated as a suspension containing 250 g/L of glyphosate (present as potassium salt), 25 g/L of mesotrione and 250 g/L of S-metolachlor and R-enantiomer. This end-use product has a density of 1.1169 g/mL and pH of 4.0. The required chemistry data for Magna Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Magna Herbicide was considered toxicologically equivalent to the precedent product.

The use pattern of Magna Herbicide on glyphosate tolerant field corn is similar to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators and postapplication workers is not expected to exceed the current exposure to the registered products of these active ingredients. No health concerns are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for glyphosate, mesotrione and S-metolachlor were submitted to support the registration of Magna Herbicide.

The use directions on the Magna Herbicide label, including the target crop (i.e., field corn), method (ground), rate and timing of application, geographic restrictions, pre-harvest intervals, and crop rotation restrictions are similar to the precedent end-use product.

The changes in the formulation of Magna Herbicide are not expected to significantly impact the magnitude of glyphosate, mesotrione and S-metolachlor residues in/on treated field corn.



Based on this assessment, residues are not expected to increase and will be covered under the maximum residue limits (MRLs) currently established at 3 ppm for glyphosate in/on field corn, at 0.01 ppm for mesotrione in/on field corn, and at 0.1 ppm for S-metolachlor in/on corn (<u>http://pr-rp.hc-sc.gc.ca/mrl-lrm/results-eng.php</u>). Consequently, dietary exposure to residues of glyphosate, mesotrione and S-metolachlor is not expected to increase with the registration of Magna Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional risk to the environment is expected from the registration of the end-use product, Magna Herbicide. The use pattern for this product fits within the registered use pattern for the active ingredients. The product label meets current labeling standards and includes the appropriate buffer zones.

Value Assessment

The availability of Magna Herbicide would provide farmers another option to manage both grasses and broadleaf weeds in glyphosate tolerant field corn. Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Magna Herbicide was compared to the formulation of the cited precedent product. It was concluded that differences in the formulations were unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Value information from field research trials conducted in Ontario in 2016 was also submitted for review. The trial information corroborated the conclusion from the formulation comparison.

Based on the weight of evidence, the agronomic equivalence between Magna Herbicide and the cited precedent product can be established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Magna Herbicide label.

Conclusion

The PMRA has reviewed the information provided to support the registration of Magna Herbicide. Based on the results of this review, Magna Herbicide is acceptable for registration.

References

2865305	2018, Weed management in corn with Sharda herbicides applied poste-mergence I (Confidential), DACO: 10.2.3.3.
2865306	2018, Efficacy: Small-scale trials (field, greenhouse), DACO: 10.2.3.3, CBI.
2865324	2018, Efficacy, phytotoxicity and yield for Sharda CropChem Ltd. generic herbicides in field corn, DACO: 10.2.3.3.
2865298	2017, ENFORCEMENT ANALYTICAL METHOD, DACO: 3.4.1,3.4.2 CBI

2865304	2018, DACO 3 Extras - Magna Herbicide (Parent), DACO:
	3.1.1,3.1.2,3.1.3,3.1.4,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5,3.5.8
2865307	2018, DESCRIPTION OF STARTING MATERIALS, DACO: 3.2.1,3.2.2, 3.2.3,3.3.1
	CBI
2865311	2017, ENFORCEMENT ANALYTICAL METHOD, DACO: 3.4.1,3.4.2 CBI
2865312	2017, PH, DACO: 3.4.2,3.5.1,3.5.10,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7 CBI
2865313	2017, CORROSION CHARACTERISTICS, DACO: 3.5.10,3.5.14 CBI
2865636	2018, Glyphosate acid 25.0% + Mesotrione 2.5% + S-Metolachlor 25.0% SC:
	Determination of the Oxidizing Properties and Explosive Properties, DACO: 3.5.12,3.5.8
	Determination of the Oxidizing Properties and Explosive Properties, Direct. 5.5.12,5.5.

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