



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2025-0530
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Applicant: Rainbow CropSciences Inc.
Product: Rainbow Glyphosate 540 SL
Registration Number: 36033
Active ingredient (a.i.): Glyphosate (present as potassium salt)
PMRA Document Number: 3824786

Purpose of Application

The purpose of this application was to register the end-use product, Rainbow Glyphosate 540 SL, based on a registered precedent product.

Chemistry Assessment

Rainbow Glyphosate 540 SL is formulated as a solution containing glyphosate present as potassium salt at a concentration of 540 g/L. This end-use product has a density of 1.37 g/mL and pH of 4.8 (1% aqueous solution). The required chemistry data for Rainbow Glyphosate 540 SL have been provided, reviewed, and found to be acceptable.

Health Assessments

Rainbow Glyphosate 540 SL is considered to be toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Rainbow Glyphosate 540 SL is considered to be of low acute toxicity via the oral and dermal routes of exposure and of slight acute toxicity via the inhalation route of exposure. It is considered to be mildly irritating to the eyes and skin and is not considered to be a potential skin sensitizer.

The use pattern of Rainbow Glyphosate 540 SL is comparable to the registered use pattern of the precedent product. Therefore, potential exposures for mixers, loaders, applicators, bystanders, postapplication workers and adults, youth and children entering treated residential settings, are not expected to exceed the current exposures to the registered products of glyphosate. No health risks of concern are expected for workers, bystanders, adults, youth, and children when label directions, precautions, and restrictions are followed.

No new residue data for glyphosate (present as potassium salt) were submitted or were required to support the registration of Rainbow Glyphosate 540 SL. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Rainbow Glyphosate 540 SL label, including the target crops, methods (ground and aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of glyphosate (present as potassium salt) is not expected to increase with the registration of Rainbow Glyphosate 540 SL and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The use of Rainbow Glyphosate 540 SL is within the currently registered use pattern for glyphosate (present as potassium salt). The product formulation was reviewed and no environmental issues were identified. Therefore, the environmental risk is acceptable when Rainbow Glyphosate 540 SL is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Rainbow Glyphosate 540 SL was compared to the formulation of the precedent product. The differences between the formulations are unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Rainbow Glyphosate 540 SL label.

Conclusion

Health Canada has completed an assessment of the information provided, and has found the information acceptable to support the registration of Rainbow Glyphosate 540 SL.

References

PMRA

Document

Number

Reference

3684384	2025, Rainbow Glyphosate 540 SL - Physical and Chemical Properties and Waiver Requests, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.11,3.5.12, 3.5.13,3.5.15,3.5.4,3.5.5
3684386	2024, Glyphosate 540G/L SL: Determination of the Physico-chemical Properties, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3684387	2024, Glyphosate 540G/L SL: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
3684388	2024, Glyphosate 540G/L SL: Validation of the Analytical Method for the Determination of Active Ingredient Content, DACO: 3.4.1 CBI
3684389	2024, Manufacture Process of Glyphosate 540G/L SL (Present as Potassium Salt 662G/L), DACO: 3.2.1,3.2.2 CBI

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