Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-7111
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Applicant: AGX Pioneer Enterprise Limited
Product: VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution
Registration Number: 35665
Active ingredient (a.i.): Glyphosate (present as potassium salt)
PMRA Document Number: 3675156

Purpose of Application

The purpose of this application was to register the end-use product, VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution, based on registered precedent products.

Chemistry Assessment

VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution 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 a pH of 4.68. The required chemistry data for VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution have been provided, reviewed and found to be acceptable.

Health Assessments

VANGUARD GLYPHOSATE 540 Liquid Herbicide solution is considered toxicologically equivalent to a precedent product; therefore, no toxicology data were required. VANGUARD GLYPHOSATE 540 Liquid Herbicide solution 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 to be considered mildly irritating to the eyes and skin and is not considered a potential skin sensitizer.

The use pattern of VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution is comparable to the registered use pattern of the precedent products.

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.

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No new residue data for glyphosate were submitted or were required to support the registration of VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution label, including the target crops, methods (ground and aerial), rates and timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the labels of the precedent end-use products.

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 is not expected to increase with the registration of VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution 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 VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution for non-selective weed control is within the currently registered use pattern for glyphosate. Therefore, the risk is acceptable when VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution 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 VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution was compared to the formulation of a precedent product. The differences between the formulations were considered minor, and are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, use claims found on the precedent product labels are supported for inclusion on the VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of VANGUARD GLYPHOSATE 540 Liquid Herbicide Solution.

References

PMRA Document Number	Reference
3535768	2023, Manufacturing process, DACO: 3.2.2 CBI
3535769	2023, discussion of the formation of impurities of toxicological concern, DACO: 3.2.3
3535770	2023, Enforcement analytical method, DACO: 3.4.1
3535772	2023, Color, physical state and odor, DACO: 3.5.1,3.5.2,3.5.3
3535774	2023, Container material and description, DACO: 3.5.5
3535775	2023, Density, DACO: 3.5.6
3535776	2023, pH, DACO: 3.5.7
3535777	2023, Oxidizing or reducing action, DACO: 3.5.8
3535778	2023, Viscosity, DACO: 3.5.9
3535779	2023, Storage stability data, DACO: 3.5.10
3535780	2023, Flash point, DACO: 3.5.11
3535782	2023, Miscibility, DACO: 3.5.13

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