

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-5893

Application: Submissions Subject to Protection of Proprietary Interests in

Pesticide Data Policy-Equivalency/Data Compensation Assessment

Product: Gallop **Registration Number:** 34489

Active ingredient (a.i.): Glyphosate, present as isopropylamine and postassium salt

PMRA Document Number: 3310591

Purpose of Application

The purpose of this application was to register Gallop, a new herbicide end-use product to control non-selective weeds in a variety of crops and sites, based on a precedent product.

Chemistry Assessment

Gallop is formulated as a solution containing glyphosate, present as isopropylamine and potassium salt at a concentration of 540 g/L. This end-use product has a density of 1.2342 g/mL and pH of 4.52 (1% solution). The required chemistry data have been provided, reviewed and found to be acceptable.

Health Assessments

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

The use pattern of Gallop is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers, as well as to adults and children entering treated sites, is not expected to exceed the current exposure to the registered product of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for glyphosate were submitted or are required to support the registration of Gallop. Previously reviewed residue data were re-assessed in the framework of this application.



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

Residues are not expected to be greater than that for 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 Gallop and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Gallop is within the registered use pattern of glyphosate, present as isopropylamine and potassium salt, therefore, no additional risk is expected from the use of Gallop. The label includes all the required environmental precautions and directions for use statements, as well as spray buffer zones information, which adequately mitigate risks to the environment.

Risk from use of Gallop is acceptable from an environmental perspective when used according to label directions.

Value Assessment

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

The formulation of Gallop was compared to the formulations of the cited precedent product. The differences between the formulations were considered acceptable and unlikely to result in any significant impact on product performance, in terms of efficacy and crop tolerance. All uses and claims found on the precedent product label are supported for inclusion on the Gallop label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Gallop.

References

PMRA	Reference
Document No.	
3056994	2019, Additional Product Chemistry for Sharda G54 IPA, DACO: 3.1.1, 3.1.3,
	3.1.4, 3.5.12, 3.5.13, 3.5.15, 3.5.4, 3.5.5, 3.5.8
3056999	2017, Validation of Analytical Method for Determination of Active Ingredient
	Content of Glyphosate 54% SL, DACO: 3.4.1
3057000	2017, Stability of Glyphosate 54% SL at 0 C, DACO: 3.5.10
3057001	2018, Accelerated Storage Stability and Corrosion Characteristics of
	Glyphosate 54% SL, DACO: 3.5.10, 3.5.14
3057002	2017, Flash Point of Glyphosate 54% SL, DACO: 3.5.11
3057003	2017, Auto-Ignition of Glyphosate 54% SL, DACO: 3.5.11
3057004	2017, Appearance (Colour, Physical State and Odour) of Glyphosate 54% SL,
	DACO: 3.5.1, 3.5.2, 3.5.3
3057005	2017, Specific Gravity of Glyphosate 54% SL, DACO: 3.5.6
3057006	2017, Relative Density of Glyphosate 54% SL, DACO: 3.5.6
3057007	2017, pH of Glyphosate 54% SL, DACO: 3.5.7
3057008	2018, Oxidizing Properties of Glyphosate 54% SL, DACO: 3.5.8
3057009	2017, Viscosity of Glyphosate 54% SL, DACO: 3.5.9
3182374	2020, Formulation Process, DACO: 3.2.2 CBI

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