



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-3742
Application: Application subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) Policy-Equivalency/Data Compensation Assessment
Product: Glyphumax
Registration Number: 35175
Active ingredient (a.i.): Glyphosate (present as potassium salt)
PMRA Document Number (English PDF): 3524401

Purpose of Application

The purpose of this application was to register Glyphumax, a commercial class end-use product, based on a registered precedent product.

Chemistry Assessment

Glyphumax 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 1.3721 g/mL and a pH of 5.31. The required chemistry data for Glyphumax have been provided, reviewed and found to be acceptable.

Health Assessments

Glyphumax is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Glyphumax 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. It is considered mildly irritating to the eyes and skin, and it is not considered a dermal sensitizer.

The use pattern of Glufumax is comparable to the registered use pattern of the precedent product. *Therefore, potential exposure for mixers, loaders, applicators, bystanders and post-application workers is not expected to exceed the current exposure to the registered products of glyphosate. 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 were required to support the registration of Glyphumax. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Glyphumax label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, and feeding 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 are not expected to

increase with the registration of Glyfumax and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

After a scientific review of the available information, the PMRA has concluded that the environmental risks associated with the use of Glyfumax are acceptable when used according to the label directions.

Value Assessment

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

The formulation of Glyfumax was compared to the formulation of the 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, all uses and claims found on the precedent product label are supported for inclusion on the Glyfumax 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 Glyfumax.

References

PMRA

Document

Number	Reference
3376860	2016, Validation of Analytical Method for Determination of Active Ingredient Content of Glyphosate Potassium 660 g/L SL, DACO: 2.14.13,3.4.1 CBI
3376861	2016, Accelerated Storage Stability and Corrosion Characteristics of Glyphosate Potassium 660 g/L SL, DACO: 2.14.13,3.4.1,3.5.1,3.5.14,3.5.2,3.5.3,3.5.7 CBI
3376862	2016, Specific Gravity of Glyphosate Potassium 660 g/L SL, DACO: 3.5.6
3376864	2021, Applicants Name and Office Address, Formulating Plants Name and Office Address and Product Identity, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13, 3.5.15,3.5.5
3376869	2016, Viscosity of Glyphosate Potassium 660 g/L SL, DACO: 3.5.9
3394724	2022, Manufacturing Process of Glyphosate Acid 540g/L SL, DACO: 3.2.1,3.2.2 CBI
3503137	2023, Deficiency Response, DACO: 3.4.1 CBI

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written

permission of Health Canada, Ottawa, Ontario K1A 0K9.