

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2021-3118

Application: New End-Use Product (Product Chemistry) – Guarantee, Identity

of Formulants and Proportion of Formulants

Product: Bioprotec Herbicide Ready to Use

Registration Number: 34766

Active ingredients (a.i.): Citric acid and lactic acid

PMRA Document Number: 3428044

Purpose of Application

The purpose of this application was to register a domestic end-use product, Bioprotec Herbicide Ready to Use, for use on turf to partially suppress bird's foot trefoil, black medick, wood sorrel, red clover and white clover.

Chemistry Assessment

Bioprotec Herbicide Ready to Use is formulated as a solution containing citric acid at a concentration of 0.47% and lactic acid at a concentration of 0.42%. This end-use product has a density of 1.01-1.02 g/mL and pH of 3.2-3.6. The required chemistry data for Bioprotec Herbicide Ready to Use have been provided, reviewed and found to be acceptable.

Health Assessments

A detailed review of the toxicological database was conducted for Bioprotec Herbicide Ready to Use. Previously reviewed toxicological data for citric acid and lactic acid were considered acceptable to characterize the hazard profile of Bioprotec Herbicide Ready to Use.

Citric acid and lactic acid are of low acute toxicity, however, both lactic and citric acid are slightly irritating to the skin, and eye irritation studies indicated that, at the concentrations found in Bioprotec Herbicide Ready to Use, citric and lactic acid are capable of producing moderate to severe injury to the eye, particularly with repeated or prolonged exposure. Appropriate label statements and requirements for basic personal protective equipment will minimize exposure for individuals with repeated or prolonged exposure.

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, however, the risk is acceptable provided workers follow label directions and use personal protective equipment (PPE) as instructed.



Label warnings, directions for use, and risk mitigation measures are adequate to protect users of Bioprotec Herbicide Ready to Use. Overall, risks to domestic users are acceptable when the precautionary statements on the labels are followed which include PPE.

Residential and non-occupational exposure to Bioprotec Herbicide Ready to Use is expected to be low when label directions are observed. Consequently, the risk to bystanders and individuals in residential areas and the general public is acceptable.

Residues of citric acid and lactic acid on treated food crops are possible at the time of harvest. Dietary risk to humans from the use of Bioprotec Herbicide Ready to Use is acceptable due to the low toxicity profile of citric acid and lactic acid. In addition, the likelihood of residues contaminating drinking water supplies is minimal and not expected to contribute to increased dietary exposure. The levels of citric acid and lactic acid that would result on food crops from the use of Bioprotec Herbicide Ready to Use are expected to be much lower than levels already consumed in the Canadian diet from other sources. Therefore, the specification of a maximum residue limit (MRL) under the *Pest Control Products Act* is not required for citric acid and lactic acid.

Environmental Assessment

The registration of Bioprotec Herbicide Ready to Use for use as a herbicide on turf does not pose any additional risk to the environment when used according to label directions.

Value Assessment

The formulation of Bioprotec Herbicide Ready-to-Use was compared to the registered formulation of a precedent product and the differences between the formulations were considered minor and are unlikely to result in any significant impact on product performance. In addition, the applicant provided data from one greenhouse trial and one field trial in which the efficacy of Bioprotec Herbicide Ready-to-Use was comparable to that of the precedent product. The biological equivalence between products can be established and all uses and claims found on the precedent product label are supported for inclusion on the Bioprotec Herbicide Ready-to-Use label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register Bioprotec Herbicide Ready to Use.

References

PMRA Document Number	Reference
3248906	2021, Description of Starting Materials, DACOs 3.2.1 to 3.2.3, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
3248908	2021, DACO 3.4.1 - 3 Enforcement Analytical Method, DACO: 3.4,3.4.1 CBI
3248910	2021, DACO 3.4.2 Analysis of [CBI Removed], DACO: 3.4,3.4.2 CBI
3248911	2021, Chemical and Physical Properties of the technical grade active ingredient, DACOs 3.5.1 to 3.5.15, DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.13, 3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3248915	2021, Storage stability report, DACO: 3.5,3.5.10 CBI
3248933	2021, Manufacturing process, DACO: 3.2.2 CBI
3248934	2021, [CBI Removed] methods, DACO: 3.4,3.4.2 CBI
3248935	2021, Protocole de dosage d'acide lactique et d'acide citrique par spectrophotometrie, DACO: 3.4,3.4.1 CBI
3264850	2021, Amended DACO 3.5.5, DACO: 3.5.5 CBI
3375026	2022, Storage stability, DACO: 3.5.10 CBI
3248931	2021, Data part 4 Toxicology - Human health, DACO: 4.1,4.2,4.2.1,4.2.2, 4.2.3,4.2.4,4.2.5,4.2.6
3248930	2021, DACO 5.2 Use description, DACO: 5.2 CBI
3248892	2021, DACO 10.1 Value Summaries, DACO: 10.1
3248929	2021, Experience : avril-mai 2019, DACO: 10.2.3.3

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