

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

Application Number: 2012-2991
Application: New end-use product chemistry – guarantee, identity and proportion of formulants
Product: Bioprotec Lawn Herbicide Ready to Use
Registration Number: 30883
Active ingredients (a.i.): Citric acid and lactic acid
PMRA Document Number: 2252342

Purpose of Application

The purpose of this application was to register a new domestic end-use product, Bioprotec Lawn Herbicide Ready to Use, for control of bird's-foot trefoil, black medick, wood sorrel, red clover, and white clover in established lawns. Bioprotec Lawn Herbicide Ready to Use contains the active ingredients citric acid (guarantee 4.24 g/L) and lactic acid (guarantee 4.75 g/L), which are present as fermentation products of the microbial pest control agents *Lactobacillus rhamnosus* strain LPT-21, *Lactobacillus casei* strain LPT-111, *Lactococcus lactis* ssp. *cremoris* strain M11/CSL, *Lactococcus lactis* ssp. *lactis* strain LL64/CSL, and *Lactococcus lactis* ssp. *lactis* strain LL102/CSL.

Bioprotec Lawn Herbicide Concentrate has been supported for registration under application number 2012-2988. Bioprotec Lawn Herbicide Concentrate is applied as a dilution, in a proportion of 28% product to 72% water. Bioprotec Lawn Herbicide Ready to Use is a pre-mixture of 28% Bioprotec Lawn Herbicide Concentrate with 72% water. As such, the data submitted under application 2012-2988 was also used to support application 2012-2991.

In addition, Bioprotec Lawn Herbicide Concentrate is based on the precedent commercial end-use product Kona (Registration number 29603). Bioprotec Lawn Herbicide Concentrate is similar to Kona with the difference being that the adjuvants are formulated into Bioprotec Lawn Herbicide Concentrate, whereas, Kona must be tank-mixed with an adjuvant.

Chemistry Assessment

Bioprotec Lawn Herbicide Ready to Use contains the active ingredients lactic acid and citric acid (present as fermentation products of *Lactobacillus casei* strain LPT-111, *Lb. rhamnosus* strain LPT-21, *Lactococcus lactis* ssp. *lactis* strain LL64/CSL, *Lc. lactis* ssp. *lactis* strain LL102/CSL, and *Lc. lactis* ssp. *cremoris* strain M11/CSL) at 4.24 and 4.75 g/L respectively. The product characterization and analysis database is complete with the condition that confirmatory microbial contamination and potency estimation analysis data; and confirmatory storage stability data are submitted once available.

Health Assessments

The toxicological database from the end-use product Kona was cross-referenced in support of the registration of the new end-use product, Bioprotec Lawn Herbicide Ready to Use. Based on these data, Bioprotec Lawn Herbicide Ready to Use is expected to have low toxicity and to be irritating to the skin and eyes. No further data are required since the corresponding database for Kona, is complete and the formulation ingredients contained in Bioprotec Lawn Herbicide Ready to Use are not of toxicological concern.

Bioprotec Lawn Herbicide Ready to Use is for a domestic use, however, the application rate and methods are the same as currently registered for the commercial use product, Kona. Although personal protective equipment are not required for the domestic use, no additional risks to human health and safety are anticipated since the potential and frequency for exposure is considerably lower for the domestic product. Standard precautionary and first aid statements on the label are sufficient to cover any health risks from occupational and bystander exposure routes that may arise from the use of this new end-use product. The human health and safety database for Bioprotec Lawn Herbicide Ready to Use is complete.

Environmental Assessment

The use pattern for Bioprotec Lawn Herbicide Ready to Use is consistent with the use pattern of the registered end-use product, Kona.

Based on a review of the existing database for these active ingredients, no additional risks to the environment are anticipated from the use of Bioprotec Lawn Herbicide Ready to Use; and the standard precautionary statements on the label are sufficient to cover any environmental risks arising from the use of this new product. The environmental database for Bioprotec Lawn Herbicide Ready to Use is complete.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website www.healthcanada.gc.ca/pesticideincident. As of March 1, 2013, there were no incidents related to health or the environment reported in the PMRA Incident reporting database or the California Department of Pesticide regulation (CalDPR) for products containing *Lactobacillus casei* strain LPT-111, *Lb. rhamnosus* strain LPT-21, *Lactococcus lactis* spp. *lactis* strain LL64/CSL, *Lc. lactis* spp. *lactis* strain LL102/CSL, and *Lc. lactis* spp. *cremoris* strain M11/CSL, citric acid, or lactic acid for use as pesticides since June 1, 2011, the date of the previous incident report assessment for these active ingredients. In addition, there were no environmental incidents reported in the US EPA's Ecological Incident Information System (EIIS) for products containing the ingredients listed above for use as pesticides since June 1, 2011.

Value Assessment

Since Bioprotec Lawn Herbicide Ready to Use is a pre-mixture of 28% Bioprotec Lawn Herbicide Concentrate with 72% water, information submitted in support of the registration of Bioprotec Lawn Herbicide Concentrate under application number 2012-2988 is applicable to Bioprotec Lawn Herbicide Ready to Use.

The availability of Bioprotec Lawn Herbicide Ready to Use will offer an additional weed management tool for domestic use on turf grass.

Conclusion

The PMRA has completed an assessment of available information for Bioprotec Lawn Herbicide Ready to Use and has found the information sufficient to support full registration with the condition that confirmatory data are submitted to complete the chemistry data package.

References

PMRA Document Number	Reference
2214587	2010, Field study report - BLHRTU 13. DACO M10.2.2.
2214588	2010, Field study report - BLHRTU 14. DACO M10.2.2.
2214589	2010, Field study report - BLHRTU 15. DACO M10.2.2.
2214604	2012, Product characterization and analysis M 2.1, DACO: M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 CBI
2214605	2012, Active ingredient or MPCA, DACO: M2.10.1 CBI
2214606	2012, Five batches analysis, DACO: M2.10.1 CBI
2214607	2012, Analysis for microbial contaminants, DACO: M2.10.2 CBI
2214608	2012, Five batches analysis, DACO: M2.10.2 CBI
2214609	2012, Analysis for other unintentional ingredients, DACO: M2.10.3 CBI
2214610	2012, Storage stability testing, DACO: M2.11 CBI
2214611	2012, Summary of physical and chemical properties, DACO: M2.12 CBI
2214612	2012, Origin, derivation, and identification of MCPAs, DACO: M2.7.1 CBI
2214613	2007, <i>Lactobacillus rhamnosus</i> , DACO: M2.7.2 CBI
2214614	2012, Biological properties of the MCPA(s), DACO: M2.7.2 CBI
2214615	2002, Probiotic effects of <i>Lactobacillus rhamnosus</i> Rosell-11, DACO: M2.7.2 CBI
2214616	2007, <i>Lactobacillus casei</i> , DACO: M2.7.2 CBI
2214617	2012, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2214618	2002, Certificato oanalisi, DACO: M2.8 CBI
2214621	2002, DOM, DACO: M2.8 CBI
2214622	2012, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2214623	2012, Five batches analysis, DACO: M2.8 CBI
2214624	2012, Disclosure of ingredients, DACO: M2.9.1 CBI
2214625	2012, Potency estimation and product guarantee, DACO: M2.9.2 CBI
2214626	2005, Sucres et acides organiques avec HPLC dionex, DACO: M2.9.2 CBI
2214627	2012, Unintentional ingredients, DACO: M2.9.3 CBI
2286044	Clarification response
2214628	2012, Summary, DACO: M4.1
2214629	2012, Summary, DACO: M4.2.1
2214630	2012, Acute oral infect and toxicity, DACO: M4.2.2
2214631	2012, Summary, DACO: M4.3.1
2214632	2012, Acute dermal toxicity, DACO: M4.4
2214633	2012, Summary, DACO: M4.5.1
2214634	2012, Dermal irritation study, DACO: M4.5.2
2214635	2012, Reporting of hypersensitivity incidence, DACO: M4.6
2214636	2012, Other studies and data, DACO: M4.9
2214637	2012, Summary, DACO: M9.1
2214638	2012, Avian oral toxicity, DACO: M9.2.1
2214639	2012, Fresh water fish, DACO: M9.4.1
2214640	2012, Terrestrial arthropods, DACO: M9.5.1
2214641	2012, Aquatic arthropods, DACO: M9.5.2

2214642	2012, Non-Arthropods invertebrates, DACO: M9.6
2214643	2012, Terrestrial plants, DACO: M9.8.1
2214644	2012, Aquatic plants, DACO: M9.8.2

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