

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

Application Number: 2012-2988

Application: New end-use product chemistry – guarantee, identity and

proportion of formulants

Product: Bioprotec Lawn Herbicide Concentrate

Registration Number: 30881

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

PMRA Document Number: 2252282

Purpose of Application

The purpose of this application was to register a new domestic end-use product, Bioprotec Lawn Herbicide Concentrate, for control of bird's-foot trefoil, black medick, wood sorrel, red clover, and white clover in established lawns. Bioprotec Lawn Herbicide Concentrate contains the active ingredients citric acid (guarantee 17.13 g/L) and lactic acid (guarantee 19.14 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 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 Concentrate 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* spp. *lactis* strain LL64/CSL, *Lc. lactis* spp. *lactis* strain LL102/CSL, and *Lc. lactis* spp. *cremoris* strain M11/CSL) at 17.13 and 19.14 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 Concentrate. Based on these data, Bioprotec Lawn Herbicide Concentrate 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 Concentrate are not of toxicological concern.

Bioprotec Lawn Herbicide Concentrate is for 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 the new end-use product. The human health and safety database for Bioprotec Lawn Herbicide Concentrate is complete.

Environmental Assessment

The use pattern for Bioprotec Lawn Herbicide Concentrate 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 Concentrate; 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 Concentrate 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

Information submitted included efficacy data from three field trials conducted in Quebec in 2010. The efficacy of a 50% Bioprotec Lawn Herbicide Concentrate spray mixture was directly compared to that of a 50% Kona spray mixture for control of white clover. The level of white clover control provided by Bioprotec Lawn Herbicide Concentrate was comparable to that provided by Kona. Injury to turf grass was also assessed in these trials and it was concluded that the tolerance of lawn turf to Bioprotec Lawn Herbicide Concentrate was comparable to Kona. Therefore, it was concluded that Bioprotec Lawn Herbicide Concentrate is agronomically equivalent to Kona.

While Bioprotec Lawn Herbicide Concentrate was tested at a higher concentration than that which is labeled (28%), the efficacy of Bioprotec Lawn Herbicide Concentrate applied as a spot treatment is expected to be similar to that of Kona applied broadcast at a similar concentration of active ingredient and crop oil type adjuvants for control of the same weeds. Similarly, the degree of tolerance of lawn turf to spot applications of Bioprotec Lawn Herbicide Concentrate would be expected to be similar to that of Kona applied at the same concentration.

The availability of Bioprotec Lawn Herbicide Concentrate will offer an additional weed management tool for domestic use on turf grass. Bioprotec Lawn Herbicide Concentrate, which is formulated with crop oil type adjuvants, only requires mixing with water prior to application.

Conclusion

The PMRA has completed an assessment of available information for Bioprotec Lawn Herbicide Concentrate 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	Reference
Document	
Number	
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.
2214492	2012, Product characterization and analysis, DACO:
2214402	M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 CBI
2214493	2012, Active ingredient or MPCA, DACO: M2.10.1 CBI
2214494	2012, Five batches analysis, DACO: M2.10.1 CBI
2214495	2012, Analysis for microbial contaminants, DACO: M2.10.2 CBI
2214496	2012, Five batches analysis, DACO: M2.10.2 CBI
2214497	2012, Analysis for other unintentional ingredients, DACO: M2.10.3 CBI
2214498	2012, Storage stability testing, DACO: M2.11 CBI
2214499	2012, Summary of physical and chemical properties, DACO: M2.12 CBI
2214500	2012, Origin, derivation and identification of MPCAs, DACO: M2.7.1 CBI
2214501	2002, Probiotic Effects of <i>Lactobacillus rhamnosus</i> Rosell-11, DACO: M2.7.2 CBI
2214502	2007, Lactobacillus rhamnosus, DACO: M2.7.2 CBI
2214503	2007, Lactobacillus casei, DACO: M2.7.2 CBI
2214504	2012, Biological properties of the MCPA(s), DACO: M2.7.2 CBI
2214505	2012, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2214506	2002, DOM, DACO: M2.8 CBI
2214507	2002, Certificato danalisi, DACO: M2.8 CBI
2214508	2012, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2214509	2012, Five batches analysis, DACO: M2.8 CBI
2214510	2012, Product specifications, DACO: M2.9.1 CBI
2214511	2012, Potency estimation and product guarantee, DACO: M2.9.2 CBI
2214513	2005, Sucres et acides organiques avec HPLC dionex, DACO: M2.9.2 CBI
2286044	Clarification response
2214516	2012, Summary, DACO: M4.1
2214518	2012, Summary, DACO: M4.2.1
2214519	2012, Acute oral infect and toxicity, DACO: M4.2.2
2214520	2012, Summary, DACO: M4.3.1
2214521	2012, Acute dermal toxicity, DACO: M4.4
2214522	2012, Summary, DACO: M4.5.1
2214523	2012, Dermal irritation study, DACO: M4.5.2
2214524	2012, Reporting of hypersensitivity incidence, DACO: M4.6
2214525	2012, Other studies and data, DACO: M4.9
2214526	2012, Summary, DACO: M9.1
2214527	2012, Avian oral toxicity, DACO: M9.2.1
2214528	2012, Fresh water fish, DACO: M9.4.1
2214529	2012, Terrestrial arthropods, DACO: M9.5.1
2214530	2012, Aquatic arthropods, DACO: M9.5.2
2214531	2012, Non-Arthropods invertebrates, DACO: M9.6

2214532	2012, Terrestrial plants, DACO: M9.8.1
2214533	2012, Aquatic plants, DACO: M9.8.2

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