

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

Application Number: 2012-2959
Application: Changes to Product Guarantee and Changes to Identity and Proportion of Formulants
Product: Bioprotec Fungicide Roses Ready to Use
Registration Number: 30905
Active ingredients (a.i.): Citric acid [CIA] and Lactic acid [LCT]
PMRA Document Number: 2290845

Background

The domestic class fungicide, Bioprotec Fungicide Roses Ready to Use, has the same use pattern as Existens Fungicide and Bactericide Rose and Vegetable (Registration Number 30109). The end-use product (EP) contains the registered Technical Grade Active Ingredient (TGAI), *Lactobacillus casei* Technical (Registration Number 29599). The active ingredients in the EP are lactic acid and citric acid that are produced by the TGAI.

Purpose of Application

The purpose of this application was to register a new domestic ready-to-use formulation for the suppression of powdery mildew and black spot on roses. The application was based on the precedent products, Existens Fungicide and Bactericide Rose and Vegetable (Registration Number 30109) and Bioprotec Fungicide and Bactericide Tomato and Vegetable Garden (Registration Number 30457).

A concurrent application for a similar product, Bioprotec Fungicide and Bactericide Tomato and Vegetable Garden Ready to Use (Registration Number 30906), was reviewed at the same time.

Chemistry Assessment

Bioprotec Fungicide Roses Ready to Use contains the active ingredients lactic acid and citric acid (present as fermentation products of *Lactobacillus casei* strain LPT-111) at 0.53 and 0.27 g/L respectively. The product characterization and analysis database is complete with the provision 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 (EP) Existens Fungicide and Bactericide Rose and Vegetable (Registration Number 30109) was cross-referenced in support of the registration of the EP, Bioprotec Fungicide Roses Ready to Use. Based on this data the EP is expected to have low toxicity and to be irritating to the skin and eyes. No further data are required for this EP since the corresponding database for Existens Fungicide and Bactericide Rose and Vegetable is complete and the formulation ingredients are not of toxicological concern.

Since the use pattern is the same as an existing registered EP, no additional risks to human health and safety are anticipated from the use of Bioprotec Fungicide Roses Ready to Use. Standard precautionary and first aid statements on the labels are sufficient to cover any health risks from occupational, bystander, and dietary exposure routes that may arise from the use of the EP. The human health and safety database for Bioprotec Fungicide Roses Ready to Use is complete.

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, citric acid, or lactic acid for use as pesticides since May 18, 2011, the date of the previous incident report assessment for these active ingredients.

Environmental Assessment

The use pattern for the EP is consistent with the use pattern of the registered EP, Existens Fungicide and Bactericide Rose and Vegetable (Registration Number 30109).

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 environmental incidents reported in the PMRA Incident reporting database nor in the US EPA's Ecological Incident Information System (EIIS) for products containing *Lactobacillus casei* strain LPT-111, citric acid, or lactic acid for use as pesticides since May 20, 2011, the date of the previous incident report assessment for these active ingredients.

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 Fungicide Roses Ready to Use. The standard precautionary statements on the labels are sufficient to cover any environmental risks arising from the use of Bioprotec Fungicide Roses Ready to Use.

Value Assessment

The applicant provided data submitted previously for a precedent product containing the same active ingredients. The precedent product is registered for suppression of black spot and powdery mildew on rose at rates of 1.5 – 2.5% dilution applied to runoff. Bioprotec Fungicide Roses Ready to Use requires no dilution. The rate of application is equivalent to the 2.5% dilution rate of the precedent product. The ready to use formulation is intended for use in outdoor gardens, greenhouses, and on indoor plants and landscapes.

A total of two trials were submitted to support the claims of suppression of black spot (1) and powdery mildew (1) on rose. The submitted trials have been reviewed previously; the claims were supported at rates of 1.5 – 2.5% dilution sprayed to runoff. The applicant justified the use of the 2.5% dilution rate in a rationale. Application of the higher rate is justifiable to address higher disease pressures. The rate of application for the ready to use formulation is supported. The claims of suppression of black spot and powdery mildew on rose are supported based on the previous review of data.

Bioprotec Fungicide Roses Ready to Use is intended for domestic use; all constituents are natural and food grade. Both citric and lactic acids have low toxicity and negligible risk. In addition, both citric and lactic acids are identified on the Organic Production Systems Permitted Substances List (CFIA). The registration of this product provides home gardeners with an option for disease suppression on roses. The ready to use formulation requires no mixing, eliminating the chance of over application of the pesticide when used by non-professional applicators.

Conclusion

The PMRA has determined it to be acceptable to register Bioprotec Fungicide Roses Ready to Use for the suppression of powdery mildew and black spot on roses.

References

PMRA

Number	Reference
2213683	2012, Product Characterization and Analysis, DACO: M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 CBI
2213684	2012, Active Ingredient or MPCA, DACO: M2.10.1 CBI
2213685	2012, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
2213686	2012, Analysis for Other Unintentional Ingredients, DACO: M2.10.3 CBI
2213687	2012, Storage Stability Testing, DACO: M2.11 CBI
2213688	2012, Summary of Physical and Chemical Properties, DACO: M2.12 CBI
2213689	2012, Origin, Derivation, and Identification of MCPAs, DACO: M2.7.1 CBI
2213690	2007, <i>Lactobacillus casei</i> , DACO: M2.7.2 CBI
2213691	2012, Biological properties of MPCA(S), DACO: M2.7.2 CBI
2213692	2010, E-mail, DACO: M2.7.2 CBI
2213693	2012, Characterization of MCPAs Derived Through Recombinant Nucleic Acid Technologies, DACO: M2.7.3 CBI
2213694	2012, Quality control results for five batches of Bioprotec Fungicide Roses Ready to Use, DACO: M2.8 CBI
2213695	2012, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2213696	2012, Manufacturing Methods and Quality Assurance, DACO: M2.8 CBI
2213697	2012, Potency Estimation and Product Guarantee, DACO: M2.9.2 CBI
2213698	2012, Unintentional Ingredients, DACO: M2.9.3 CBI
2213752	2012, Product Characterization and Analysis, DACO: M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 CBI
2213753	2012, Active Ingredient or MPCA, DACO: M2.10.1 CBI
2213754	2012, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
2213755	2012, Analysis for Other Unintentional Ingredients, DACO: M2.10.3 CBI
2213756	2012, Storage Stability Testing, DACO: M2.11 CBI
2213757	2012, Summary of Physical and Chemical Properties, DACO: M2.12 CBI
2213758	2012, Origin, Derivation, and Identification of MCPAs, DACO: M2.7.1 CBI
2213759	2010, E-mail, DACO: M2.7.2 CBI
2213760	2007, <i>Lactobacillus casei</i> , DACO: M2.7.2 CBI
2213761	2012, Biological properties of MPCA(S), DACO: M2.7.2 CBI
2213762	2012, Characterization of MCPAs Derived Through Recombinant Nucleic Acid Technologies, DACO: M2.7.3 CBI
2213763	2012, Manufacturing Methods and Quality Assurance, DACO: M2.8 CBI

2213764 2012, Manufacturing methods and quality assurance, DACO: M2.8
CBI

2213765 2012, Quality control results for five batches of Bioprotec Fungicide
Roses Ready to Use, DACO: M2.8 CBI

2213766 2012, Potency Estimation and Product Guarantee, DACO: M2.9.2
CBI

2213767 2012, Unintentional Ingredients, DACO: M2.9.3 CBI

2213769 2012, Summary, DACO: M4.1

2213770 2012, Summary, DACO: M4.2.1

2213771 2012, Acute Oran Infectivity and Toxicity, DACO: M4.2.2

2213772 2012, Acute pulmonary infectivity and toxicity, DACO: M4.2.3

2213773 2012, Summary, DACO: M4.3.1

2213775 2012, Infectivity, DACO: M4.3.2

2213777 2012, Acute dermal toxicity, DACO: M4.4

2213779 2012, Summary, DACO: M4.5.1

2213780 2012, Dermal irritation study, DACO: M4.5.2

2213781 2012, Reporting of hypersensitivity incidence, DACO: M4.6

2213782 2012, Other studies and data, DACO: M4.9

2213699 2012, Summary, DACO: M4.1

2213700 2012, Summary, DACO: M4.2.1

2213701 2012, Acute Oran Infectivity and Toxicity, DACO: M4.2.2

2213702 2012, Acute pulmonary infectivity and toxicity, DACO: M4.2.3

2213703 2012, Summary, DACO: M4.3.1

2213704 2012, Infectivity, DACO: M4.3.2

2213705 2012, Acute dermal toxicity, DACO: M4.4

2213706 2012, Summary, DACO: M4.5.1

2213707 2012, Dermal irritation study, DACO: M4.5.2

2213708 2012, Reporting of hypersensitivity incidence, DACO: M4.6

2213709 2012, Other studies and data, DACO: M4.9

2213783 2012, Summary, DACO: M9.1

2213784 2012, Avian oral toxicity, DACO: M9.2.1

2213785 2012, Fresh water fish, DACO: M9.4.1

2213786 2012, Terrestrial Arthropods, DACO: M9.5.1

2213787 2012, Aquatic arthropods, DACO: M9.5.2

2213788 2012, Non-Arthropods invertebrates, DACO: M9.6

2213789 2012, Microorganisms, DACO: M9.7

2213790 2012, Terrestrial Plants, DACO: M9.8.1

2213791 2012, Aquatic plants, DACO: M9.8.2

2213710 2012, Summary, DACO: M9.1

2213711 2012, Avian oral toxicity, DACO: M9.2.1

2213712 2012, Fresh water fish, DACO: M9.4.1

2213713 2012, Terrestrial Arthropods, DACO: M9.5.1

2213714 2012, Aquatic arthropods, DACO: M9.5.2

2213715 2012, Non-Arthropods invertebrates, DACO: M9.6

2213716 2012, Microorganisms, DACO: M9.7

2213717 2012, Terrestrial Plants, DACO: M9.8.1

2213719 2012, Aquatic plants, DACO: M9.8.2

2213677 2012, Summary, DACO: M10.1
2213678 2012, Field studies, DACO: M10.2.2
2213679 2009, Field studies, DACO: M10.2.2
2213680 2012, Phytotoxicity and phytopathogenicity, DACO: M10.3.1
2213681 2012, Effects on MPCA performance, DACO: M10.3.2.1
2213682 2012, Effects of the EP, DACO: M10.3.2.2

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