

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.11, 3.12 Application

Application Number: 2021-3117
Application: New End-Use Product (Product Chemistry) – Guarantee, Identity of Formulants and Proportion of Formulants, and New Product Label – New Pests and New Site or Host
Product: Bioprotec Garden and Ornamentals
Registration Number: 34765
Active ingredients (a.i.): Citric acid and lactic acid
PMRA Document Number: 3428662

Purpose of Application

The purpose of this application was to register a domestic end-use product, Bioprotec Garden and Ornamentals, for use against certain fungal or bacterial pathogens on fruit, vegetable and ornamental crops grown in the field and/or greenhouse.

Chemistry Assessment

Bioprotec Garden and Ornamentals is formulated as a solution containing citric acid at a concentration of 1.41% and lactic acid at a concentration of 2.54%. This end-use product has a density of 1.07 – 1.08 g/mL and pH of 3.2-3.6. The required chemistry data for Bioprotec Garden and Ornamentals have been provided, reviewed and found to be acceptable.

Health Assessments

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

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 Garden and Ornamentals, 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 Garden and Ornamentals. 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 Garden and Ornamentals 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 Garden and Ornamentals 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 Garden and Ornamentals 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 Garden and Ornamentals for use as a bactericide and fungicide on terrestrial food crops, greenhouse food and non-food crops, and outdoor ornamentals does not pose any additional risk to the environment when used according to label directions.

Value Assessment

The efficacy and crop safety of Bioprotec Garden and Ornamentals was compared to that of cited precedent products. Based on this comparison and a set of field bridging trials, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Additional field efficacy trials supported claims to suppress fire blight on apple and powdery mildew on grape. Therefore, the value of all claims registered on the precedent products as well as the claims on apple and grape is determined to be acceptable for Bioprotec Garden and Ornamentals.

The availability of Bioprotec Garden and Ornamentals will provide domestic users with an additional product to manage common fungal or bacterial diseases on grape, apple, roses, greenhouse and outdoor ornamentals including cut flowers and greenhouse and field-grown cucumbers, squashes and pumpkins.

Conclusion

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

References

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| 3248481 | 2021, DACO 3.4.1 - 3 Enforcement Analytical Method, DACO: 3.4,3.4.1 CBI |
| 3248483 | 2021, DACO 3.4.2 Analysis of [CBI Removed], DACO: 3.4,3.4.2 CBI |
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