

Evaluation Report for Category B, Subcategories 2.3, 2.4, 2.5 Application

Application Number: 2021-5851
Application: Changes to End-use Product (Product Chemistry)-Identity and Proportion of Formulants, and Formulation Type
Product: Botanigard ES
Registration Number: 29320
Active ingredient (a.i.): *Beauveria bassiana* strain GHA
PMRA Document Number: 3577915

Purpose of Application

The purpose of this application was to amend the registered formulation for Botanigard ES.

Product Characterization and Analysis

The data provided was acceptable to support the new formulation of Botanigard ES. Data from a sufficient number of acceptable batches were provided to support the new product guarantee for the new formulation of Botanigard ES.

Health Assessments

No new data on *Beauveria bassiana* strain GHA were submitted in support of the new formulation for Botanigard ES. In previous reviews, *Beauveria bassiana* strain GHA in Botanigard ES, was found to be of low toxicity and was not infective when administered via the oral, pulmonary (instillation) and intraperitoneal routes, but was considered to be a mild ocular irritant. Botanigard ES was found to be of low toxicity by the oral route and to be a mild skin irritant and moderate ocular irritant. The new formulants are not expected to impact the toxicity profile via the oral, dermal or ocular routes. As is the case for all microorganisms, *Beauveria bassiana* strain GHA was considered to be a potential sensitizer.

Botanigard ES is currently registered for use on ornamentals, vegetables, herbs, strawberries and wasabi produced in greenhouses, as well as on cannabis that is produced commercially indoors, for the control of whiteflies, aphids and thrips. Botanigard ES is applied using spray equipment at rates ranging from 0.5-2L/400L spray volume.

The new formulation does not present an increased dietary or occupational risk. As the use site (greenhouse), rate, method, interval and timing of application remains the same as the current registered uses of Botanigard ES on food crops, an occupational exposure assessment was not required. The risks from occupational and dietary exposures associated with the new formulation of Botanigard ES are acceptable.

The available information is sufficient to support the labeled use of the new formulation of Botanigard ES on the currently registered ornamental and greenhouse food crops.

For the new formulation of Botanigard ES, the potential consumer exposure to residues remaining on treated cannabis or the pyrolysis by-products of these residues in smoke or vapour was assessed. Foliar application of Botanigard ES must be limited to the vegetative stage of growth of cannabis plants; this includes plants grown for propagation.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* (PCPA) for the purposes of the adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Residues of *Beauveria bassiana* strain GHA on treated food crops are possible at the time of harvest. Dietary risk to humans from use of the new formulation of Botanigard ES is acceptable due to the low toxicity profile of *Beauveria bassiana* strain GHA and Botanigard ES, and as the level of *beauvericin* on treated food commodities is expected to be negligible. In addition, the likelihood of residues contaminating drinking water supplies is negligible to non-existent.

Therefore, the PMRA has determined that specification of an MRL under the *Pest Control Products Act* is not required for *Beauveria bassiana* strain GHA.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The new formulation of Botanigard ES was supported by a scientific rationale that compared it to the earlier formulation of Botanigard ES and demonstrated that similar performance can be expected when applied following the same use pattern.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the amendment of the registered formulation of Botanigard ES.

References

| PMRA Document Number | Reference |
|-----------------------------|---|
| 3339690 | 2022, Rationale To Support Bridging Of Data For Botanigard ES, DACO: M10.5 CBI |
| 3408080 | 2022, Three Lot Analysis of Two Formulations of a WP product, BotaniGard 22WP and Three Lot Analysis of One Formulation of an ES product, BotaniGard ES, DACO: M2.9.2 CBI |
| 3510484 | 2023, Use Description/Scenario (Application and Post Application) for Application of Botanigard ES on Cannabis, DACO: 5.2 |
| 3510486 | 2023, Residues on Cannabis following Applications of Botanigard ES, DACO: 7.4.1 |
| 3510487 | 2023, Botanigard ES: Request for a Waiver from the Requirements for Pyrolysis Testing, DACO: 7.8 CBI |

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