

Evaluation Report for Category B, Subcategory 1.1, 3.12, 3.13 Application

Application Number: 2021-5506
Application: Changes to Product Chemistry – New Source (site) same registrant,
Changes to Product Labels – New Site or Host and Precautions
Product: BioTitan GR
Registration Number: 33924
Active ingredient (a.i.): *Beauveria bassiana* strain ANT-03
PMRA Document Number : 3383442

Purpose of Application

The purpose of this application was to register new formulating sites, add a use on vineyard turf to control chinch bug and larvae of European chafer and Japanese beetle, and to amend the precautionary statements on the product label for BioTitan GR.

Product Characterization and Analysis

The data provided is acceptable to support new formulating sites. Data from a sufficient number of batches were provided to support the product guarantee and confirms that beauvericin is at an acceptable level in BioTitan GR.

Human Health and Safety Testing

An acute inhalation toxicity study with a wettable powder formulation containing the MPCA was submitted. The study was determined to be unacceptable as it did not meet the guideline requirement for particle size of the aerosolized test substance and because the test material contained formulation ingredients. Therefore, there is no change to the toxicological profile or hazard labelling of BioTitan GR.

Environmental Fate and Toxicity Testing

The use of BioTitan GR on vineyard turf will not result in an increased risk to the environment when label directions are followed.

Value Assessment

To support a claim to reduce the number of chinch bug and the larvae of European chafer and Japanese beetle in vineyard turf, value information consisting of one field efficacy trial and a scientific rationale to extrapolate from registered uses on turf was submitted. The submitted value information is sufficient to support a claim that BioTitan GR will reduce the number of larvae of European chafer, Japanese beetle, and chinch bug at a rate of 20g/m² on turf in vineyards.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to amend the registration of new formulating sites and the use on vineyard turf for BioTitan GR. However, the amendments to the precautionary statements on the product label were not supported.

References

PMRA Document Number	References
3276670	2021, Analysis for Microbial Contaminants, DACO: M2.10.2
3276671	2021, Total bacteria, yeasts and molds count in technical grade of Beauveria bassiana DACO: M2.10.2 CBI
3361857	2021, analysis for microbial contaminants, DACO: M2.10.2
3361858	2022, analysis for other unintentional ingredients, DACO: M2.10.3 CBI
3361859	2022, limit of beauvericin on mix cereals, DACO: M2.10.3 CBI
3361860	2022, statement method validation mixed cereals DACO: M2.10.3 CBI
3361856	2022, name and address for formulating plant, DACO: M2.3
3276664	2021, Manufacturing methods and quality assurance, DACO: M2.8
3276665	2021, Supplemental Manufacturing Process Description for Bioceres GR (Beauveria bassiana strain ANT-03), DACO: M2.8 CBI
3276667	2021, Potency Estimation and product guarantee, DACO M2.9.2
3276668	2021, Germination assessment of Beauveria bassiana conidia DACO: M2.9.2 CBI
3276669	2021, Conidia concentration of Beauveria bassiana, DACO: M2.9.2 CBI
3276672	2021, acute inhalation toxicity, DACO: M4.9
3276673	2021, Bioceres WP Acute Inhalation Toxicity in Rats, DACO: M4.9
3020276	2015, Efficacy of Bioceres-GR against chafer white grubs on turfgrass, DACO: M10.2.2
3276677	2021, Part M10.1: Value (including efficacy), DACO: M10.0

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