

Evaluation Report for Category B, Subcategory 1.3, 3.13 Application

Application Number: 2021-2115
Application: Changes TGAI Product Chemistry – New Source (site) same registrant, Changes to Product Labels - Precautions
Product: BioCeres D GR
Registration Number: 33925
Active ingredient (a.i.): *Beauveria bassiana* strain ANT-03
PMRA Document Number: 3367949

Purpose of Application

The purpose of this application was to register a new formulating site and new formulating methods for BioCeres D GR and amend the precautionary statements on the product label.

Product Characterization and Analysis

The data provided is acceptable to support the new formulating site and new formulating methods. Data from a sufficient number of batches were provided to support the product guarantee.

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 of BioCeres D GR.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the registration of a new formulating site and formulating methods for the end-use product *Beauveria bassiana* strain ANT-03. However, the amendments to the precautionary statements on the product label were not supported.

References

PMRA Document Number	References
3232289	2021, Manufacturing method and quality assurance, DACO: M2.8
3232290	2020, Manufacturing process of B. bassiana granular, DACO: M2.8 CBI
3232291	2020, Manufacturing process of bioceres GR, DACO: M2.8 CBI
3232293	2020, Ana-01 germination assessment of Beauveria bassiana conidia, DACO: M2.9.2 CBI
3232294	2020, Ana-002 conidia concentration of Beauveria bassiana, DACO: M2.9.2 CBI
3232296	2020, Ana-008 total bacterial, yeasts and molds count in technical grade of B. bassiana, DACO: M2.10.2 CBI
3243150	2021, Potency estimation and product guarantee, DACO: M2.9.2
3243151	2021, Analysis of microbial contaminant, DACO: M2.10.2
3299204	2018, Blending of bioceres WP, DACO: M2.8 CBI
3299205	2021, Certificate of analysis, DACO: M2.8
3299206	2021, Analysis of unintentional ingredient, DACO: M2.10.3
3299207	2021, Manufacturing of b bassiana granule, DACO: M2.8 CBI
3299208	2021, Manufacturing process of bioceres GR, DACO: M2.8 CBI
3299209	2013, Analysis of beauvericin in the fungus B. bassiana, DACO: M2.10.3 CBI
3318344	2022, Analysis of other unintentional ingredients, DACO: M2.10.3
3347979	2022, Analysis for the other unintentional ingredients, DACO M2.10.3
3347980	2022, Limit of beauvericin, DACO M2.10.3 CBI
3350796	2022, Statement method validation. DACO M2.10.3 CBI
3232297	2021, Acute inhalation toxicity, DACO: M4.9
3232298	2021, Bioceres WP acute inhalation toxicity in rats, DACO: M4.9

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.