

## Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.5 Application

**Application Number:** 2018-6274  
**Application:** New End-use Product (Product Chemistry) - Identity of Formulants, Proportion of Formulants, Formulation Type  
**Product:** BioCeres EC  
**Registration Number:** 33493  
**Active ingredient (a.i.):** *Beauveria bassiana* strain ANT 03  
**PMRA Document Number :** 3005595

### Purpose of Application

The purpose of this application was to register a new end-use product, BioCeres EC, to reduce numbers of whiteflies, aphids and thrips in greenhouse tomatoes, cucumbers, peppers, herbs and spices, sweet potato slips and ornamentals; and in cannabis (marihuana) produced commercially indoors.

### Product Characterization and Analysis Assessment

Information and data on product characterization and analysis were submitted in accordance with the PMRA requirements. This information included descriptions of manufacturing and formulating processes, quality control practices, product specifications, storage stability, and physical/chemical properties.

The manufacturing process and quality assurance associated with the formulation of BioCeres EC were described in sufficient detail and determined to be appropriate. Acceptable representative potency and microbial contaminant screening data were also submitted. The storage stability data on BioCeres EC was found to be acceptable and showed that *B. bassiana* strain ANT-03 was stable at refrigerated temperatures (4°C) over a period of up to 6 months. Acceptable physical and chemical properties were also submitted for BioCeres EC.

### Health Assessments

BioCeres EC is a new end-use product containing the microbial pest control agent (MPCA), *Beauveria bassiana* strain ANT-03. No new toxicological data were submitted in support of this new product. Instead, an acceptable scientific rationale was submitted in lieu of testing. Based on a review of the available information/data in the existing database for the precedent product and the technical grade active ingredient, BioCeres EC is considered to be of low acute toxicity via the oral, intratracheal and dermal routes. BioCeres EC is not considered to be a dermal irritant, however, it is considered to be an eye irritant and, like all MPCAs, it is a potential sensitizer.

When handled according to prescribed label instructions, the potential for dermal, eye and inhalation exposure for mixer/loaders, applicators, and handlers exists, with the primary source of exposure to workers being dermal and to a lesser extent inhalation. In

individuals exposed to large quantities of BioCeres EC, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since all microorganisms, including *B. bassiana* strain ANT-03, contain substances that are potential sensitizers. Therefore, anyone handling or applying BioCeres EC must wear appropriate personal protective equipment (PPE) such as waterproof gloves, long-sleeved shirts, long pants, eye goggles, a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter, and socks and shoes. Also, re-entry into treated areas is prohibited for 4 hours or until the sprays have dried unless wearing appropriate PPE, including long-sleeved shirt, long pants, waterproof gloves and socks and shoes.

The dietary risk for the general population and sensitive subpopulations such as infants and children is acceptable since a review of *B. bassiana* strain ANT-03 previously demonstrated no pathogenicity, infectivity or oral toxicity, and this MPCA is not known to produce the secondary metabolites beauvericin, bassianolide, oosporein, bassiacridin, bassianin or tenellin. In addition, exposure to the MPCA via the food use of BioCeres EC should not be greater than existing exposure to this MPCA since its use pattern is the same as that of the precedent product containing this MPCA. The likelihood of *B. bassiana* strain ANT-03 entering neighbouring aquatic environments or surface water run-off from greenhouse use of BioCeres EC is considered low.

For cannabis, the risk to consumers following the consumption of extracts is acceptable since residues are likely reduced through processing, and a review of *B. bassiana* strain ANT-03 previously demonstrated no pathogenicity, infectivity or oral toxicity, and this MPCA is not known to produce the secondary metabolites beauvericin, bassianolide, oosporein, bassiacridin, bassianin or tenellin. In addition, the potential for the production of any unusual hazardous pyrolytic products is low and therefore the risk to consumers following the inhalation of cannabis smoke is acceptable.

### **Environmental Assessment**

An environmental assessment was not required for this application.

### **Value Assessment**

A bridging trial, comparing the efficacy of BioCeres EC to a registered product with another formulation type, supported the use of BioCeres EC against whiteflies, aphids and thrips on the crops listed on the label.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of BioCeres EC.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
2938963	2018, Manufacturing method and quality assurance, DACO: M2.8 CBI
2938964	2018, Manufacturing process for conidiospores of <i>Beauveria bassiana</i> ANT-03, DACO: M2.8 CBI
2938965	2018, Manufacturing process for BioCeres EC, DACO: M2.8 CBI
2938971	2018, Potency estimation and product guarantee, DACO: M2.9.2
2938972	2018, Viability of <i>Beauveria bassiana</i> conidiospores in BioCeres EC, DACO: M2.9.2
2938973	2018, Storage stability testing, DACO: M2.11
2938974	2018, Summary of physical and chemical properties, DACO: M2.12
2938975	2018, Specific gravity, DACO: M2.12
2938976	2018, Viscosity rotational methods, DACO: M2.12
2938979	2018, Dermal irritation study, DACO: M4.5.2 CBI
2938983	2018, Efficacy, laboratory growth chamber trials, DACO: 10.2.3.2
2938984	2018, Non safety adverse effects, DACO: 10.3.2

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2019

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.