

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2020-3196
Application: Changes to Product Labels – New Pests and New Site or Host
Product: BioCeres EC
Registration Number: 33493
Active ingredient (a.i.): *Beauveria bassiana* strain ANT 03
PMRA Document Number : 3222478

Purpose of Application

The purpose of this application was to amend the label of BioCeres EC to add a new pest, the twospotted spider mite, and to add use on greenhouse crops, greenhouse ornamentals, and cannabis produced commercially indoors.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Since the human health and safety data packages for this product are considered complete and there were no changes in the end-use formulation, no additional toxicological information was required.

The rate, method, and timing of application for the new use patterns are consistent with existing registered uses for this microbial pest control agent (MPCA). The added impact of the new uses of BioCeres EC on dietary and occupational exposure is expected to be negligible, and therefore, no additional exposure information is required to support the proposed new pest and crops.

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 ANT-03 on treated food crops are possible at the time of harvest. Dietary risk to humans from the proposed use of BioCeres EC is acceptable due to the low acute oral toxicity of *B. bassiana* strain ANT-03 and that metabolites of toxicological significance are not known to be produced by this MPCA. In addition, the

likelihood of residues contaminating drinking water supplies is low. Therefore, the PMRA has determined that specification of an MRL under the PCPA is not required for *B. bassiana* strain ANT-03.

Environmental Assessment

No new data were submitted in support of the request to expand the label of BioCeres EC to include a new pest and new crops. Since the environmental safety data package for this end-use product is considered complete and there were no changes in the end-use formulation, no additional environmental toxicological information was required. Previously submitted information indicates that the use of BioCeres EC on greenhouse food, greenhouse ornamentals, and cannabis produced indoors does not pose an environmental risk of concern to non-target organisms if the directions on the label are followed. The rates, methods of application, and timing are consistent with existing uses on another end-use product label containing this microbial pest control agent (MPCA). The addition of a new pest and new crops to the label of BioCeres EC is not expected to harm non-target organisms.

Value Assessment

The results of greenhouse studies and a scientific rationale demonstrated that BioCeres EC, applied following label directions, can be expected to reduce the numbers of twospotted spider mites in greenhouse tomatoes, cucumber, lettuce, eggplant, peppers, herbs and spices (CG 19), Brassica vegetable transplants, onion transplants, sweet potato slips, Asian water spinach (tung choy, kankon, rao muong), mint, strawberry and ornamentals, as well as in cannabis produced commercially indoors. The addition of this claim to the label of BioCeres EC will provide growers with a new tool to manage twospotted spider mites on listed greenhouse or indoor crops and may reduce the risk of resistance development to conventional insecticides.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the amendments to the label of BioCeres EC.

References

| PMRA Document Number | References |
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| 3140848 | 2020, Value, filed study and phytotoxicity, DACO: M10.0,M10.2.2,M10.3.1 |
| 3140849 | 2020, Biological activity of BioCeres EC against two spotted spider mites, DACO: M10.2.2 |
| 3217809 | 2021, Efficacy study, DACO: M10.2 |
| 3217810 | 2021, Efficacy greenhouse, DACO: 10.2.3.3 |
| 3217811 | 2021, BioCeres EC, two-spotted spider mite, DACO: 10.2.3.3 |

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