

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2023-6938
Application: Changes to End-use Product (Product Chemistry) - Guarantee
Applicant: Andermatt Canada Incorporated
Product: Bassidor
Registration Number: 34656
Active ingredient (a.i.): *Beauveria bassiana* strain R444
PMRA Document Number: 3658721

Purpose of Application

The purpose of this application was to change the address of the formulating site of Bassidor, and to increase the claim for storage stability from 6 to 24 months when stored at 4°C.

Product Characterization and Analysis

Sufficient information and data were provided to demonstrate that Bassidor manufactured at the new site will be equivalent to that manufactured at the currently registered site. Furthermore, sufficient information and data were provided to extend the storage period of Bassidor to 24 months when stored at 4°C.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to change the manufacturing site of Bassidor, and to increase the claim for storage stability from 6 to 24 months when stored at 4°C.

References

PMRA

Document

Number

Reference

2971907	2018, M 2.8 Manufacturing Methods and Quality Assurance, DACO: M2.8 CBI
2971913	2018, M 2.9.2 Appendix 1, DACO: M2.9.2 CBI
2971915	2018, M 2.10.1 Active Ingredient or MPCA, DACO: M2.10.1 CBI
2971916	2018, M 2.10.2 Analysis for Microbial Contamination, DACO: M2.10.2 CBI
3532838	2023, PCP34656 Bassidor Name and Address of Applicant, DACO: M2.1 CBI
3532840	2023, PCP34656 Bassidor Name and Address of Formulation Plant, DACO: M2.3 CBI
3532841	2023, PCP34656 Bassidor Manufacturing and Quality Assurance, DACO: M2.8 CBI
3532842	2023, PCP34656 Bassidor Appendix 1 Production Site Statement, DACO: M2.8 CBI
3532844	2023, PCP34656 Bassidor Disclosure of Ingredients, DACO: M2.9 CBI
3532851	2021, PCP34656 Bassidor Appendix 2 5 Batch Analysis APIS 012 022 5, DACO: M2.9.2 CBI
3532852	2023, PCP34656 Bassidor Analytical Data and Methodology, DACO: M2.10 CBI
3532855	2021, PCP34656 Bassidor Appendix 1 5 Batch Analysis APIS, DACO: M2.10.2 CBI
3532857	2023, PCP34656 Bassidor Storage Stability Testing, DACO: M2.11 CBI
3532858	2021, PCP34656 Bassidor Appendix 1 APIS Storage Stability Report, DACO: M2.11 CBI
3597185	2024, M2.10.1 Active Ingredient or MPCA, DACO: M2.10.1 CBI
3597186	2024, M2.10.2 Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
3597187	2024, M2.10.2 Appendix 1 APIS Response Letter, DACO: M2.10.2 CBI
3597188	2024, M2.10.2 Appendix 2 qPCR Method Validation, DACO: M2.10.2 CBI
3597189	2024, M2.11 Storage Stability Testing, DACO: M2.11 CBI
3597190	2021, M2.11 Appendix 1 Storage Stability Report, DACO: M2.11 CBI
3656023	2024, Potency Estimation and Product Guarantee Bassidor Deficiency response, DACO: M2.9.2 CBI
3656024	2024, Appendix 1 Justification of Content Range, DACO: M2.9.2 CBI
3656025	2024, Appendix 2 Historical Shelf Life Data, DACO: M2.11, M2.9.2 CBI
3656026	2024, Storage Stability Testing, DACO: M2.11 CBI

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