

Evaluation Report for Category B, Subcategory B.2.3,B.2.4 Application

Application Number: 2016-3174
Application: Changes to EP Product Chemistry-Identity and Proportion of Formulants
Product: Blossom Protect
Registration Number: 30552
Active ingredients (a.i.): *Aureobasidium pullulans* DSM 14940 and DSM 14941
PMRA Document Number: 2695213

Background

Blossom Protect is currently fully registered (Reg. No. 30552). This end-use product was first registered in Canada in 2012 as a biological bactericide to manage fireblight in pome fruit and certain ornamentals.

Purpose of Application

The purpose of this submission is to amend the formulation and register new formulating sites for the end-use product Blossom Protect.

Chemistry Assessment

Sufficient batch analysis data for microbial contamination analysis and potency estimation were submitted to support the registration of the new manufacturing locations and formulating sites for Blossom Protect. Storage stability data submitted to support amended storage statements on the labels of Blossom Protect were reviewed and found to be acceptable.

Health Assessments

An acute dermal toxicity and dermal irritation data waiver rationale was reviewed and determined to be acceptable. The proposed formulation is toxicologically equivalent to the registered formulation. No further toxicity data were required to support the registration of the new Blossom Protect formulation.

Environmental Assessment

Because the new formulation is toxicologically equivalent to the registered formulation, it will not pose an additional hazard to non-target organisms. No further data are required to support the registration of the proposed new formulation of Blossom Protect.

Value Assessment

The changes in formulation are not expected to impact product performance. From a value perspective, the new formulation was determined to be supported.

Conclusion

The PMRA has conducted a review of the information provided in support of this application. Based on the results of this review, registration of the amended formulation and the two new formulating sites are determined to be supported.

References

PMRA Document Number	Reference
2652164	2016, Manufacturing methods and quality assurance, DACO: M2.8 CBI
2652165	2014, Certificate of analysis, DACO: M2.9.2 CBI
2652166	2016, Certificate of analysis, DACO: M2.9.2 CBI
2652167	2016, Certificate of analysis, DACO: M2.9.2 CBI
2652168	2016, Certificate of analysis, DACO: M2.9.2 CBI
2652169	2016, Rationale in support of the storage stability, DACO: M2.11 CBI
2652171	2016, Interim Report Storage stability of Blossom Protect after 24 months at 8°C, DACO: M2.11
2652172	2015, Final Report Storage stability of the formulation Blossom Protect over 18 months at 20°C, DACO: M2.11

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