

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2018-5628
Application: B.1.3: Change in Specifications
Product: DiPel 2X DF Biological Insecticide Dry Flowable
Registration Number: 26508
Active ingredients (a.i.): *Bacillus thuringiensis*, var. *kurstaki* strain ABTS-351
PMRA Document Number: 3097768

Purpose of Application

The purpose of this application was to amend the storage statement on the product. The end-use product label for DiPel 2X DF Biological Insecticide Dry Flowable currently states that the product may be stored at 0 – 25°C for a period of 24 months from the date of manufacture.

Chemistry Assessment

Storage stability data were reviewed and found to be acceptable. The amendment to the label, that the storage period be increased from 24 months to 36 months is acceptable.

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has reviewed the information provided in support of increasing the storage period from 24 months to 36 months. Based on the results of this review, the storage period increasing from 24 months to 36 months for DiPel 2X DF Biological Insecticide Dry Flowable is acceptable.

References

3038171 2004, DiPel WG Storage Stability, DACO: M2.11

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