

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2017-2870
Application: Change in Product Specifications
Product: Loopex
Registration Number: 31791
Active ingredients (a.i.): *Autographa californica* nucleopolyhedrovirus FV11
PMRA Document Number: 2798997

Purpose of Application

The purpose of this application was to amend the storage stability up to 12 months.

Chemistry Assessment

Storage stability and microbial contaminant analysis data were provided for two batches of Loopex that were stored at various temperatures for up to 12 months. The tested batches were stable when stored at -18°C and 5°C for up to 12 months of storage. At these temperatures and storage periods, microbial contaminant levels remained within the required limits.

The storage period can, therefore, be extended to 12 months at temperatures of up to 5°C.

Health, Environment and Value Assessments

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

Conclusion

The PMRA has reviewed the information provided in support of the 12 month storage stability claim. Based on the results of this review, the 12 month storage stability claim is acceptable.

References

- 2774296 2017, Loopex Storage Stability and Physical/Chemical Characteristics at various temperatures, DACO: M2.11
- 2774297 2017, M 2.11 Appendix 1 Microbial Analysis Results, DACO: M2.11

ISSN: 1911-8082

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