

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2009-2095
Application: Conversion to full registration without consultation
Product: Cydia Pomonella Granulovirus
Registration Number: 26532
Active ingredients (a.i.): *Cydia pomonella* granulovirus
PMRA Document Number: 1871467

Background

Cydia Pomonella Granulovirus was granted conditional registration in Canada and the detailed review supporting the conditional registration can be found in Regulatory Note REG2000-10 *Virosoft CP4/Cydia pomonella* granulosis virus.

Purpose of Application

The purpose of this application was to convert the product registration status of Cydia Pomonella Granulovirus from conditional to full.

This document presents the evaluation of the information provided in support of the conversion of the registration of the product from conditional to full.

Chemistry Assessment

The active ingredient has been identified to the strain level and is known as *Cydia pomonella* granulovirus strain CMGv4.

Methods to distinguish strain CMGv4 from other strains of *Cydia pomonella* granuloviruses were submitted and were found to be acceptable. The registrant has confirmed that the new source of the microbial pest control agent was not re-isolated from the field and remains the same as submitted in the original submission.

A description of the methods used for preservation and maintenance of the production strain was provided and found to be acceptable.

Occlusion body (OB) counts were submitted for four production batches of Virosoft CP4. In order to achieve the label guarantee of 4×10^{13} OBs/L, the product is concentrated and subsequently resuspended in a suitably smaller volume.

Health Assessments

In lieu of tissue culture testing, a waiver rationale based on the specificity of baculoviruses and published findings from cell culture testing of various baculoviruses was submitted. The waiver rationale was limited in utility and considered supplemental as the cited literature was not provided. However, based on PMRA's knowledge and familiarity with baculoviruses and the relevant published literature demonstrating that these insect viruses have a low potential to infect or transform mammalian cells, no further information to address this requirement is required.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to convert *Cydia Pomonella Granulovirus* from conditional to full registration.

References

Part M2 – Product Characterization and Analysis

- 1770462 2009, Origin, Derivation and Identification of MPCA, DACO: M2.7.1
1770463 2009, CBI Reference Document - Origin, Derivation and Identification of MPCA, DACO: M2.7.1 CBI
1770464 2009, Manufacturing Methods and Quality Assurance, DACO: M2.8
1770465 2009, CBI Reference Document - Manufacturing Methods and Quality Assurance, DACO: M2.8 CBI

Part M4 – Human Health and Safety

- 1770466 2009, Tissue Culture, DACO: M4.7
1770468 2009, Tissue Culture, DACO: M4.7

Additional Data

- 1853767 Miller, L.K., Lu, A., The Molecular Basis of Baculovirus Host Range - Chapter 9, Pages 217-235, DACO: M4.7
1853774 Volkman, L.E., Goldsmith, P.A., 1982, *In vitro* Survey of Autographa californica Nuclear Polyhedrosis Virus Interaction with Nontarget Vertebrate Host Cells, Applied and Environmental Microbiology, Mar. 1983, p. 1085-1093, Vol. 45, No. 3, DACO: M4.7
1853783 Ignoffo, C.M., 1972, *In vitro* Attempts to Infect Primate Cells with the Nucleopolyhedrosis Virus of Heliothis, Journal of Invertebrate Pathology 20, 321-325 (1972), DACO: M4.7
1853790 McIntosh, A.H., Maramorosch, K., 1973, Retention of Insect Virus Infectivity in Mammalian Cell Cultures, New York Entomological Society, LXXXI: 175-182, September, 1973, DACO: M4.7
1856323 Reimann, R., Miltenburger, H.G., 1983, Cytogenetic Studies in Mammalian Cells After Treatment with Insect Pathogenic Viruses [Baculo Viridae] *In Vitro* Studies with Mammalian Cell Lines, Entomophaga 28 (1), 33-44, DACO: M4.7

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