

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-0456
Application: Changes to TGAI Product Chemistry-New Source (site) same registrant
Product: Disparvirus Technical
Registration Number: 24778
Active ingredient (a.i.): *Lymantria dispar* multicapsid Nucleopolyhedrovirus
PMRA Document Number: 3441611

Purpose of Application

The purpose of this application was to register a new source of the technical grade active ingredient (TGAI) Disparvirus Technical, containing *Lymantria dispar* multicapsid Nucleopolyhedrovirus (LdMNPV).

Product Characterisation and Analysis

The information supplied to register a new manufacturing site along with new manufacturing methods of Disparvirus Technical, is acceptable.

Acceptable methodologies for detection, isolation and enumeration of the active ingredient, LdMNPV, were submitted. LdMNPV has been previously fully characterized with respect to the origin of the isolate, natural occurrence and biological properties. The quality assurance procedures used to limit insect parts and contaminating microorganisms during the manufacture of Disparvirus Technical are acceptable.

The guarantee of the TGAI is expressed in units of occlusion bodies (OBs)/g. In lieu of data for Disparvirus Technical, representative data on three batches of an end-use product (EP), consisting of both potency data and OB counts, were submitted.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of three batches of EP using standard microbiological methods as well as by results of mouse toxicity testing. All batches of the EP conform to the limits set out in the Organization for Economic Co-operation and Development (OECD) issue paper on microbial contaminants for microbial pest control products.

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 support the registration of the new source of *Lymantria dispar* multicapsid Nucleopolyhedrovirus for Disparvirus Technical.

References

PMRA Doc Number	Citation
2329656	2006, Diet-surface overlay bioassay for potency determination of microbial products against lepidopteran larvae, DACO: M2.9.2 CBI
2329668	M4 Human Health and Safety Testing waiver rationale, DACO: M4.1
2329756	M4.5.2 Litton Bionetics 1975, DACO: M4.5.23.0
2329765	M9 Environmental Toxicology/Nontarget Organism Testing M 9.1 Summary, DACO: M9.1
2410353	M4.4 Acute Dermal Toxicity, DACO: M4.4
3311651	Zhang et al., 2010, Molecular comparison of alphabaculovirus-based product: Gypchek with Disparvirus (<i>Lymantria dispar</i>) and TM-Biocontrol -1 with Virtuss (<i>Orgyia pseudotsugata</i>), DACO: M2.8
3311657	2022, M2.9.2 Potency Estimation and Product Guarantee, DACO: M2.9.2 CBI
3311658	2022, M2.9.2 Appendix 1, DACO: M2.9.2 CBI
3311659	2022, M2.9.3 Unintentional Ingredients, DACO: M2.9.3 CBI
3311660	2022, M2.10.2 Microbial Contamination, DACO: M2.10.2 CBI
3311661	2022, M2.10.2 Appendix 1, DACO: M2.10.2, M2.9.2 CBI
3311662	2022, Mouse IP Safety Study, DACO: M2.10.2 CBI
3319102	2022, M2.10.2 CofA BoVir Batch 110, DACO: M2.10.2 CBI
3319103	2022, M2.10.2 CofA BoVir Batch 114, DACO: M2.10.2 CBI
3319104	2022, M2.10.2 CoFA BoVir Batch 115, DACO: M2.10.2 CBI
3319121	2022, M2.8 Manufacturing and QA Clarifications, DACO: M2.8 CBI

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