Renewal
Assessment Report

Cydia pomonella GV

Madex Twin

Volume 3 – B.5 Analytical methods

Rev. 0 – 16 October 2020

Rapporteur Member State: Germany

Co-Rapporteur Member State: The Netherlands

Version history

When	What
16 October 2020	First version submitted to EFSA

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS.

Table of contents

B Summary, evaluation and assessment of the data and information

B.5 Analytical methods

B.5.1 Methods for the analysis of the preparation

MADEX TWIN contains the new CpGV isolate CpGV-V22 which, in contrast to the other CpGV isolates, also infects larvae of the oriental fruit moth, *Grapholita molesta*. CpGV-M and CpGV-V22 can only be distinguished by molecular genetic methods or by biotests with *G. molesta* larvae. The formulation of MADEX TWIN is identical to the formulation MADEX containing the isolate CpGV-M. MADEX and MADEX TWIN contain the same co-formulants in the same contents, but contain a different virus isolate.
The product MADEX was the representative formulation for the inclusion of *Cydia pomonella* Granulovirus in the list of approved substances of Regulation (EU) 1107/2009.

B.5.1.1 Methods for the identification and the determination of the content of the micro-organism(s) in the preparation

B.5.1.2 See MADEX, B.5.1.1: Methods to establish regular control of the preparation to show that it does not contain other organisms than the indicated ones and to establish uniform

See MADEX, B.5.1.2

B.5.1.3 Methods to identify any contaminating micro-organisms of the preparation

See MADEX, B.5.1.3

B.5.1.4 Methods for the determination of relevant impurities or metabolites in the manufactured material

See MADEX, B.5.1.4

B.5.1.5 Methods used to determine the storage stability and shelf life of the preparation

See MADEX, B.5.1.5

B.5.2 Methods to determine and quantify residues (viable or non-viable)

See MADEX, B.5.2

B.5.3 References relied on

No references submitted.