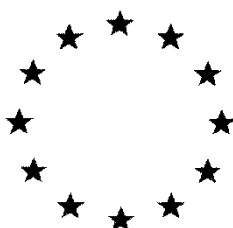


European Commission



**Draft Renewal Assessment Report prepared according to
Regulation (EC) N° 1107/2009**

Heptamaloxyloglucan

Volume 3 – B.3 (AS)

Rapporteur Member State: France
Co-Rapporteur Member State: Spain

Version History

When	What
2020-09	Initial RAR

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. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

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B.3. DATA ON APPLICATION

B.3.1. USE OF THE ACTIVE SUBSTANCE

Heptamaloxyloglucan (technical material EL101GV) is used to protect grapevine against frost.

B.3.2. FUNCTION

The asserted function is the protection against the cold stress. Heptamaloxyloglucan is a protective elicitor of the grapevine against freezing temperatures.

B.3.3. EFFECTS ON HARMFUL ORGANISMS

This active substance does not exhibit direct effect on harmful organisms.

It acts as an elicitor which must preserve the chemical structure and conformation of the xyloglucan heptamer XFG in order to increase the cold resistance of the grapevine.

B.3.4. FIELD OF USE ENVISAGED

Heptamaloxyloglucan is intended to be used in field for grapevine protection against frost damages.

B.3.5. HARMFUL ORGANISMS CONTROLLED AND CROPS OR PRODUCTS PROTECTED OR TREATED

Heptamaloxyloglucan is intended to be used in field for grapevine protection against frost damages.

B.3.6. MODE OF ACTION

Heptamaloxyloglucan is a signal molecule (elicitor). The signal is recognized at the surface of the leaf, it induces a succession of biochemical activations: heptamaloxyloglucan interferes directly by regulating the accumulation of free radicals involved in the "oxydative burst" which is generated by the cold stress. The application of heptamaloxyloglucan initiates a cascade of biochemical reactions leading to the accumulation of cryoprotectant molecules, glucose for example.

It acts as an elicitor exhibiting chemical structure and conformation of XFG xyloglucan heptamer when it protects grape wine plants against frost. As the result of its binding by receptors at the cell surface, second messengers including changes in redox ratio, membrane potential and production of active oxygen species are generated and diffused to specific targets within the cell to bring about physiological responses occurring on the time scale of minutes.

The early responses e.g. the increase of glutathione reductase activity and a shift in the partitioning of photosynthates toward soluble sugar synthesis are the mechanisms underlying acclimation to cold temperatures.

The final response involves an osmoregulation which lowers the freezing point of cells and prompts the acclimatization to cold conditions.

By the way, heptamaloxyloglucan improves the freezing tolerance of vine since it limits tissue necrosis, mediates osmotic adjustment for protecting organelles and can reduce the inhibition of photosynthesis.

Cited reference

Report	KCA 3.6/1 – Lienart Y.. (2006), unpublished report.
Title	EL101 GV - Mode of Action, ELICITYL, report EL101GV-150106-01
Guideline	Not applicable
GLP	No

Abstract:

The mode of action is composed of 3 different steps describing the perception of signal, the transduction events and then the expression of the plant cell responses. These steps explain why a nanomolar range of the active substance concentration is enough to assure efficacy.

Step 1: Perception, Xyloglucan as ligand of receptor site(s)

The recognition of the molecule xyloglucan is done by receptor sites associated with plasma membranes whose existence and characteristics were specified in vitro.

Step 2: transduction, Xyloglucan recognition generates second messengers

As a result of its binding on cell surface receptors, second messengers including changes in the redox ratio, membrane potential and production of active oxygen species are generated and diffused to specific targets within the cell.

Step 3: expression, the early responses induced by the elicitor

The early responses are characterized by the increase of glutathione reductase activity and a shift in the partitioning of photosynthates toward soluble sugar synthesis. The application of EL101GV results in the limitation of foliar necrosis and in the redistribution of the metabolic pathways involved in the synthesis of sugars, neutral and/or phosphorylated. These observed variations are the mechanisms underlying the acclimation to cold temperatures.

B.3.7. INFORMATION ON THE OCCURRENCE OR POSSIBLE OF THE DEVELOPMENT OF RESISTANCE AND APPROPRIATE MANAGEMENT STRATEGIES

Not relevant. Heptamaloxyloglucan is not intended for the control of harmful organisms.

B.3.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities ^{2,3} Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used ¹ Y/N If yes, for which data point?
KCA 3.6/01	Lienart, Y.	2006	EL101 GV - Mode of Action ELICITYL report EL101GV-150106-01 GLP: No Published: No	N	N	-	Elicityl	Y A II 3.5/1

¹ In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.

² See Art.3 of Annex of Regulation No 283/2013 and 284/2013

³ The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).