European Commission

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

Heptamaloxyloglucan

Volume 3 – B.3 (PPP) – PEL101GV

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 AND EFFICACY

B.3.1. FIELD OF USE ENVISAGED

PEL101GV is used to protect grapevines against frost.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

PEL101GV, which contains as the only ingredient heptamaloxyloglucan, is not intended to afford protection against harmful organisms.

B.3.3. DETAILS OF INTENDED USE

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	mg a.i./hl min max (l)	Water l/ha min max	mg a.i./ha min max (l)		
Vine	FR	PEL101GV	F	Frost damage	XX	780 g/kg	Foliar spraying using an air pressured system	BBCH 07-16 (budding to 6 leaves) Early spring	4	4 days	109.2 mg mg ai/hL	100-400	0.54 – 437 mg ai/ha	F	1-4 applications 12 to 48 h before freezing temperatures

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

RMS comment: This GAP table format is different from the one provided by the applicant. RMS has updated the table format following EFSA request. EFSA has requested to "update the GAP table using the template on the EC website (for chemical active substances)". The applicant is kindly asked to check if this update is in accordance with its initial GAP table.

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

The formulation PEL101GV contains 1000 g of EL101GV (technical active substance) /kg of formulation, i.e. 780 g of heptamaloxyloglucan (minimal pure active substance)/kg of formulation.

Based on spray volumes for the representative crop, the concentrations of PEL101GV in ready-to-use spray are calculated below for grapevines:

- The concentration is 109,2 mg active substance (pure)/100L, corresponding to 140 mg of active substance (technical)/100 L, corresponding to 140 mg PEL101GV/100 L.

- The application spray volume is 100 - 400 L/ha depending on the equipment used. As a consequence, the maximum application rate is 437 mg of active substance (pure)/ha, corresponding to 560 mg of active substance (technical)/ha, corresponding to 560 mg PEL101GV/ha.

B.3.5. METHOD OF APPLICATION

The application spray volume is 100-400 L/ha depending on the equipment used.

Application of PEL101GV must be done by spraying method using a pressurized system. Different technologies could be used: pneumatic system, system with nozzle (liquid stream, air/liquid stream).
The spraying application must be directed as much precisely as possible on buds or leaves at early development stages (BBCH 07- BBCH 16) to avoid important product loss.

According to the applicant, to have the best efficiency, the spraying should be generated with 150 - 200 µm diameter droplets.

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

Maximum number of applications and their timings:
The maximum number of applications to grapevines is 4 per growing season and the minimum interval between applications is 4 days. The pre-harvest interval (PHI) is covered by the period remaining to grape harvest.
The product must be applied between 12 to 48 hours before the occurrence of freezing temperatures. Once the weather forecast is available it is recommended to first get organized during the morning (by cleaning the containers and by making the product dilution) and then to apply the product in the afternoon.

Growth stages of crops or plants to be protected:
The applications are typically made from bud burst to 6 leaves elongation (growth stage BBCH 07 to BBCH 16).

Development stages of the harmful organism concerned:
Not applicable.

Duration of protection afforded by each application:
The duration of protection after one application is 4 days.

Duration of protection afforded by the maximum number of applications:
Each application enables a protection of 4 days after application. Thus, with 4 successive applications spaced of 4 days, the duration of protection is 16 days.

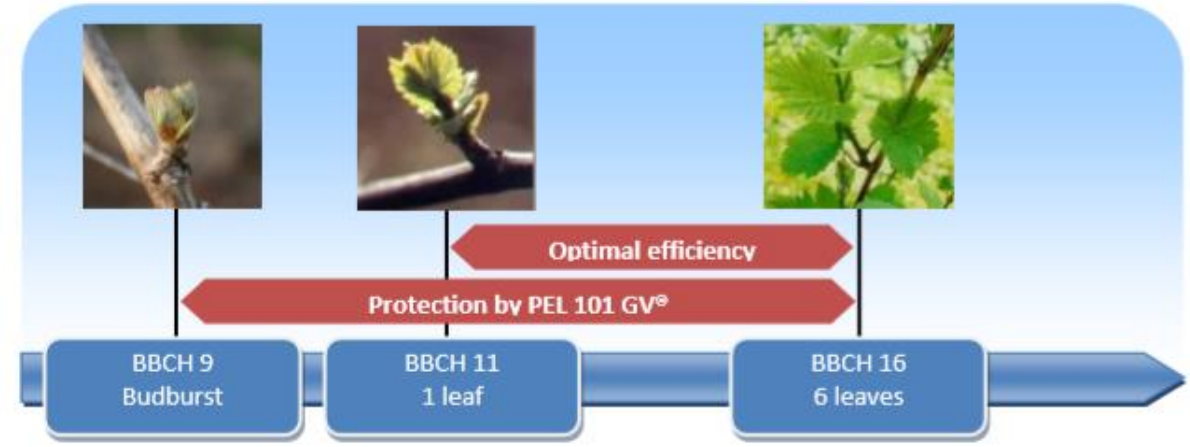
B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

Not relevant for the representative use (Grapevines).

B.3.8. PROPOSED INSTRUCTIONS FOR USE

Conditions of use as described in the document KCP 3.8.01 PEL101GV – Insctruction for use – 2018:

CONDITIONS OF USE
PEL 101 GV® enables the reduction of vigneyard sensitivity to spring frost of 1 to 2°C. It can be used from the growth stage "budburst" (BBCH09/Eichorn-Lorenz 05/stade C) au to the growth stage "6 unfolded leaves" (BBCH16/Eichorn-Lorenz 13/stade F).



2 conditions of treatment are possible:

- 1. Program 1 – Before the frost event
  PEL 101 GV® must be applied between 12 to 48 hours prior to a frost event. Once the weather forecast is available and a frost event is forecasted, it is important to apply the product as soon as possible.
  Recommendation: treat on the morning of the day before the frost event with a relative humidity >60%.

- 2. Program 2 - Systematic
  A systematic treatment is possible to cover all the period of risk. Apply the first treatment 3 days after the growth stage "budburst" and apply 2 treatments with a time interval of 10 days each. In case of a frost event forecast 5 days after the treatment, apply PEL 101 GV® the day before the forecasted frost event, and repeat the treatment 10 days after.

DOSE RATE
One vial of PEL 101 GV® needs to be diluted in 100 liters of water to treat 1 hectare.

Culture	Dose		Growth stage	Protection duration
	Surface	Vial		
Vineyard (aerial parts)	1 hectare **(Spray volume 100 L/ha)**	1	From "budburst" (BBCH 09) to "6 unfolded leaves" (BBCH 16)	**4 days** after treatment

PREPARATION OF THE TREATMENT
The tank should be thoroughly rinsed to avoid any trace of previous treatment.

0- Fill up the tank with water up to 50% of the final volume.
1- Open the flask(s) entitled PEL 101 GV®.
2- Add water into the flask(s) with the pipette.

3- Plug up again with the rubber cap and shake to obtain a homogeneous solution.
4- Open the flask(s) again.
5- Pour the obtained solution in the half-filled tank.
6- Rinse the flask(s) with water by repeating operation 2 to 5 at least twice.
7- Top up the tank to the final volume.
Apply as soon as possible. PEL 101 GV® stability in solution is not guaranteed after 12 hours.

SPRAY APPLICATION
Application must be done by spraying the diluted solution using a hydraulic sprayer. Recommended spray volume is 100 L/ha. To have the best efficiency the spray pattern must mostly include 150-200µm diameter droplets. Avoid run off.

Caution: Avoid runoff. Spray the treatment under acceptable weather conditions (at least 3 hours before rain forecast).

STABILITY / STORAGE
PEL 101 GV® (lyophilised product) is stable for three years in its original sealed flask when stored between +5°C to +35°C.

SAFETY PRECAUTIONS
PEL 101 GV® does not have any other effect on grapevine than enhancing its natural resistance to a frost event. More particularly, it does not have any insecticide, fungicide nor bactericide activity. PEL 101 GV® respects the environment because of the low dose used and its biodegradability.

In accordance with current regulations, PEL 101 GV® is free of toxicological classification. No specific risk is incurred by the user under normal conditions of use. However, we recommend applying Good Agricultural Practices for the preparation of the porridge. SP1: Do not contaminate water with the product or its container. Please refer to the MSDS for more details.

B.3.9. EFFECTIVENESS

PEL101GV is presently the only one Heptamaloxyloglucan based product registered in EU (in France only). The only one use registered is the use frost damage on vine described in B.3.3.

Considering that the substance is approved and authorization of the plant protection product containing the substance have already been evaluated according to the Uniform Principles (Regulation (EC) No 546/2011), no other efficacy documentation is deemed to be necessary at this stage.

More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

In the frame of this dossier, the applicant has provided a dossier of efficacy based on data submitted for previous PEL101GV registration. Considering the use against frost, this product is not concerned by resistance phenomenon. Therefore the efficacy is still considered as acceptable.

For information, here under is a summary of the main conclusions of previous efficacy evaluation of the product performed in 2007 and of post-registration data submitted in 2014 in France:

Preliminary tests
Preliminary tests realized in climate chambers allowed to choose PEL101GV as the best molecule, to justify the concentration and the dosage, to test different frost conditions (latency, length, temperature), to evaluate persistence of activity, to find the best time for treating and to show the correlation between elicitation and neutral and phosphate sugars levels.
The trials presented point the fact that this product is an elicitor, which induces cold resistance and reduces damages due to frost events in spring on the first growth stages of vine.
The trials in climatic room show a correlation between the protection level and the answer of biological markers which are the neutral sugars (glucose, fructose, sucrose) or phosphated (glucose-1-phosphate, Glucose-6-phosphate, etc.).

Efficacy
Trials have been made with 3 vine types : Cabernet sauvignon, Pinot Noir et Chardonnay.
Even if applications of PEL101GV have been made according to meteorological announcements of frost event, this one has not happen. Efficacy has been evaluated by observation of cold resistance markers identified beyond, i.e. sugar levels which are linked with cold protection indices.
It was not possible to observe the decrease of the leaves damages but neutral and phosphate sugar levels have been measured. In controlled conditions, an increase of the sugar level has been noticed, allowing to suppose that the elicitor induced alterations in the metabolic ways which gives to cells a protection gain against frost.
According to the vine type, optimal dosages and persistence are:

- for Chardonnay, the most sensitive vine type, is better protected during 3 days with a concentration of PEL101GV from 54 to 162 µg/L,
- for Pinot noir during 9 days with a concentration of PEL101GV of 5.4 µg/L,
- for Cabernet sauvignon, the most resistant vine type, during 14 days with a concentration of PEL101GV from 54 to 162 µg/L

The answer is dose dependant and vine type dependent but the lack of statistical tests do not allow to be sure of this relationship. The applicant does not propose any exact dose of application per hectare, only the fact that it must be under 500 mg/ha.

The eliciting effect of PEL 101GV has been demonstrated with the measure of biological markers (sugar levels) in field conditions. The correlation between the rate of biological markers and the frost resistance in controlled conditions has been demonstrated before.
It is proposed to give an authorization with a monitoring to adapt the dosage.
However, it is necessary to dispose of a measure of the direct effect on the necroses due to frost in field conditions.

Summary of post-registration data submitted in 2014 in France:
The petitioner has established 7 trials in order to evaluate the efficacy of PEL101GV.
In 4 of those 7 trials, the product was not applied according to the claimed GAP (applied to soon regarding plant phenology). Therefore, the efficacy of the product during those 4 trials was low.
During the 3 trials in which the application was realized at the good phenological stage, the efficacy of the product PEL101GV was assessed regarding several parameters such as number of bunches per plant, mean weight per bunches and mean yield per plant. Number of frozen bud was evaluated in only 1 single trial whereas it was the aim of the post-approval demand. However, the parameters evaluated can be considered as efficacy in an indirect way. The level of indirect protection can be considered as good since in all trials, number of bunches per plant, mean weight per bunches and mean yield per plant were improved in plots treated with PEL101GV. In the trial in which number of frozen buds was evaluated, the application of PEL101GV significantly reduces the number of frozen buds (13 % vs. 27% in the UTC). The data provided are considered as satisfying.

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

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

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

No adverse effects on treated crops were identified in previous evaluation. However no data was provided on the potential effect on vinification.

Applicant is invited to pay attention to argue the absence of negative effects on vinification following the use of PEL101GV. Data may be based on practical field data from technical institutes.

These consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

No undesirable or unintended side-effects were identified in previous evaluation.

More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.13. 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?

[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).