

REGISTRATION REPORT

Part A

Risk Management

Product code: PEL101GV

Product name(s): PEL101GV

Chemical active substance(s):

Heptamaloxyloglucan, min. 780 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal)

Applicant: Elicityl S.A.

Date: 16 September 2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company ELICITYL S.A. has requested a marketing authorisation in France for the product PEL101GV (product code: PEL101GV), containing min. 780 g/kg heptamaloxyloglucan¹ as a frost damage protector for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

Appendix 3 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of ELICITYL S.A.'s application submitted on 31/05/2023 to market PEL101GV in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance heptamaloxyloglucan of this product in France and in other Member States (MSs) of the Southern zone.

Heptamaloxyloglucan is a low risk active substance, therefore PEL101GV shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2023-1860) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of PEL101GV has been made using endpoints agreed in the EU peer review of heptamaloxyloglucan. It also includes assessment of data and information related to PEL101GV where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2022/2315 of 25 November 2022 renewing the approval of the low-risk active substance heptamaloxyloglucan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"](#); SANCO/11244/2011 rev. 5

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of PEL101GV.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant:

« No new studies have been conducted for this application dossier.

All of the studies presented in this dossier have already been submitted by Elicityl S.A. for the authorisation of PEL101 GV in France and for the approval and renewal of approval of the active substance at EU level. Therefore, all the studies submitted have already been evaluated by experts according to Uniform Principles. ».

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	PEL101GV
Product name in MS	PEL101GV
Authorisation number	2070108
Kind of use	Professional use
Low risk product (article 47)	Yes
Function	Frost damage protector
Applicant	ELICITYL S.A.
Active substance(s) (incl. content)	Heptamaloxyloglucan, min. 780 g/kg
Formulation type	XX ⁵ (Lyophilisate (freeze-dried cake))

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁵ The codes which are the closest to the formulation are water-soluble powder (SP), water-soluble granule (SG) or water-soluble tablet (ST) as 'PEL101GV' is a solid to be used for dissolution in water. However, the representative formulation is neither a powder nor a granule or a tablet, therefore it is labelled as 'XX' (see renewal report SANTE/2022/10198 Rev 0 14 October 2022)

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Packaging	Bottle of Glass borosilicate (0,0002 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for PEL101 GV resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	None
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	/

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁶ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021⁷ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁸ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021⁹ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop¹⁰ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

⁶ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁷ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁸ SANCO document “guidance document: - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹⁰ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

2.5.1 Restrictions linked to the PPP

The authorisation renewal of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Bystander and resident protection	
-	Respect an unsprayed zone of 10 meters from the last treated raw and : - areas where bystanders are present during treatment - areas where residents could be present.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters ¹¹ to surface water bodies.
Other specific restrictions	
Re-entry period	6 hours.
Storage	-
SPa 1	-
Risk mitigation measures	-
Risk mitigation measures	None
-	

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

¹¹ in consistency with French Order of 4 May 2017 (Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime), modified by the French Order of 27 December 2019.

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2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2025-09-16

PPP (product name/code): PEL101GV
Active substance 1: Heptamaloxyloglucan
Safener: -
Synergist: -
Applicant: ELICITYL S.A.
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Frost damage protector

Formulation type: XX ^(a, b)
Conc. of a.s. 1: min. 780 g/kg ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☒
Non-professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis per ha ^(f) RMS conclusion
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Vine	F	Frost damage	Foliar spraying using an air pressured system	BBCH 07-16 (budding to 6 leaves) Early spring	a) 4 b) 4	4 days	a) 69 - 560 mg/ha b) 277 - 2240 mg/ha	a) 54 – 437 mg/ha b) 216 – 1750 mg/ha	100- 400	F	Acceptable 1-4 applications 12 to 48 h before freezing temperatures

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

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** The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and 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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The plant protection product PEL101GV is made of 100% technical active substance PEL101GV. The appearance of the product is that of highly expanded white beige freeze dried cake and is odourless. Based on literature, structural formula and oxygen balance, it is concluded that the preparation is not flammable, not explosive and does not possess oxidizing or auto-flammability properties. It has a pH value of approximately 7.0 in a 1% w/v aqueous solution. There is no effect high temperature on the stability of the formulation, since after 14 days at 54°C in a glass container, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a water-soluble powder formulation. The intended concentration of use is 0.0000173% w/v to 0.00056 % w/v. The product is not intended to be used in tank mixtures.

The commercial packaging is a Bottle (up to 2L) of Glass borosilicate.

3.2 Efficacy (Part B, Section 3)

The efficacy level of the product PEL101GV is considered acceptable for the claimed use ;

The phytotoxicity level of the product PEL101GV is considered negligible for the claimed use ;

The risks of negative impact on yield, quality, - and propagation are considered negligible ;

The risk of negative impact on wine-making is considered acceptable ;

The risk of negative impact on succeeding crops is considered negligible.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

The method is suitable for the determination of heptamaloxyloglucan in the preparation PEL101GV since it has been accepted for the determination of heptamaloxyloglucan in the technical active substance by RMS in the RAR. The active substance contain Patulin as relevant impurity and as the plant protection product PEL101GV is made of 100% w/w technical active substance ,the same method already accepted for the determination of Patulin in the technical active substance by RMS in the RAR has been reapplied to the preparation .

3.3.2 Analytical methods for residues

No methods are required for residues, as the active substance heptamaloxyloglucan is a natural substance, and that there is no definition of residues or MRL are set in plant ,sol ,air ,water and animal matrices.

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3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

PEL101GV has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin and eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model 2022:

		Heptamaloxyloglucan
Model data	Level of PPE	% of systemic AOEL (AOEL = 416 mg/kg bw/day*)
Application rate		560 mg a.s./ha
Vine, (4 x 0.00056 kg product/ha, 100 L/ha, application equipment: vehicle-mounted <u>upward</u> spraying)		
Spray application out-door (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	<0.01
Vine, (4 x 0.00056 kg product/ha, 100 L/ha, application equipment: manual hand-held <u>upward</u> spraying)		
Spray application out-door (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	<0.01
Vine, (4 x 0.00056 kg product/ha, 100 L/ha, application equipment: manual knapsack <u>upward</u> spraying)		
Spray application out-door (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	<0.01

* As surrogate, the value of 416 mg/kg b.w./day could be used for comparison of exposure to the daily sugar consumption (WHO).

Conclusion: According to the exposure assessment using EFSA model, operator exposure to PEL101GV is below the value of 416 mg/kg b.w./day (daily sugar consumption) with work wear.

3.4.3 Worker exposure

Based physico-chemical properties of heptamaloxyloglucan, exposure via the dermal route is considered not to be relevant. Therefore, no unacceptable risk is expected for the worker re-entering into treated crops after application.

3.4.4 Bystander exposure

According to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032):

“When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

Since no AAOEL has been established during renewal of Heptamaloxyloglucan, no acute bystander exposure assessments can be performed with the EFSA model. Therefore, only resident exposure is performed and covers bystander exposure.

3.4.5 Resident exposure

Considering proposed uses, resident exposure was estimated using the EFSA model 2022:

Heptamaloxyloglucan		
Model data		% of systemic AOEL (AOEL = 416 mg/kg bw/day*)
Number of applications and application rate		4 x 560 mg a.s./ha
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3.0 µg/cm ² /kg a.s./ha Interval between treatments: 4 days		
Resident child Body weight: 10 kg	Drift (75 th perc.)	<0.01
	Vapour (75 th perc.)	<0.01
	Deposits (75 th perc.)	<0.01
	Re-entry (75 th perc.)	-
	Sum (mean)	<0.01
Resident adult Body weight: 60 kg	Drift (75 th perc.)	<0.01
	Vapour (75 th perc.)	<0.01
	Deposits (75 th perc.)	-
	Re-entry (75 th perc.)	-
	Sum (mean)	<0.01

* As surrogate, the value of 416 mg/kg b.w./day could be used for comparison of exposure to the daily sugar consumption (WHO).

Conclusion: According to the exposure assessment using EFSA model, resident exposure to PEL101GV

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is below the value of 416 mg/kg b.w./day (daily sugar consumption) without mitigation measures.

3.4.6 Combined exposure

Not relevant (only one active substance).

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. The active substance heptamaloxyloglucan has been included in Annex IV of Regulation (EC) 396/2005 by Regulation (EC) 500/2013 of 30 May 2013.

No MRL are deemed necessary according to the EFSA Peer Review (EFSA Journal 2022;20(3):7210), in the absence of the need for toxicological reference values for heptamaloxyloglucan the investigation of residues and consumer exposure estimates are not necessary.

The chronic and the short-term intakes of heptamaloxyloglucan residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS, agrees with the authorization of the intended uses.

Table: Information on PEL101GV (KCA 6.8)

Crop	PHI for PEL101GV proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for PEL101GV proposed by zRMS	zRMS Comments (if different PHI proposed)
		Heptamaloxyloglucan		
Grape-vines	F	Not relevant		

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for PEL101GV
Crop group	Led by heptamaloxyloglucan	
None	Not relevant	-

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of heptamaloxyloglucan in soil and surface water have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided. PEC soil and PEC_{sw} derived for the active substance are used for the ecotoxicological risk assessment. Considering the nature of the active substance, exposure of groundwater compartment to the heptamaloxyloglucan is not expected. Consequently, no risk assessment of groundwater contamination is deemed necessary.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance heptamaloxyloglucan is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None .

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Appendix 1 Copy of the product authorisation



PEL101GV_PREX_202
3-1860_D.pdf

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Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



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Front face:

PEL101GV®

Vigne

Renforcement de la résistance aux gelées de printemps

AMM N°2070108
Phytopharmaceutique de biocontrôle

ELICITYL S. A.



PEL101GV

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05/2023**Back face:**

PEL101GV®

Renforcement de la résistance aux gelées de printemps

AMM n°2070108

Détenteur de l'AMM : ELICITYL S.A. (746 av Ambroise Croizat - 38920 Crolles - France)

Produit phytopharmaceutique de biocontrôle

PEL101GV® est un activateur végétal (stimulant des défenses naturelles de la plante) utilisé préventivement sur la vigne afin de limiter les nécroses foliaires provoquées par le gel de printemps.

IMPORTANT**Lire la notice explicative avant utilisation.**

La boîte contient 5 flacons de 54 mg de PEL101GV®.

COMPOSITION**Type de formulation : XX**

Teneur en substance active: 874 g/kg / 87.4% p/p EL101GV® (Heptamaloxyloglucan).

PEL101GV® (AMM n°2070108)

- | | |
|--------|--|
| EUH401 | Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement. |
| P501 | Éliminer le contenu/récipient conformément à la réglementation locale. |
| SP1 | Ne pas polluer l'eau avec le produit et son emballage. |

EN CAS D'URGENCE**Composer le 15, le 112 ou contacter le centre anti-poison le plus proche**

Puis signaler vos symptômes au réseau PhytAttitude. N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de données de sécurité disponible sur demande.

N° de lot et date de fabrication : voir sur l'emballage.

**RESERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL
RÉEMPLOI DE L'EMBALLAGE INTERDIT**



PREMIERS SECOURS

En cas d'exposition par inhalation :

En cas de gêne, emmener la personne exposée à l'air frais. Restez au chaud et au repos.

Consulter un médecin ou un centre antipoison si des symptômes apparaissent.

En cas de contact avec les yeux :

Laver abondamment à l'eau douce et propre pendant 10 minutes en isolant les paupières. Enlevez les lentilles de contact si la victime les porte et vous pourrez les enlever facilement.

En cas de projection ou de contact avec la peau :

Enlevez immédiatement tout vêtement souillé ou éclaboussé. Laver la peau à l'eau et au savon.

Consultez un médecin en lui montrant l'étiquette en cas de douleur, de rougeur ou de lésions cutanées.

En cas d'ingestion : En cas d'ingestion, si la quantité est faible, rincer la bouche avec de l'eau et consulter un médecin. Gardez la personne exposée au repos. Consulter un médecin en lui montrant l'étiquette pour juger de la possibilité d'un suivi et d'un traitement secondaire en milieu hospitalier, le cas échéant.

CONDITIONS D'UTILISATION

- Programme de traitement n° 1 (sur la base de l'alerte au gel)

Le produit doit être appliqué entre 12 à 48 heures avant l'évènement gélif.

PEL101GV® diminue de 1 à 2 degrés °C la sensibilité de la culture au gel et peut être utilisé du stade de croissance "bourgeon éclaté" (BBCH 07) à "6 feuilles étalées" (BBCH 16). PEL101GV® reste actif pendant 4 jours après application. PEL101GV® peut être appliqué à nouveau 5 jours après l'application précédente, à raison de 4 applications maximum par saison.

- Programme de traitement n° 2 (systématique)

Un traitement systématique est possible pour couvrir toute la période à risque. Appliquer le premier traitement 3 jours après le stade pointe verte puis appliquer 2 traitements à 10 jours d'intervalle. En cas d'alerte au gel plus de 5 jours après le traitement, effectuer l'application la veille du gel annoncé (cf. programme n°1) puis continuer le calendrier d'application avec l'intervalle initial de 10 jours.

Respecter un maximum de 4 applications par cycle cultural.

PRÉPARATION DU TRAITEMENT

La cuve de remplissage doit être rincée entièrement pour éliminer toutes traces de traitement précédent. Remplir la cuve à la moitié du volume final. Ouvrir le(s) flacon(s) PEL101GV® (dépendant du volume final, voir notice). Ajouter l'eau dans le flacon avec la pipette fournie. Remettre le bouchon plastique du flacon et secouer la solution. Verser le flacon dans la cuve et rincer deux fois le flacon à l'eau. Compléter jusqu'au volume final. Appliquer dès que possible dans les 12 heures.

CONDITIONS D'APPLICATION

Application dans les conditions normales recommandées (se référer à la notice d'utilisation) avec le matériel conventionnel de pulvérisation. Volume de pulvérisation recommandé : 100 - 400 L/ha. Éviter tout ruissellement. Aucun problème de solubilité ou de viscosité.



Tableau des usages - Traitement des parties aériennes

Le flacon PEL101GV doit être dilué dans 100 à 400 litres d'eau pour traiter 1 hectare.

Culture	Cible	Dose		Nombre max. d'applications par cycle cultural	Stade croissance	Durée effet
		Surface traitee	Nombre de flacons			
Vigne (parties aériennes)	Renforcement de la résistance aux gelées de printemps	1 hectare (100 – 400 L.eau/ha) (max. : 0.5 g/ha)	1	4 applications	De bourgeon éclaté (BBCH 07) à 6 feuilles étalées (BBCH 16)	4 jours après application selon programme n°1

PRÉCAUTIONS

Aucun risque spécifique dans les conditions normales d'utilisation. Conformément à la réglementation en vigueur, PEL101GV® est exempt de classement toxicologique. Toutefois, nous recommandons d'appliquer les Bonnes Pratiques Agricoles pour la préparation de la bouillie. Se référer à la fiche de sécurité pour plus de détails.

RECOMMANDATIONS POUR LES MELANGES

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

BONNES PRATIQUES PHYTOSANITAIRES

Respecter les bonnes pratiques d'application.

STOCKAGE DU PRODUIT

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

NETTOYAGE DU PULVERISATEUR ET GESTION DES FONDS DE CUVE

À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

ELIMINATION DU PRODUIT, DE L'EMBALLAGE

Réemploi de l'emballage interdit.

Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte l'élimination des déchets dangereux.

EN CAS DE DEVERSEMENT ACCIDENTEL

Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

LES BONS GESTES POUR TRAITER EN TOUTE SÉCURITÉ



• N'utilisez les produits phytopharmaceutiques que si nécessaire.



• Protégez votre santé et celle de votre entourage.



• Surveillez les conditions météorologiques.



• Protégez les points d'eau.



• Protégez les pollinisateurs.



• Préservez la faune sauvage.



 D'INFOS SUR [HTTPS://WWW.UIPP.ORG/PHYTOPRATIQUE/](https://www.uipp.org/phytopratique/) : FLASHEZ-MOI

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite. Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

Fabriqué en France par ELICITYL S.A.
Détenteur de l'AMM : ELICITYL S.A.

ELICITYL S.A. - 746 av Ambroise Croizat - 38920 Crolles - France
Tél : +33 (0)4 76 40 71 61 - Fax : +33(0)4 76 45 59 50



PEL101GV

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05/2023**Bottle:****PEL101GV®**

Détenteur de l'AMM et fabricant : ELICITYL S.A.
38920 Crolles, France
Tel: +33 (0)4 76 40 71 61
contact@elicityl.fr

Renforcement de la résistance aux gelées de printemps
Heptamaloxyloglucan

Remplir le flacon d'eau avant dilution dans 100 - 400 litres. La stabilité de PEL101GV® en solution n'est pas garantie après 12h (se référer à la notice d'utilisation)

Produit phytopharmaceutique de biocontrôle - AMM n°2070108

PEL101GV® (AMM n°2070108)

EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
P501	Éliminer le contenu/réceptacle conformément à la réglementation locale.
SP1	Ne pas polluer l'eau avec le produit et son emballage.

Stockage dans local à température ambiante dans l'emballage original.

Contenance : 54 mg
Lot :