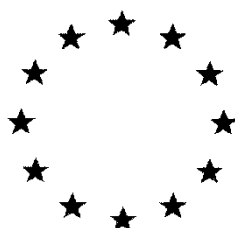


# ***European Commission***



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

## **Heptamaloxyloglucan**

### **Volume 3 – B.8 (PPP) – PEL101GV**

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

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## 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.8. ENVIRONMENTAL FATE AND BEHAVIOUR

The representative formulation (PEL101GV) is equivalent to the technical active substance (EL101GV), which has a minimum purity of 78%. The active substance is heptamaloxyloglucan.

Heptamaloxyloglucan acts as a stimulator of plant defence natural mechanisms (“elicitor”) in order to increase the cold resistance of the grapevine. The intended use for PEL101GV is reminded in the following table.

**Table B.8 (PPP) - 1: Intended uses for PEL101GV**

Crop	Maximum number of applications	Interval between applications (days)	Application rate (mg a.s./ha/application)	Growth stage
Vine	4	4	0.69 - 560	BBCH 07-16

Heptamaloxyloglucan is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose, xylose, galactose and fucose) after degradation. No other relevant metabolites, degradation or reaction products are expected to appear.

It is anticipated that the fate and environmental behaviour of the active substance is not influenced by the formulation. Therefore, no product specific studies are shown in the present Document. In the following table, data available that are considered in the environmental exposure assessment for heptamaloxyloglucan, are summarized.

**Table B.8 (PPP) - 2: Physical and chemical properties of heptamaloxyloglucan**

Parameter	Value
Molecular formula	C <sub>40</sub> H <sub>70</sub> O <sub>33</sub>
Molecular mass	1078.96 g/mol
Vapour pressure	1.1 x 10 <sup>-11</sup> Pa
Solubility in water	558 g/L at 20°C
The solubility of heptamaloxyloglucan was determined in the following solvents at 20°C (in mg/L) :	
n-heptane:	1
p-xylene:	<1
1,2-dichloroethane:	15
methanol:	10000
acetone:	3
ethyl acetate:	1
n-octanol:	19
Log Kow	<0

### B.8.1. FATE AND BEHAVIOUR IN SOIL

The representative formulation (PEL101GV) is equivalent to the technical active substance (EL101GV). Please refer to Volume 3 – B8 (AS) for studies with active substance.

#### B.8.1.1. Route and rate of degradation in soil

Please refer to B.8.1.

#### B.8.1.2. Mobility in soil

Please refer to B.8.1.

### B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC<sub>s</sub>)

As a worst case it is considered that there is no degradation of the active substance between the applications and all calculations are made based on initial soil concentrations.

**Table B.8 (PPP) - 3: Input parameters related to application for PEC<sub>soil</sub> calculations**

Use No.	1
Crop	Vines
Application rate (g as/ha)	0.560
Number of applications/interval	4 applications / 4 days
Crop interception (%)	40 (worst-case corresponding to BBCH 07)
Soil bulk density (g/cm <sup>3</sup> )	1.5
Depth of soil layer (relevant for plateau concentration) (cm)	5

**Table B.8 (PPP) - 4: PEC<sub>soil</sub> for heptamaloxyloglucan on vines**

Number of applications	Total application rate (g/ha) (no degradation between applications)	PEC <sub>soil</sub> (mg/kg soil)
1	0.56	0.0004
2	1.12	0.0009
3	1.68	0.0013
4	2.24	0.0018

The calculated PEC<sub>soil</sub> after application of global application is **0.0018 mg a.s./kg soil**.

### **B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC<sub>gw</sub>)**

The applicant did not provide any PEC<sub>gw</sub> calculations for heptamaloxyloglucan. RMS reminds that heptamaloxyloglucan is naturally present in the environment. It is a xyloglucan-derived oligosaccharide, which is an intermediate compound of natural organic matter decomposition process. It undergoes degradation by endogenous soil microorganisms naturally occurring in soil. Due to the ready biodegradability of heptamaloxyloglucan and to its sensitivity to the attack from many bacteria strains in soil giving raise to monomeric sugars as transformation product, heptamaloxyloglucan is not expected to reach groundwater.

In addition, this point was discussed in PRAPeR 67 meeting of experts. The experts concluded that heptamaloxyloglucan and its degradation products would not reach deeper soil layers such that groundwater concentrations would exceed 0.1µg/L, despite the fact that heptamaloxyloglucan would be expected to have low soil adsorption.

Therefore, in this specific case, it is agreed that no concern is expected for the groundwater and no PEC<sub>gw</sub> calculations are deemed necessary.

### **B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT**

The representative formulation (PEL101GV) is equivalent to the technical active substance (EL101GV). Please refer to Volume 3 – B8 (AS) for studies with active substance.

#### **B.8.4.1. Aerobic mineralisation in surface water**

Please refer to B.8.4.

#### B.8.4.2. Water/sediment study

Please refer to B.8.4.

#### B.8.4.3. Irradiated water/sediment study

Please refer to B.8.4.

### B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC<sub>sw</sub>, PEC<sub>sd</sub>)

The application parameters were as follows for vines

**Table B.8 (PPP) - 5: Input parameters related to application for PEC<sub>sw/sed</sub> calculations**

Plant protection product	PEL101GV
Use No.	1
Crop	Vines, early applications
Application rate (g as/ha)	0.56
Number of applications/interval (d)	4 / 0 (worst case)
Global application rate (g as/ha)	2.24 (= 4*0.56)
Crop interception	Not relevant for Step 1
Application window	Not relevant for Step 1
Models used for calculation	<i>FOCUS Steps 1-2 version 3.2</i>

**Table B.8 (PPP) - 6: Input parameters related to active substance heptamaloxyloglucan for PEC<sub>sw/sed</sub> calculations STEP 1**

Parameter	Value	Reference
Name	heptamaloxyloglucan	
Water solubility [mg/L]	558 000 at 20°C	Volume 3 – B2 (CA), point 2.5
K <sub>OC</sub> [L/kg]	0 10 000	Worst-case value for PEC <sub>sw</sub> Worst-case value for PEC <sub>sed</sub>
Total system DT <sub>50</sub> [days]	1000 at 20°C	Worst-case value

The maximum initial PECs for heptamaloxyloglucan in the surface water and in the sediment, calculated with FOCUS Step 1 are presented below (two simulations have been conducted separately for surface water and sediment):

**Table B.8 (PPP) - 7: FOCUS Step 1 PEC<sub>sw</sub> and PEC<sub>sed</sub> for heptamaloxyloglucan multiple applications of PEL101GV to vines (early applications)**

FOCUS Step	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
	Single global application	Single global application

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Step 1	0.77	5.35
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**B.8.6. FATE AND BEHAVIOUR IN AIR****B.8.6.1. Route and rate of degradation in air and transport via air**

The representative formulation (PEL101GV) is equivalent to the technical active substance (EL101GV). Please refer to Volume 3 – B8 (AS) for studies with active substance.

**B.8.6.2. Predicted environmental concentrations from airborne transport**

Concentrations from airborne transport are expected to be negligible. No calculations were performed.

**B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE**

No other routes of exposure are relevant for the representative uses of heptamaloxyloglucan.

**B.8.8. REFERENCES RELIED ON**

No study provided