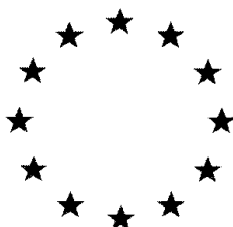


# **European Commission**



**VOLUME 3 – Annex B (PPP)**

**Laminarin**

**B.2 Physical and chemical properties**

**Rapporteur Member State: The Netherlands**

**April 2016**

**Draft Re-Assessment Report and Proposed decision of the Netherlands  
prepared in the context of the possible renewal of laminarin under Regulation  
(EC) 1107/2009**

### Version history page

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## B.2 Physical and chemical properties

### B.2.1 Vacciplant Fruits et Légumes

Data presented in the table below are all new data generated to support the representative product Vacciplant Fruits et Légumes. Based on the intended use, the concentration at which the product is applied ranges from 0.05% to 2%.

Test or study & Annex point	Guideline and Method	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
B 2.1-Appearance	Visual assessment	Batch No.14041175 (4.17% w/w – 43.7 g/L)	<u>Before and after storage for 2 weeks at 54°C:</u> Pale brown viscous liquid.	Y	CP 2.1/01, Cage S., 2015	<b>Acceptable</b>
B 2.2 Explosive properties and oxidizing properties	Expert statement	-	Not expected to present a significant hazard for explosivity. Not expected to present a significant hazard for oxidising properties.	N	CP 2.2/01, Ambrosi D., Michelet D., 2015	<b>Acceptable</b> None of the components of the formulation are classified as explosive or oxidising in the sense of Regulation (EC) 1272/2008.
B 2.3 Flammability and self-heating	Expert statement	-	Not expected to present a significant hazard for flammability. Not expected to present a significant hazard for auto-flammability.	N	CP 2.2/01, Ambrosi D., Michelet D., 2015	<b>Acceptable</b> None of the components of the formulation are classified as flammable or self-heating in the sense of Regulation (EC) 1272/2008.
B 2.4 Acidity or alkalinity and pH value	CIPAC MT 75.3	Batch No.14041175 (4.17% w/w –	<u>Before storage:</u> pH = 4.4 (1% w/v dilution) at 20°C pH = 3.7 (neat formulation) at 20°C	Y	CP 2.1/01, Cage S., 2015	<b>Acceptable</b>

Test or study & Annex point	Guideline and Method	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		43.7 g/L)	After storage for 2 weeks at 54°C: pH = 4.4 (1% w/v dilution) at 20°C pH = 4.0 (neat formulation) at 20°C			
	CIPAC MT 191		Before storage: 0.13% w/w as H <sub>2</sub> SO <sub>4</sub>  After storage for 2 weeks at 54°C: 0.09% w/w as H <sub>2</sub> SO <sub>4</sub>	Y		Acceptable
B 2.5 Viscosity and surface tension	OECD No.114	Batch No.14041175 (4.17% w/w – 43.7 g/L)	At 20°C, 150 to 5400 mPa.s. At 40°C, 130 to 2600 mPa.s. (Pseudoplastic fluid)	Y	CP 2.1/01, Cage S., 2015	Acceptable
	EC Method A.5, OECD No.115	Batch No.14041175 (4.17% w/w – 43.7 g/L)	Neat solution: At 25°C: 33.5 mN/m. At 40°C: 32.0 mN/m.  0.075% v/v dilution at 20°C: 42.5 mN/m  2% v/v dilution at 20°C: 34.0 mN/m	Y	CP 2.1/01, Cage S., 2015	Acceptable
B 2.6 Relative density and bulk density	EC Method A.3, OECD No.109	Batch No.14041175 (4.17% w/w – 43.7 g/L)	$D_{4}^{20} = 1.047$	Y	CP 2.1/01, Cage S., 2015	Acceptable
B 2.7 Storage Stability and shelf-life: effects of temperature on technical characteristics of	CIPAC MT 46.3	Batch No.14041175 (4.17% w/w – 43.7 g/L)	The test item was considered to be stable after 2 weeks at 54°C with regard to: - aspect of product (see CP 2.1) - aspect and weight of packaging (see below)	Y	CP 2.1/01, Cage S., 2015	Acceptable The product is stable for 2 weeks at 54 °C. All required properties for an SL were

Test or study & Annex point	Guideline and Method	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
the plant protection product			<ul style="list-style-type: none"> <li>- active substance content (see below)</li> <li>- pH of neat product and 1% dilution, and free acidity (see CP 2.4)</li> <li>- persistent foaming (see CP 2.8.2)</li> <li>- dilution stability (see CP 2.8.4)</li> </ul> <p><b>Aspect and weight of packaging:</b> 1 L white plastic PE-EV bottle with a white screw capped lid. The packaging showed no significant change, discoloration, signs of permeation or defect after storage. No significant difference in weight was observed. Weight difference over storage: Glass bottle: - 0.38% Commercial container: -0.03%</p> <p><b>Active substance content:</b> <u>Before storage:</u> 4.17% w/w (43.7 g/L) <u>After storage for 2 weeks at 54°C:</u> 4.15% w/w (-0.5% from T0) (43.4 g/L) (-0.7% from T0)</p>			<p>tested.</p> <p><b>Packaging</b> The applicant has clarified EV refers to ethylvinylalcohol.</p> <p><b>Analytical method</b> The method was validated in the report. Please refer to Volume 3CP B-5 for validation data.</p> <p><b>Shelf-life</b> A 2 year shelf-life study is not yet available and will be required. This data requirement can be addressed for the zonal authorization procedure of the product.</p>
B 2.8.1 Wettability	Not required (SL).					
B 2.8.2 Persistence of foaming	CIPAC MT 47.2	Batch No.14041175 (4.17% w/w – 43.7 g/L)	2% v/v: <u>Before and after storage for 2 weeks at 54°C:</u> No foam was observed (0 sec., 10 sec., 1 min., 3 min., 12 min.).	Y	CP 2.1/01, Cage S., 2015	<p><b>Acceptable</b> The highest proposed in-use concentration is 2%. The test is representative.</p>
B 2.8.3	Not required (SL).					



Test or study & Annex point	Guideline and Method	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility, spontaneity and dispersion stability						
B 2.8.4 Degree of dissolution and dilution stability	CIPAC MT 41.1	Batch No.14041175 (4.17% w/w – 43.7 g/L)	<p>2% v/v:  <u>Before and after storage for 2 weeks at 54°C:</u>            Uniform dispersion formed with no sediment present. No sediment observed after standing for 30 minutes. After standing for 24 hours, approximately 0.5 mL layer of fine particles observed at base of cylinder.</p> <p><u>Before storage:</u>            0.5 mg residue (wet sieve analysis)  <u>After storage for 2 weeks at 54°C:</u>            0.3 mg residue (wet sieve analysis)</p>	Y	CP 2.1/01, Cage S., 2015	<p><b>Acceptable</b>            The highest proposed in-use concentration is 2%. The test is representative.</p> <p>CIPAC MT41.1 is not yet published, but is provisional and available on <a href="http://www.cipac.org">www.cipac.org</a>.</p> <p>According to the test method the content of the active substance in the residue should be determined. As the amount of residue is no more than 0.5mg/100mL = 5mg/L in comparison to the concentration of 2%<math>\times</math>43.7g/L = 874mg/L, the amount of precipitated active substance is &lt;&lt;1%,</p>

Test or study & Annex point	Guideline and Method	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
						which is considered acceptable to the RMS.
B 2.8.5.1 Particle size distribution	Not applicable (SL).					
B 2.8.5.2 Dust content	Not applicable (SL).					
B 2.8.5.3 Attrition	Not applicable (SL).					
B 2.8.5.4 Hardness and integrity	Not applicable (SL).					
B 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability	Not required (SL).					
B 2.8.7 Flowability, pourability and dustability	Not applicable (SL).					
B 2.9 Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised	No data available.					
B 2.10 Adherence and distribution to seeds	Not applicable (SL).					
B 2.11 Other studies	-					



### **B.2.2 Summary**

The representative product Vacciplant Fruits et Légumes is a pale brown viscous soluble concentrate (SL). It is not hazardous in the sense of its physical and chemical properties and does not need to be classified as flammable, self-heating, oxidising or explosive. The pH of the product is 3.7 with an acidity of 0.13% H<sub>2</sub>SO<sub>4</sub>. The viscosity shows a non-Newtonian correlation to the shear rates applied with a range of 150 to 5400 mPa.s at 20°C. The product is surface active with a surface tension of 33.5mN/m at 25°C. Its relative density is 1.047.

In 1L PE-EV containers, the product was stable for 2 weeks at 54°C. All relevant technical properties were investigated. The product does not foam and is sufficiently stable when diluted with water at the highest proposed in-use concentration.

A 2 year shelf-life study is not yet available and will be required. This data requirement can be addressed for the zonal authorization procedure of the product.

### B.2.3 References relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 2.1/01	Cage S.	2015	Laminarin Formulation, Vacciplant Fruits et Légumes Accelerated Storage Stability for 2 Weeks at 54°C Huntingdon Life Sciences Eye Research Centre Eye, Suffolk, UK Study No.DQU0006-report GLP - Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary for the registration of Vacciplant Fruits et Légumes - has not been submitted in the past - has been made in accordance with the GLP principles	Laboratoires Goëmar S.A.S.
CP 2.2/01	Ambrosi D., Michelet D.	2015	Literature review on auto-flammability, flammability, explosive properties, oxidising properties of the ingredients of the product Vacciplant Fruits et Légumes Ambrosi Scientific Consulting 71570 Chaintré, France A.S.C. Report No.14/22 Not GLP – Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that no auto-flammability/ flammability/ oxidizing/explosives properties are expected. - has not been submitted in the past	Laboratoires Goëmar S.A.S.