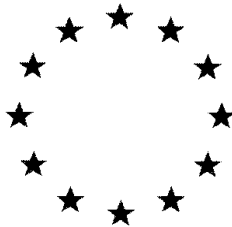


European Commission



VOLUME 3 – Annex B (PPP)

Laminarin

B.4 Further information

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**

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B.4 Further information

B.4.1 Safety intervals and other precaution to protect humans, animals and the environment

According to the Review Report SANCO/10488/04-rev.3 (04 October 2004), no ADI, ARfD were allocated for Laminarin. Laminarin is exempted from the requirement of residues data.

Pre-harvest interval (in days) for each relevant crop:

According to above argumentation, no PHI is necessary.

Re-entry period (in days) for livestock, to areas to be grazed:

According to above argumentation, no re-entry period for livestock is necessary.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated:

According to above argumentation, no re-entry period for man is necessary.

Withholding period (in days) for animal feeding stuffs:

According to above argumentation, no withholding period for animal feedingstuffs is necessary.

Waiting period (in days) between application and handling of treated products:

According to above argumentation, no period between application and handling treated products is necessary.

Waiting period (in days) between last application and sowing or planting succeeding crops

According to above argumentation, no waiting period before sowing or planting succeeding crops to be protected is necessary. Moreover, Vacciplant Fruits et Légumes is quickly destroyed in the soil.

Information on specific conditions under which the preparation may or may not be used

There are no specific agricultural, plant health or environmental conditions under which the preparation may or may not be used.

B.4.2 Recommended methods and precautions

Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

The product Vacciplant Fruits et Légumes is not classified. No specific risk is expected upon handling and use.

Usual precautions relative to the handling and use plant protection products should be followed.

Nature and characteristics of protective clothing proposed

Please refer to the Safety Data Sheet for Vacciplant Fruits et Légumes in Document KCP 4.2/01.

Suitability and effectiveness of protective clothing and equipment

No data is available.

Procedures for cleaning application equipment and protective equipment

There is no particular recommendation for cleaning application equipment.

There is no particular recommendation for cleaning of protective equipment.

Effectiveness of the cleaning procedures

No specific information is available regarding the effectiveness of the cleaning procedures proposed.

Procedures for handling and storage (warehouse and user level)

The recommendations made are the same as those when handling plant protection products.

Procedures for transport

The product is not regulated for transport.

Procedures in case of fire

Flash Point:	Not applicable (solid)
Hazardous Combustion Products:	Carbon monoxide (CO), Carbon dioxide (CO ₂)
Extinguishing Media:	All extinguishing agents usable (water spray or mist, foam, powders, CO ₂)
Unusual Fire and Explosion Hazards:	None
Fire Fighting Equipment:	Fire fighters and others exposed to products of combustion should wear chemical protection clothing and autonomous breathing equipment. Equipment should be thoroughly decontaminated after use.

Combustion products likely to be generated in the event of fire

See above.

Procedures to minimise the generation of waste

Wash the container three times and add the rinsate to spray solution.

For disposal of unused products, refer to a licensed contractor for collection and disposal of hazardous waste/products.

Do not re-use empty containers.

Dispose of empty packages through the specific collection services.

B.4.3 Emergency measures in case of an accident

Containment of spillages

No data provided.

Decontamination of areas, vehicles and buildings

No data provided.

Disposal of damaged packaging, adsorbents and other materials

For disposal of damaged packaging, adsorbents and other materials, refer to a licensed contractor for collection and disposal of hazardous waste/products.

Protection of emergency workers and bystanders

No data provided.

First aid measures

No data provided.

The references in the summary document to the SDS of the product should be replaced by the corresponding text included in the SDS (CP 4).

B.4.4 Packaging, compatibility of the plant protection product with proposed packaging materials

5 L container :	Material :	HDPE (density = 1.4)
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	Shape/size :	square, handle isolated from the content dimensions: 192mm*140mm*302 mm
	Opening :	63 mm diameter
	Closure :	screw cap with additional tamper evident, e.g. sealing disk
4*5 L box :	Material :	double-face corrugated board 0.694 kg/m ²
	Size :	dimensions: 385mm*284mm*307 mm
1 L container :	Material:	white coex PE/PA (weight : 80gr)
	Size:	height: 242 mm diameter: 89 mm
	Opening:	42 mm diameter
	Closure:	screw cap with additional tamper evident, e.g. sealing disk
1*1L box :	Material:	double-face corrugated board bc 50 white
	Size:	dimensions: 450 mm*185 mm*257 mm

The types of packaging fulfil UN requirements for the transport of dangerous goods.

RMS remark

The proposed packaging (HDPE and HDPE/PA) may not be considered representative for the packaging tested in the storage stability study (PE-EV); the regulation 284/2013/EU requires that the shelf-life is determined in the exact same material as proposed for the European market. Extrapolation of packaging materials is not harmonised.

B.4.5 Procedures for destruction or decontamination of the plant protection product and its packaging

B.4.5.1 Neutralisation procedures

Details of proposed procedures for neutralisation of small quantities (user level)

No specific procedure has been developed.

Evaluation of products of neutralization (small quantities)

No specific procedure has been developed.

Procedures for disposal of small quantities of neutralised waste

No specific procedure has been developed.

Details of proposed procedures for large quantities (warehouse level)

No specific procedure has been developed.

Evaluation of products of neutralisation (large quantities)

No specific procedure has been developed.

Procedures for disposal of large quantities of neutralised waste

No specific procedure has been developed.

B.4.5.2 Controlled incineration

Chemical active substances as well as plant protection products containing them, contaminated materials, or contaminated packaging shall be disposed of through controlled incineration in a licensed incinerator in accordance with the criteria laid down in Directive 94/67/EC of the Council.

No other method is currently available.

B.4.6 References relied on

Data point	Author(s)	Year	Title Source Company, Report No. GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.2/01	Anonymous	2015	Safety data sheet – Product: Vacciplant Fruits et Légumes Revision date 2015/01/23 Regulations (EC) No.1907/2006 – No.453/2010 GLP: no Published	N	N	-	Laboratoires Goëmar SAS