

# **European Commission**



## **List of Endpoints**

**Laminarin**

**Rapporteur Member State: The Netherlands**

**April 2016**

## List of end points

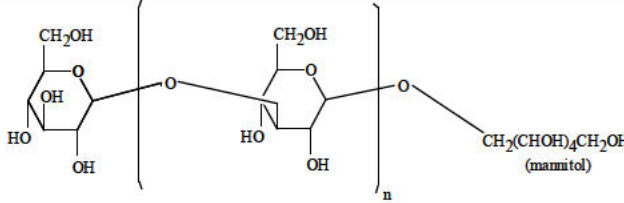
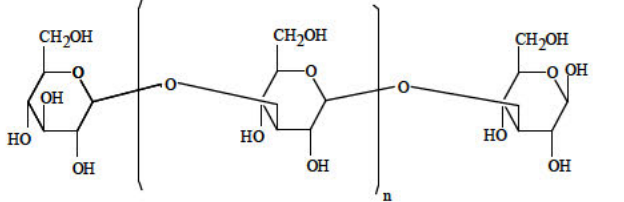
Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	April 2016	Laminarin

## Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

### Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Laminarin
Function (e.g. fungicide)	Elicitor of the crop's self-defence mechanisms
Rapporteur Member State	Netherlands
Co-rapporteur Member State	France

### Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)
Chemical name (CA)	Laminaran
CIPAC No	671
CAS No	9008-22-4
EC No (EINECS or ELINCS)	232-712-4
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	860 g/kg on dry matter
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities are present in technical Laminarin
Molecular formula	(C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>n</sub> n = 20 to 30
Molar mass	3240 – 4860 g/mol
Structural formula	 <p>M-series molecules</p>  <p>G-series molecules</p>

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**Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis****Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

Melting point (state purity)	Decomposes before melting
Boiling point (state purity)	Decomposes before boiling
Temperature of decomposition (state purity)	>200 °C (98%)
Appearance (state purity)	White to off-white crystals (98%)
Vapour pressure (state temperature, state purity)	< 2.6x10 <sup>-5</sup> Pa at 25°C (98%)
Henry's law constant (state temperature)	< 3.45x10 <sup>-7</sup> Pa m <sup>3</sup> mol <sup>-1</sup> (23-25°C)
Solubility in water (state temperature, state purity and pH)	301.5 g/L at 23°C (98%) No pH dependence expected
Solubility in organic solvents (state temperature, state purity)	in g/L (98%) n-heptane <10 mg/L, expressed as glucose xylene <10 mg/L, expressed as glucose 1,2-dichloroethane <10 mg/L, expressed as glucose Methanol 60 mg/L, expressed as glucose Acetone 21 mg/L, expressed as glucose Ethylacetate <10 mg/L, expressed as glucose
Surface tension (state concentration and temperature, state purity)	72.2 mN/m at 20.2°C (1g/L)(98%) Not a surface active material
Partition coefficient (state temperature, pH and purity)	log P <sub>OW</sub> = -1.6 (pH 4, 7 and 9) (98%)
Dissociation constant (state purity)	No dissociation within an environmentally relevant pH range.
UV/VIS absorption (max.) incl. ε (state purity, pH)	At pH 1.9: λ <sub>max</sub> = 264 nm; ε = 245 to 294 L mol <sup>-1</sup> .cm <sup>-1</sup> At pH 7.0: λ <sub>max</sub> = 260 nm; ε = 242 to 290 L mol <sup>-1</sup> .cm <sup>-1</sup> At pH 11.8: λ <sub>max</sub> = 258 nm; ε = 264 to 317 L mol <sup>-1</sup> .cm <sup>-1</sup>
Flammability (state purity)	Not flammable in the sense of Reg (EC) 1272/2008 Self-ignition >420°C (both 90% pure)
Explosive properties (state purity)	Not explosive (theoretical consideration)
Oxidising properties (state purity)	Not oxidising (theoretical consideration)

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**Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis**

**Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)**  
**(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)**

**PPP (product name/code)**      **Vacciplant Fruits et Légumes**

**active substance 1**      Laminarin

**active substance 2**      none

**active substance**      none

**Formulation type:**      **SL**

**Conc. of as 1:** 45 g/L

**Conc. of as 2:** not relevant.

**Conc. of as:** not relevant

**safener- None**

**synergist**None

**Conc. of safener:** not relevant

**Conc. of synergist:** not relevant

**Applicant:**      **Laboratoires Goëmar SAS**

**Zone(s):**      central/southern/EU

**professional use**      ☒

**non professional use**      ☒

**Verified by MS:** Yes

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Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
1	EU	Apple (MABSD)	F	Gloeosporium GLOESP  Powdery mildew <i>Podosphaera leucotricha</i> PODOLE  Scab <i>Venturia inaequalis</i> VENTIN	Foliar spraying	BBCH 11- 89 March to November	20 / (7 days)	Standard orchard 1 L/ha  LWA 0.67 L/ha	Standardorch ard 45 g a.s./ha  LWA 30.2 g as/ha	200 - 500	0	a)  Per season: 20  b) 20 L/ha  c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.

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					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
2	EU	Apple (MABSD)	F	Fire blight <i>Erwinia amylovora</i> EWIAM	Foliar spraying	BBCH 56- 89 April to November	7 / (10 days)	Standard orchard : 0.75 L/ha  LWA : 0.5 L/ha	Standard orchard : 33.8 g a.s./ha  LWA 22.5 g a.s./ha	500- 1000	0	a) Per season: 7  b) 5.25L/ha LWA: 3.5L/ha  c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.
3	EU	Pear (PYUCO)	F	Fire blight <i>Erwinia amylovora</i> EWIAM	Foliar spraying	BBCH 56- 89 April to November	7 / (10 days)	Standard orchard : 0.75 L/ha  LWA : 0.5 L/ha	Standard orchard : 33.8 g a.s./ha  LWA 22.5 g a.s./ha	500- 1000	0	a) Per season: 7  b) 5.25L/ha LWA: 3.5L/ha  c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.

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					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
4	EU	Vine (VITVI)	F	Powdery mildew <i>Erysiphe necator</i> UNCINE	Foliar spraying	BBCH 11- 89  April to october	10 / (10 days)	2 L/ha	a) 90 g a.s./ha	100- 1000	0	a) Per season: 10 b)20L/ha
5	EU	Lettuce (LACSA)	F, G	Downy mildew <i>Bremia lactucae</i> BREMLA	Foliar spraying	BBCH 13- 49  January to Decembe r	per cycle: 6 per / 7 days season: 16 /( 7 days)	2.5 L/ha	113 g a.s./ha	500- 1000	0	a)Per crop:6 Per season: 16 b)Per cycle: 15L/ha Per season:40L/ha
6	EU	Strawberry (FRASS)	F, G	Powdery mildew <i>Podosphaera aphanis</i> ODOAP	Foliar spraying	BBCH 12- 92  March to October	7 / (7 days)	Min : 0.75 l Max : 1 L/ha	45 g a.s./ha	300- 1000	0	a)Per crop : 7 Per season : 7 b) 7L/ha c) Min 0.75 L/ha Max 1L/ha

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Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
7	EU	Strawberry (FRASS)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI  Leaf spot <i>Mycosphaerella fragariae</i> MYCOFR  Leaf scorch <i>Diplocarpon earliana</i> DIPCEA  Leather rot <i>Phytophthora cactorum</i> PHYTCC	Foliar spraying	BBCH 12- 92  February to Septembe r	7 / (5-7 days)	Min 1 L/ha Max 2 L/ha	Min 45 g a.s./ha Max 90 g a.s./ha	300- 1000	0	a)Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha  c)Apply Vacciplant at 1 L/ha for water volume below 500 L/ha. Above 500 L/ha keep the product concentration at 0.2 L/hL .



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					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
8	EU	Tomato (LYPES)	F, G	Bacterial speck <i>Pseudomonas syringae</i> pv tomato PSDMTM	Foliar spraying	BBCH 10- 89 April to October	7 / (7 days)	Min 1 L/ha Max 2 L/ha	Min 45 g a.s./ha Max 90 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha c)
9	EU	Tomato (LYPES)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI	Foliar spraying	BBCH 10- 89 January to Decembe r	7 / (7 days)	Min 1.5 L/ha Max 3 L/ha	Min 67.5 g a.s./ha Max 135 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b)Min: 10.5L/ha Max: 21L/ha
10	EU	Tomato (LYPES)	F, G	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89 March to Decembe r	7 / (7 days)	1 L/ha	45 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b) 7 L/ha

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					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
11	EU	Zucchini (CUUPG)	F, G	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89  January to Decembe r	6 / (5 days)	0.75 L/ha	33.8 g a.s./ha	100-500	0	a) Per crop: 6 Per season: 6 b) 4.5L/ha
12	EU	Pumpkins (CUUMA)	F	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89  January to Decembe r	6 / (5 days)	0.75 L/ha	33.8 g a.s./ha	100-500	0	a) Per crop:6 Per season: 6 b) 4.5L/ha
13	EU	Aubergine (SOLME) Pepper (CPSAN)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI	Foliar spraying	BBCH 60- 89  February to October	7 / (7 days)	3 L/ha	135 g a.s./ha	500- 1300	0	a) Per crop :7 Per season: 7 b) 21L/ha c)
14	EU	Lettuce (LACSA)	F	Grey mould <i>Botrytis</i> sp. BOTRSP	Foliar spraying	BBCH 16- 49  January to Decembe r	7 / (7 days)	3 L/ha	135 g a.s./ha	750- 1000	0	a) Per crop: 7 Per season: 7 b) 21L/ha

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Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
15	EU	Greenbean (PHSVV)	F,	Grey mould <i>Botrytis</i> spp. BOTRSP	Foliar spraying	BBCH 51- 89 March to Septembe r	7 / (7 days)	3 L/ha	a) 135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha
16	EU	Cucurbits: Cucumber (CUMSA) Zucchini (CUUPG)	F, G	Grey mould <i>Botrytis</i> spp. BOTRSP	Foliar spraying	BBCH 60- 89 January to Decembe r	7 / (7 days)	3 L/ha	135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha
17	EU	Cucumber (CUMSA)	F, G	Downy mildew <i>Pseudoperonospora cubensis</i> PSPECU	Foliar spraying	BBCH 51- 89 January to Decembe r	7 / (7 days)	3 L/ha	135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha c)
18	EU	Kiwi (ATICH)	F	Bacterial canker <i>Pseudomonas syringae</i> pv. <i>Actinidiae</i> PSDMAK	Foliar spraying	BBCH 11-  March to Novembe r	7/(10 days)	2 L/ha	90 g a.s./ha	700- 1000	0	a) Per season: 7 b) 14L/ha

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<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

**Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)**

**Regulation (EC) N° 1107/2009 Article 8.1(g)**

**Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Not applicable, inclusion in Annex IV of Reg (EC) 396/2005															

- |   |   |
|---|---|
| <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
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### Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Further information, Efficacy

##### Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

It was already demonstrated in biological assessment dossiers submitted for Vacciplant Fruits et Légumes in Belgium (2008) that this product reached a level of control sufficient when applied as preventive treatment on fruits and vegetables crops against a wide range of various pathogens.

For further information see also Volume 1 level 1: 1.5.4 Overview on authorisations in EU Member States.

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013).

The representative uses of the GAP are supported.

##### Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The representative uses of the GAP are supported, no negative effects are known.

##### Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

No undesirable or unintended side-effects on adjacent or succeeding crops are known when the product is applied as indicated on the label.

The representative uses of the GAP are supported.

##### Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

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### Methods of Analysis

#### Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Open, awaiting batch analysis data
Impurities in technical a.s. (analytical technique)	Open, awaiting batch analysis data
Plant protection product (analytical technique)	IC

#### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

##### Residue definitions for monitoring purposes

Food of plant origin	MRL exempt
Food of animal origin	MRL exempt
Soil	No residue definition proposed
Sediment	No residue definition proposed
Water surface	No residue definition proposed
drinking/ground	No residue definition proposed
Air	No residue definition proposed
Body fluids and tissues	No residue definition proposed

##### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required; MRL exempt
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required; MRL exempt
Soil (analytical technique and LOQ)	Not required, no residue definition proposed
Water (analytical technique and LOQ)	Not required, no residue definition proposed
Air (analytical technique and LOQ)	Not required, no residue definition proposed
Body fluids and tissues (analytical technique and LOQ)	Not required, no residue definition proposed

#### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	name
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Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>1</sup>:

No current harmonised classification.

Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

None

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<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>2</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.



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## Section 2 Mammalian Toxicology

### Impact on Human and Animal Health

#### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	High bioavailability (90%) within 24h
Toxicokinetics	No information available.
Distribution	Uniformly distributed
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Rapid and extensive (approx. 90%) via breath and flatus
Metabolism in animals	Extensively metabolised via colonic microbiota fermentation: production of Short Chain Fatty Acids
<i>In vitro</i> metabolism	Not determined
Toxicologically relevant compounds (animals and plants)	None: laminarin is a polysaccharide of glucose and mannitol
Toxicologically relevant compounds (environment)	None: laminarin is a polysaccharide of glucose and mannitol

#### Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD <sub>50</sub> oral	> 2000 mg/kg bw	
Rat LD <sub>50</sub> dermal	> 5000 mg/kg bw	
Rat LC <sub>50</sub> inhalation	> 1.02 mg/L air /4h ( <i>head-nose only</i> )	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising ( <i>M&amp;K test</i> )	
Phototoxicity	Not required	

#### Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat: no effects Dog: no effects	
Relevant oral NOAEL	90-day, dog: 1000 mg/kg bw per day 90-day rat: 1000 mg/kg bw per day	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	No data - not required	

**List of end points**

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**Section 2 Mammalian Toxicology****Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)**

<i>In vitro</i> studies	Ames test: negative Chromosome aberration in CHO cells (public literature): negative	
<i>In vivo</i> studies	Micronucleus: negative	
Photomutagenicity	not required	
Potential for genotoxicity	<i>Laminarin</i> is unlikely to be genotoxic	

**Long-term toxicity and carcinogenicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.5)**

Long-term effects (target organ/critical effect)	No data - not required	
Relevant long-term NOAEL	No data - not required	
Carcinogenicity (target organ, tumour type)	No data - not required	
Relevant NOAEL for carcinogenicity	No data - not required	

**Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)****Reproduction toxicity**

Reproduction target / critical effect	No data - not required	
Relevant parental NOAEL	No data - not required	
Relevant reproductive NOAEL	No data - not required	
Relevant offspring NOAEL	No data - not required	

**Developmental toxicity**

Developmental target / critical effect	Rat: Maternal toxicity: no effects Developmental toxicity: no effects Rabbit: Maternal toxicity: no effects Developmental toxicity: no effects	
Relevant maternal NOAEL	Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	

**Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)**

Acute neurotoxicity	No data - not required	
Repeated neurotoxicity	No data - not required	

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### Section 2 Mammalian Toxicology

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)

No data - not required

### Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance

No data - not required

Endocrine disrupting properties

No data - not required

Studies performed on metabolites or impurities

No data - not required

### Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Due to the nature of the active substance no medical surveillance is carried out.

### Summary<sup>3</sup> (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	Not allocated		
Acute Reference Dose (ARfD)	Not allocated		
Acceptable Operator Exposure Level (AOEL)	Not allocated		
Acute Acceptable Operator Exposure Level (AAOEL)	Not allocated		

### Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation

10% (default) for concentrate and dilution

### Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Use: lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, tractor mounted equipment, downward, application rate 0.135 kg a.s./ha

<u>Exposure estimates</u> (model):	<u>% of AOEL</u>
<u>German model</u>	
Without PPE:	<1
<u>UK POEM</u>	
Without PPE:	1

<sup>3</sup> If available include also reference values for metabolites

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## Section 2 Mammalian Toxicology

	<p><u>Use:</u> apples, pear, vine, strawberry, tomato, aubergine, pepper and kiwi, tractor mounted equipment, upward, application rate 0.090 kg a.s./ha</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>German model</u></p> <p>Without PPE: &lt;1</p> <p><u>UK POEM</u></p> <p>Without PPE: 2</p>
	<p><u>Use:</u> lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, handheld equipment, downward, application rate 0.135 kg a.s./ha</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>UK POEM</u></p> <p>Without PPE: &lt;1</p>
	<p><u>Use:</u> apples, pear, vine, strawberry, tomato, aubergine, pepper and kiwi, handheld equipment, upward, application rate 0.090 kg a.s./ha</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>German model</u></p> <p>Without PPE: &lt;1</p> <p><u>UK POEM</u></p> <p>Without PPE: 1</p>
	<p><u>Use:</u> lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, handheld equipment, greenhouse, application rate 0.135 kg a.s./ha</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>Dutch greenhouse model</u></p> <p>Without PPE: &lt;1</p>
Workers	<p><u>Use:</u> apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, field use, application rate 10 times 0.090 kg a.s./ha, TC 10000</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>EUROPOEM II</u></p> <p>Without PPE: 4</p>
	<p><u>Use:</u> lettuce, strawberry, tomato, aubergine, pepper, cucumber, zucchini, application rate 7 times 0.135 kg a.s./ha, TC 4500</p> <p><u>Exposure estimates (model):</u> % of AOEL</p> <p><u>Dutch greenhouse model</u></p> <p>Without PPE: 2</p>
Bystanders and residents	<1 % of AOEL ( <i>EUROPOEM II, German guidance paper and UK PSD guidance document</i> )

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## Section 2 Mammalian Toxicology

### Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>4</sup> :

Peer review proposal <sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

laminarin

No current harmonised classification.

None

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>5</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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## Section 3 Residues

### Residues in or on treated products food and feed

### Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

<b>Primary crops</b> (Plant groups covered) <b>OECD Guideline 501</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>Application(s)</b>	<b>DAT (days)</b>
	Fruit crops			
	Root crops			
	Leafy crops			
	Cereals/grass crops			
	Pulses/Oilseeds			
	Miscellaneous			
No plant metabolism studies submitted, not required				
<b>Rotational crops</b> (metabolic pattern) <b>OECD Guideline 502</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>PBI (days)</b>	<b>Comments</b>
	Root/tuber crops			
	Leafy crops			
	Cereal (small grain)			
	Other			
Rotational crop and primary crop metabolism similar?	No rotational crop metabolism studies submitted, not required			
<b>Processed commodities</b> (standard hydrolysis study) <b>OECD Guideline 507</b>	<b>Conditions</b>			
	20 min, 90°C, pH 4			
	60 min, 100°C, pH 5			
	20 min, 120°C, pH 6			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Standard hydrolysis studies were not conducted, not required.			
Plant residue definition for monitoring (RD-Mo) <b>OECD Guidance, series on pesticides No 31</b>		Not required		
Plant residue definition for risk assessment (RD-RA)		Not required		
Conversion factor (monitoring to risk assessment)		-		

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### Section 3 Residues

#### Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen			
	Goat/Cow			
	Pig			
	Fish	mg/kg DM		
	No livestock metabolism studies submitted, not required			
Time needed to reach a plateau concentration in milk and eggs (days)	No study submitted, not required			
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	not required			
Animal residue definition for risk assessment (RD-RA)	not required			
Conversion factor (monitoring to risk assessment)	-			
Metabolism in rat and ruminant similar (Yes/No)	-			
Fat soluble residues (Yes/No) (FAO, 2009)	Not relevant			

#### Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502	No confined rotational crop studies submitted, not required
Field rotational crop study OECD Guideline 504	No field rotational crop studies submitted, not required

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## Section 3 Residues

### Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

#### OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
High water content						
High oil content						
High protein content						
High starch content						
High acid content						
No storage stability studies submitted, not required						
Animal	Animal commodity	T (°C)	Stability (Month/Year)			
	Muscle					
	Liver					
	Kidney					
	Milk					
	Egg					
No storage stability studies submitted, not required						



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## Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) [OECD Guideline 509](#), [OECD Guidance, series on pesticides No 66](#) and [OECD MRL calculator](#)

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
No supervised residue trials submitted, not required						

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

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## Section 3 Residues

### Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Not relevant				

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## Section 3 Residues

### Residues from livestock feeding studies (Regulation (EU) No 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey		Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes/No		Yes/No		Yes/No		Yes/No		Yes/No	
Feeding study submitted										
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals
Muscle										
Fat										
Meat <sup>(b)</sup>										
Liver										
Kidney										
Milk <sup>(a)</sup>										
Eggs										
Method of calculation <sup>(c)</sup>										

(a): Estimated HR calculated at 1N level (estimated mean level for milk).

(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

# List of end points

## Rapporteur Member State

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## Section 3 Residues

### STMR calculations

**Median expected intake**  
(mg/kg bw/d)  
(mg/kg DM for fish)

**Representative feeding level** (mg/kg bw/d, mg/kg DM for fish) and **N rates**

Muscle

Fat

Meat<sup>(a)</sup>

Liver

Kidney

Milk

Eggs

Method of calculation<sup>(c)</sup>

Ruminant				Pig/Swine		Poultry		Fish	
Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
Dairy cattle		Lamb		Finishing		Layer		Trout	
						Turkey			
Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N

<sup>(a)</sup>: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(b)</sup>: When the mean level is set at the LOQ, the STMR is set at the LOQ.

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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### Section 3 Residues

#### Conversion Factors (CF) for monitoring to risk assessment

Not relevant

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## Section 3 Residues

### Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

#### OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies <sup>(a)</sup>	Processing Factor (PF)		Conversion Factor (CF <sub>p</sub> ) for RA <sup>(b)</sup>
		Individual values	Median PF	
No studies submitted, not required				

<sup>(a)</sup>: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

<sup>(b)</sup>: When the residue definition for risk assessment differs from the residue definition for monitoring

### Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

**Including all uses** (representative uses and uses related to an MRL application).

<b>ADI</b>	Not required
TMDI according to EFSA PRIMo	Not required
NTMDI, according to (to be specified)	Not required
IEDI (% ADI), according to EFSA PRIMo	Not required
NEDI (% ADI), according to (to be specified)	Not required
Factors included in the calculations	
<b>ARfD</b>	Not required
IESTI (% ARfD), according to EFSA PRIMo	Not required
NESTI (% ARfD), according to (to be specified)	Not required
Factors included in IESTI and NESTI	

### Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code <sup>(a)</sup>	Commodity/Group	MRL/Import tolerance <sup>(b)</sup> ( mg/kg) and Comments
<b>Plant commodities</b>		
		Since laminarin is a natural oligosaccharide and an ADI and/or ARfD are not necessary, it is proposed to maintain the MRL exemption through the inclusion in Annex IV of Regulation (EC) 396/2005.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (\*) after the figure.

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### Section 4 Environmental fate and behaviour

#### Environmental fate and behaviour

##### Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	No study submitted, not required. Laminarin is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose) after degradation
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Laminarin is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose) after degradation . No other relevant metabolites, degradation or reaction products are expected to appear.

##### Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	No study submitted, not required.
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No relevant metabolites, degradation or reaction products are expected to appear

##### Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Laminarin has a low molar absorption coefficient ( $\epsilon = 160 \text{ dm}^3 \cdot \text{mol}^{-1} \cdot \text{cm}^{-1}$ ), no photo degradation is expected to occur. No metabolites.
Mineralisation at study end	No study submitted, not required.
Non-extractable residues at study end	No study submitted, not required.

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### Section 4 Environmental fate and behaviour

#### Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions						
Soil type	X <sup>6</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. ( $\chi^2$ )	Method of calculation
no study, not required				30 (default) <sup>1</sup>			

<sup>1</sup> Technical Guidance Document on Risk Assessment, Part II, European Chemicals Bureau, 2003

#### Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

no study, not required

#### Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Parent	Soil photolysis					
Soil type	X <sup>7</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) calculated at ??°N	St. ( $\chi^2$ )	Method of calculation
no study, not required						

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>6</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

<sup>7</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.



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### Section 4 Environmental fate and behaviour

#### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>d</sub> <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>F</sub> <sub>oc</sub> (mL/g)	1/n
no study, not required							

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

\*Only relevant after implementation of the published EFSA guidance.

#### Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

no study, not required

## List of end points

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### Section 4 Environmental fate and behaviour

#### Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

no study, not required

#### Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 4: stable at 20 °C less than 10% degradation

pH 7: stable at 20 °C less than 10% degradation

pH 9: stable at 20 °C less than 10% degradation

#### Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

stable due to its low molar absorption coefficient

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

not relevant

#### ‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable  
(yes/no)

yes, study available

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## Section 4 Environmental fate and behaviour

### Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. (χ <sup>2</sup> )	Method of calculation
				At study temp	Normalise d to <i>x</i> °C <sup>c)</sup>		At study temp	Norma lised to <i>x</i> °C <sup>c)</sup>		
no study, not required										

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

<sup>c)</sup> Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

### Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water*	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. ( $\chi^2$ )	Method of calculation
no study, not required										

\* A value of 15 days could be considered here, based upon the TGD.

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Normalised using a Q10 of 2.58

### Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air

Not studied - no data requested

Photochemical oxidative degradation in air

-

Volatilisation

from plant surfaces: -

from soil: -

Metabolites

none

### Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for

Soil:Laminarin  
Surface water:Laminarin

## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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### Section 4 Environmental fate and behaviour

groundwater exposure

Sediment: Laminarin  
Ground water: Laminarin  
Air: Laminarin

### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

### Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

no monitoring data available, not required

Surface water (indicate location and type of study)

no monitoring data available, not required

Ground water (indicate location and type of study)

no monitoring data available, not required

Air (indicate location and type of study)

no monitoring data available, not required

### PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent

DT<sub>50</sub> (d): 30 days

Method of calculation

Kinetics: not applicable

Field or Lab: not relevant

Application data

Crop: lettuce  
Depth of soil layer: 5cm  
Soil bulk density: 1.5g/cm<sup>3</sup>  
% plant interception: 25%  
Number of applications: 16  
Interval (d): 7  
Application rate(s): 113 g a.s./ha

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	n.c.		0.700	
Short term 24h	n.c.	n.c.	0.684	0.692
2d	n.c.	n.c.	0.668	0.684
4d	n.c.	n.c.	0.638	0.668
Long term 7d	n.c.	n.c.	0.595	0.646

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PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
28d	n.c.	n.c.	0.366	0.515
50d	n.c.	n.c.	0.265	0.448
100d	n.c.	n.c.	0.069	0.273
Plateau concentration	n r.			

## PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

no calculations performed, not required

Application rate

-

\* Only relevant after implementation of the published EFSA guidance.

## PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

Due to the ready biodegradability of Laminarin and to its sensitivity to the attack from many bacteria strains in soil giving raise to glucose, there is no chance that Laminarin will ever reach the ground water level. Therefore there is no need to consider PEC<sub>gw</sub>

## PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Version control no. of FOCUS calculator: v1.1  
Molecular weight 3240-4860 (g/mol):  
K<sub>OC</sub>/K<sub>OM</sub> (mL/g): log P<sub>ow</sub> = -1.6  
DT<sub>50</sub> soil (d): 30 days (default)  
DT<sub>50</sub> water/sediment system (d): 15 d (default)  
DT<sub>50</sub> water (d): 15 d (default)  
DT<sub>50</sub> sediment (d): 1000 d (default)  
Crop interception (%): minimal crop cover

Parameters used in FOCUS<sub>sw</sub> step 3 (if performed)

not calculated

Application rate

Crop and growth stage: orchards/ vines/ fruiting vegetables BBCH 11-89; leafy vegetables BBCH 16-49  
Number of applications: orchards 20; vines 10; vegetables 7  
Interval (d): orchards/vegetables 7; vines 10  
Application rate(s): orchards 45 g a.s./ha; vines 90 g

## List of end points

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### Section 4 Environmental fate and behaviour

a.s./ha; vegetables 135 g a.s./ha  
 Application window: Orchards and vines: March-May, June-Sept; vegetables (leafy/fruiting) March-May, June-Sept, Oct-Feb

FOCUS STEP 1 Scenario orchards early	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	387.59		<0.001	
	24 h	370.09	378.84	<0.001	<0.001
	2 d	353.38	370.25	<0.001	<0.001
	4 d	322.18	353.90	<0.001	<0.001
	7 d	280.47	331.16	<0.001	<0.001
	14 d	202.96	285.40	<0.001	<0.001
	21 d	146.87	217.42	<0.001	<0.001
	28 d	106.28	171.03	<0.001	<0.001
	50 d	38.45	151.11	<0.001	<0.001
	100d	3.81	83.05	<0.001	<0.001

FOCUS STEP 1 Scenario orchards late	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	347.18		<0.001	
	24 h	331.50	339.34	<0.001	<0.001
	2 d	316.53	331.65	<0.001	<0.001
	4 d	288.59	316.99	<0.001	<0.001
	7 d	251.23	296.63	<0.001	<0.001
	14 d	181.80	255.64	<0.001	<0.001
	21 d	131.55	222.20	<0.001	<0.001
	28 d	95.20	194.75	<0.001	<0.001
	50 d	34.44	135.35	<0.001	<0.001
	100d	3.42	74.39	<0.001	<0.001

## List of end points

**Rapporteur Member State**      **Month and year**      **Active substance and Plant Protection Product (Name)**

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### Section 4 Environmental fate and behaviour

FOCUS STEP 2 Scenario orchards early minimal crop cover	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	24.09		<0.001	
	24 h	23.01	23.55	<0.001	<0.001
	2 d	21.97	23.02	<0.001	<0.001
	4 d	20.03	22.00	<0.001	<0.001
	7 d	17.44	20.59	<0.001	<0.001
	14 d	12.62	17.74	<0.001	<0.001
	21 d	9.13	15.42	<0.001	<0.001
	28 d	6.61	13.52	<0.001	<0.001
	42 d	3.46	10.63	<0.001	<0.001
Southern EU	0 h	38.17		<0.001	
	24 h	36.45	37.31	<0.001	<0.001
	2 d	34.80	36.47	<0.001	<0.001
	4 d	31.73	34.86	<0.001	<0.001
	7 d	27.62	32.62	<0.001	<0.001
	14 d	19.99	28.11	<0.001	<0.001
	21 d	14.46	24.43	<0.001	<0.001
	28 d	10.47	21.42	<0.001	<0.001
	42 d	5.48	16.85	<0.001	<0.001

FOCUS STEP 2 Scenario orchards late minimal crop cover	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	24.09		<0.001	
	24 h	23.01	23.55	<0.001	<0.001
	2 d	21.97	23.02	<0.001	<0.001
	4 d	20.03	22.00	<0.001	<0.001
	7 d	17.44	20.59	<0.001	<0.001
	14 d	12.62	17.74	<0.001	<0.001
	21 d	9.13	15.42	<0.001	<0.001
	28 d	6.61	13.52	<0.001	<0.001



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FOCUS STEP 2 Scenario orchards late minimal crop cover	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d	3.46	10.63	<0.001	<0.001
Southern EU	0 h	31.13		<0.001	
	24 h	29.73	30.43	<0.001	<0.001
	2 d	28.38	29.74	<0.001	<0.001
	4 d	25.88	28.43	<0.001	<0.001
	7 d	22.53	26.60	<0.001	<0.001
	14 d	16.30	22.92	<0.001	<0.001
	21 d	11.80	19.93	<0.001	<0.001
	28 d	8.54	17.47	<0.001	<0.001
	42 d	4.47	13.74	<0.001	<0.001

FOCUS STEP 1 Scenario vegetables fruiting	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	323.69		<0.001	
	24 h	309.07	316.38	<0.001	<0.001
	2 d	295.12	309.21	<0.001	<0.001
	4 d	269.06	295.55	<0.001	<0.001
	7 d	234.23	276.56	<0.001	<0.001
	14 d	169.50	238.34	<0.001	<0.001
	21 d	122.66	207.17	<0.001	<0.001
	28 d	88.76	181.58	<0.001	<0.001
	50 d	32.11	126.20	<0.001	<0.001
	100 d	3.19	69.36	<0.001	<0.001

FOCUS STEP 1 Scenario vines early	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	308.10		<0.001	
	24 h	294.18	301.14	<0.001	<0.001
	2 d	280.90	294.32	<0.001	<0.001



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FOCUS STEP 1 Scenario vines early	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	4 d	256.10	281.31	<0.001	<0.001
	7 d	222.95	263.24	<0.001	<0.001
	14 d	161.33	226.86	<0.001	<0.001
	21 d	116.74	197.19	<0.001	<0.001
	28 d	84.48	172.83	<0.001	<0.001
	50 d	30.57	120.12	<0.001	<0.001
	100 d	3.03	6.02	<0.001	<0.001

FOCUS STEP 1 Scenario vines late	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	324.08		<0.001	
	24 h	309.45	316.77	<0.001	<0.001
	2 d	295.47	309.59	<0.001	<0.001
	4 d	269.39	295.91	<0.001	<0.001
	7 d	234.52	276.90	<0.001	<0.001
	14 d	169.71	238.63	<0.001	<0.001
	21 d	122.80	207.42	<0.001	<0.001
	28 d	88.87	181.80	<0.001	<0.001
	50 d	32.15	126.35	<0.001	<0.001
	100 d	3.19	69.44	<0.001	<0.001

FOCUS STEP 2 Scenario Vines early minimal crop cover	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	15.84		<0.001	
	24 h	15.13	15.49	<0.001	<0.001
	2 d	14.44	15.14	<0.001	<0.001
	4 d	13.17	14.47	<0.001	<0.001
	7 d	11.46	13.54	<0.001	<0.001
	14 d	8.30	11.67	<0.001	<0.001
	21 d	6.00	10.14	<0.001	<0.001

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### Section 4 Environmental fate and behaviour

FOCUS STEP 2 Scenario Vines early minimal crop cover	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	28 d	4.34	8.89	<0.001	<0.001
	42 d	2.27	6.99	<0.001	<0.001
Southern EU	0 h	30.17		<0.001	
	24 h	28.81	29.49	<0.001	<0.001
	2 d	27.51	28.83	<0.001	<0.001
	4 d	25.08	27.55	<0.001	<0.001
	7 d	21.84	25.78	<0.001	<0.001
	14 d	15.80	22.22	<0.001	<0.001
	21 d	11.43	19.32	<0.001	<0.001
	28 d	8.27	16.93	<0.001	<0.001
	42 d	4.33	13.32	<0.001	<0.001

FOCUS STEP 2 Scenario Vines late minimal crop cover	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	15.84		<0.001	
	24 h	15.13	15.49	<0.001	<0.001
	2 d	14.44	15.14	<0.001	<0.001
	4 d	13.17	14.47	<0.001	<0.001
	7 d	11.46	13.54	<0.001	<0.001
	14 d	8.30	11.67	<0.001	<0.001
	21 d	6.00	10.14	<0.001	<0.001
	28 d	4.34	8.89	<0.001	<0.001
	42 d	2.27	6.99	<0.001	<0.001
Southern EU	0 h	23.01		<0.001	
	24 h	21.97	22.49	<0.001	<0.001
	2 d	20.97	21.98	<0.001	<0.001
	4 d	19.13	21.01	<0.001	<0.001
	7 d	16.65	19.66	<0.001	<0.001
	14 d	12.05	16.94	<0.001	<0.001
	21 d	8.72	14.73	<0.001	<0.001
	28 d	6.31	12.91	<0.001	<0.001

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### Section 4 Environmental fate and behaviour

FOCUS STEP 2 Scenario Vines late minimal crop cover	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d	3.30	10.15	<0.001	<0.001

FOCUS STEP 1 Scenario vegetables leafy	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	323.69		<0.001	
	24 h	309.07	316.38	<0.001	<0.001
	2 d	295.12	309.21	<0.001	<0.001
	4 d	269.06	295.55	<0.001	<0.001
	7 d	234.23	276.56	<0.001	<0.001
	14 d	169.50	238.34	<0.001	<0.001
	21 d	122.66	207.17	<0.001	<0.001
	28 d	88.76	181.58	<0.001	<0.001
	50 d	32.11	126.20	<0.001	<0.001
	100 d	3.19	69.36	<0.001	<0.001

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

not relevant

## List of end points

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## Section 5 Ecotoxicology

### Ecotoxicology

**Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)**

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail	a.s.	Acute	LD <sub>50</sub>	> 1700
	Preparation	Acute	LD <sub>50</sub>	None submitted or required
	a.s.	Long-term	LD <sub>50</sub> /10	> 170
	a.s.	Long-term	NOEC/NOAEC/NOAEL	None submitted.
Mammals				
Rat	a.s.	Acute	LD <sub>50</sub>	> 2000
Rat	Preparation	Acute	LD <sub>50</sub>	> 2000
Rat	a.s.	Long-term 90 day oral	NOAEL	1000
Endocrine disrupting properties (Annex Part A, points 8.1.5)				
None.				
Additional higher tier studies (Annex Part A, points 10.1.1.2):				
None.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):				
None.				

**Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)**

**Lettuce, tomato, zucchini, pumpkin, eggplant, cucumber, strawberry, green bean at 135 g a.s./ha [x 7 applications]**

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous	Acute	40.7322	> 42	10
All	Small omnivorous	Long-term	11.5911	> 14.7	5
Screening Step (Mammals)					
All	Small herbivorous	Acute	34.9866	> 57.2	10
All	Small herbivorous	Long-term	12.9327	77.5	5
Risk from bioaccumulation and food chain behaviour (Not relevant – logKow = -1.6)					

## List of end points

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## Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Risk from consumption of contaminated water</b>					
Scenarios	Indicator or focal species	Time scale	PEC <sub>dw</sub> x DWR	TER	Trigger
Leaf scenario	Birds	acute	0.017	> 100000	5
<b>Puddle scenario, Screening step</b>					
1) Application rate (351 g a.s./ha)/1700 mg/kg bw <50, TER calculation not needed.					
2) Application rate (351 g a.s./ha)/2000 mg/kg bw <3000, TER calculation not needed.					

## Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

\*This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Laboratory tests				
Fish				
<i>O. mykiss</i>	a.s.	Acute 96 hr (semi-static)	Mortality, LC <sub>50</sub>	> 100 mg a.s./L <sub>(nom)</sub>
<i>Danio rerio</i>	a.s.	Acute 96 hr (semi-static)	Mortality, LC <sub>50</sub>	> 100 mg a.s./L <sub>(nom)</sub>
<i>Brachidanio rerio</i>	Preparation	Acute 96 hr (static)	Mortality, LC <sub>50</sub>	> 103.9 mg prep./L (> 4.8 mg a.s./L <sub>(mm)</sub> )
Aquatic invertebrates				
<i>Daphnia magna</i>	a.s.	48 h (semi-static)	Mortality, EC <sub>50</sub>	> 100 mg a.s./L <sub>(nom)</sub>
<i>Daphnia magna</i>	Preparation	48 h (static)	Mortality, EC <sub>50</sub>	> 103 mg prep./L (> 4.89 mg a.s./L <sub>(mm)</sub> )
Sediment-dwelling organisms				
No data presented or required.				
Algae				
<i>S. capricornutum</i>	a.s.	72 h (semi-static)	Growth rate: E <sub>r</sub> C <sub>50</sub> (NOEC)  Biomass: E <sub>b</sub> C <sub>50</sub> (NOEC)	> 100 mg a.s./L <sub>(nom)</sub>  > 100 mg a.s./L <sub>(nom)</sub>

## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product ( <b>Name</b> )
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### Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
<i>Desmodesmus subspicatus</i>	Preparation	72 h (static)	Growth rate: E <sub>r</sub> C <sub>50</sub> (NOEC)  Biomass: E <sub>b</sub> C <sub>50</sub> (NOEC)	> 100 mg prep./L (> 4.8 mg a.s./L (mm)) > 100 mg prep./L (> 4.8 mg a.s./L (mm))
Higher plant				
<i>Lemna gibba</i>	a.s.	(static, or semi-static or flow- through)	Fronds number, EC <sub>50</sub> (NOEC)  <u>FronD area/fresh weight/dry weight</u> , E <sub>r</sub> C <sub>50</sub> (NOEC)	mg or µg a.s./L <sub>(nom)</sub> or (mm)
Potential endocrine disrupting properties (Annex Part A, point 8.2.3)				
None.				

<sup>1</sup>(<sub>nom</sub>) nominal concentration; (<sub>mm</sub>) mean measured concentration; prep.: preparation; a.s.: active substance

**List of end points**

<b>Rapporteur Member State</b>	<b>Month and year</b>	<b>Active substance and Plant Protection Product (<b>Name</b>)</b>
The Netherlands	April 2016	Laminarin

**Section 5 Ecotoxicology****Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

	Active substance	Metabolite1	Metabolite2	Metabolite3
logP <sub>O/W</sub>	-1.6			

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The Netherlands	April 2016	Laminarin

## Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS<sub>sw</sub> step 1-2 - TERs for laminarin – leafy and fruiting vegetables at 135 g a.s./ha x 7 applications

Scenario	PEC global max (µg L)	fish acute	Aquatic invertebrates	Algae	Higher plant
		<i>All tested</i>	<i>Daphnia magna</i>	<i>All tested</i>	<i>Lemna gibba</i>
		LC <sub>50</sub>	EC <sub>50</sub>	EC <sub>50</sub>	EC <sub>50</sub>
		100000 µg/L	100000 µg/L	4800 µg/L	x.xx µg/L
<b>FOCUS Step 1</b>	388	> 258	> 258	> 12.4	
<b>FOCUS Step 2</b>					
North Europe	71.7	> 1394	> 1394	> 66.7	
South Europe	57.8	> 1730	> 1730	> 83	
Trigger		100	100	10	10



## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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## Section 5 Ecotoxicology

### Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

\*This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>Apis mellifera</i>	a.s.,	Acute	Oral toxicity (LD <sub>50</sub> )	> 118.64 µg/bee
	a.s.,	Acute	Contact toxicity (LD <sub>50</sub> )	> 100 µg/bee

### Risk assessment for – lettuce at 135 g a.s./ha x 7 applications

Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i>	a.s., preparation	HQcontact	<1.35	50

### Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

#### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	a.s., preparation	Mortality, LR <sub>50</sub>  Reproduction, ER <sub>50</sub>	114.7 g/ha  > 370 g/ha
<i>Aphidius rhopalosiphi</i>	a.s., preparation	Mortality, LR <sub>50</sub>  Reproduction, ER <sub>50</sub>	> 370 g/ha  > 370 g/ha

### First tier risk assessment for – lettuce at 135 g a.s./ha x 7 applications

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in-field	HQ off-field <sup>1</sup> (1m)	Trigger
Phyliq	<i>Typhlodromus pyri</i>	114.7	<b>4.0</b>	0.07	2
Phyliq	<i>Aphidius rhopalosiphi</i>	> 370	< 1.24	< 0.02	2

<sup>1</sup>indicate distance assumed to calculate the drift rate

## List of end points

**Rapporteur Member State**      **Month and year**      Active substance and Plant Protection Product (**Name**)

The Netherlands	April 2016	Laminarin
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## Section 5 Ecotoxicology

### Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha) <sup>1,2</sup>	End point	% effect <sup>3</sup>	ER <sub>50</sub>
					Mortality, reproduction		

<sup>1</sup> indicate whether initial or aged residues

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

<sup>3</sup> indicate if positive percentages relate to adverse effects or not

**Risk assessment** for – [representative use] at [application rate] g a.s./ha [x number of applications]  
based on extended lab test or aged residue tests

Species	ER <sub>50</sub> (g/ha)	In-field rate	Off-field rate <sup>1</sup>

<sup>1</sup> indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field tests
Field studies
Additional specific test

## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
The Netherlands	April 2016	Laminarin

## Section 5 Ecotoxicology

### Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity
Earthworms					
	a.s.	Soil incorporation 10% OM	Chronic	Growth, reproduction, behaviour	NOEC 262 mg a.s./kg d.w.soil EC <sub>10</sub> , EC <sub>20</sub> could not be calculated as there were no significant effects up to the highest tested dose
Nitrogen transformation		a.s. preparation		Laminarin is quickly degraded by soil micro-organisms which have laminarase. No effect on microbial soil processes is expected.	

### Toxicity/exposure ratios for soil organisms

Lettuce at 135 g a.s./ha x 7 applications

Test organism	Test substance	Time scale	Soil PEC <sub>ini</sub>	TER	Trigger
Earthworms					
<i>Eisina</i>	a.s.	Chronic	0.700	356	5

### Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER<sub>50</sub> tests should be provided

Laboratory dose response tests

Species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g/ha) <sup>2</sup>	TER	Trigger
Extended laboratory studies : Semi-field and field test:						

## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product ( <b>Name</b> )
The Netherlands	April 2016	Laminarin

## Section 5 Ecotoxicology

Species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g/ha) <sup>2</sup>	TER	Trigger

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

## Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	Sludge microorganisms contain laminarase, therefore no effect on sludge microorganisms is expected.

## Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

Compartment	
soil	laminarin
water	laminarin
sediment	laminarin
groundwater	laminarin

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

## List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product ( <b>Name</b> )
The Netherlands	April 2016	Laminarin

## Section 5 Ecotoxicology

### Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	laminarin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>8</sup> :	No current harmonised classification.
Peer review proposal <sup>9</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	None

<sup>8</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>9</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

**List of end points**

<b>Rapporteur Member State</b>	<b>Month and year</b>	<b>Active substance and Plant Protection Product (<b>Name</b>)</b>
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**Appendix****Used compounds code(s)**

<b>Code/Trivial name*</b>	<b>IUPAC name/SMILES notation</b>	<b>Structural formula</b>

\* The compound code / trivial name in bold is the name used in the list of endpoints.