



Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **assimilated Regulation No 1107/2009**
as it applies in Great Britain

**Aqueous extract from the germinated seeds
of sweet Lupinus albus**

List of Endpoints

Great Britain

February 2025

Version History

When	What
June 2024	Initial DAR
February 2025	Updates made after ECP
February 2025	Updates made after additional information submitted post ECP
	Updates made after public consultation
	Updates made after additional information submitted post public consultation
	[Updates made after any additional steps not covered by the above]

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Background

This template for the List of Endpoints reflects the new data requirements for active substances and plant protection products as set out in assimilated Regulations No 283/2013 and 284/2013 of 1 March 2013, in accordance with assimilated Regulation No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

This template should be used in conjunction with the

- TEMPLATE TO BE USED FOR ASSESSMENT REPORTS (SANCO/12592/2012)
- TEMPLATE TO BE USED FOR ASSESSMENT REPORTS REGARDING LEVEL 3 OF VOLUME 1 (SANCO/11114/2012).

It is envisaged that there will be a general review of the templates for the List of Endpoints within the next years.

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

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

Implementation schedule

This document as regards the list of endpoints for chemical active substances has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014. The list of endpoints for microorganisms has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014.

This template should be used for assessment reports prepared for active substances for which an application for the approval or renewal of approval has been submitted as from 1 March 2015.

Preferably these templates should also be used for assessment reports for all active substances (chemicals as well as microorganisms):

- For which an application for approval has been submitted after 1 January 2014 (i.e. an application according to the data requirements as laid down in assimilated Regulation No 283/2013 and No 284/2013),
- covered by assimilated Regulation No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in assimilated Regulation No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market for which an application for the renewal of approval has been submitted before 1 March 2015.

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

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

Identity, Physical and Chemical Properties, Details of Uses, Further Information (assimilated Regulation No 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Aqueous extract from the germinated seeds of sweet Lupinus albus
Function (e.g. fungicide)	Fungicide

Identity (assimilated Regulation No 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	Not applicable (natural plant protein)
Chemical name (CA)	Not applicable (natural plant protein)
CIPAC No	N/A
CAS No	Not available for aqueous extract from the germinated seeds of sweet Lupinus albus Lead component BLAD: 1219521-95-5
EC No (EINECS or ELINCS)	701-313-1
FAO Specification	Not available
Minimum purity of the active substance as manufactured	Lead component BLAD: 20 % w/w (nominal), min-max: 18.8 % w/w - 21.2 % w/w
Identity of relevant impurities (of toxicological, ecotoxicological and/or	Quinolizidine alkaloids (QAs) with a limit of 0.005% w/w with lupanine as a marker compound, Max. 0.0035 % w/w

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environmental concern) in the active substance as manufactured	<p>None</p> <p>It is noted that the applicant proposed inclusion of quinolizidine alkaloids at total QAs max. 0.005 % w/w. Quinolizidine alkaloids may be present in lupin seeds, which subsequently may then be found in the aqueous extract from the germinated seeds of sweet Lupinus albus at low levels. If the content of the total QAs in the extract exceeds 0.006 % w/w, which may be indicated by the content of lupanine, they are designated as relevant impurities and a clause may be required to limit their concentration.</p>
Molecular formula	N/A
Molar mass	N/A
Structural formula	N/A

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Physical and chemical properties (assimilated Regulation No 283/2013, Annex Part A, point 2)

Melting point (purity)	N/A
Boiling point (purity)	100°C (100%)
Temperature of decomposition (purity)	N/A
Appearance (purity)	Dark brown coloured, viscous liquid with a pungent odour
Vapour pressure (temperature, purity)	Not determined
Henry's Law constant (temperature)	Not determined
Solubility in water (temperature, purity and pH)	Not determined
Solubility in organic solvents (temperature, purity)	Not determined
Surface tension (concentration and temperature, purity)	29.3 mN/m at 1.00 g/L aqueous dilution at 20.2°C
Partition coefficient (temperature, pH and purity)	Not determined
Dissociation constant (purity)	Not determined
UV/VIS absorption (max.) incl. ϵ (purity, pH)	For the lead component BLAD: UV-vis absorption spectra, neutral, 1.857×10^{-6} mol/L

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	Wavelength of maximum (nm)	Molar absorption coefficient (ε) value calculated (L/(mol·cm))
	204.944	1.862 x 10 ⁶
	276.233	1.335 x 10 ⁵
	289.97*	6.139 x 10 ⁴
	UV-vis absorption spectra, acidic, 2.114 x 10 ⁻⁷ mol/L	
	Wavelength of maximum (nm)	Molar absorption coefficient (ε) value calculated (L/(mol·cm))
	201.124	3.903 x 10 ⁶
	276.009	6.149 x 10 ⁴
	289.97*	9.461 x 10 ³
	*there were no maxima at this wavelength, but the applicant calculated the molar absorption coefficients in neutral and acidic conditions. The data is presented for completeness UV-vis absorption spectra, alkaline, 4.229 x 10 ⁻⁷ mol/L	

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	Wavelength of maximum (nm)	Molar absorption coefficient (ϵ) value calculated (L/(mol·cm))
	208.415	2.979×10^6
	290.391	1.655×10^5
Flammability (purity)	Not flammable – flash point >100°C	
Explosive properties (purity)	Not explosive	
Oxidising properties (purity)	Not oxidising	

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Classification and labelling with regard to physical and chemical data (assimilated Regulation No 283/2013, Annex Part A, point 10)

Substance	Aqueous extract from the germinated seeds of sweet Lupinus albus
Mandatory classification according to assimilated Regulation No 1272/2008 and its Adaptations to Technical Process.	No current harmonised classification.
GB Authority proposal¹ for mandatory classification according to assimilated Regulation (EC) No 1272/2008:	No mandatory classification in GB is proposed (HSE, 2023) ²

¹ It should be noted that mandatory classification and labelling is formally proposed and decided in accordance with assimilated Regulation No 1272/2008. Proposals for mandatory classification made in the context of the evaluation procedure under assimilated Regulation No 1107/2009 are not formal proposals.

² HSE (2023) MCL Technical Report: proposal for mandatory classification and labelling (MCL) of 'aqueous extract from the germinated seeds of sweet Lupinus albus', based on Annex VI, Part 2 of the assimilated CLP Regulation No 1272/2008. Date of report: November 2023. Accessed date: 30th April 2024. Available at <https://www.hse.gov.uk>

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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 (Aqueous extract from the germinated seeds of sweet Lupinus albus)

(Assimilated Regulation No 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	L a.i./ha min max (*) (kg/ha)		
Strawberry	GB	PROBLAD PLUS	F	Foliar fungi BOTRCI SPHRMA	Soluble concentrate (SL)	1000 g/kg (PROBLAD PLUS is a UVCB substance and is considered to be 100% pure with the lead component BLAD at 250g/L)	Foliar overall	BBCH 61-89 Spring to Summer	1-6	8 days	0.251-0.893 kg a.i./hL	450-1000	Min 2.0 (2.51) Max 3.2 (4.016)	01	Equivalent to maximum 800 g/ha lead component (BLAD) Note: (kg/ha) is based on a density of 1.255 g/mL.

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Strawberry	GB	PROBLAD PLUS	G	Foliar fungi BOTRCI SPHRMA	Soluble concentrate (SL)	1000 g/kg (PROBLAD PLUS is a UVCB substance and is considered to be 100% pure with the lead component BLAD at 250 g/L)	Foliar overall	BBCH 61-89 All seasons	1-6	8 days	0.251-0.893 kg a.i./hL	450-1000	Min 2.0 (2.51) Max 3.2 (4.016)	01	Equivalent to maximum 800 g/ha lead component (BLAD) Note: (kg/ha) is based on a density of 1.255 g/mL.
Tomatoes	GB	PROBLAD PLUS	F	Foliar fungi BOTRCI OIDINL	Soluble concentrate (SL)	1000 g/kg (PROBLAD PLUS is a UVCB substance and is considered to be 100% pure with the lead component BLAD at 250 g/L)	Foliar overall	BBCH 61-89 Spring to Summer	1-6	8 days	0.251-2.01 kg a.i./hL	200-1000	Min 2.0 (2.51) Max 3.2 (4.016)	01	Equivalent to maximum 800 g/ha lead component (BLAD) Note: (kg/ha) is based on a density of 1.255 g/mL.
Tomatoes	GB	PROBLAD PLUS	G	Foliar fungi BOTRCI OIDINL	Soluble concentrate (SL)	1000 g/kg (PROBLAD PLUS is a UVCB substance and is considered to	Foliar overall	BBCH 61-89 All seasons	1-6	8 days	0.251-2.01 kg a.i./hL	200-1000	Min 2.0 (2.51)	01	Equivalent to maximum 800 g/ha lead component (BLAD)

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						be 100% pure with the lead component BLAD at 250 g/L)							Max 3.2 (4.016)		Note: (kg/ha) is based on a density of 1.255 g/mL.
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<p>(a) For crops, the GB 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) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil borne 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. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(j) Growth stages 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 (Aqueous extract from the germinated seeds of sweet Lupinus albus))

Assimilated Regulation No 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)	GB or country For IT	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.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water Volume L/ha min-max	kg a.s./ha min-max (l) a) max rate per appl b) max total rate per crop/ season		
MRL Application (according to Article 8.1(g) of assimilated Regulation No 1107/2009)															
Strawberry	UK	PROBLAD	F	Botrytis cinerea (BOTRCI) Powdery mildew, including Podosphaera aphanis (PODOAP), Oidium sp.	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 40-94 Spring to Summer	6	8 days	0.4016 -0.892	450-1000	4.016	1	Open field, open protective structures (nets and open plastic covers) and walk-in tunnels. Note permanent

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

Crop and/or situation (a)	GB or country For IT	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.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water Volume L/ha min-max	kg a.s./ha min-max (l) a) max rate per appl b) max total rate per crop/season		
				(OIDISP), Erysiphe sp. (ERYSSP)											protected uses assessed in interzonal dRR
Table and Wine Grapes	UK	PROBLAD	F	Botrytis cinerea (BOTRCI) Erysiphe necator (UNCINE)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 55-89 Spring to Autumn	6	7 days	0.4016 -2.008	200-1000	4.016	1	LWA conversions will be proposed and considered in the dRR/BAD
Stone Fruit (Peach, Plum, Sweet Cherry, Sour Cherry, Apricot, Nectarine)	UK	PROBLAD	F	Monilinia sp. (MONISP), including: M. laxa, (MONILA), M. fruticola (MONIFC) and M. fructigena (MONIFG) Powdery mildew, including: Podosphaera pannosa	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 71-87 Spring to Autumn	3	7 days	0.2677 - 0.4016	1000-1500	4.016	1	<u>Qualified recommendations for use proposed.</u> extrapolated from SEU stone fruit efficacy data. Note environmental risk assessment for UK specific GAP (which differs from

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Crop and/or situation (a)	GB or country For IT	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.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				(SPHRPA), Podospaera sp. (PODOSP), Podospaera leucotricha (PODOLE), Sphaerotheca sp. (SPHRSP)											CEU GAP in time of application), is provided in the national addenda B8 and 9
Walnuts	UK	PROBLAD	F	Monilinia sp. (MONISP), including M. laxa (MONILA), M. fructicola (MONIFC) and M. fructigena (MONIFG) Powdery mildew, including Phyllactinia guttata (PHYLGU), Podospaera pannosa (SPHRPA), Podospaera sp. (PODOSP), Podospaera	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 71-87 Spring to Autumn	3	7 days	0.2677 - 0.4016	1000- 1500	4.016	1	<u>Qualified recommend ations for use proposed.</u> extrapolated from SEU stone fruit efficacy data. Note environment al risk assessment for UK specific GAP (which differs from CEU GAP in time of application), is provided in the national

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				leucotricha (PODOLE), Sphaerotheca sp. (SPHRSP)											addenda B8 and 9
Hazelnuts	UK	PROBLAD	F	Monilinia sp. (MONISP), including M. laxa, (MONILA), M. fructicola (MONIFC) and M. fructigena (MONIFG) Powdery mildew, including Phyllactinia guttata (PHYLGU), Podospharea pannosa (SPHRPA), Podosphaera sp. (PODOSP), Podospharea leucotricha (PODOLE), Sphaerotheca sp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 71-87 Spring to Autumn	3	7 days	0.2677 - 0.4016	1000-1500	4.016	1	<u>Qualified recommendations for use proposed</u> , extrapolated from SEU stone fruit efficacy data. Note environmental risk assessment for UK specific GAP (which differs from CEU GAP in time of application), is provided in the national addenda B8 and 9

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
Chestnuts	UK	PROBLAD	F	Monilinia sp. (MONISP), including M. laxa, (MONILA), M. fructicola (MONIFC) and M. fructigena (MONIFG) Powdery mildew, including Erysiphe flexuosa (ERYSFL), Podospharea pannosa (SPHRPA), Podosphaera sp. (PODOSP), Podospharea leucotricha (PODOLE), Sphaerotheca sp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 71-87 Spring to Autumn	3	7 days	0.2677 - 0.4016	1000-1500	4.016	1	<u>Qualified recommendations for use proposed.</u> extrapolated from SEU stone fruit efficacy data. Note environmental risk assessment for UK specific GAP (which differs from CEU GAP in time of application), is provided in the national addenda B8 and 9

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
Almonds	UK	PROBLAD	F	Monilinia sp. (MONISP), including M. laxa, (MONILA), M. fructicola (MONIFC) and M. fructigena (MONIFG) Powdery mildew, including Erysiphe flexuosa (ERYSFL), Podospharea pannosa (SPHRPA), Podosphaera sp. (PODOSP), Podospharea leucotricha (PODOLE), Sphaerotheca sp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 71-87 Spring to Autumn	3	7 days	0.2677 - 0.4016	1000-1500	4.016	1	<u>Qualified recommendations for use proposed.</u> extrapolated from SEU stone fruit efficacy data. Note environmental risk assessment for UK specific GAP (which differs from CEU GAP in time of application), is provided in the national addenda B8 and 9

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
Strawberry	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including Podosphaera aphanis (PODOAP), Oidium sp. (OIDISP), Erysiphe sp. (ERYSSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 40-94 Spring to Summer	6	8 days	0.4016 -0.892	450-1000	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance)
Tomato	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Oidium neolycopersici (OIDINL), Podosphaera sp. (PODOSP),	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				Leveillula taurica (LEVETA), Leveillula sp. (LEVESP)											in the dRR/BAD
Aubergine	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, Leveillula taurica (LEVETA) and Oidium neolycopersici (OIDINL).	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD
Cucumber	UK	PROBLAD	G	Powdery mildew, including Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP),	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)											conversions will be proposed and considered in the dRR/BAD
Courgette and Summer Squash	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water Volume L/ha min-max	kg a.s./ha min-max (l) a) max rate per appl b) max total rate per crop/season		
Melon	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD
Watermelon	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including:	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)											will be proposed and considered in the dRR/BAD
Pumpkin and Winter squash	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
				Sphaerotheca spp. (SPHRSP)											
Gherkins	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
Pepper	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Leveillula taurica (LEVETA), Leveillula sp. (LEVESP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD
Chilli Pepper	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Leveillula taurica (LEVETA), Leveillula sp. (LEVESP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water Volume L/ha min-max	kg a.s./ha min-max (l) a) max rate per appl b) max total rate per crop/season		
Okra	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Powdery mildew, including: Golovinomyces cichoracearum (ERYSCI), Erysiphe spp. (ERYSSP), Podosphaera fuliginea (SPHRFU) and Sphaerotheca spp. (SPHRSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions will be proposed and considered in the dRR/BAD
Sweetcorn	UK	PROBLAD	G	Botrytis cinerea (BOTRCI) Erysiphe spp. (ERYSSP)	Soluble Concentrate	UVCB 100%	Foliar overall	BBCH 20-89 All seasons	6	7 days	0.2677 -2.008	200-1500	4.016	1	Permanent glasshouses and walk-in tunnels (define as per EFSA guidance). LWA conversions

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					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min- max (k)	Interval between application (min)	kg a.s. /hL min- max (l)	Water Volume L/ha min- max	kg a.s./ha min- max (l) a) max rate per appl b) max total rate per crop/ season		
															will be proposed and considered in the dRR/BAD

<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>(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. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</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>
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(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(m) PHI - minimum pre-harvest interval
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	

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Further information, Efficacy

Effectiveness (assimilated Regulation No 284/2013, Annex Part A, point 6.2)

The representative uses/GAP's are supported.

Adverse effects on field crops (assimilated Regulation No 284/2013, Annex Part A, point 6.4)

The representative uses/GAP's are supported.

Observations on other undesirable or unintended side-effects (assimilated Regulation No 284/2013, Annex Part A, point 6.5)

The representative uses/GAP's are supported.

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

No metabolites have been determined in soil, therefore consideration of metabolites in groundwater is not necessary.

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Methods of Analysis

Analytical methods for the active substance (assimilated Regulation No 283/2013, Annex Part A, point 4.1 and assimilated Regulation No 284/2013, Annex Part A, point 5.2)

Technical a.s.	HPLC-UV Modified Lowry method, UV/Vis
Impurities in technical a.s.	GC-FID GC-MS/MS
Plant protection product	HPLC-UV Modified Lowry method, UV/Vis

Analytical methods for residues (assimilated Regulation No 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin	Not required
Food of animal origin	Not required
Honey	Not required
Soil	Not required
Sediment	Not required
Water surface	Not required
Drinking / Ground	Not required

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Air	Not required
Body fluids and tissues	Not required

Monitoring/Enforcement methods

Food/feed of plant origin	Not required
Food/feed of animal origin	Not required
Honey	Not required
Soil	Not required
Water	Not required
Air	Not required
Body fluids and tissues	Not required

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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics)
(assimilated Regulation No 283/2013, Annex Part A, point 5.1 as applicable in GB)

Rate and extent of oral absorption/systemic bioavailability	No specific data and none are required. The active substance is a UVCB plant extract, with all components (except intact BLAD which is subject to degradation to its amino acids in the gastro-intestinal tract) expected to be well absorbed. An estimate of 100% oral absorption can be applied in derivation of the AOEL.
Toxicokinetics	Tissue concentrations of all the components of the active substance are under physiological control as they are compounds naturally found in edible plant material.
Distribution	Extensive metabolism means that the active substance and its metabolites/derivatives are widely distributed.
Potential for bioaccumulation	No evidence for accumulation.
Rate and extent of excretion	No specific data, none required.
Metabolism in animals	The lead component, BLAD, is a polypeptide which is expected to undergo complete metabolism in mammals. Other components in the active substance are expected to follow the same extent of metabolism, with no metabolites of concern being formed.
In vitro metabolism	Not required

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Section 2 Mammalian Toxicology

Toxicologically relevant compounds (animals and plants)	Aqueous extract from the germinated seeds of sweet Lupinus albus
Toxicologically relevant compounds (environment)	Aqueous extract from the germinated seeds of sweet Lupinus albus

Acute toxicity (assimilated Regulation No 283/2013, Annex Part A, point 5.2)

Rat LD₅₀ oral	> 5000 mg/kg bw
Rat LD₅₀ dermal	> 2000 mg/kg bw
Rat LC₅₀ inhalation	> 5.34 mg/l air /4h (nose only)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitisation	Not sensitising (Buehler) and published literature
Phototoxicity	Not required

Short-term toxicity (assimilated Regulation No 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	90-day oral rat: Minimal vacuolation in the brain and spinal cord (single animal) 22-day dermal rat: Local effects on the skin (hyperkeratosis, scabbing, erythema), no systemic effects
Relevant oral NOAEL	90-day rat: 500 mg/kg bw per day

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

	22-day, rat: 1000 mg/kg bw per day
Relevant dermal NOAEL	22-day, rat: Local effects NOAEL 300 mg/kg bw per day
Relevant inhalation NOAEL	No data - not required

Genotoxicity (assimilated Regulation No 283/2013, Annex Part A, point 5.4)

In vitro studies	Ames test: negative (\pm S9) Mouse lymphoma gene mutation: negative (-S9), positive (+S9) Micronucleus assay: negative (\pm S9)
In vivo studies	Comet assay (stomach): negative
Photomutagenicity	No data -not required
Potential for genotoxicity	Aqueous extract from the germinated seeds of sweet Lupinus albus is unlikely to be genotoxic

Long-term toxicity and carcinogenicity (assimilated Regulation No 283/2013, Annex Part A, point 5.5)

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

List of end points

Competent Authority	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Relevant NOAEL for carcinogenicity	Not required
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List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

Reproductive toxicity (assimilated Regulation No 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

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

Developmental toxicity

Developmental target / critical effect	No data- not required
Relevant maternal NOAEL	Not required
Relevant developmental NOAEL	Not required

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

Neurotoxicity (assimilated Regulation No 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	Study not required
Repeated neurotoxicity	Study not required
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Study not required

Other toxicological studies (assimilated Regulation No 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Not required
Endocrine disrupting properties	Aqueous extract from the germinated seeds of sweet Lupinus albus is not an endocrine disruptor
Studies performed on metabolites or impurities	Not required

Medical data (assimilated Regulation No 283/2013, Annex Part A, point 5.9)

	Limited; new active substance, no detrimental effects on health in manufacturing personnel
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List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

Summary³ (assimilated Regulation No 1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	5	rat, 90-day	100
Acute Reference Dose (ARfD)	Not required	-	-
Acceptable Operator Exposure Level (AOEL)	5	rat, 90-day	100*
Acute Acceptable Operator Exposure Level (AAOEL)	Not required	-	-

* No correction for limited oral absorption/bioavailability is required.

Dermal absorption (assimilated Regulation No 284/2013, Annex Part A, point 7.3)

Representative formulation (indicate name, type e.g. EC and concentration of active substance)	No data - none required Default value of 2510 % for concentrate and dilution (EFSA 2017 guidance)
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Exposure scenarios (assimilated Regulation No 284/2013, Annex Part A, point 7.2)

Operators	<p><u>Model: EFSA Calculator (Version 30th March 2015, EFSA 2014 Guidance)</u></p> <p><u>Use: Outdoor tomatoes and strawberries, vehicle mounted boom sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 11</p>
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³ If available include also reference values for metabolites

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

	<p><u>Use: Outdoor tomatoes and strawberries, handheld manual (tank and lance) sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 5</p>
	<p><u>Use: Outdoor tomatoes and strawberries, handheld knapsack sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 2</p>
	<p><u>Model: EUROPOEM</u></p> <p><u>Use: Protected tomatoes and strawberries, handheld manual (tank and lance) sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 12</p>
	<p><u>Model: EUROPOEM & EFSA Calculator (Version 30th March 2015, EFSA 2014 Guidance)</u></p> <p><u>Use: Protected tomatoes and strawberries, handheld knapsack sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 13</p>
	<p><u>Model: Online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance)</u></p> <p><u>Use: Outdoor tomatoes and strawberries, vehicle mounted boom sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 9.6</p>
	<p><u>Use: Outdoor tomatoes and strawberries, handheld manual (tank and lance) sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 5.5</p>
	<p><u>Use: Outdoor tomatoes and strawberries, handheld knapsack sprayer, 4.016 kg a.s./ha</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 1.8</p>
	<p><u>Use: Protected tomatoes and strawberries, 'normal' crop culture, handheld manual (tank and lance) sprayer, 4.016 kg a.s./ha.</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 6.1</p>

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

	<p><u>Use: Protected tomatoes and strawberries, 'normal' crop culture, handheld knapsack sprayer, 4.016 kg a.s./ha.</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 6.3</p> <p><u>Use: Protected tomatoes and strawberries, 'normal' crop culture, manual trolley sprayer, 4.016 kg a.s./ha.</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 2.4</p> <p><u>Use: Protected tomatoes and strawberries, 'dense' crop culture, handheld manual (tank and lance) sprayer, 4.016 kg a.s./ha.</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 95.9</p> <p><u>Use: Protected tomatoes and strawberries, 'dense' crop culture, handheld knapsack sprayer, 4.016 kg a.s./ha.</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 96.1</p>
Workers	<p><u>Model: EFSA Calculator (Version 30th March 2015, EFSA 2014 Guidance)</u></p> <p><u>Use: Outdoor tomatoes, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 32</p> <p><u>Use: Outdoor strawberries, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 38</p> <p><u>Use: Protected tomatoes, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (without workwear) 74</p> <p><u>Use: Protected strawberries, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (without workwear) 74</p> <p><u>Model: Online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance)</u></p> <p><u>Use: Outdoor tomatoes, 4.016 kg a.s./ha, reaching/picking</u></p>

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

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	<p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 31.9</p> <p><u>Use: Outdoor strawberries, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 38.3</p> <p><u>Use: Protected tomatoes, 4.016 kg a.s./ha, reaching/picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (without workwear) 75.1</p> <p><u>Model: HSE Decline Model (Utilising data from the EFSA 2022 Guidance)</u></p> <p><u>Use: Protected strawberries, 4.016 kg a.s./ha, searching, reaching and picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (without workwear) 161</p> <p><u>Use: Protected strawberries, 4.016 kg a.s./ha, searching, reaching and picking</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (with workwear) 46</p> <p><u>Use: Protected strawberries, 4.016 kg a.s./ha, searching, reaching and picking. 21 days post application</u></p> <p style="text-align: right;"><u>% of AOEL</u></p> <p>No PPE (without workwear) 98.8</p>																
Residents and Bystanders	<p><u>Model: EFSA Calculator (Version 30th March 2015, EFSA 2014 Guidance)</u></p> <p><u>Use: Outdoor tomatoes and strawberries, vehicle mounted boom sprayer, 4.016 kg a.s./ha</u></p> <table> <tr> <td><u>Child Resident</u></td><td style="text-align: right;"><u>% of AOEL</u></td></tr> <tr> <td>Spray Drift</td><td style="text-align: right;">1</td></tr> <tr> <td>Vapour</td><td style="text-align: right;"><1</td></tr> <tr> <td>Surface Deposits</td><td style="text-align: right;">1</td></tr> <tr> <td>Entry into Treated Crops</td><td style="text-align: right;">5</td></tr> <tr> <td>(Mean) sum of all Pathways</td><td style="text-align: right;">5</td></tr> <tr> <td><u>Adult Resident</u></td><td style="text-align: right;"><u>% of AOEL</u></td></tr> <tr> <td>Spray Drift</td><td style="text-align: right;"><1</td></tr> </table>	<u>Child Resident</u>	<u>% of AOEL</u>	Spray Drift	1	Vapour	<1	Surface Deposits	1	Entry into Treated Crops	5	(Mean) sum of all Pathways	5	<u>Adult Resident</u>	<u>% of AOEL</u>	Spray Drift	<1
<u>Child Resident</u>	<u>% of AOEL</u>																
Spray Drift	1																
Vapour	<1																
Surface Deposits	1																
Entry into Treated Crops	5																
(Mean) sum of all Pathways	5																
<u>Adult Resident</u>	<u>% of AOEL</u>																
Spray Drift	<1																

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 2 Mammalian Toxicology

	Vapour	<1
	Surface Deposits	<1
	Entry into Treated Crops	3
	(Mean) sum of all Pathways	3
	<u>Model: Online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance)</u>	
	<u>Use: Outdoor tomatoes and strawberries, vehicle mounted boom sprayer, 4.016 kg a.s./ha</u>	
	<u>Child Resident</u>	<u>% of AOEL</u>
	Spray Drift	1.1
	Vapour	0.02
	Surface Deposits	0.7
	Entry into Treated Crops	5.4
	(Mean) sum of all Pathways	5.4
	<u>Adult Resident</u>	<u>% of AOEL</u>
	Spray Drift	0.3
	Vapour	0.005
	Surface Deposits	0.2
	Entry into Treated Crops	3.0
	(Mean) sum of all Pathways	2.7
	<u>Use: Protected tomatoes and strawberries, vehicle mounted boom sprayer, 4.016 kg a.s./ha</u>	
	<u>Child Resident</u>	<u>% of AOEL</u>
	Spray Drift	5.6
	Vapour	0.02
	Surface Deposits	0.4
	Entry into Treated Crops	N/A
	(Mean) sum of all Pathways	4.0
	<u>Adult Resident</u>	<u>% of AOEL</u>
	Spray Drift	3.1
	Vapour	0.005
	Surface Deposits	0.1
	Entry into Treated Crops	N/A
	(Mean) sum of all Pathways	2.1

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 2 Mammalian Toxicology

Classification with regard to toxicological data (assimilated Regulation No 283/2013, Annex Part A, Section 10)

Substance	Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>
Mandatory classification according to assimilated Regulation No 1272/2008 and its Adaptations to Technical Process as applicable in GB:	No current harmonised classification.
GB Authority proposal⁴ for mandatory classification according to assimilated Regulation No 1272/2008 as applicable in GB:	No mandatory classification in GB is proposed (HSE, 2023) ⁵

⁴ It should be noted that mandatory classification and labelling is formally proposed and decided in accordance with assimilated Regulation No 1272/2008. Proposals for mandatory classification made in the context of the evaluation procedure under assimilated Regulation No 1107/2009 are not formal proposals.

⁵ HSE (2023) MCL Technical Report: proposal for mandatory classification and labelling (MCL) of 'aqueous extract from the germinated seeds of sweet *Lupinus albus*', based on Annex VI, Part 2 of the assimilated CLP Regulation No. 1272/2008. Date of report: November 2023. Accessed date: 30th April 2024. Available at <https://www.hse.gov.uk>

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (assimilated Regulation No 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered)	Crop group	Crop(s)	Application(s)	DAT (days)
	Fruit	-	-	-
	Root crops	-	-	-
	Leafy crops	-	-	-
	Cereals/grass crops	-	-	-
	Pulses and oilseed	-	-	-
	Miscellaneous	-	-	-
	No data provided – evidence based on literature and limited data suggests that the nature of residue will be a mixture of BLAD and degradation of the applied proteins into naturally occurring amino acids, simple carbohydrates and lipids which are indistinguishable from the breakdown of other naturally occurring substances. It is therefore not possible or necessary to identify the components formed following treatment of crops with PROBLAD PLUS. These components are not considered to be of any concern for consumers given they are natural components of foodstuffs.			
Rotational crops (metabolic pattern)	Crop group	Crop(s)	PBI (days)	Comments
	Root/tuber crops	-	-	-
	Leafy crops	-	-	-
	Cereals (small grain)	-	-	-

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 3 Residues

	Other	-	-	-
Rotational crop and primary crop metabolism similar?	No data provided. PROBLAD PLUS is readily biodegradable in soil; aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> will be subject to biological degradation into natural components (amino acids) in the soil after application, and not persist in the natural environment. Therefore no further consideration of residues in rotational crops is required.			
Processed commodities (Standard hydrolysis study)	Conditions	-		
	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?	No data provided - Given the low levels expected in treated crops, and nature of the residue, there is sufficient information and confidence that there are no concerns with residues in processed commodities.			
Plant residue definition for enforcement (RD-Enf)		Not required (based on the uses considered in this assessment only)		
Plant residue definition for risk assessment (RD-RA)		Not required (based on the uses considered in this assessment only)		

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Conversion factor (enforcement to risk assessment)	N/A
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Metabolism in livestock (assimilated Regulation No 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

Animals covered	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate / comment
	Laying hen	-	-	-
	Goat / Cow	-	-	-
	Pig	-	-	-
	Fish	-	-	-
	(Not required and not provided. The representative uses do not form a significant part of livestock diets.)			
Time needed to reach a plateau concentration in milk and eggs (days)		N/A		
Animal residue definition for monitoring (RD-Mo)		Not required (based on the uses considered in this assessment only)		
Animal residue definition for risk assessment (RD-RA)		Not required (based on the uses considered in this assessment only)		
Conversion factor (monitoring to risk assessment)		N/A		
Metabolism in rat and ruminant similar (Yes/No)		N/A		
Fat soluble residues (Yes/No)		Not able to determine		

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 3 Residues

Nature of residues in Honey

Honey residue definition for enforcement (RD-Enf)	Not required (based on the uses considered in this assessment only)
Honey residue definition for risk assessment (RD-RA)	Not required (based on the uses considered in this assessment only)
Conversion factor (enforcement to risk assessment)	N/A

Residues in succeeding crops (assimilated Regulation No 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect)	No data provided. PROBLAD PLUS is readily biodegradable in soil; aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> will be subject to biological degradation into natural components (amino acids) in the soil after application, and not persist in the natural environment. Therefore no further consideration of residues in rotational crops is required.
Field rotational crop study	No data provided. PROBLAD PLUS is readily biodegradable in soil; aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> will be subject to biological degradation into natural components (amino acids) in the soil after application, and not persist in the natural environment. Therefore no further consideration of residues in rotational crops is required.

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Stability of residues (assimilated Regulation No 283/2013, Annex Part A, point 6.1)

No data provided. Uncertainty regarding storage stability considered within the assessment.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Summary of residues data from the supervised residue trials (assimilated Regulation No 283/2013, Annex Part A, point 6.3)

Commodity	Outdoor / Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials representative for the intended GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Tomato	GB outdoor	BLAD < 0.03 0.6 mg/kg x 2 (note: a validated LOQ has not been established)	Trials are not fully relevant to the proposed GAPs but are supportive information for low residues	-	-	-
Strawberry	GB outdoor	BLAD < 0.03 0.6 mg/kg x 2 (note: a validated LOQ has not been established)	Trials are not fully relevant to the proposed GAPs but are supportive information for low residues	-	-	-

(a):Residues trials data relevant to the agricultural practices and climatic conditions in the UK, Indoor for glasshouse/protected crops. Country for an import tolerance.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

(b): Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, Enf/RA differentiate data expressed according to the residue definition for Enforcement and Risk Assessment.

(c): **HR**: Highest residue, according to the residue for risk assessment. When residue definition for enforcement and risk assessment differs, HR according to residue definition for enforcement reported in brackets (HR_{Enf}).

(d): **STMR**: Supervised Trials Median Residue. When residue definition for enforcement and risk assessment differs, STMR according to definition for enforcement reported in brackets (STMR_{Enf}).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Summary of data on residues in honey and related matrices (assimilated Regulation No 283/2013, Annex Part A, point 6.10.1)

No data submitted or required.

In accordance with SANTE/11956/2016 rev.9, tomatoes are not considered melliferous therefore no further consideration is required.

Strawberries are considered melliferous therefore exposure to honey bees cannot be ruled out on this basis. Based on the low levels of BLAD found in plants in the studies provided to address plant metabolism and magnitude of residues in plants, significant residues are unlikely to be found in the flowering parts of strawberry plants. Hence, significant residues are not expected to be present in bee products. Additionally, the aqueous extract from the germinated seeds of sweet Lupinus albus is comprised of naturally occurring seed storage proteins found in lupin plants, which are themselves foraged by bees. Therefore the components that bees are potentially exposed to are not a concern in terms of potential residues in honey for the assessment of consumer exposure.

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Inputs for animal dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
<p>The proposed representative uses of PROBLAD PLUS are on strawberries and tomatoes which are not used as feed for livestock.</p> <p>The uses proposed to support MRLs beyond the representative uses also do not comprise a significant portion of livestock diets.</p>				

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 3 Residues

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

No data submitted or required. The proposed representative uses of PROBLAD PLUS are on strawberries and tomatoes which are not used as feed for livestock. The uses proposed to support MRLs beyond the representative uses also do not comprise a significant portion of livestock diets.

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Conversion Factors (CF) for enforcement to risk assessment

N/A

Processing factors (assimilated Regulation No 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

No data provided.

Given the low levels expected in treated crops, and nature of the residue, there is sufficient information and confidence that there are no concerns with residues in processed commodities. No further information is required to address the effects of processing on residues of aqueous extract from the germinated seeds of sweet Lupinus albus.

Consumer risk assessment (assimilated Regulation No 283/2013, Annex Part A, point 6.9) Including all uses (representative uses and uses related to an MRL application).

ADI	5 mg/kg bw per day (based on 'PROBLAD PLUS')
NEDI (% ADI), according to UK model	Highest NEDI: N/A see Volume 1
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: N/A see Volume 1
Factors included in the calculations	None
ARfD	Not required
NESTI (% ARfD), according to UK model	N/A
IESTI (% ARfD), according to EFSA PRIMo	N/A
Factors included in IESTI and NESTI	N/A

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

List of end points

Competent Authority	Month and year	Active Substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 3 Residues

Aqueous extract from the germinated seeds of sweet Lupinus albus is proposed to be included in Part 4 of the GB MRL statutory Register and is exempt from MRLs.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (assimilated Regulation No 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Non-extractable residues after 100 days	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents

Route of degradation (anaerobic) in soil (assimilated Regulation No 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Non-extractable residues after 100 days	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Route of degradation (photolysis) on soil (assimilated Regulation No 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)	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Mineralisation at study end	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents
Non-extractable residues at study end	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents

Rate of degradation in soil (aerobic) laboratory studies active substance (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.1.1 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.1)

Aqueous extract from the germinated seeds of sweet Lupinus albus and lead compound BLAD are readily biodegradable; ECHA guidance (2017) proposes a first order half-life of 30 days in soil (300 or 3000 days for compounds with higher Kd) for use in exposure models for readily biodegradable substances (no temperature correction required).

Rate of degradation in soil (aerobic) laboratory studies transformation products (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.1.2 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Rate of degradation field soil dissipation studies (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.2.1 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.2.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	300# (d) (value from ECHA guidance(2017) for ready biodegradable compounds with higher Kp	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	N/A	N/A
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	N/A	N/A

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

a soil DT50 of 30 days can be accepted in future risk assessments

Soil accumulation (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.2.2 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Not required
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Rate of degradation in soil (anaerobic) laboratory studies active substance (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.1.3 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (assimilated Regulation No 283/2013, Annex Part A, point 7.1.2.1.4 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.1.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Rate of degradation on soil (photolysis) laboratory active substance

(assimilated Regulation No 283/2013, Annex Part A, point 7.1.1.3)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Soil adsorption active substance (assimilated Regulation No 283/2013, Annex Part A, point 7.1.3.1.1 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.2.1)

For the major component protein BLAD (20% of the product) a Koc of 10000 L/kg was estimated and used for groundwater risk assessment.

Soil adsorption transformation products (assimilated Regulation No 283/2013, Annex Part A, point 7.1.3.1.2 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.2.1)

For the quinolizidine alkaloid marker compound lupanine a Koc of 1287 L/kg was estimated using MCI method with the KOCWIN (version 2) model and Koc of 57.3 L/kg was estimated using QSAR method with the KOCWIN (version 2) model. Both values are used for groundwater risk assessment

Mobility in soil column leaching active substance (assimilated Regulation No 283/2013, Annex Part A, point 7.1.4.1.1 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.2.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Mobility in soil column leaching transformation products (assimilated Regulation No 283/2013, Annex Part A, point 7.1.4.1.2 and assimilated Regulation No 284/2013, Annex Part A, point 9.1.2.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Lysimeter / field leaching studies (assimilated Regulation No 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and assimilated Regulation No 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Hydrolytic degradation (assimilated Regulation No 283/2013, Annex Part A, point 7.2.1.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Aqueous photochemical degradation (assimilated Regulation No 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

'Ready biodegradability' (assimilated Regulation No 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	Yes (PROBLAD PLUS and major constituent BLAD are both readily biodegradable)
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Aerobic mineralisation in surface water (assimilated Regulation No 283/2013, Annex Part A, point 7.2.2.2 and assimilated Regulation No 284/2013, Annex Part A, point 9.2.1)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Water / sediment study (assimilated Regulation No 283/2013, Annex Part A, point 7.2.2.3 and assimilated Regulation No 284/2013, Annex Part A, point 9.2.2)

Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents. Based upon classification as readily biodegradable a DT50 in surface water of 15 (d) is agreed. A DT50 in sediment of 300 (d) is agreed (default value from ECHA guidance(2017) for ready biodegradable compounds with higher Kp).

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

Fate and behaviour in air (assimilated Regulation No 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.
Volatilisation (BBA guideline)	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.
Metabolites	Not required and impossible to conduct for naturally occurring plant extract composed of many different constituents.

Residues requiring further assessment (assimilated Regulation No 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 groundwater exposure	<p>Soil: Aqueous extract from the germinated seeds of sweet Lupinus albus</p> <p>Surface water: Aqueous extract from the germinated seeds of sweet Lupinus albus</p> <p>Sediment: Aqueous extract from the germinated seeds of sweet Lupinus albus</p> <p>Ground water: polypeptide BLAD and lupanine</p> <p>Air: Aqueous extract from the germinated seeds of sweet Lupinus albus</p>
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List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour


Definition of the residue for monitoring (assimilated Regulation No 283/2013, Annex Part A, point 7.4.2)

	See section 5, Ecotoxicology
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Monitoring data, if available (assimilated Regulation No 283/2013, Annex Part A, point 7.5)

Soil	Not required; a naturally occurring plant extract
Surface water	Not required; a naturally occurring plant extract
Ground water	Not required; a naturally occurring plant extract
Air	Not required; a naturally occurring plant extract

PEC_{soil} (assimilated Regulation No 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent	DT₅₀ (d)	300  days
Method of calculation	Kinetics	SFO
	Field or Lab	Based on ready biodegradability screening study and ECHA guidance for readily biodegradable compound.
Application data	Crop	Strawberry
	Application rate(s)	4016 g a.s./ha

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

	% plant interception	60%
	Number of applications	6
	Interval (d)	8
	Depth of soil layer	5 cm
	Soil bulk density	1.5 g/cm ³

a soil DT50 of 30 days can be accepted in future risk assessments

PEC _(Soil) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.14		12.28	
Short term 24h		2.12		12.26
2d		2.10		12.25
4d		2.06		12.22
Long term 7d		2.00		12.28
28d		1.64		11.89
50d		1.35		11.59
100d		0.92		10.96
Plateau concentration	Not relevant			

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

PEC ground water (assimilated Regulation No 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL 4.4.4; PELMO 5.5.3 Crop: strawberry and tomato Crop uptake factor: 0
Input parameters for BLAD (major constituent of PROBLAD PLUS)	Molecular weight (g/mol): 10000 Vapour pressure at 20°C (Pa): 0 Water solubility (mg/L): 1×10^6 Koc (L/kg): 10000 1/n: 1 DT50 soil (days): 300 Plant uptake factor: 0
Input parameters for lupanine (relevant impurity of PROBLAD PLUS)	Molecular weight (g/mol): 248.4 Vapour pressure at 20°C (Pa): 0 Water solubility (mg/L): 1×10^6 Koc (L/kg): 57.3 / 1287 Kfom (L/kg): 33 / 747 1/n: 1 DT50 soil (days): 30 / 300 Plant uptake factor: 0
Application rate	Gross application rate: 4016 g/ha. Crop growth stage: BBCH 61-89 Canopy interception %: 60 (strawberry) and 80 (tomato) Application rate net of interception: 1606 g/ha (strawberry) and 803 g/ha (tomato). No. of applications: 6

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

	Time of application (absolute or relative application dates): 01/06 (absolute) first application date in strawberries and 12/07 (absolute) first application date in tomato
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* Only relevant after implementation of the published EFSA guidance.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

Model	Scenario	BLAD (µg/L)	Lupanine (µg/L)*
PEARL	Hamburg (strawberry)	< 0.001	< 0.001
	Kremsmünster (strawberry)	< 0.001	< 0.001
	Châteaudun (tomato)	< 0.001	< 0.001
PELMO	Hamburg (strawberry)	< 0.001	< 0.001
	Kremsmünster (strawberry)	< 0.001	< 0.001
	Châteaudun (tomato)	< 0.001	< 0.001

*using both high and low DT50 and Koc

PEC(gw) From lysimeter / field studies

No lysimeter studies were undertaken or required.

PEC surface water and PEC sediment (assimilated Regulation No 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Calculation method	Spray drift: HSE Excel Calculator (first tier); Drainflow: HSE Excel Calculator (first tier);
PROBLAD PLUS - parameters used in UK only spraydrift and drainflow considerations	Molecular weight (g/mol): 10000 Koc (mL/g): 1000* DegT50 soil (d): 300* DisT50 water (d): 15*

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

	<p>DegT50 sediment (d): 300*</p> <p>Maximum in sediment (% AR): 100 (default worst case)</p> <p>*ECHA guidance for readily biodegradable compound</p>
Application rate	<p>Crop and growth stage: wheat BBCH 61-89</p> <p>For spray drift assessment:</p> <p>Number of applications: 6</p> <p>Interval (d): 8</p> <p>Application rate(s): 4016 g a.s./ha</p> <p>For drainflow assessment:</p> <p>Number of applications: 1</p> <p>Application rate: 9208 g a.s./ha (based on equivalent application to give a PEC_{Soil} initial value of 12.277 mg/kg i.e. after 6 x 4016 g a.s./ha applied with 60% interception)</p> <p>Application window: in drainflow period</p>

Spraydrift PEC_{sw} outputs

Spray Drift – PROBLAD PLUS			
Buffer zone (m)	Drift rate (%)*	PEC_{sw} (µg/L)	PEC_{Sed} (µg/kg)
1	2.01	63.3	-
5	0.68	13.1	-

*for three or more applications

Spray Drift – BLAD			
Buffer zone (m)	Drift rate (%)*	PEC_{sw} (µg/L)	PEC_{Sed} (µg/kg)
1	2.01	12.85	-
5	0.68	2.66	-

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 4 Environmental fate and behaviour

*for three or more applications

Drainflow PEC_{sw} (tier 1) outputs

Component	PEC _{sw} (µg/L)	PEC _{SED} (µg/kg)
PROBLAD PLUS	14.166	-

*output for multiple applications based upon PEC_{soil} value

Component	PEC _{sw} (µg/L)	PEC _{SED} (µg/kg)
BLAD	2.873	13.26

*output for multiple applications based upon PEC_{soil} value

Estimation of concentrations from other routes of exposure (assimilated Regulation No 284/2013, Annex Part A, point 9.4)

No other routes of exposure required further consideration.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (assimilated Regulation No 283/2013, Annex Part A, point 8.1 and assimilated Regulation No 284/2013, Annex Part A, point 10.1)

Species	Test substances	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Rat*	Preparation, PROBLAD PLUS	Acute	LD ₅₀	> 5000
Mammals				
Rat	Preparation, PROBLAD PLUS	Acute	LD ₅₀	> 5000
<p>Endocrine disrupting properties (Annex Part A, points 8.1.5)</p> <p>No endocrine disruptor studies were conducted or were considered necessary in the toxicology assessment. There were no indications of adverse effects on the endocrine system in the 90 day oral study in the rat. The main components of aqueous extract from the germinated seeds of sweet Lupinus albus have been identified as water, proteins, carbohydrates and lipids. These components are naturally occurring and will already contribute a large portion of the diet of terrestrial vertebrates. The lead component, BLAD, is a polypeptide which, under normal mammalian metabolism, will be broken down under enzymatic processes in the gastrointestinal tract, enter the amino acid pool and be consumed into normal metabolic processes. As such, the potential effects on endocrine disruption are not considered to be relevant and no further consideration is required.</p>				
<p>Additional higher tier studies (Annex Part A, points 10.1.1.2):</p>				

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

No higher tier studies were necessary.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians)
(Annex Part A, points 8.1.4, 10.1.3):

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* In absence of avian toxicity data, the mammalian endpoint is used.

Toxicity/exposure ratios for terrestrial vertebrates (assimilated Regulation No 284/2013, Part A, Annex point 10.1)

Strawberries and tomatoes (BBCH 61 – 89) at 4016 g a.s./ha x 6 applications

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Steps (Birds)					
Strawberries and tomatoes	Small omnivorous bird	Acute	1211.7	<u>4.12</u>	10
All		Chronic	No data		5
Tier 1 (Birds)					
Fruiting vegetables BBCH 71 - 89	Frugivorous bird "crow"	Acute	437.98	11.4	10
Fruiting vegetables BBCH ≥ 50	Small granvorous bird "finch"	Acute	56.46	88.6	10
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark"	Acute	54.94	91.0	10

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Fruiting vegetables BBCH 71 – 89	Frugivorous bird “starling”	Acute	376.94	13.3	10
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wagtail”	Acute	192.29	26.0	10
Strawberries BBCH ≥ 40	Small omnivorous bird “lark”	Acute	73.25	68.3	10
Strawberries BBCH 61 – 89	Frugivorous bird “starling”	Acute	206.02	24.3	10
Strawberries BBCH ≥ 20	Small insectivorous bird “wagtail”	Acute	192.29	26.0	10
		Chronic	No data		5

Screening Step (Mammals)

Tomatoes	Small herbivorous mammal	Acute	1040.8	<u>4.8</u>	10
Strawberries	Small herbivorous mammal	Acute	903.4	<u>5.5</u>	10
		Chronic	No data		5

Tier 1 (Mammals)

Fruiting vegetables	Frugivorous mammal “rat”	Acute	344.9	14.5	10
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List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH 71 – 89					
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew”	Acute	41.2	121.4	10
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal “vole”	Acute	312.1	16	10
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse”	Acute	39.7	125.9	10
Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew”	Acute	41.2	121.4	10
Strawberries BBCH ≥ 40	Small herbivorous mammal “vole”	Acute	416.6	12.0	10
Strawberries BBCH ≥ 40	Large herbivorous mammal “lagomorph”	Acute	106.8	46.8	10
Strawberries BBCH ≥ 40	Small omnivorous mammal “mouse”	Acute	52.6	95.1	10
Higher tier (Mammals): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]					

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Risk from bioaccumulation and food chain behaviour Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> (PROBLAD PLUS), and the lead component BLAD, have been demonstrated to be readily biodegradable according to the conditions of OECD 301 D and 301 B (see Vol. 3 CA B8.2.2.1). Therefore the exposure and potential for bioaccumulation will be limited due to the rapid breakdown and no consideration of secondary poisoning is considered to be necessary. Furthermore, PROBLAD PLUS is a complex mixture and none of the components are isolated during preparation of the product. It is therefore not considered relevant to derive a log Kow for PROBLAD PLUS.					
Risk from consumption of contaminated water					
Puddle scenario, Screening step 1) Application rate (g a.s./ha)/relevant endpoint < 50 (koc < 500 L/kg), TER calculation not needed 2) Application rate (g a.s./ha)/relevant endpoint < 3000 (koc ≥ 500 L/kg), TER calculation not needed					
The ratios of effective application rate to acute endpoint (AREff/endpoint) are below the relevant trigger of 3000 for PROBLAD PLUS, therefore no calculation of TER is required					

Underlined values indicate failing scenarios

Toxicity data for all aquatic tested species (assimilated Regulation No 283/2013, Annex Part A, points 8.2 and assimilated Regulation No 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.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Laboratory test				
Fish				
Onchorhynchus mykiss	Preparation PROBLAD PLUS	Acute 96 hr (semi-static)	Mortality, LC ₅₀	> 100 mg prep./L _(nom) Supporting information only#
Aquatic invertebrates				
Daphnia magna	Preparation PROBLAD PLUS	48 h (semi-static)	Mortality, EC ₅₀	<u>> 75 mg/L_(mm)</u>
Daphnia magna	Preparation PROBLAD PLUS	21 d (static, or semi-static or flow-through)	Reproduction, NOEC	<u>2.7 mg/L_(mm)</u>
Sediment-dwelling organisms: No studies with sediment-dwelling organisms have been conducted. PROBLAD PLUS is readily biodegradable and any residues in water bodies will be rapidly degraded. However, given the high K_{oc}, partitioning into sediment is likely to occur. In the absence of specific data with sediment-dwelling organisms, the margin of safety in the chronic aquatic invertebrate risk assessment is considered.				
Algae				
Raphidocelis subcapitata	Preparation PROBLAD PLUS	72 h (semi-static)	Growth rate: E _r C ₅₀ E _r C ₁₀ (NOEC) Yield: E _y C ₅₀ (NOEC)	<u>51 mg/L_(mm)</u> 7.5 mg/L (6.6 mg/L) 12 mg/L _(mm) (6.6 mg/L)

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
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Further testing on aquatic organisms

No further testing conducted or required

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

No ecotoxicological data are available to assess the endocrine disrupting properties of aqueous extract from the germinated seeds of sweet Lupinus albus. The main components of aqueous extract from the germinated seeds of sweet Lupinus albus are water proteins and carbohydrates which are already likely to form part of the diet of aquatic organism. Although there is some uncertainty in relying on dietary exposure studies to assess the risk via aquatic exposure, the published literature does not indicate any adverse effects from inclusion of lupin seeds in fish diets. HSE considers that no further consideration of endocrine disruption is required.

¹_(nom) nominal concentration; _(mm) mean measured concentration. #Study not considered suitable for use in risk assessment due to lack of analytical measurement, but considered as supporting information. **Study not considered suitable for use in risk assessment due to lack of analytical measurement. Underlined values indicate critical endpoints used in risk assessment.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

Bioconcentration in fish is not expected, no data has been provided.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (assimilated Regulation No 284/2013, Annex Part A, point 10.2)

PEC/RAC ratios for aqueous extract of germinated seeds of sweet *Lupinus albus* - at 4016 g a.s./ha (worst case GAP for proposed use).

Group	Aquatic invertebrates acute	Aquatic invertebrates long-term	Algae
Test species	<i>D. magna</i>	<i>D. magna</i>	<i>R. subcapitata</i>
Endpoint	EC ₅₀	NOEC	ErC ₅₀
(µg a.s./L)	75000	2700	51000
AF	100	10	10
RAC (µg a.s./L)	750	270	5100

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 5 Ecotoxicology

Group		Aquatic invertebrates acute	Aquatic invertebrates long-term	Algae
Entry pathway / Buffer zone [m] / season	PEC sw (µg a.s./L)	PEC/RAC (= ETR)		
Spray drift Standard distance (1 m)	63.3	0.0844	0.234	0.0124
Drainage	14.166	0.019	0.052	0.0028

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Effects on bees (assimilated Regulation No 283/2013, Annex Part A, point 8.3.1 and assimilated Regulation No 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
Apis mellifera	Preparation PROBLAD PLUS	Acute	Oral toxicity (LD ₅₀)	<u>> 109.42 µg/bee</u>
Apis mellifera	Preparation PROBLAD PLUS	Acute	Contact toxicity (LD ₅₀)	<u>> 100 µg/bee</u>
Bombus terrestris	Preparation PROBLAD PLUS	Acute	Oral toxicity (LD ₅₀)	> 2320.9 µg/bee
Bombus terrestris	Preparation PROBLAD PLUS	Acute	Contact toxicity (LD ₅₀)	> 1200.0 µg/bee
Apis mellifera	Preparation PROBLAD PLUS	Chronic	10 d LDD ₅₀ 10 d LC ₅₀	361.9 µg/bee/day 24975 mg PROBLAD PLUS/kg diet
Apis mellifera	Preparation PROBLAD PLUS	Bee brood development	22 d EC ₅₀ larvae	>1000 mg PROBLAD PLUS/kg diet
			22 d NOEC	1000 mg PROBLAD PLUS/kg diet
			22 d ED ₅₀	> 154 µg PROBLAD PLUS/larva
			22 d NOED	154 µg PROBLAD PLUS/larva

Underlined values indicate critical endpoints used in risk assessment.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Potential for accumulative toxicity:
Semi-field test (Cage and tunnel test) Not required
Field tests Not required

Risk assessment for – tomatoes and strawberries at 4016 g a.s./ha x 6 applications

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Preparation PROBLAD PLUS	HQcontact	< 402.2	< 50
Apis mellifera	Preparation, PROBLAD PLUS	HQoral	< 36.7	< 50

Effects on other arthropod species (assimilated Regulation No 283/2013, Annex Part A, point 8.3.2 and assimilated Regulation No 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	Preparation, PROBLAD PLUS	Mortality, LR ₅₀	> 10500 ml/ha
Aphidius rhopalosiphi	Preparation, PROBLAD PLUS	Mortality, LR ₅₀	> 10500 ml/ha

First tier risk assessment for – strawberries at 3200 mL a.s./ha x 6 applications

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
PROBLAD PLUS	Typhlodromus pyri	> 10500	0.97	0.015	2
PROBLAD PLUS	Aphidius rhopalosiphi	> 10500	0.97	0.015	2

¹Using drift rate 1.64% for 6 applications to strawberries at 1 m.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (mL/ha) ^{1,2}	Corrected mortality (%)	% effect on reproduction ³	End point	ER ₅₀ ^{2,4}
Typhlodromus pyri	Protonymphs	PROBLAD PLUS, dwarf French bean leaves (2D exposure)	Mortality: 7 d Fecundity: 7 d Total: 14 d	500	0	18.6	Mortality: Reproduction:	> 8000 > 8000
				1000	0	13.7		
				2000	0	22.0		
				4000	7	2.9		
				8000	5	30.7		
Aphidius rhopalosiphi	Adult	PROBLAD PLUS, Barley seedlings (3D exposure)	Mortality: 48 h Fecundity: 24 h Mummy development: 10 d	500	0.0	34.7	Mortality: Reproduction:	> 8000 > 8000
				1000	6.7	36.7		
				2000	0.0	37.3		
				4000	6.7	32.7		
				8000	13.3	36.7		
Chrysoperla carnea	First instar larvae	PROBLAD PLUS, French bean leaves (2D exposure)	Total: 39 d	3200	21.2	7.1	Mortality Reproduction:	> 10240 > 10240
				10240	18.2	1.9		

¹ initial residues

² mL formulated product/ha

³ A negative value indicates an increase relative to the control, a positive value a decrease.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet <i>Lupinus albus</i>

Section 5 Ecotoxicology

⁴ The reproductive endpoint is defined as the 'highest tested rate with < 50 % effect on reproduction' as opposed to a true ER₅₀ value

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Semi-field tests
No data- not required
Field studies
No data-not required
Additional specific test
No data- not required

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (assimilated Regulation No 283/2013, Annex Part A, points 8.4, 8.5, and assimilated Regulation No 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
Earthworms					
Eisenia andrei	Preparation, PROBLAD PLUS	Mixed into soil, 10 % peat	Chronic	Mortality, biomass, reproduction	NOEC = 100 mg/kg soil dw NOEC _{CORR} = 50 mg/kg soil dw EC ₁₀ > 100 mg/kg soil dw EC _{10 CORR} > 50 mg/kg soil dw
Eisenia andrei	Preparation, PROBLAD PLUS	Mixed into soil, 10 % peat	Chronic	Mortality	NOEC = 250 mg/kg soil dw <u>NOEC_{CORR}</u> <u>≡</u> <u>125 mg/kg soil dw</u>

CORR = corrected endpoint as worst case assumption of log Pow > 2.

Underlined values indicate critical endpoints used in risk assessment.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Higher tier testing (e.g. modelling or field studies)
No data- not required

Nitrogen transformation	Preparation, PROBLAD PLUS	+ 6.31% effect at day 28 at 5.2 mg product/kg d.w.soil -5.42 % effect at day 28 at <u>52 mg product/kg d.w. soil</u>
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- = inhibition, + = stimulation, underlined values indicate critical endpoints used in risk assessment

Toxicity/exposure ratios for soil organisms

Tomatoes and Strawberries at 4016 g a.s./ha x 6 applications

Test organism	Test substance	Time scale	Soil PEC ¹	TER	Trigger
Earthworms					
Eisenia andrei	Preparation, PROBLAD PLUS	Chronic	12.277	5.1	5
Other soil macroorganisms No data was provided with Hypoaspis aculeifer or Folsomia candida. In accordance with the data requirements, data from the non-target arthropods Aphidius rhopalosiphi and Typhlodromus pyri have been used in an initial risk assessment. Given that an acceptable risk to both A. rhopalosiphi and T. pyri was demonstrated using standard Tier I glass plate studies, it is considered that no data is required on the soil macro-organisms and an acceptable risk may be concluded.					

¹max. PEC_{Soil} initial

Effects on terrestrial non target higher plants (assimilated Regulation No 283/2013, Annex Part A, point 8.6 and assimilated Regulation No 284/2013 Annex Part A, point 10.6)

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology Screening data

No data- not required

Laboratory dose response tests

Species	Test substance	ER ₅₀ (g/ha) ² vegetative vigour	ER ₅₀ (g/ha) ² emergence	Exposure ¹ (g/ha) ²	TER	Trigger
Brassica napus, Cucumis sativus, Lactuca sativa, Lycopersicon esculentum, Zea mays, Allium cepa	PROBLAD PLUS	> 2510	-	322.08	> 7.79	5
Brassica napus, Cucumis sativus, Lactuca sativa, Lycopersicon esculentum, Zea mays, Allium cepa	PROBLAD PLUS	> 4016	> 4016	322.08	> 12.46	5

Extended laboratory studies : Not required

Semi-field and field test: Not required

¹ based on worst case use on tomatoes using Ganzelmeier drift data. Drift value 8.02% considering distance of 3 m from edge of crop.

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

² g formulated product/ha

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Effects on biological methods for sewage treatment (assimilated Regulation No 283/2013, Annex Part A, point 8.8)

Test type/organism	End point
Activated sludge	
Pseudomonas sp	No data- PROBLAD PLUS and the lead component BLAD have been demonstrated to be readily biodegradable in accordance with OECD 301.

Monitoring data (assimilated Regulation No 283/2013, Annex Part A, point 8.9 and assimilated Regulation No 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. None submitted. Available monitoring data concerning effect of the PPP. None submitted.
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Definition of the residue for monitoring (assimilated Regulation No 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

Compartment	
soil	Not applicable
water	Not applicable
sediment	Not applicable
groundwater	Not applicable

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

List of end points

Competent Authority	Month and year	Active substance (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (assimilated Regulation No 283/2013, Annex Part A, Section 10)

Substance	Name
Mandatory classification according to assimilated Regulation No 1272/2008 and its Adaptations to Technical Process:	No current harmonised classification.
GB Authority proposal⁶ for harmonised classification according to assimilated Regulation No 1272/2008:	No mandatory classification in GB is proposed (HSE, 2023) ⁷

⁶ It should be noted that mandatory classification and labelling is formally proposed and decided in accordance with assimilated Regulation No 1272/2008. Proposals for mandatory classification made in the context of the evaluation procedure under assimilated Regulation No 1107/2009 are not formal proposals.

⁷ HSE (2023) MCL Technical Report: proposal for mandatory classification and labelling (MCL) of 'aqueous extract from the germinated seeds of sweet Lupinus albus', based on Annex VI, Part 2 of the assimilated CLP Regulation No. 1272/2008. Date of report: November 2023. Accessed date: 30th April 2024. Available at <https://www.hse.gov.uk>

List of end points

Competent Authority Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
CRD	June 2024	Aqueous extract from the germinated seed of sweet Lupinus albus

Appendix

Used compounds code(s)

None

Further information

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