



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**

Volume 3 – B.3 (PPP) PROBLAD **PLUS**

Data on Application & Efficacy

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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B.3. Data on application and efficacy

This Draft Assessment Report has been drafted by the HSE based on information submitted by the applicant. HSE considers that the applicant has satisfactorily addressed the Efficacy related requirements for approval of new active substances.

There may be references to PROBLAD PLUS within the DAR, however the applicant has confirmed that the tradename for the product will be PROBLAD in GB.

B.3.1. Field of use envisaged

PROBLAD PLUS (active substance: aqueous extract from the germinated seeds of sweet *Lupinus albus*) is a foliar fungicide containing 20% w/w of the lead component BLAD protein (equivalent to 250g BLAD/L) of the lead component BLAD for the control of botrytis grey mould and powdery mildew in strawberry and tomato.

B.3.2. Effects on harmful organisms

The product works via contact action. BLAD is the lead component of PROBLAD PLUS. It is a naturally-occurring, “toxicologically innocuous” polypeptide, present in *Lupinus albus* seedlings. BLAD binds in a very strong manner to chitin, a major component of the fungal cell wall, inhibiting fungal growth. In addition, BLAD degrades chitin by catalysing the successive removal of the N-acetyl-D-glucosamine terminal chitin monomers, and destroying the fungal cells

B.3.3. Details of intended use

The applicant requests representative uses for GB as in the EU.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: development al stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicati ons (days)	L product/ ha (kg product/ ha) a) max. rate per appl. b) max. total rate per crop /season	L as/ha (kg as/ha) a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max		
1	SEU / CEU	Strawberry	F	Foliar fungi BOTRCI SPHRMA	Foliar overall	BBCH 61-89 Spring to Summer	a) 1 b) 6	8	a) 3.2 (4.016)† b) 19.2 (24.096) †	a) 3.2 (4.016) † b) 19.2 (24.096) †	450- 1000	0	Equivalent to maximum 800 g/ha lead component (BLAD)
2	EU	Strawberry	G	Foliar fungi BOTRCI SPHRMA	Foliar overall	BBCH 61-89 All seasons	a) 1 b) 6	8	a) 3.2 (4.016)† b) 19.2 (24.096) †	a) 3.2 (4.016) †	450- 1000	0	Equivalent to maximum 800 g/ha lead

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										b) 19.2 (24.096) †			component (BLAD)
3	SEU / CEU	Tomatoes	F	Foliar fungi BOTRCI OIDINL	Foliar overall	BBCH 61-89 Spring to Summer	a) 1 b) 6	8	a) 3.2 (4.016)† b) 19.2 (24.096) †	a) 3.2 (4.016) † b) 19.2 (24.096) †	200- 1000	0	Equivalent to maximum 800 g/ha lead component (BLAD)
4	EU	Tomatoes	G	Foliar fungi BOTRCI OIDINL	Foliar overall	BBCH 61-89 All seasons	a) 1 b) 6	8	a) 3.2 (4.016)† b) 19.2 (24.096) †	a) 3.2 (4.016) † b) 19.2 (24.096) †	200- 1000	0	Equivalent to maximum 800 g/ha lead component (BLAD)

*PROBLAD PLUS is a UVCB substance and is considered to be 100% pure with the lead component BLAD at 250 g/L

† based on a density of 1.255 g/mL

**Remarks
table heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
- (c) g/kg or g/l

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks
columns:**

- | | |
|---|---|
| <p>1 Numeration necessary to allow references</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application</p> <p>5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.</p> <p>6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.</p> | <p>7 Growth stage at first and 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>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product</p> <p>10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</p> <p>13 PHI - minimum pre-harvest interval</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions</p> |
|---|---|

EFSA - The technical material is only a hypothetical stage in the continuous production process of the end use product. As a consequence, the specification is given only for the formulation 'PROBLAD PLUS' (the formulation is intended to be marketed as 'PROBLAD').

For information for product submission in GB, tomatoes are grown in fully protected conditions, whilst strawberries are grown in tunnels, glasshouses and outdoors. A range of doses is not usually accepted for a claim, justification/data will need to be provided to support a change in dose in relation to disease pressure

B.3.4. Application rate and concentration of the active substance

The intended application rate for PROBLAD PLUS on strawberry and tomato is 2–3.2 L/ha.

This delivers 2.51–4.02 kg/ha of the aqueous extract from the germinated seeds of sweet *Lupinus albus* and 500–800 g/ha of the lead component BLAD.

B.3.5. Method of application

PROBLAD PLUS is applied as a foliar spray using spray equipment commonly used for making ground applications as well as sprinkler/irrigation systems commonly used for chemigation. Water volumes of 450–1000 L/ha are to be used on strawberry and 200–1000 L/ha on tomato.

B.3.6. Number and timing of applications and duration of protection

Crop	Number of application	Timing of application	Duration of protection (days)
Strawberry	1-6	BBCH 61-89	7-10
Tomato	1-6	BBCH 61-89	7-10

B.3.7. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

There are no restrictions proposed on the draft label for PROBLAD PLUS. No data are required as there are no detectable residues in the treated crop.

In Volume 3 CA B.9.6.2, a seedling emergence study has been provided. The study methodology was based on OECD Guideline for the Testing of Chemicals No. 208. The tested crops included 2 monocotyledonous species (*Zea mays*, *Allium cepa*) and

4 dicotyledonous species (*Brassica napus*, *Cucumis sativus*, *Lactuca sativa*, *Lycopersicon esculentum*). PROBLAD PLUS was applied at the maximum proposed rate of 3.2 L/ha in 200 L/ha water volume. No evidence of phytotoxicity was recorded. The risk to succeeding crops is considered low.

Further consideration will be provided at product authorisation. The subsequent product application must outline the risk to succeeding crops in line with EPPO PP 1/207

B.3.8. Proposed instructions for use

PROBLAD PLUS is a preventative fungicide in strawberry and tomato. See section B.3.3 above. Do not make more than two sequential applications before alternating to a labelled fungicide with a different mode of action.

B.3.9. Effectiveness

The applicant has presented 9 efficacy trials, 5 conducted in Portugal (Mediterranean EPPO climatic zone) and 4 in the USA.

It will be important to provide sufficient Maritime data to support product uses, in accordance with relevant EPPO standards and GB/NI specific guidance for strawberries:

<https://www.hse.gov.uk/pesticides/assets/docs/major-uk-pests.pdf>

Trials conducted in Portugal

5 trials were conducted over 5 years between 2007-2013. All were performed to GEP by an officially recognised facility, in accordance with EPPO guidelines.

Rocha, J.P. (2007)

A preliminary screening trial was performed in 2007 to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 4 g BLAD lead component/L against powdery mildew on grapes.

14 applications were made with an interval of 7-13 days between crop growth stages BBCH 53-79. Applications were performed preventatively before the appearance of disease symptoms. A water volume of 1000 L/ha was used.

1 assessment was conducted at crop growth stage BBCH 81, measuring disease severity over 100 grape bunches. Disease severity in the untreated control at assessment was 5.6%. Disease control data are presented below.

Table 3.9-1: (data from Table CP 6.9.1/01-03 in MCP 6) Efficacy of PROBLAD treatments and control standards against powdery mildew on grapes.

Treatment	Disease severity in each of 4 replicates				Average	%Efficacy Abbott	Significance 5%
	I	II	III	IV			
1-Untreated	1.2	3.9	6.7	10.7	5.6		c
2-PROBLAD (200 g BLAD/ha)	1.3	0.8	0.0	1.1	0.8	80.5	b
3-PROBLAD (300 g BLAD/ha)	0.3	0.4	0.3	0.0	0.2	94.1	a
4-PROBLAD (500 g BLAD/ha)	0.1	0.3	0.0	0.3	0.2	96.1	a
5-STROBY 50WG (250 g/ha)	0.0	0.0	0.0	0.0	0.0	100.0	a
6-HORIZON (400 mL/ha)	0.0	0.0	0.0	0.0	0.0	100.0	a

The data demonstrate a benefit of use for PROBLAD PLUS against powdery mildew. A dose response was recorded, with 125 L/ha PROBLAD PLUS (500 g BLAD/ha) achieving the highest level of control. PROBLAD PLUS applications at 300 and 500 g BLAD/ha achieved control that is statistically comparable to the reference products, whilst application at 200 g BLAD/ha recorded a lower level of control (80.5%).

Rocha, J.P. (2009)

A preliminary screening trial was performed in 2009 to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 6 g BLAD lead component/L against Botrytis on strawberry.

13 applications were made with an interval of 7-10 days between crop growth stages BBCH 73-89. Applications were performed preventatively before the appearance of disease symptoms. A water volume of 1000 L/ha was used.

22 assessments were conducted between 10th March and 8th June, measuring the number of fruits with disease symptoms. Disease severity in the untreated control at assessment was 8.1%. Disease control data are presented below.

Table 3.9-2: (data from Table CP 6.9.1/02-07 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on strawberry. Values correspond to the average of data collected in 22 assessments.

Treatment	Disease severity in each of 3 replicates			Average	%Efficacy Abbott	Significance 5%
	I	II	III			
1-Untreated	10.9	6.3	7.6	8.1		b
2-PROBLAD (300 g BLAD/ha)	2.2	3.0	1.6	2.2	70.4	a
3-PROBLAD (500 g BLAD/ha)	1.6	2.7	1.9	2.0	72.5	a
4-PROBLAD (700 g BLAD/ha)	1.3	0.8	1.7	1.2	84.3	a
11-Control Standard	2.0	1.6	2.1	1.9	76.2	a

The data demonstrate a benefit of use for PROBLAD PLUS against Botrytis. A dose response was recorded, with 116.7 L/ha PROBLAD PLUS (700 g BLAD/ha) achieving the highest level of control. PROBLAD PLUS applications at 300, 500 and 700 g BLAD/ha achieved control that is statistically comparable to the reference product.

Rocha, J.P. (2011)

An efficacy field trial was performed in 2011 to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against Botrytis on strawberry.

10 applications were made with an interval of 6-8 days between crop growth stages BBCH 71-85. Applications were performed preventatively before the appearance of disease symptoms. A water volume of 1000 L/ha was used.

16 assessments were conducted between 14th April and 10th June, measuring the number of fruits with disease symptoms. Disease severity in the untreated control at assessment was 9.7%. Disease control data are presented below.

Table 3.9-3: (data from Table CP 6.9.1/03-07 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on strawberry. Values correspond to the average of data collected in 16 assessments.

Treatment	Dose rate (L/ha)	Disease severity in each of 4 replicates				Average	%Efficacy Abbott	Significance
		I	II	III	IV			
1- Untreated		17.8	3.7	9.4	7.9	9.7		c
2- PROBLAD (250 g BLAD/ha)	1	7.3	2.1	5.4	5.3	5.0	44.4	b
3- PROBLAD (500 g BLAD/ha)	2	4.0	1.6	4.3	2.3	3.1	64.9	a
4- PROBLAD (750 g BLAD/ha)	3	5.1	1.5	3.6	3.0	3.3	63.6	a
5-Control Standard		5.3	1.6	5.3	4.7	4.2	52.8	b

The data demonstrate a benefit of use for PROBLAD PLUS against Botrytis. 2 L/ha PROBLAD PLUS (500 g BLAD/ha) achieved the highest level of control, with no improvement in control recorded at 3 L/ha (700 g BLAD/ha). PROBLAD PLUS applications at 500 and 700 g BLAD/ha achieved significantly greater control than the reference product, whilst application at 250 g BLAD/ha recorded a lower level of control (52.8%).

Rocha, J.P. (2012)

An efficacy field trial was performed in 2012 to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against powdery mildew on tomato.

5 applications were made with an interval of 6-12 days between crop growth stages BBCH 72-81. Applications were performed preventatively before the appearance of disease symptoms. A water volume of 1000 L/ha was used.

2 assessments were conducted on the 6th and 12th November, measuring the % affected foliar area on 100 leaf samples. Disease severity in the untreated control at assessment was 2.37% at first assessment and 3.33% at second assessment. Disease control data are presented below.

Table 3.9-4: (data from Table CP 6.9.1/04-05 in MCP 6) Efficacy of PROBLAD treatments and control standards against powdery mildew on tomato at 2 assessment timings

Treatment	Dose rate (L/ha)	% Efficacy Abbott				Average
		6 th Nov	Signific. 5%	12 th Nov	Signific. 5%	
1-Untreated (Disease severity)		2.4	b	3.3	b	2.8
2.PROBLAD (300 g BLAD/ha)	1.2	51.2	a	50.3	a	50.8
3.PROBLAD (400 g BLAD/ha)	1.6	75.6	a	67.5	a	71.6
4.PROBLAD (500 g BLAD/ha)	2.0	60.9	a	65.7	a	63.3
5.PROBLAD (600 g BLAD/ha)	2.4	68.9	a	79.0	a	74.0
6.PROBLAD (700 g BLAD/ha)	2.8	82.1	a	86.2	a	84.1
7. ORTIVA 250 g	1.0	71.3	a	66.2	a	68.7

Although disease severity in the untreated is low, the data demonstrate a benefit of use for PROBLAD PLUS against powdery mildew. 2.8 L/ha PROBLAD PLUS (700 g BLAD/ha) achieved the highest level of control. PROBLAD PLUS applications at 400, 600 and 700 g BLAD/ha achieved greater control than the reference product, whilst application at 300 and 500 g BLAD/ha recorded lower levels of control (50.8% and 63.3%).

Rocha, J.P. (2013)

An efficacy field trial was performed in 2013 to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against *Botrytis* on tomato.

6 applications were made with an interval of 6-11 days between crop growth stages BBCH 69-83. Applications were performed preventatively before the appearance of disease symptoms. A water volume of 1000 L/ha was used.

2 assessments were conducted on the 21st Nov and 5th December, measuring the number of stems and fruits with disease symptoms. Disease severity in the untreated control at assessment was 7.3% on stems and 3.6% on fruits. Disease control data are presented below.

Table 3.9-5: (data from Table CP 6.9.1/05-06 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on tomato at 2 assessment timings

		Affected stems (10 plants)				
Treatment	Dose rate (L/ha)	% Efficacy Abbott				Average
		21 st Nov	Signific. 5%	5 th Dec	Signific. 5%	
1.Untreated (disease incidence)		7.3	a	7.3	a	7.3
2.PROBLAD (300 g BLAD/ha)	1.2	13.8	a	3.4	a	8.6
3.PROBLAD (500 g BLAD/ha)	2.0	31.0	a	31.0	a	31.0
4.PROBLAD (700 g BLAD/ha)	2.8	48.3	a	41.4	a	44.9
5. SIGNUM (1.5 Kg/ha)		37.9	a	37.9	a	37.9

For assessments on stems, the data demonstrate a benefit of use for PROBLAD PLUS against Botrytis. 1.2 L/ha PROBLAD PLUS (300 g BLAD/ha) recorded a low level of control. 2 L/ha applications of PROBLAD PLUS (500 g BLAD/ha) recorded 31% control, comparable to the reference product. 2.8 L/ha applications of PROBLAD (700 g BLAD/ha) recorded greater control than the reference product.

Table 3.9-6: (data from Table CP 6.9.1/05-07 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on tomato at 2 assessment timings

		Affected fruits (50 fruits)				
Treatment	Dose rate (L/ha)	% Efficacy Abbott				Average
		21 st Nov	Signific. 5%	5 th Dec	Signific. 5%	
1.Untreated (disease incidence)		2.1	a	5.1	a	3.6
2.PROBLAD (300 g BLAD/ha)	1.2	55.6	ab	71.4	ab	63.5
3.PROBLAD (500 g BLAD/ha)	2.0	88.9	b	76.2	ab	82.6
4.PROBLAD (700 g BLAD/ha)	2.8	88.9	b	90.5	b	89.7
5. SIGNUM (1.5 Kg/ha)		100.0	b	76.2	ab	88.1

Although disease incidence in the untreated is low, assessments on fruits demonstrate a benefit of use for PROBLAD PLUS against Botrytis. 2.8 L/ha PROBLAD PLUS (700 g BLAD/ha) recorded the highest level of control (89.7%), exceeding that achieved by the reference product (88.1%). 2 L/ha PROBLAD PLUS (500 g BLAD/ha) recorded 82.6% control, comparable to the reference product. 1.2 L/ha PROBLAD PLUS (300 g BLAD/ha) recorded a lower level of control (63.5%).

Trials conducted in the USA

4 trials were conducted in 2011. The applicant claims that 3 of these trials were conducted in a climate comparable to the Mediterranean EPPO climatic zone and 1 was conducted in a climate comparable to the Maritime/Mediterranean EPPO climatic zone.

Dunbar, D. (2011)a

An efficacy field trial was conducted to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against Botrytis on strawberry.

5 applications were made with an interval of 10 days between 25th July and 5th September. A water volume of 1000 L/ha was used.

5 assessments were conducted between the 10th August and 16th September, measuring disease incidence and severity on fruits. Disease incidence in the untreated control at final assessment was 21.9%, whilst disease severity at final assessment was 8.8%. Disease control data are presented below.

Table 3.9-7: (data from Table CP 6.9.2/01-04 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on strawberry.

Treatment	Dose rate (L/ha)	%Incidence on Fruit					%Efficacy (Incidence)					Average
		6DA2	4DA3	8DA4	4DA5	11DA5	6DA2	4DA3	8DA4	4DA5	11DA5	
1.Untreated		3.8	13.1	20.6	23.1	21.9						
2.PROBLAD BL178 (340 g BLAD/ha)	1.35	1.9	8.8	20.6	22.5	18.8	50.0	32.8	0.0	2.6	14.2	19.9
3.PROBLAD BL178 (500 g BLAD/ha)	2.0	2.5	6.3	8.1	11.9	11.9	34.2	51.9	60.7	48.5	45.7	48.2
4.PROBLAD BL178 (675 g BLAD/ha)	2.7	0.0	2.5	6.9	6.3	9.4	100.0	80.9	66.5	72.7	57.1	75.4
5. PRISTINE (0.56 Kg/ha)		3.8	6.9	18.1	18.1	16.9	0.0	47.3	12.1	21.6	22.8	20.8

In terms of disease incidence, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. 2.7 L/ha PROBLAD PLUS (675 g BLAD/ha) recorded the highest level of control (75.4%). Both 2 L/ha and 2.7 L/ha applications of PROBLAD PLUS (500 and 675 g BLAD/ha) recorded greater control than the reference product, whilst 1.35 L/ha PROBLAD PLUS (340 g BLAD/ha) recorded comparable control to the reference product.

Table 3.9-8: (data from Table CP 6.9.2/01-05 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on strawberry.

Treatment	Dose rate (L/ha)	% severity on Fruit					%Efficacy (Severity)					Average
		6DA2	4DA3	8DA4	4DA5	11DA5	6DA2	4DA3	8DA4	4DA5	11DA5	
1.Untreated		0.5	1.8	6.2	7.2	8.8						
2.PROBLAD BL178 (340 g BLAD/ha)	1.35	0.1	0.8	4.9	5.2	6.3	80.0	55.6	21.0	27.8	28.4	42.5
3.PROBLAD BL178 (500 g BLAD/ha)	2.0	0.1	0.4	1.6	1.7	2.9	80.0	77.8	74.2	76.4	67.0	75.1
4.PROBLAD BL178 (675 g BLAD/ha)	2.7	0.0	0.2	1.1	1.4	2.6	100.0	88.9	82.3	80.6	70.5	84.4
5. PRISTINE (0.56 Kg/ha)		0.4	0.9	5.0	5.2	6.2	20.0	50.0	19.4	27.8	29.5	29.3

In terms of disease severity, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. 2.7 L/ha PROBLAD PLUS (675 g BLAD/ha) recorded the highest level of control (84.4%). 1.35 L/ha, 2 L/ha and 2.7 L/ha applications of PROBLAD PLUS (340, 500 and 675 g BLAD/ha) recorded greater control than the reference product.

Dunbar, D. (2011)b

An efficacy field trial was conducted to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against Botrytis on tomato.

6 applications were made with an interval of 7 days between 22nd April and 27th May. A water volume of 500 L/ha was used.

5 assessments were conducted between the 6th May and 3rd June, measuring disease incidence and severity on fruits. Disease incidence in the untreated control at final assessment was 45%, whilst disease severity at final assessment was 19.8%. Disease control data are presented below.

Table 3.9-9: (data from Table CP 6.9.2/02-04 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on tomato.

Treatment	Dose rate (L/ha)	%Incidence on Fruit				%Efficacy (Incidence)				Average
		7DA3	7DA4	7DA5	7DA6	7DA3	7DA4	7DA5	7DA6	
1.Untreated		8.0	24.8	38.3	45.0					
2.PROBLAD BL178 (370 g BLAD/ha)	1.5	1.5	12.8	20.0	26.0	81.3	48.4	47.8	42.2	54.9
3.PROBLAD BL178 (550 g BLAD/ha)	2.2	0.0	0.0	0.5	1.0	100.0	100.0	98.7	97.8	99.1
4.PROBLAD BL178 (750 g BLAD/ha)	3.0	0.0	0.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0
5. ENDURA (0.63 Kg/ha)		0.0	0.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0

In terms of disease incidence, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. 2.2 L/ha and 3 L/ha PROBLAD PLUS (550 and 750 g BLAD/ha) recorded 99.1 and 100% control, comparable to the reference product. 1.5 L/ha PROBLAD PLUS (370 g BLAD/ha) achieved a lower level of control (54.9%).

Table 3.9-10: (data from Table CP 6.9.2/02-05 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on tomato.

Treatment	Dose rate (L/ha)	%severity on Fruit				%Efficacy (Severity)				Average
		7DA3	7DA4	7DA5	7DA6	7DA3	7DA4	7DA5	7DA6	
1.Untreated		2.6	14.5	17.5	19.8					
2.PROBLAD BL178 (370 g BLAD/ha)	1.5	0.2	5.8	11.8	13.5	97.5	76.6	32.9	70.0	69.2
3.PROBLAD BL178 (550 g BLAD/ha)	2.2	0.0	0.0	0.1	1.5	100.0	100.0	99.3	98.9	99.5
4.PROBLAD BL178 (750 g BLAD/ha)	3.0	0.0	0.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0
5. ENDURA (0.63 Kg/ha)		0.0	0.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0

In terms of disease severity, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. 2.2 L/ha and 3 L/ha PROBLAD PLUS (550 and 750 g BLAD/ha) recorded 99.5 and 100% control, comparable to the reference product. 1.5 L/ha PROBLAD PLUS (370 g BLAD/ha) achieved a lower level of control (69.2%).

Dunbar, D. (2011)c

An efficacy field trial was conducted to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against Botrytis on grapes.

3 applications were made with an interval of 12-76 days between 27th May and 23rd August. A water volume of 1000 L/ha was used.

1 assessment was conducted on 12th September (20 days after third application), measuring disease incidence and severity on fruits. Disease incidence in the untreated control at assessment was 60%, whilst disease severity at assessment was 9.7%. Disease control data are presented below.

Table 3.9-11: (data from Table CP 6.9.2/03-03 in MCP 6) Efficacy of PROBLAD treatments and control standards against Botrytis on grapes.

Treatment	Dose rate (L/ha)	%Incidence on Fruit		%Severity on fruit	
		20DA3	% Efficacy Abbott	20DA3	% Efficacy Abbott
1.Untreated		60.0		9.7	
2.PROBLAD BL178 (500 g BLAD/ha)	2.0	27.5	54.2	6.2	36.1
3.PROBLAD BL178 (675 g BLAD/ha)	2.7	46.3	22.8	8.3	14.4
4.PROBLAD BL178 (840 g BLAD/ha)	3.37	30.0	50.0	7.2	25.8
5. ENDURA (0.56 Kg/ha)		32.5	45.8	8.9	8.2

In terms of disease incidence, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. PROBLAD PLUS applications at 2 L/ha and 3.37 L/ha (500 and 840 g BLAD/ha) recorded greater control than the reference product. 2.7 L/ha PROBLAD PLUS (675 g BLAD/ha) recorded a lower level of control (22.8%).

In terms of disease severity, a benefit of use has been demonstrated for PROBLAD PLUS against Botrytis. Although PROBLAD PLUS applications achieved only low levels of control (14.4-36.1%), all recorded greater control than the reference product.

Dunbar, D. (2011)d

An efficacy field trial was conducted to evaluate the fungicidal activity of PROBLAD PLUS SL formulation containing 250 g BLAD lead component/L against powdery mildew on grapes.

7 applications were made with an interval of 10-14 days between 26th April and 5th July. A water volume of 1000 L/ha was used.

10 assessments were conducted between 10th May and 13th July, measuring disease incidence on fruits and severity on leaves. Disease incidence in the untreated control at final assessment was 30%, whilst disease severity at final assessment was 98.5%. Disease control data are presented below.

Table 3.9-12: (data from Table CP 6.9.2/04-04 in MCP 6) Efficacy of PROBLAD treatments and control standards against powdery mildew on grapes.

Treatment	Dose rate (L/ha)	%Incidence on leaves					%Efficacy (Incidence on leaves)					Average
		1DA3	6DA3	6DA4	3DA5	10DA5	1DA3	6DA3	6DA4	3DA5	10DA5	
1.Untreated		7.5	9.0	14.0	28.8	30.0						
2.PROBLAD BL178 (340 g BLAD/ha)	1.35	1.8	2.5	3.8	9.0	10.0	76.0	72.2	72.9	68.8	66.7	71.3
3.PROBLAD BL178 (500 g BLAD/ha)	2.0	2.3	3.0	4.5	10.8	10.3	69.3	66.7	67.9	62.5	65.7	66.4
4.PROBLAD BL178 (675 g BLAD/ha)	2.7	1.8	2.8	3.3	8.0	10.3	76.0	68.9	76.4	72.2	65.7	65.7
5. PRISTINE (0.56 Kg/ha)		3.3	5.3	3.0	5.0	7.5	56.0	41.1	78.6	82.6	75.0	75.0

In terms of disease incidence, a benefit of use has been demonstrated for PROBLAD PLUS against powdery mildew. PROBLAD PLUS applications at 1.35 L/ha, 2 L/ha and 2.7 L/ha (340, 500 and 675 g BLAD/ha) recorded 65.7-71.3% control, similar to the reference product which achieved 75% control.

Table 3.9-13: (data from Table CP 6.9.2/04-05 in MCP 6) Efficacy of PROBLAD treatments and control standards against powdery mildew on grapes.

Treatment	Dose rate (L/ha)	%Severity on fruit						%Efficacy (Severity on fruit)						Average
		6DA4	3DA5	10DA5	6DA6	1DA7	8DA7	6DA4	3DA5	10DA5	6DA6	1DA7	8DA7	
1.Untreated		19.4	27.8	58.8	73.8	92.8	98.5							
2.PROBLAD BL178 (340 g BLAD/ha)	1.35	5.8	8.0	10.5	42.5	65.0	95.3	70.3	71.2	82.1	42.4	30.0	3.2	49.9
3.PROBLAD BL178 (500 g BLAD/ha)	2.0	7.8	11.8	24.8	44.3	61.3	91.3	60.0	57.6	57.8	40.0	33.9	7.3	42.8
4.PROBLAD BL178 (675 g BLAD/ha)	2.7	5.0	6.5	21.8	47.5	62.3	88.5	74.4	76.6	62.9	35.6	32.9	10.2	48.8
5. PRISTINE (0.56 Kg/ha)		5.5	6.5	8.8	20.0	18.5	16.0	71.8	76.6	85.0	72.9	80.1	83.8	78.4

In terms of disease severity, a benefit of use has been demonstrated for PROBLAD PLUS against powdery mildew. PROBLAD PLUS applications at 1.35 L/ha, 2 L/ha and 2.7 L/ha (340, 500 and 675 g BLAD/ha) recorded 42.8-49.9% control. Although this demonstrates control lower than the reference product, the table above shows PROBLAD PLUS performed comparably to the reference product at low-moderate disease pressures, it was only at high disease pressure that the performance of PROBLAD PLUS reduced.

Overall conclusion

The submitted data demonstrate that PROBLAD PLUS is sufficiently effective against the target diseases on strawberry and tomato in GB. A full assessment of the effectiveness and the minimum effective dose of PROBLAD PLUS will be made at the product authorisation stage.

For the subsequent product application, further consideration will be necessary. Efficacy trials must be performed in accordance with EPPO guidelines, using application rates and target pests/crops that reflect the intended uses on the proposed label. A sufficient number of efficacy trials must be performed in agronomic and climatic conditions relevant to GB. It will be important to provide sufficient Maritime data to support product uses, in accordance with relevant EPPO standards and GB/NI specific guidance for strawberries:

<https://www.hse.gov.uk/pesticides/assets/docs/major-uk-pests.pdf>

In GB, tomatoes are grown in fully protected conditions, whilst strawberries are grown in tunnels, glasshouses and outdoors.

The proposed label for PROBLAD PLUS does not include use on grapes, yet data have been generated on grapes. GB are interested in obtaining on-label uses for grape vine.

B.3.10. Information on the development of resistance

PROBLAD PLUS is a fungicide with contact action. BLAD is the lead component of PROBLAD PLUS, it is a naturally-occurring polypeptide, present in *Lupinus albus* seedlings. BLAD binds strongly to chitin, a major component of the fungal cell wall, inhibiting fungal growth. In addition, BLAD degrades chitin by catalysing the successive removal of the N-acetyl-D-glucosamine terminal chitin monomers, destroying the fungal cells.

BLAD is classified by FRAC (Fungicide Resistance Action Committee) in Group BM01 (previously Group M12), having multi-site contact activity with multiple effects and is thus considered low risk of developing resistance. It is intended that no more

than 2 sequential applications occur before alternating to a labeled fungicide with a different mode of action.

A detailed consideration of the resistance risk of PROBLAD PLUS will be made at the product authorisation stage.

B.3.11. Adverse effects on treated crops

Crop safety in strawberry, tomato and grapes has been considered in all efficacy trials conducted in Portugal and USA. PROBLAD PLUS (250 g BLAD/L formulation) has been tested at rates between 1 and 3.37 L/ha. No phytotoxicity to foliage or fruits were observed from any of the PROBLAD PLUS treatments in the 9 efficacy trials conducted in Portugal (5) and USA (4).

B.3.12. Observations on other undesirable or unintended side-effects

This point will be considered in full at the product authorisation stage. Effects on succeeding crops are considered in section B.3.7. (above).

Adjacent crops

No restrictions are proposed on the draft label. The maximum application rate of PROBLAD PLUS is 3.2 L/ha. The estimated drift of a plant protection product at a distance of 1m from the crop being sprayed is 2.77% (Ganzelmeier & Rautmann, 2000). When applied at the maximum application rate, a spray drift of 2.77% results in a PER_{off-field} (predicted environmental rate) at 1 m of 88.6 ml f.p./ha.

In Volume 3 CA B.9., 2 vegetative vigour studies have been provided in accordance with OECD 227. Across both studies, the worst-case ED₅₀ value was 2000 ml f.p./ha. Therefore, the amount of PROBLAD PLUS that may drift onto adjacent crops at 1 m is unlikely to have a negative effect on plants. The risk to adjacent crops is considered low. The risk to adjacent crops will be evaluated at the product authorisation stage.

Tank cleaning

In a report produced by W.D. Gravelle (2014), it was demonstrated that a double rinse procedure with water is sufficient to remove 99% of BLAD from the application equipment. (MCP section 4)

In the vegetative vigour tests presented in Volume 3 CA B.9.6, the worst-case ED₅₀ value was 2000 ml f.p./ha. This is equivalent to 62.5% of the maximum application rate of PROBLAD PLUS. According to ISO 16119, up to 2.6% of the spray solution

will remain in the application equipment. Therefore, it is unlikely that any remaining residues of PROBLAD PLUS will have a negative effect on crops subsequently treated with the same application equipment.

The effectiveness of any proposed tank cleaning method will be evaluated at the product authorisation stage.

Effects on beneficial and other non-target organisms

Across the 5 efficacy trials conducted in Portugal, PROBLAD PLUS applications were found to have no effect on a variety of non-target insect species. A full assessment of effects on non-target organisms was undertaken in the Ecotoxicology section.

B.3.13. References relied on

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 4.2 / 0001	Gravelle, W.D.	2014	Effectiveness of cleaning procedures, small scale (amended) CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	N/A

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.1 / 0001	Rocha, J.P.	2007	Evaluation of PROBLAD fungicide efficacy on the control of powdery mildew (<i>Uncinula necator</i> (Schw.) Burr – UNCINE) in grape (<i>Vitis vinifera vinifera</i> – VITVI) CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.1 / 0002	Rocha, J.P.	2009	Evaluation of PROBLAD Fungicide efficacy on the control of Botrytis (Botryotinia fuckeliana – sexual form of Botrytis cinerea – BOTRCI) in strawberry (Fragaria x ananassa – FRAAN) CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.1 / 0003	Rocha, J.P.	2011	Evaluation of PROBLAD Fungicide efficacy on the control of Botrytis (Botryotinia fuckeliana – sexual form of Botrytis cinerea – BOTRCI) in strawberry (Fragaria x ananassa – FRAAN) CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.1 / 0004	Rocha, J.P.	2012	Evaluation of PROBLAD Fungicide efficacy on the control of powdery mildew (<i>Leveillula taurica</i> – LEVETA) in tomato (<i>Lycopersicon esculentum</i> – LYPES) CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

KCP 6.9.1 / 0005	Rocha, J.P.	2013	Evaluation of PROBLAD Fungicide efficacy on the control of Botrytis (<i>Botryotinia fuckeliana</i> – sexual form of <i>Botrytis cinerea</i> – BOTRCI) in tomato (<i>Solanum lycopersicum</i> – LYPES)	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None
			CEV SA					
			GLP					
			Not published					
KCP 6.9.2 / 0001	Study summary: Dunbar, D.; Original	2011	Control of Botrytis fruit rot and Powdery Mildew on	N	Y	Data protection is claimed in accordance with Article 59 of assimilated	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
	report: Hurstack, R.		Strawberries with PROBLAD BL178 CEV SA Not published			Regulation No 1107/2009		

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.2 / 0002	Dunbar, D.	2011	Control of Botrytis Fruit Rot of Tomatoes with PROBLAD BL 178 CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.2 / 0003	Dunbar, D.	2011	Control of Botrytis Bunch Rot on Grapes with PROBLAD BL 178 CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate Study Y/N	Data Protection Claimed Y/N	Justification if Data Protection is claimed	Owner	Previous evaluation
KCP 6.9.2 / 0004	Dunbar, D.	2011	Control of Powdery Mildew on Grapes with PROBLAD BL 178 CEV SA GLP Not published	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV SA	None