



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.2 (PPP) PROBLAD PLUS

Physical & Chemical Properties

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.2. Physical and chemical properties of the plant protection product problad plus

PROBLAD PLUS has the same composition as the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*. It is a soluble concentrate (SL formulation) with the lead component BLAD protein present at 20% w/w. The supplied GAP recommends the highest in use concentration of 2.0% w/v (equal to 1.6% v/v) and the lowest in use concentration of 0.25% w/v (equal to 0.2% v/v). The formulation is intended to be marketed as 'PROBLAD'.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. Appearance						
Physical state and colour B.2.1/01	Visual assessment OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	Dark brown coloured, viscous liquid with a pungent odour	Acceptable	Y	Gravelle W. D., 2014a (35988)
	Visual assessment	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	Dark brown coloured, viscous liquid with a pungent odour	Acceptable	Y	Gravelle W. D., 2016 (35987)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	Visual assessment OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	PROBLAD PLUS Lot #: 040511 20% BLAD	Dark brown colour, very viscous liquid, sweet-like odor	Acceptable	Y	Wo C., 2012b (32388)
B.2.2. Explosive and oxidizing properties						
Explosive properties B.2.2/01	EEC A14	PROBLAD PLUS Batch: 16102012 20% w/w BLAD	Thermal test: no explosion occurred before 300s, yellow/orange flame was observed after about 20s Shock: no evidence of ignition, explosion or decomposition PROBLAD PLUS is not explosive	Acceptable Correct method A14 was used. The formulation was not sensitive to the effect of flame and shock. PROBLAD PLUS is not explosive No classification required.	Y	Cage S., 2013 (MIB0036)
Oxidizing properties B.2.2/02	EEC A21	PROBLAD PLUS Batch: 16102012 20% w/w BLAD	Mean pressure rise time for test substance was significantly higher than for the reference substance. PROBLAD PLUS is not oxidising	Acceptable Correct method A21 was used. PROBLAD PLUS is not oxidising No classification required.	Y	Cage S., 2013 (MIB0036)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.3. Flammability and auto-flammability						
Flash point of the liquids formulations B.2.3/01	ASTM D93 OPPTS 830.6315	PROBLAD PLUS Lot #: 040511 20% BLAD	Flash point above 100°C, not flammable	Acceptable Method A9 was recommended for this test, but the applicant used ASTM D93 which is a closed cup method and can be considered acceptable. No classification required.	Y	Wo C., 2012b (32388)
Flammability of solid formulations B.2.3/02				Not required for an SL formulation.		
Self-heating of formulation B.2.3/03	-	-	<p>The active substance (as manufactured) is a very viscous liquid that is an aqueous solution and as such the self-heating test (UN N.4) is not applicable to liquids.</p> <p>If the auto-ignition temperature (in accordance with EC A.15) was performed, this would essentially provide a result for an aqueous solution rather than the lead component.</p> <p>In addition, the flash point test was performed and a value of > 100°C was obtained, which is consistent with an aqueous solution and</p>	Acceptable Please refer to information provided in support of this data requirement for the active substance: A theoretical estimation based on structure meeting the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria can be made. In accordance with Appendix 6, there are no chemical groups present in the molecule associated with explosive or self reactive properties. Additionally, there is sufficient evidence that the	-	-

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			therefore the test substance can be classified as non-flammable.	substance does not ignite spontaneously on coming into contact with air at normal temperatures and forms a stable mixture in water.		
B.2.4. Acidity/alkalinity and pH value						
pH of the neat aqueous formulation B.2.4/01	CIPAC MT 75.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	pH of the neat formulation before storage was not reported 12 months storage at ambient temperature: 6.30 at 23.3°C 6.29 at 25.3°C 24 months storage at ambient temperature: 6.21 at 23.7°C 36 months storage at ambient temperature: 6.26 at 21.2°C	Acceptable pH of the neat formulation before and after storage should be provided, but only after storage data is available. The applicant provided a case: The pH of neat product has not been measured throughout the storage stability. Based on results obtained for 1% solution, the pH does not change significantly after storage, thus the data after 12 months and 24 months storage should be representative. Additionally, the pH of the neat product is stated as being 6.5 in report Gravelle, 2014a (35988) as part of the test substance details (certificate of analysis; non-GLP information) and the SDS states that pH of the neat product is between 5.0 and 7.5. Overall, this is considered a minor deficiency and no further data is required.	Y	Gravelle W. D., 2016 (35987)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				A minor GLP exception was noted where wt/vol dilution was prepared instead of wt/wt. It is not expected to have significant impact on the results.		
<p>pH of a 1% dilution of the solid or non aqueous formulation</p> <p>B.2.4/02</p>	CIPAC MT 75.3 and OPPTS 830.7000	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	6.342 at 21.6°C	<p>Acceptable</p> <p>A minor GLP exception was noted where wt/vol dilution was prepared instead of wt/wt. It is not expected to have significant impact on the results.</p>	Y	Gravelle W. D., 2014a (35988)
	CIPAC MT 75.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	6.342 at 21.6°C	<p>Acceptable</p> <p>A minor GLP exception was noted where wt/vol dilution was prepared instead of wt/wt. It is not expected to have significant impact on the results.</p>	Y	Gravelle W. D., 2016 (35987)
	CIPAC MT 75 OPPTS 830.7000	PROBLAD PLUS Lot #: 040511; Batch 1 20% BLAD	6.38 at 22.8°C	<p>Acceptable</p> <p>Method MT 75 (one calibration point) was used instead of MT 75.3 (two calibration points). Considering that the pH values are in the middle of 4 to 10 range, it is acceptable. Additionally, multiple results across different studies, using a range of methods, give similar results (the difference < 0.2 pH units) which supports the acceptability of this data.</p>	Y	Wo C., 2012b (32388)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Acidity / Alkalinity B.2.4/03	-	-	-	Not required as the pH is in the range between 4 and 10	-	-
B.2.5. Viscosity and surface tension						
Viscosity of the liquid formulation B.2.5/01	ASTM D445/D446 OPPTS 830.7100 (equivalent to CIPAC MT 22)	PROBLAD PLUS Lot #: 040511; Batch 1 20% BLAD	1 cSt = 1 mm ² /s 20°C 765.9 cSt 40°C 230.2 cSt	<p>Acceptable</p> <p>The applicant confirmed that the formulation is a Newtonian liquid, therefore only kinematic viscosity was reported. Kinematic viscosity was measured at 20 and 40°C.</p> <p>The test was performed using capillary viscometers therefore shear rate was not applicable. The specific viscometer used was as specified in the test guideline (size 450).</p> <p>Test method OPPTS 830.7100 is equivalent to CIPAC MT 22 therefore the results can be accepted.</p> <p>The formulation does not contain 10% of a substance which has been classified as Category 1 aspiration hazard, no classification based on viscosity is required.</p>	Y	Wo C., 2012b (32388)
	EC A5	PROBLAD PLUS	22.4 mN/m at 1.6% w/v at 20°C	Acceptable	Y	Wo C., 2018

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Surface tension of the formulation B.2.5/02		Batch #: C191804-002 20% BLAD		Correct method A5 was used. The applicant should use the highest in use concentration (1.6% v/v, equal to 2% w/v), but 1.6% w/v has been used instead. The value can be consider close enough to the highest in use concentration, therefore it is acceptable. Surface active product.		(48183)
	EC A.5 OECD 115	PROBLAD PLUS Batch: 16102012 20% w/w BLAD	29.3 mN/m at 1.00 g/L aqueous dilution	Supporting information, test at 1.00 g/L Correct method was used, but the concentration tested should be the highest in use concentration (1.6% v/v)	Y	Lien T. P., 2013 (S13-00831)
B.2.6. Relative density and bulk density						
Relative density of the liquid formulation B.2.6/01	OECD TG 109	PROBLAD PLUS Lot #: 040511; Batch 1 20% BLAD	1.255 g/mL at 20°C (mean or two results) Relative density: 1.257 at 20°C	Acceptable Correct test guideline OECD 109 was used.	Y	Wo C., 2012b (32388)
Bulk density (pour and tap) of powder or granules	-	-	-	Not required for an SL formulation.	-	-

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference										
B.2.6/02																
B.2.7. Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product																
Stability after accelerated storage (54°C during 14 days) B.2.7/01	MT 46.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	<div>Conducted in 125 mL HDPE bottles</div> <table><tr><td colspan="2">Accelerated storage MT 46.3</td></tr><tr><td>Initial</td><td>After 14 days at 54°C</td></tr><tr><td colspan="2">Active substance content, BLAD: Modified Lowry Method Lupanine: GC/FID SANCO/3030/99 rev.5</td></tr><tr><td>BLAD 20.17% ± 1.28% w/w Lupanine 0.0044% w/w ± 0.0002%</td><td>BLAD 19.67% w/w (average of two independent samples: 18.40% and 20.95%) Lupanine 0.0029% w/w ± 0.0002%</td></tr><tr><td colspan="2">Appearance, visual observation</td></tr></table>	Accelerated storage MT 46.3		Initial	After 14 days at 54°C	Active substance content, BLAD: Modified Lowry Method Lupanine: GC/FID SANCO/3030/99 rev.5		BLAD 20.17% ± 1.28% w/w Lupanine 0.0044% w/w ± 0.0002%	BLAD 19.67% w/w (average of two independent samples: 18.40% and 20.95%) Lupanine 0.0029% w/w ± 0.0002%	Appearance, visual observation		<u>Active substance content</u> The content of lead component BLAD is decreasing by about 2.48% after storage which is acceptable. It is an average of two results, each result was based on analysis of 6 samples in triplicate. One of the individual results (18.40%) indicates a decrease greater than 5% (8.8% decrease) in the lead component content, but the second result is within the acceptable limit. The lead component is a hard to quantify BLAD protein and the changes in BLAD concentration are expected to be due to the analytical error. If any degradation occurs, the degradation products are expected to be lower molecular weight proteins. Additionally, the applicant provided a study (see Section B2.11) which shows that PROBLAD PLUS is still effective after storage. The modified Lowry method was used for quantification and has been considered fit for purpose, see section Volume 3 CA B5.	Y	Gravelle W. D., 2014a (35988)
Accelerated storage MT 46.3																
Initial	After 14 days at 54°C															
Active substance content, BLAD: Modified Lowry Method Lupanine: GC/FID SANCO/3030/99 rev.5																
BLAD 20.17% ± 1.28% w/w Lupanine 0.0044% w/w ± 0.0002%	BLAD 19.67% w/w (average of two independent samples: 18.40% and 20.95%) Lupanine 0.0029% w/w ± 0.0002%															
Appearance, visual observation																

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			Dark brown, viscous liquid with a pungent odour	Dark brown, viscous liquid with a pungent odour	The applicant also provided data on Lupanine (a representative of quinolizidines identified as potentially relevant impurities) and its content decreases on storage by about 60 %. This value is based on average of three samples analysed in duplicate. Considering that the impurity was stable in the ambient storage and the concentration is very low, any decomposition products will be in marginal concentrations. This is acceptable. Method GC-FID was used for quantification, see section Volume 3 CA B5, and is considered fit for purpose. For further consideration of the levels of lupanine and the QAs see section Volume 4 section C.1.3.1.		
			pH (1% w/w) CIPAC MT 75.3 and OPPTS 830.7000				
			6.342 at 21.6°C	5.992 at 21.2°C			
			Dilution stability, CIPAC MT 41.1 and MT 18.1.3 (CIPAC Standard Water C)				
			Standard Water C				
			0.40 g test substance in 100 mL water		<u>Appearance</u> Acceptable. No changes to appearance before and after storage.		
			Clear light brown solution	Clear light brown solution	<u>pH</u> Acceptable. The applicant provided only 1% solution data, but the data on the neat substance was submitted for 2 year ambient storage and the applicant provided a case in Section B.2.4/01.		
			About 3 mL particles separation	About 3 mL particles separation			
			A few particles suspended in the solution	A few particles suspended in the solution			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			Significant sedimentation observed	Significant sedimentation observed	Minimal changes to pH values of 1% solution before and after storage. <u>Dilution stability</u> Standard Water C was used instead of Standard Water D. CIPAC Standard Water C is 500 ppm hardness, pH of 7 to 8 and the calcium to magnesium ratio 4:1. CIPAC Standard Water D is 342 ppm hardness, pH 6.6 to 7 and the calcium to magnesium ratio 4:1. Therefore there isn't considered to be a considerable difference between the waters, especially since the result of “suspension not stable after 18 hours” is obtained. Due to the closeness in nature of the waters, a similar result is expected when testing in CIPAC Standard Water D. The concentration tested (0.4% w/v) is lower than the highest possible in-use concentration (2% w/v). An unstable suspension was observed in the test at 0.4% w/v; an unstable suspension is also expected at the higher concentration (2% w/v). Further data at higher concentrations has not been provided.		
			Suspension not stable over 18 h	Suspension not stable over 18 h			
			Packaging, visual observation				
			In tact	No signs of cracking, pitting, or fogging. Mean weight change – 0.2%			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				<p>When using method MT 41.1, the amount of residue after 24 h should be determined on a 75 µm sieve according to a procedure adapted from 'MT 185 (b) Wet sieving' and the content of the active substance in this residue should be analysed. This has not been provided. It is expected that particles > 75 µm will be retained based on the results obtained.</p> <p><u>Additional evidence that the separated material will not block application equipment, present an unacceptable risk to the operator, lead to unacceptable residues or crop safety concerns has been provided:</u></p> <p>An additional test on sprayability was performed at the highest in use concentration (1.6% v/v) on the commercial scale plant protection product to demonstrate if the inhomogeneity of the preparation causes nozzle blockage during spraying (see 2.11/02). This study showed that no nozzle blockage occurs when applied at the highest use rate and that a constant amount of the product is sprayed throughout the spray duration. Testing was performed using CIPAC standard waters A and D.</p>		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference						
				<p>In addition, based on extensive efficacy trials testing, which will be submitted with the product registration, material separation will not block application equipment, will not present an unacceptable risk to the operator and will not lead to unacceptable residues / crop safety concerns. When the product is mixed/loaded/applied according to the label instructions and using typical spraying equipment, there are no expected issues or concerns.</p> <p><u>Packaging</u></p> <p>Acceptable</p> <p>No changes to the appearance of the packaging and minimal decrease of weight after storage (-0.2%, about 0.35 g)</p>								
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	<table><tr><td colspan="2">Conducted in 50 mL glass graduated centrifuge tubes</td></tr><tr><td>Initial</td><td>After 7 days at 0°C</td></tr><tr><td colspan="2">Appearance, visual observation</td></tr></table>	Conducted in 50 mL glass graduated centrifuge tubes		Initial	After 7 days at 0°C	Appearance, visual observation		Acceptable No phase separation was observed after storage, the formulation is stable in cold conditions.	Y	Gravelle W. D., 2014b (35989)
Conducted in 50 mL glass graduated centrifuge tubes												
Initial	After 7 days at 0°C											
Appearance, visual observation												

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			Dark brown colured, viscous liquid	Dark brown colured, viscous liquid No phase separation			
Shelf life following storage at ambient temperature B.2.7/03	CIPAC MT 46.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	Conducted in 250 mL HDPE bottle		<u>Active substance content</u>	Y	Gravelle W. D., 2016 (35987)
			Initial	After storage at ambient conditions	Acceptable. Considering the mean content of the lead component BLAD in samples before and after storage, a significant change is not observed. However, variation between content of samples at each time point is observed and when some individual samples are considered, the content of lead component BLAD is changing by up to 7.5% after 2 years storage. Considering that the changes are inconsistent and in some samples the content increases by 7.44% and in some samples the content decreases by 6.1%, the variation is likely caused by analytical error. This is acceptable in this case. The modified Lowry method was used for quantification and has been considered fit for purpose, see section Volume 3 CA B5. The applicant also provided data on Lupanine (a representative of quinozilidines identified as potentially		
			Active substance content BLAD: Modified Lowry Method Lupanine: GC/FID				
			BLAD	BLAD			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
				<p>3.93 (average of three results: 18.94 ± 3.87 19:56 ± 2.96 21.67 ± 1.73) 36 months: 20.48 ± 1.21% w/w</p> <p>Lupanine</p> <p>Initial 0.0044% w/w ± 0.0002</p> <p>3 months 0.0043% w/w ± 0.0003</p> <p>6 months 0.0043% w/w ± 0.0005</p> <p>12 months 0.0043% w/w ± 0.0001</p> <p>24 months 0.0043% w/w ± 0.0002</p> <p>36 months Not determined</p>	<p>relevant impurities) and its content is stable on storage (change of 0.0001%). All of lupanine samples are an average of three samples analysed in duplicates. This is acceptable. GC-FID was used for quantification, see section Volume 3 CA B5 and is considered fit for purpose, see section Volume 4. The QAs are not listed as relevant impurities therefore no further consideration required. For further consideration of the levels of lupanine and the QAs see section Volume 4 section C.1.3.1.</p> <p>Appearance</p> <p>Acceptable</p> <p>No changes to appearance before and after storage.</p> <p>pH</p> <p>Acceptable.</p> <p>The applicant provided only 1% solution data before and after storage and neat solution data after storage. A case from the applicant is provided in Section B.2.4/01.</p> <p>Minimal changes to pH values of 1% solution before and after storage.</p>		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			Appearance, visual observation		Minimal change to pH values of the neat formulation before and after storage. <u>Dilution stability</u> Standard Water C was used instead of Standard Water D. CIPAC Standard Water C is 500 ppm hardness, pH of 7 to 8 and the calcium to magnesium ratio 4:1. CIPAC Standard Water D is 342 ppm hardness, pH 6.6 to 7 and the calcium to magnesium ratio 4:1. Therefore there isn't considered to be a considerable difference between the waters, especially since the result of "suspension not stable after 18 hours" is obtained. Due to the closeness in nature of the waters, a similar result is expected when testing in CIPAC Standard Water D. The concentration tested (0.4% w/v) is lower than the highest possible in-use concentration (2% w/v). An unstable suspension was observed in the test at 0.4% w/v; an unstable suspension is also expected at the higher concentration (2% w/v). Further data at higher concentrations has not been provided.		
			Dark brown viscous liquid with a pungent odour	Dark brown viscous liquid with a pungent odour			
			pH (1% w/w) CIPAC MT 75.3 and OPPTS 830.7000				
			6.342 at 21.6°C	3 months 6.243 at 21.6°C 6 months 6.232 at 23.6°C 12 months 5.924 at 24.8°C 5.90 at 25.3°C 24 months 5.94 at 24.7°C 36 months 5.86 at 16.5°C			
			pH (neat) CIPAC MT 75.3				
			Not reported	12 months 6.30 at 23.3°C			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
				6.29 at 25.3°C (confirmation test) 24 months 6.21 at 23.7°C 36 months 6.26 at 21.1°C	When using method MT 41.1, the amount of residue after 24 h should be determined on a 75 µm sieve according to a procedure adapted from 'MT 185 (b) Wet sieving' and the content of the active substance in this residue should be analysed. This has not been provided. It is expected that particles > 75 µm will be retained based on the results obtained.		
			Dilution stability, CIPAC MT 41.1 and MT 18.1.3 (CIPAC Standard Water C) Standard Water C 0.40 g test substance in 100 mL water		<u>Additional evidence that the separated material will not block application equipment, present an unacceptable risk to the operator, lead to unacceptable residues or crop safety concerns has been provided:</u>		
			Clear light brown solution About 3 mL particles separation A few particles suspended in the solution Significant sedimentation observed	3 months: Clear light brown solution About 5 mL particles separation A few particles suspended in the solution	An additional test on sprayability was performed at the highest in use concentration (1.6% v/v) on the commercial scale plant protection product to demonstrate if the inhomogeneity of the preparation causes nozzle blockage during spraying (see 2.11/02). This study showed that no nozzle blockage occurs when applied at the highest use rate and that a constant amount of the product is sprayed throughout the spray duration. Testing was performed using CIPAC standard waters A and D.		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
			Suspension not stable over 18 h	Significant sedimentation observed	In addition, based on extensive efficacy trials testing, which will be submitted with the product registration, material separation will not block application equipment, will not present an unacceptable risk to the operator and will not lead to unacceptable residues / crop safety concerns. When the product is mixed/loaded/applied according to the label instructions and using typical spraying equipment, there are no expected issues or concerns. <u>Packaging</u> Acceptable. No changes to the appearance of the packaging and minimal decrease of weight after storage (-0.22%)		
			Suspension not stable over 18 h				
			With further storage period time points of sampling, only the volume of particle separation has changes				
			6 months – 2 mL				
			12 months – 3 mL				
			24 months – 3- 4 mL				
			36 months – 5 mL				
			Packaging, visual observation				
				Total weight change up to – 0.32%			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8. Technical characteristics of the plant protection product						
B.2.8.1. Wettability						
Wettability of solid formulation B.2.8.1/01				Not required for an SL formulation.		
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.3	PROBLAD PLUS C2009-001 21.0% BLAD	The temperature of the test 22°C 0.2% v/v CIPAC Water D Initial 54 mL, 54 mL 10s 10 mL, 12 mL 1 min 4 mL, 4 mL 3 min 0 mL, 0 mL 12 min 0 mL, 0 mL	Acceptable. Two samples were tested in each concentration and the highest of the two results reported. This test was performed in correct concentrations, which are the highest and lowest in use concentrations, in this case 2.0% w/v (1.6% v/v) and 0.251% w/v (0.2% v/v). Correct CIPAC Standard Water was used. The amount of foam after 1 min was within acceptable limit.	Y	Comb T., 2020 (ENV-20-338)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			1.6% v/v CIPAC Water D Initial 102 mL, 108 mL 10s 78 mL, 84 mL 1 min 10 mL, 10 mL 3 min 6 mL, 6 mL 12 min 6 mL, 6 mL			
	CIPAC MT 47.2	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	0.82 g test substance in 200 mL (0.41% w/v) CIPAC Water C, initial sample 10s – 28.7%, 99 mL 60s – 32.3%, 94.5 mL 180s – 31.1%, 89.5 mL 720s – 28.0%, 77.0 mL CIPAC Water D, 12 months sample 10s – 31.75%, 90.5 mL 60s – 29.10%, 81.5 mL 180s – 28.47%, 79.0 mL	Not acceptable, the applicant provided acceptable data above. The applicant used method MT 47.2 instead of MT 47.3. Incorrect concentration was tested and incorrect CIPAC Standard Water was used. Foam volumes after 1 min were above the acceptable limit. The applicant provided a case based on this batch of PROBLAD PLUS being a pilot scale process - small variations in the concentration of the antifoam agent influenced the results.	Y	Gravelle W. D., 2014a (35988) Gravelle W. D., 2016 (35987)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			720s – 26.97%, 73.5 mL	Acceptable data is presented above and the applicant confirmed that no issues with operator safety were observed during efficacy trials. Additionally, the label for the product contains instructions on correct mixing the product to avoid excessive foaming.		
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01				Not required for an SL formulation.		
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02				Not required for an SL formulation.		
Dispersion stability of SE, OD or EG formulation B.2.8.3/03				Not required for an SL formulation.		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01				Not required for an SL formulation.		
Dilution stability of water soluble formulation B.2.8.4/02	CIPAC MT 41.1 CIPAC MT 18.1.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	Standard Water C 0.40 g test substance in 100 mL water Clear light brown solution, about 3 mL particles separation, a few particles suspended in the solution, significant sedimentation observed Suspension not stable over 18 h	Standard Water C was used instead of Standard Water D. CIPAC Standard Water C is 500 ppm hardness, pH of 7 to 8 and the calcium to magnesium ratio 4:1. CIPAC Standard Water D is 342 ppm hardness, pH 6.6 to 7 and the calcium to magnesium ratio 4:1. Therefore there isn't considered to be a considerable difference between the waters, especially since the result of "suspension not stable after 18 hours" is obtained. Due to the closeness in nature of the waters, a similar result is expected when testing in CIPAC Standard Water D.	Y	Gravelle W. D., 2014a (35988)
	CIPAC MT 41.1 CIPAC MT 18.1.3	PROBLAD PLUS Lot #: 16102012 20.17% BLAD	Standard Water C 0.40 g test substance in 100 mL water Clear light brown solution, about 3 mL particles separation, a few particles suspended in the solution, significant sedimentation observed	The concentration tested (0.4% w/v) is lower than the highest possible in- use concentration (2% w/v). An unstable suspension was observed in the test at 0.4% w/v; an unstable suspension is also expected at the higher concentration (2% w/v).	Y	Gravelle W. D., 2016 (35987)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Suspension not stable over 18 h	<p>Further data at higher concentrations has not been provided.</p> <p>When using method MT 41.1, the amount of residue after 24 h should be determined on a 75 µm sieve according to a procedure adapted from 'MT 185 (b) Wet sieving' and the content of the active substance in this residue should be analysed. This has not been provided. It is expected that particles > 75 µm will be retained based on the results obtained.</p> <p><u>Additional evidence that the separated material will not block application equipment, present an unacceptable risk to the operator, lead to unacceptable residues or crop safety concerns has been provided:</u></p> <p>An additional test on sprayability was performed at the highest in use concentration (1.6% v/v) on the commercial scale plant protection product to demonstrate if the inhomogeneity of the preparation causes nozzle blockage during spraying (see 2.11/02). This study showed that no nozzle blockage occurs when applied at the highest use rate and that a constant amount of the product is sprayed throughout the spray duration. Testing was</p>		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				<p>performed using CIPAC standard waters A and D.</p> <p>In addition, based on extensive efficacy trials testing, which will be submitted with the product registration, material separation will not block application equipment, will not present an unacceptable risk to the operator and will not lead to unacceptable residues / crop safety concerns. When the product is mixed/loaded/applied according to the label instructions and using typical spraying equipment, there are no expected issues or concerns.</p>		
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation B.2.8.5.1/01				Not required for an SL formulation.		
Size distribution of particles of powder or suspension concentrate formulation				Not required for an SL formulation.		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.5.1/02						
Nominal size range of granule B.2.8.5.1/03				Not required for an SL formulation.		
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01				Not required for an SL formulation.		
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01				Not required for an SL formulation.		
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01				Not required for an SL formulation.		
Integrity of tablets				Not required for an SL formulation.		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.5.4/02						
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re- emulsifiability of formulation B.2.8.6/01				Not required for an SL formulation.		
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01				Not required for an SL formulation.		
Pourability of suspensions B.2.8.7/02				Not required for an SL formulation.		
Dustability of dustable powders after accelerated storage B.2.8.7/03				Not required for an SL formulation.		

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised						
Physical and chemical compatibility of tank mixtures B.2.9/01			The applicant confirms that PROBLAD is not intended to be used in tank mixture. The product does not have a mixing partner, and therefore testing is not considered necessary.	All references to tank mixing are to be removed from the draft label for PROBLAD PLUS	N/A	N/A
B.2.10. Adherence and distribution to seeds						
Distribution and adhesion to seeds B.2.9.10/01				Not required for an SL formulation.		
B.2.11. Other studies						
Effectiveness after storage B.2.11/01	Not reported	Aged PROBLAD PLUS: Lot #16102012 Fresh PROBLAD PLUS: Not reported	PROBLAD PLUS was incorporated into modified Potato Dextrose Agar and a plant fungal pathogen was inoculated onto it. Percent inhibition: Fresh PROBLAD PLUS 91.9% Aged PROBLAD PLUS 88.6%	Additional study on fungicidal activity after storage was submitted, it is considered supportive information. The applicant reported 3.3% decrease in the percentage inhibition.	N	Centrella B., 2015 (CEV032714)

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				A laboratory study has been provided (Centrella, 2015 (CEV032714) that compares fungicide effectiveness before and after 24 months of storage at ambient temperature. Percentage inhibition of BLAD was calculated on treated agar plates by comparison to a control sample. Percentage inhibition before storage was 91.9%, whilst percentage inhibition after 24 months storage was 88.6%. The study demonstrates a difference in effectiveness before and after storage of < 5%. The applicant states that this difference is negligible. The Efficacy field data provided for PROBLAD demonstrate highly variable control. This variation far exceeds, and therefore accounts for, the variation seen in the Centrella, 2015 study. This laboratory study provides an indication of effectiveness of the stored product. However, Efficacy would expect differing results if the stored product was tested in field trials. Consideration of storage stability will be considered further by Chemistry and Efficacy at the product authorisation stage.		
Spray application testing B.2.11/02	Not specified	PROBLAD PLUS Lot #: C191906-001	The test item was diluted at a rate of 1.6% v/v in CIPAC waters A and D, on a 4 litre scale. The content of BLAD lead protein was determined in the spray solution during and	Acceptable. This additional study demonstrates that the adverse dilution stability results are not a concern when the product is applied using commercial	Y	Bance, G., 2021 JD/21/001/2

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
		20.5% BLAD	after the test. The method used was validated in study JD/21/001/1. CIPAC Water D			application equipment. The separated material observed in the laboratory tests is not expected to block application equipment or present an unacceptable risk to the operator or lead to unacceptable residues or crop safety concerns. The modified Lowry method used is considered fit for purpose; see Volume 3 CA B5.		
			Nozzle retention description	A few small black and white flakes				
			Nozzle retention (g)	0.0011				
			Content of BLAD in spray solution	µg	µg/µL			
			Initial	16.12	3.22			
			Spray aliquot 1 (0-1 mins spraying)	18.13	3.63			
			Spray aliquot 2 (1-2 mins spraying)	17.84	3.57			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			Spray aliquot 3 (2-3 mins spraying)	17.00	3.40			
			Spray aliquot 4 (3-4 mins spraying)	18.94	3.79			
			CIPAC Water A					
			Nozzle retention description	A few small black and white flakes				
			Nozzle retention (g)	0.0005				
			Content of BLAD in spray solution	µg	µg/µL			
			Initial	18.76	3.75			
			Spray aliquot 1	19.16	3.83			

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Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			(0-1 mins spraying)					
			Spray aliquot 2 (1-2 mins spraying)	18.13	3.63			
			Spray aliquot 3 (2-3 mins spraying)	17.73	3.55			
			Spray aliquot 4 (3-4 mins spraying)	18.02	3.60			
			BLAD lead component content in the spray solution aliquots did not show a decreasing trend with spray time in both CIPAC Standard Waters A & D. No blockage of the nozzle filter was observed.					

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PROBLAD PLUS is an SL formulation (soluble concentrate). The formulation is a dark viscous liquid with a pungent odour. The lowest in use concentration is 0.251% w/v (equal to 0.2% v/v), and the highest in use concentration is 2.0%w/v (equal to 1.6% v/v).

PROBLAD PLUS does not require classification as flammable, oxidising or explosive and it is not classified as aspiration hazard. However, PROBLAD PLUS is considered as surface active product due to surface tension of 22.4 mN/m at 1.6% w/v at 20°C. The pH of 1% solution was measured before and after storage and it does not change significantly after storage and remains in the range of 5.9 – 6.4. The pH of the neat formulation after storage was similar (6.2 - 6.3).

Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of an SL formulation.

Adverse persistence of foaming data was reported, however this was justified based on the batch tested being from a pilot scale process and that incorrect test concentrations and CIPAC Standard Water were tested. New acceptable data were generated (testing the correct concentrations, correct CIPAC Standard Water used and amount of foam after 1 minute within the acceptable limits) and the proposed product label contains instructions on mixing the product to avoid excessive foaming.

Dilution stability tests showed an unstable suspension was formed when testing a concentration of 0.4% w/v which is lower than the highest possible in-use concentration (2% w/v). Additional evidence that the separated material will not block application equipment has been provided: A test on sprayability was performed at the highest in use concentration (1.6% v/v) on the commercial scale plant protection product, showing that no nozzle blockage occurs when the product is applied at the highest use rate and that a constant amount of the product is sprayed throughout the spray duration.

Accelerated storage stability data generated at 54°C for 2 weeks were provided demonstrating that the formulation retains its properties during storage. The content of lead component BLAD did not change significantly. Low temperature storage stability data indicated that there is no effect on the stability of the formulation. Ambient shelf-life data were submitted supporting a two year shelf life when the product is stored in HDPE containers. Further information regarding the levels of the relevant impurities before and after storage is presented in Volume 4, section C.1.3.1. Tank mixing is not anticipated for PROBLAD PLUS therefore tank mix compatibility data are not required.

B.2.12. 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
CP 2.1/01	Gravelle, W.D.	2014a	PROBLAD PLUS: Accelerated storage stability and corrosion characteristics study (amended) Company Report No. 35988 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.1/02	Gravelle, W.D.	2016	PROBLAD PLUS: Storage stability and corrosion characteristics study — 24 month interim report Company Report No.	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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			35987 Eurofins PSL, USA GLP, Unpublished					
CP 2.1/03	Wo, C.	2012b	PROBLAD PLUS: Physical and chemical characteristics: color, physical state, odor, oxidation/reduction, flammability, pH, viscosity, and density/relative density (amended) Company Report No. 32388 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.2/01	Cage, S.	2013	PROBLAD PLUS: Explosive properties and oxidising properties Company Report No. MIB0036 Huntingdon Life	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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			Sciences, Eye, UK GLP, Unpublished					
CP 2.3/01	Wo, C.	2012b	PROBLAD PLUS: Physical and chemical characteristics: color, physical state, odor, oxidation/reduction, flammability, pH, viscosity, and density/relative density Company Report No. 32388 (amended) Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.4/01	Gravelle, W.D.	2014a	PROBLAD PLUS: Accelerated storage stability and corrosion characteristics study Company Report No. 35988 (amended) Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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CP 2.4/02	Gravelle, W.D.	2016	PROBLAD PLUS: Storage stability and corrosion characteristics study – 24 month interim report Company Report No. 35987 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.4/03	Wo, C.	2012b	PROBLAD PLUS: Physical and chemical characteristics: color, physical state, odor, oxidation/reduction, flammability, pH, viscosity, and density/relative density (amended) Company Report No. 32388 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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CP 2.5/01	Wo, C.	2012b	PROBLAD PLUS: Physical and chemical characteristics: color, physical state, odor, oxidation/reduction, flammability, pH, viscosity, and density/relative density (amended) Company Report No. 32388 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.5/02	Wo, C.	2018	PROBLAD PLUS: Surface tension Company Report No. 48183 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.6/01	Wo, C.	2012b	PROBLAD PLUS: Physical and chemical	N	Y	Data protection is claimed in accordance with	CEV	None

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			characteristics: color, physical state, odor, oxidation/reduction, flammability, pH, viscosity, and density/relative density (amended) Company Report No. 32388 Eurofins PSL, USA GLP, Unpublished			Article 59 of assimilated Regulation No 1107/2009		
CP 2.7/01	Gravelle, W.D.	2014a	PROBLAD PLUS: Accelerated storage stability and corrosion characteristics study (amended) Company Report No. 35988 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.7/02	Gravelle, W.D.	2016	PROBLAD PLUS: Storage stability and corrosion characteristics study	N	Y	Data protection is claimed in accordance with Article 59 of	CEV	None

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			24 month interim report Company Report No. 35987 Eurofins PSL, USA GLP, Unpublished			assimilated Regulation No 1107/2009		
CP 2.7/03	Gravelle, W.D.	2014b	Stability of a liquid formulation at 0°C (amended) Company Report No. 35989 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.8.2/01	Gravelle, W.D.	2014a	PROBLAD PLUS: Accelerated storage stability and corrosion characteristics study (amended) Company Report No. 35988 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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CP 2.8.2/02	Gravelle, W.D.	2016	PROBLAD PLUS: Storage stability and corrosion characteristics study – 24 month interim report Company Report No. 35987 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.8.2/03	Comb, T.	2020	PROBLAD PLUS: Persistent foaming Study number: ENV- 20-338 AgroChemex Environmental Ltd GLP Unpublished	N	T	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.8.4/01	Gravelle, W.D.	2014a	PROBLAD PLUS: Accelerated storage stability and corrosion	N	Y	Data protection is claimed in accordance with	CEV	None

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			characteristics study (amended) Company Report No. 35988 Eurofins PSL, USA GLP, Unpublished			Article 59 of assimilated Regulation No 1107/2009		
CP 2.8.4/02	Gravelle, W.D.	2016	PROBLAD PLUS: Storage stability and corrosion characteristics study — 24 month interim report Company Report No. 35987 Eurofins PSL, USA GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None
CP 2.11/01	Centrella, B.	2015	Storage stability of PROBLAD PLUS biochemical fungicide: evaluation of biological activity of BLAD after two year storage stability Company Report No.	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None

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			CEV032714 Eurofins microbiology laboratories, Inc., USA Not GLP, Unpublished					
CP 2.11/02	Bance, G.	2021	Spray Application Testing of PROBLAD PLUS Study number: JD/21/001/2 Battelle UK GLP Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of assimilated Regulation No 1107/2009	CEV	None