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.8 (PPP) PROBLAD ~~PLUS~~

Environmental Fate & Behaviour

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]

Contents

B.8. Environmental fate and behaviour

B.8.1. Fate and behaviour in soil

Aqueous extract from the germinated seeds of sweet Lupinus albus, is a plant extract with fungicidal properties that can be used on food and non-food crops. It is extracted from the germinated seeds of sweet Lupinus albus and formulated into PROBLAD PLUS. The lead component BLAD, which forms 20% w/w of the PROBLAD PLUS formulation, is not isolated during the preparation of the product.

None of the individual components making up the product PROBLAD PLUS are isolated during the preparation of the product and the whole technical grade is regarded as the active substance which is described as a UVCB substance (Substance of Unknown or Variable composition, Complex reaction product or Biological material). Therefore, the majority of the testing summarised in the dossier, including the ecotoxicology studies, has been conducted with PROBLAD PLUS as the product and active substance. Therefore, environmental exposures have been generated in the main for the product PROBLAD PLUS. The applicant has presented exposures for BLAD in surface waters based upon the content in the product PROBLAD PLUS. For the calculation of concentrations in groundwater, the applicant has presented exposures for the lead component BLAD and lupanine as a substance of potential concern (SANCO/11470/2012 rev. 8.) This has been done on the understanding that the individual components in the product will dissipate at their own individual rates.

The proposed use pattern is detailed in Table 8.1-1. The intended crops are strawberry and tomato and the use pattern includes six applications of 4016 g a.s./ha, applied from BBCH 61 with a minimum 8 day treatment interval. The exposure assessment conducted for outdoor field use will be sufficiently protective to cover exposures from protected use.

The applicant has confirmed that the formulation referred to here as ‘PROBLAD PLUS’ is intended to be marketed as ‘PROBLAD’.

Table 8.1-1: Critical use pattern for aqueous extract from the germinated seeds of sweet Lupinus albus.

Use	Maximum application rate		Application method	Number of applications	Minimum application interval (days)	Application timing
	L product/ha	Kg a.s/ha[1]				
Strawberries, tomato Outdoor field and permanent glasshouse	3.2	4.016	Foliar spraying	1-6	8	BBCH 61-89

[1] Based on density of 1.255 g/ml

B.8.1.1. Route and rate of degradation in soil

Laboratory studies examining the rate of degradation in soil of the plant protection product are not required as for PROBLAD PLUS the active substance and the product are equivalent. Aqueous extract from the germinated seeds of sweet Lupinus albus along with its lead component, BLAD, have been demonstrated to be readily biodegradable (see Volume 3 CA B.8.2.2.1). According to ECHA guidance (ECHA, 2017), a positive result in a test for ready biodegradability can be considered as indicative of rapid and ultimate degradation in most environments.

B.8.1.2. Mobility in soil

Laboratory studies examining the rate of degradation in soil of the plant protection product are not required as for PROBLAD PLUS the active substance and the product are equivalent (see Volume 3 CA B.8.2.2.1 and B.8.1.4).

B.8.1.3. Rotational crop studies

Aqueous extract from the germinated seeds of sweet Lupinus albus along with its lead component, BLAD, have been demonstrated to be readily biodegradable (see Volume 3 CA B.8.2.2.1). A positive result in a test for ready biodegradability can be considered as indicative of rapid and ultimate degradation in most environments. Due to likely high Kp soil for the component BLAD the proposed DT50 in soil, based upon the ready biodegradability screening test is indicated as 300 days. However, it is recognised that degradation of the BLAD protein in soil by microbial digestion is likely

and the default value of 300 days should not be used as an indicator of persistence for this plant extract. In light of additional supporting information provided by the applicant and using a weight of evidence approach a soil DT50 value of 30 days can be used in future assessments of this compound. Therefore consideration of accumulation in soil and exposure to succeeding crops is not required.

B.8.2. Predicted environmental concentrations in soil (PEC_{Soil})

For the estimation of concentrations in soil, the applicant has assessed strawberry as a 'worst case use' (60% crop interception vs 80% for tomatoes) and used soil exposures for this critical GAP to cover all other uses. They have also proposed the use of a soil DT50 for PROBLAD PLUS and it's main component BLAD at 30 days based upon the outcome of the ready biodegrability screening test.

The applicant has calculated PEC_{Soil} values for PROBLAD PLUS based on application to strawberry. Six applications at a rate of 4016 g a.s./ha with an interval of eight days were simulated. Crop interception for strawberry at BBCH 61 is 60% according to EC groundwater interception values, therefore, 40% of the applied dose (1606 g a.s./ha) has been assumed to reach the soil at each application. Based upon this assessment an initial PEC_{Soil} value of 8.5 mg/kg is proposed.

HSE notes that ECHA guidance enables the use of results from screening tests when results from degradation tests simulating the conditions in soil are not available and gives a proposal for a first order half-life of readily biodegradable substances for use in soil exposure models as 30 days.

The ECHA guidance also notes that "The guidance for use of such data is based on the general recognition that for substances with low Kp values at present not enough empirical data is available to assume some sort of dependence of the soil biodegradation half -life on the solids/water partition coefficient. Nevertheless, for substances with high Kp values there is evidence that some sort of Kp dependence exists." Therefore, degradation half-life classes for (bulk) soil, partly based on Kp, are also also proposed.

The major component in the aqueous extract from the germinated seeds of sweet Lupinus albus is the protein BLAD which represents 20% w/w in the final product. The different constituents of PROBLAD PLUS have a Log Koc ranging from 3.11 (lupanine) up to estimates >1000 (BLAD, based upon high mw) ~~– 347~~ this means that the log Kp would range from 1.4->2200~~345~~. A higher Kp results in a DT50 of 300 or even higher 3000 days for readily biodegradable compounds (ECHA, 2017). Based upon the information presented in the ready biodegradability screening

studies and published literature a DT50 of 300 days for the product PROBLAD PLUS and it's major constituent BLAD is proposed.

Using the applicants scenario above but adjusting the soil DT50 to 300 days the following assessment has been concluded.

PEC_{Soil} values for the proposed use on strawberry have been calculated based on the following assumptions:-

- 6 applications of 4016 g/ha.
- An 8 day treatment interval
- DT50 in soil of 300 days.
- 60% crop interception.
- Soil depth of 5 cm.
- Soil bulk density of 1.5 g/cm^3

On this basis the PEC_{Soil} initial value would be 12.277 mg/kg (equivalent to 2.46 mg/kg of the lead component BLAD based on an assumed BLAD content of 20%). These exposures will be protective of the proposed use on tomato.

It is noted that the degradation endpoint used here is determined from a screening study, and there is supporting evidence presented in Volume 3 CA B.8.1 that this substance will biodegrade and be subject to microbial degradation in soil. The use of a DT50 of 300 days is therefore understood as being highly conservative and consideration of accumulation in the terrestrial environment is not considered necessary. It is further noted that following submission of additional supporting information provided by the applicant, and using a weight of evidence approach, a soil DT50 value of 30 days can be used in future assessments of this compound.

B.8.3. Predicted environmental concentrations in ground water (PEC_{GW})

Leaching simulations for BLAD and lupanine were conducted by the applicant with the FOCUS groundwater scenarios relevant to the UK in FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). The simulations were based on application of PROBLAD PLUS to strawberry and tomatoes. Six applications at a rate of 4016 g a.s/ha with an interval of eight days were simulated. Crop interception values according to the EC groundwater guidance were used resulting in 60%

interception for strawberry at BBCH 61 and 80% interception for tomato at BBCH 61. This resulted in soil loading values for strawberry at 40% of the applied dose (1606 g a.s./ha) and tomato at 20% of the applied dose (803 g a.s./ha). This has been assumed to reach the soil at each application. The soil application rates were multiplied by the mean concentrations of BLAD and lupanine in PROBLAD PLUS to derive corrected application rates for each compound and crop combination.

The applicant input parameters used in the modelling for BLAD and lupanine are summarised in Table 8.3-1 and 8.3-2. The applicant has presented predictions for groundwater exposures of lupanine based upon a substance DT50 of 30 and 300 days to account for the uncertainty in the Kfoc determinations. The EFSA guidance (EFSA, 2017) indicates that when the parameters are based upon a screening study, such as a ready biodegradability test, the adsorption potential positively correlates to a likely higher substance DT50. The calculated Koc values determined for lupanine are 57 and 1287 and based upon these values a DT50 of 30 days would be assumed. If the Koc values > 5000 is proposed this would assume a DT50 of 300 days. However it is noted that the ready biodegradability of this substance has not been confirmed, therefore HSE agrees with the modelling using the longer DT50 value for lupanine.

Table 8.3-1: Input parameters used in the modelling for BLAD

Parameter	Input	Input source/justification
Molecular weight (g/mol)	10 000	Maximum implementable value
Vapour pressure at 20°C (Pa)	0	Minimum implementable value
Water solubility at 20°C (mg/L)	1×10^6	Maximum implementable value
K_{FOC} (mL/g)	10,000	Based on QSPR estimate
K_{FOM} (mL/g)	5,800	K_{FOC}/1.724
1/n	1	FOCUS default
Method of sorption subroutine description	pH independent	
DT50 soil (days)	300#	Based on screening studies / ECHA guidance
Molar enthalpy of dissolution (kJ/mol)	27	FOCUS default
Molar enthalpy of vaporisation (kJ/mol)	95	FOCUS default
Water diffusion coefficient at 20°C PEARL (m²/d):	4.3×10^{-5}	FOCUS default
Gas diffusion coefficient at 20oC (m²/d)	0.43	FOCUS default
Temperature correction PELMO Q10 (-): PEARL (kJ/mol):	 1 0	Based on screening studies / ECHA guidance

Moisture correction PELMO/PEARL (-):	0	Based on screening studies / ECHA guidance
Plant uptake factor	0	FOCUS default

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

Table 8.3-2: Input parameters for lupanine

Parameter	Input	Input source/justification
Molecular weight (g/mol)	248.4	Calculated
Vapour pressure at 20°C (Pa)	0	Minimum implementable value
Water solubility at 20°C (mg/L)	1×10^6	Maximum implementable value
K_{FOC} (mL/g)	1287/57.3	Based on MCI/QSPR estimate
K_{FOM} (mL/g)	747/33	K_{FOC}/1.724
1/n	1	FOCUS default
Method of sorption subroutine description	pH independent	
DT50 soil (days)	300/30	ECHA guidance
Molar enthalpy of dissolution (kJ/mol)	27	FOCUS default
Molar enthalpy of vaporisation (kJ/mol)	95	FOCUS default
Water diffusion coefficient at 20°C PEARL (m²/d):	4.3×10^{-5}	FOCUS default
Gas diffusion coefficient at 20oC (m²/d)	0.43	FOCUS default
Temperature correction PELMO Q10 (-): PEARL (kJ/mol):	1 0	Based on screening studies / ECHA guidance
Moisture correction PELMO/PEARL (-):	0	Based on screening studies / ECHA guidance
Plant uptake factor	0	FOCUS default

Table 8.3-3: Simulated application dates for the FOCUS scenarios

FOCUS Scenario	Application date	
	Strawberry	Tomatoes
Châteaudun	-	12/07, 20/07, 28/07, 05/08, 13/08, 21/08 *
Hamburg	01/06, 09/06, 17/06, 25/06, 03/07, 11/07	-
Kremsmünster	01/06, 09/06, 17/06, 25/06, 03/07, 11/07	-
Okehampton	-	-

*Irrigation was applied in these crop/scenarios combination in accordance with the FOCUS recommendations

Based upon the applicants approach the predicted 80th percentile average annual concentrations of BLAD and lupanine from both PEARL and PELMO were at < 0.001 µg/L in all scenarios. HSE have validated the applicants values based upon the input parameters and application rates for PROBLAD PLUS, adjusted to assess the individual components BLAD and lupanine. It is noted that lupanine is not indicated as a relevant impurity in the aqueous extract from germinated seeds of

sweet Lupinus albus. However it is noted that quinolizidine alkaloids are detailed as substances of potential concern and in accordance with SANCO/11470/2012 rev. 8, the aqueous extract from the germinated seeds of sweet Lupinus albus is considered a 'group 2' botanical.

B.8.4. Fate and behaviour in water and sediment

B.8.4.1. Aerobic mineralisation in surface water

Laboratory studies examining the aerobic mineralisation of PROBLAD PLUS were not submitted (see Volume 3 CA B.8.2.).

B.8.4.2. Water/sediment study

Laboratory studies examining the fate and behaviour in water/sediment of the plant protection product PROBLAD PLUS were not submitted. Therefore, it is possible to extrapolate from data obtained in accordance with the requirements addressed Volume 3 CA B.8.2.

B.8.4.3. Irradiated water/sediment study

Laboratory studies examining the fate and behaviour in irradiated water/sediment of the plant protection product are not required as PROBLAD PLUS is both the active substance and the product. Therefore, it is possible to extrapolate from data obtained in accordance with the requirements addressed Volume 3 CA B.8.2.

B.8.5. Predicted environmental concentrations in surface water and sediment (PEC_{SW}, PEC_{SED})

Aqueous extract from the germinated seeds of sweet Lupinus albus along with its lead component, BLAD, have been demonstrated to be readily biodegradable (see Volume 3 CA B.8.2.2.1). A positive result in a test for ready biodegradability can be considered as indicative of rapid and ultimate degradation in most environments (ECHA, 2017). However, it is recognised that this is a screening test and ECHA guidance gives proposals for first order half-lives of readily biodegradable substances for use in exposure models as 15 days in surface water. As the available ecotoxicological data provided did not include sediment dosed studies no PEC_{SED} values have been determined.

The applicant has indicated that the approach taken within the ECHA guidance is that these values are given for a temperature of 12°C while the pesticide exposure models are standardised at 20°C. Therefore the applicant has made the case that with the Arrhenius equation and a Q10 of 2.58 the DT50 can be refined to 141 days in soil and sediment and 7 days in surface water. HSE considers that this case maybe applicable

to the more realistic worst case groundwater modelling in which multiple parameters are considered. However, this case is not applicable for the more simplistic spreadsheet tools for UK surface water assessment.

The applicant has also made the case that "because there are numerous components in PROBLAD PLUS, and none of these are isolated during the preparation of the product, experimental studies on individual components are generally not possible. Furthermore, all ecotoxicological studies have been performed on PROBLAD PLUS. Therefore, where the environment is exposed to the intact product – i.e., surface water via spray drift – PEC values are calculated for PROBLAD PLUS. The plant protection product is considered to be separated into its constituent components by transport and dissipation processes; therefore, PEC values for surface water via drainage and/or runoff are not considered relevant for PROBLAD PLUS. However, PECsw via drainage have been calculated for the lead component BLAD for illustrative purposes." This case is presented and addressed in the relevant sections below.

B.8.5.1. PECsw via spray drift

The applicant input parameters for the calculation of PEC_{SW} (spray drift) for use on strawberries and tomatoes are presented in the table below.

Table 8.5.1-1: Applicant input parameters for PEC_{SW} calculations (spray drift)

Crop	Strawberries and tomatoes
Application rate (g as/ha)	4016
Number of applications	6
Application interval (days)	8
Application method	Broadcast spray
Spray drift (%) at 1m for three or more applications	2.01
$DegT_{50}$ water (days)	7 (ECHA guidance normalized to 20°C)
PECsw (µg/L)	39.779

HSE notes that ECHA guidance enables the use of results from screening tests when results from degradation tests simulating the conditions in water are not available, and gives a proposal for a first order half-life of readily biodegradable substances for use in soil exposure models as 15 days in water. The guidance indicates that this value is likely conservative but for use in exposure models it does not need to be corrected for different environmental temperatures. In the UK assessment approach for spraydrift exposures it is not deemed appropriate to amend the generic values proposed from the outcome of the ready biodegrability study. HSE have presented exposure values for PROBLAD PLUS and the main constituent BLAD in surface water from spraydrift exposure in Table 8.5.1-2 and 8.5.1-3 below.

Table 8.5.1-2: HSE input parameters and outcome of PEC_{sw} calculations (spray drift) for PROBLAD PLUS

Crop	**Strawberries and tomatoes**
Application rate (g as/ha)	4016
Number of applications*	6 (1)
Application interval (days)	8
Application method	Broadcast spray
Spray drift (%) at 1m for six applications	1.64
$DegT_{50}$ water (days)	15
PECsw (µg/L)*	63.3 (37.01)

*exposures presented for single and multiple applications

Table 8.5.1-3: HSE input parameters and outcome of PEC_{SW} calculations (spray drift) for BLAD

Crop	Strawberries and tomatoes
Application rate (g as/ha)	803.2 (at 20%w/w of the product)
Number of applications*	6 (1)
Application interval (days)	8
Application method	Broadcast spray
Spray drift (%) at 1m for six applications	1.64
$DegT_{50}$ water (days)	15
PECsw (µg/L)*	12.66 (7.42)

*exposures presented for single and multiple applications

B.8.5.2. PECsw via drainflow

For consideration of PECsw via drainflow the applicant has proposed that it is inappropriate to conduct an assessment of drainage for the entire formulation. The plant protection product is considered to be separated into its constituent components by transport and dissipation processes; therefore, PEC values for surface water via drainage and/or runoff are not considered relevant for PROBLAD PLUS. The applicant has presented PECsw via drainage values for the lead component BLAD for illustrative purposes.

Table 8.5.1-4: Applicant input parameters for PEC_{SW} calculations (drainflow) for BLAD

Substance	**BLAD**
Use No.	1
Crop	Strawberries
Number of applications	6
Application interval (days)	8
Application rate BLAD (g as/ha)	6 x 815.25 (based 20.3% w/w in the product)
Growth stage	BBCH 61 – 89
Crop interception %	60
Application rate to soil (g/ha)	6 x 326.1
K_{FOC} (mL/g)	10000 (ECHA guidance)
Crop uptake factor	0
Soil $DegT_{50}$ at 20°C & pF2 (days)	141.2 (ECHA guidance/Normalised to 20°C)
$DegT_{50}$ water (days)	7 (ECHA guidance/Normalised to 20°C)

The applicant assessed a single maximum total dose of 1956.6 g BLAD/ha via a UK tier 1 drainflow assessment, with application during the drainflow period, which indicated a PECsw value at 1.204 µg/L.

The applicants case to not calculate PROBLAD PLUS values via drainflow is understood, however it is also recognised that the degradation of PROBLAD PLUS in soil is uncertain and the ecotoxicology data have mainly been generated with the product. Therefore HSE have presented tier 1 drainflow exposures for both PROBLAD PLUS and BLAD.

For multiple application GAPs an application rate for drainflow assessment can be derived from the peak PEC_{Soil} initial value. Based upon the proposed GAP on strawberry an initial PEC_{Soil} value for PROBLAD PLUS of 12.277 mg/kg was calculated. This would equate to an application rate of 9208 g/ha. A tier 1 drainflow assessment considering application during the drainflow period and a Koc value of 1000 mL/g, as a conservative value to cover the range of Koc values representing the constituents of PROBLAD PLUS, at 1287–10,000 L/kg. This tier 1 drainflow assessment would predict a PECsw (drainflow) value for PROBLAD PLUS at 14.166 µg/L.

Based upon the application rates of BLAD to strawberry as detailed in Table 8.5.1-4 an initial PEC_{Soil} value for main component BLAD of 2.46 mg/kg is calculated. This would equate to an application rate of 1845 g/ha. A tier 1 drainflow assessment considering application during the drainflow period and a Koc value of 1000 mL/g, as a conservative value to cover the range of Koc values representing constituents of PROBLAD PLUS, would predict a PECsw (drainflow) value for BLAD at 2.838 µg/L.

B.8.6. Fate and behaviour in air

B.8.6.1. Route and rate of degradation in air and transport via air

Studies examining fate and behaviour in air of the plant protection product are not required as PROBLAD PLUS is both the active substance and the product. (see Volume 3 CA B.8.3.). HSE notes that PROBLAD PLUS has a boiling point at 100°C (Volume 3 CA B.2), which would indicate a low vapour pressure for this aqueous extract.

B.8.6.2. Predicted environmental concentrations from airborne transport

Studies examining fate and behaviour in air of the plant protection product are not required as PROBLAD PLUS is both the active substance and the product. (see Volume 3 CA B.8.3.). As an aqueous extract the active substance and product are considered to have a low vapour pressure and analytical determinations of the properties of vapour pressure and volatility have not been provided. It is noted in Volume 3 CA B.2 that the generation of these studies is feasible but the high molecular weight of the lead component and high boiling point of this aqueous extract would indicate a low vapour pressure for this substance. Therefore predicted exposures in air have not been determined.

B.8.7. Predicted environmental concentrations from other routes of exposure

Studies estimating concentrations for other routes of exposure of the plant protection product are not required.

B.8.8. References relied on

Not applicable.