

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.1 (AS)

Identity of the Active Substance

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.1. IDENTITY	. 4
B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE	. 4
B.1.1.1. Common name proposed or ISO-accepted and synonyms B.1.1.2. Chemical name (IUPAC and CA nomenclature)	. 4 . 4
B.1.1.3. Producer's development code number	. 4
B.1.1.4. CAS, EEC and CIPAC numbers B.1.1.5. Molecular and structural formula, molecular mass	.4 .4
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance B.1.1.7. Specification of purity of the active substance in g/kg	.5
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	.5
B.1.1.9. Analytical profile of batches	. 5
B.1.2. REFERENCES RELIED ON	. 6

B.1. Identity

B.1.1. Identity of the active substance

B.1.1.1. Common name proposed or	Aqueous extract from the germinated			
ISO-accepted and synonyms	seeds of sweet Lupinus albus			
B.1.1.2. Chemical name (IUPAC and CA	nomenclature)			
IUPAC	Not applicable (natural plant protein)			
CA	Not applicable (natural plant protein)			
B.1.1.3. Producer's development code	None			
number				
B.1.1.4. CAS, EEC and CIPAC numbers				
CAS	Not available for aqueous extract from			
	the germinated seeds of sweet Lupinus			
	albus			
	Lead component BLAD: 1219521-95-5			
EEC	701-313-1			
CIPAC	Not applicable			
B.1.1.5. Molecular and structural formu	la, molecular mass			
Molecular formula	Not applicable for aqueous extract from			
	the germinated seeds of sweet Lupinus			
	albus which is a UVCB (substance			
	Substance of Unknown or Variable			
	composition, Complex reaction product			
	or of Biological material). Please refer to			
	the Volume 4 (Confidential Information)			
	section of the DAR for more information.			
Structural formula	Not applicable for aqueous extract from			
	the germinated seeds of sweet Lupinus			
	albus which is a UVCB substance.			
	Please refer to the Volume 4			
	(Confidential Information) section of the			
	DAR for more information.			
Molecular mass	Not applicable for aqueous extract from			
	the germinated seeds of sweet Lupinus			
	albus which is a UVCB substance.			
	Please refer to the Volume 4			
	(Confidential Information) section of the			
	DAR for more information.			

B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	Confidential information. Please refer to the Volume 4 (Confidential Information) section of the DAR.				
B.1.1.7. Specification of purity of the active substance in g/kg	Lead component BLAD: 20% w/w (nominal), min-max: 18.8% w/w - 21.2% w/w				
B.1.1.8. Identity and content of additives (such as stabilisers) and impurit					
B.1.1.8.1. Additives	Confidential information. Please refer to the Volume 4 (Confidential Information) section of the DAR.				
B.1.1.8.2. Significant impurities	Confidential information. Please refer to the Volume 4 (Confidential Information) section of the DAR.				
B.1.1.8.3. Relevant impurities	None It is noted that the applicant proposed inclusion of quinolizidine alkaloids at total QAs max. 0.005% w/w. Quinolizidine alkaloids (QAs) may be present in lupin seeds, which subsequently may then be found in the aqueous extract from the germinated seeds of sweet Lupinus albus at low levels. If the content of the total QAs in the extract exceeds 0.006% w/w, which may be indicated by the content of lupanine, they are designated as relevant impurities and a clause may be required to limit their concentration. Quinolizidine alkaloids: Total quinolizidine alkaloids, max. 50 mg/kg, with lupanine as a marker component, max. 35 mg/kg.				
B.1.1.9. Analytical profile of batches	Confidential information. Please refer to the Volume 4 (Confidential Information) section of the DAR.				

B.1.2. 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
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A