



Certificate of Analysis

Productname: Adeps lanae

Inspection No: L02375/0524/536

Batchnumber: 112528

Expiration date: 31.10.2025

Analysed according to: ČL 2023, Ph. Eur. 11.0

Customer: FAGRON a.s.

Sample Unit: 1 x 1 kg

Batch Size: 400 x 1 kg

Batch no. of vendor: L05609/2

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. A solution in light petroleum is opalescent.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	Conform	Conform		green
Identification B	Conform	Conform		Red / strong green fluorescence
TESTS				
Water-soluble acid or alk. substances	Conform	Conform		
Water-absorption capacity	>= 20	25	ml	
Acid value	<=1,0	0,84		
Peroxide value	<=20	5,4		
Saponification value	90 - 105	100		
Water-soluble oxidisable substances	Conform	Conform		
Paraffins	<= 1,0	0,18	%	
Pesticide residues	Conform	Conform		
Chlorides	<=150	<150	ppm	
Loss on drying	<=0,5	0,0	%	105 °C
Sulfated ash	<=0,15	0,023	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
Drop point	38 - 44	42,0	°C	
Butylhydroxytoluene	calculated value	147,476	ppm	

Quality: Excipient

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521

Performed by: QC Fagron a.s. (CZ)
Responsible: Mgr. Zdeňka Šinclová, QC
Mgr. Barbora Agatha Halouzková, QA/ QP
Date: 18.04.2024

Conclusion: **APPROVED**

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