



## Certificate of Analysis

**Productname:** Adeps lanae 50g

**Inspection No:** L02373/0524/536  
**Batchnumber:** 112533  
**Expiration date:** 31.10.2025  
**Analysed according to:** ČL 2023, Ph. Eur. 11.0

**Customer:** FAGRON a.s.  
**Sample Unit:** 2 x 50 g  
**Batch Size:** 1,300 x 50 g

**Batch no. of vendor:** L05609/2

	Requirement	Result	Unit	Standard remark
<b>CHARACTERS</b>				
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		
<b>IDENTIFICATION</b>				
Identification A	Conform	Conform		green
Identification B	Conform	Conform		Red / strong green fluorescence
<b>TESTS</b>				
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 <sup>3</sup>	<10	CFU/g	
TYMC	<=2 x 10 <sup>2</sup>	<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

<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>	779 00	<b>Fax No.</b>	+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**

This document has been produced electronically from our quality system and is valid without signature.

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