



## Certificate of Analysis

**Productname:** Adeps lanae

**Inspection No:** J07618/0922/536

**Batchnumber:** 22G22-T02-097541

**Expiration date:** 31.07.2024

**Analysed according to:** ČL 2017-Dopl.2020,Ph.Eur.10.0

**Original Manuf. Date:** 31.7.2022

**Sample Unit:** 1 x 5 g

**Batch Size:** 194 x 1 kg

**Identification of producer:** V00328

**Batch no. of vendor:** L05289/2

	Requirement	Result	Unit	Standard remark	Insp. Site
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	0,7			
Peroxide value	<=20	11			
Saponification value	90 - 105	98			
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	0,0	%		
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	40,2	°C		
Butylhydroxytoluene	calculated value	159,350	ppm		

Quality: Excipient

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

**Performed by:** Ludmila Stochlebová

**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QP

**Date:** 14.09.2022

**Conclusion:** **APPROVED**

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