

Certificate of Analysis

Productname: **Adeps lanae**

Inspection No: I05636/0821/536

Batchnumber: **21B18-T01-088468**

Expiration date: 28.02.2023

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

Original Manuf. Date: 3.2.2021

Sample Unit: 0 x 50 g

Batch Size: 20 x 10 kg

Identification of producer: V00328

Batch no. of vendor: L04858

	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			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Green	Conform			Fagron CZ
Identification B	Red / strong green fluorescence	Conform			Fagron CZ
TESTS					
Water-soluble acid or alk. substances	Conform	Conform			Fagron CZ
Water-absorption capacity	≥ 20	26	ml		Fagron CZ
Acid value	$\leq 1,0$	0,77			Fagron CZ
Peroxide value	≤ 20	15			Fagron CZ
Saponification value	90 - 105	96			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	$\leq 1,0$	0,36	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	≤ 150	Conform	µg/g		Fagron CZ
Loss on drying	$\leq 0,5$	0,2	%	105 °C	Fagron CZ
Sulfated ash	$\leq 0,15$	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	$\leq 2 \times 10^3$	Conform	CFU/g		Contract Lab
TYMC	$\leq 2 \times 10^2$	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
Drop point	38 - 44	43	°C		Fagron CZ

BHT 162,600 µg/g

Performed by: Ing. Petra Drábková

Responsible: Ing. Mgr. Kateřina Jokešová, QC
MVDr. Zdenka Borská, QA

Date: 24.08.2021

Conclusion: **APPROVED**

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