

Certificate of Analysis

Productname: Adeps lanae**Inspection No:** I05103/0721/536**Batchnumber:** 21B18-T01-087756**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 1 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	<=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	<=1,0	0,36	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	Conform	µg/g		Fagron CZ
Loss on drying	<=0,5	0,2	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 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

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Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 29.07.2021

Conclusion: **APPROVED** 

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