

Certificate of Analysis

Productname: **Adeps lanae**

Inspection No: H10228/1220/536
 Batchnumber: **20E05-T08-082460**
 Expiration date: 31.03.2022
 Analysed according to: Ph.Eur.10.0
 Original Manuf. Date: 31.3.2020

Sample Unit: 0 x 50 g
 Batch Size: 25 x 10 kg

Identification of producer: V00328
 Batch no. of vendor: L04611

	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	35	ml		Fagron CZ
Acid value	$\leq 1,0$	0,70			Fagron CZ
Peroxide value	≤ 20	7,4			Fagron CZ
Saponification value	90 - 105	101			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	$\leq 1,0$	0,20	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	≤ 150	Conform	$\mu\text{g/g}$		Fagron CZ
Loss on drying	$\leq 0,5$	0,01	%	105 °C	Fagron CZ
Sulfated ash	$\leq 0,15$	0,065	%		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 142,85 $\mu\text{g/g}$

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 14.12.2020

Conclusion: **APPROVED**

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