

Certificate of Analysis

Productname: **Adeps lanae**
 Inspection No: H10227/1220/536
 Batchnumber: **20E05-T08-082184**
 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: 50 x 1 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	<=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	<=1,0	0,20	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	Conform	µg/g		Fagron CZ
Loss on drying	<=0,5	0,01	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,065	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	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 µg/g

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1096/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Lucie Kubáňová DiS.

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

Date: 09.12.2020

Conclusion: **APPROVED**

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