



Certificate of Analysis

Productname: Adeps lanae

Inspection No: K04893/0923/536

Batchnumber: 23D11-T02-106806

Expiration date: 31.03.2025

Analysed according to: ČL2017-Dopl.2020, Ph.Eur.11.0

Original Manuf. Date: 31.3.2023

Sample Unit: 1 x 5 g

Batch Size: 164 x 1 kg

Identification of producer: V00328

Batch no. of vendor: L05449/2

	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			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		green	Fagron CZ
Identification B	Conform	Conform		Red / strong green fluorescence	Fagron CZ
TESTS					
Water-soluble acid or alk. substances	Conform	Conform			Fagron CZ
Water-absorption capacity	>= 20	25	ml		Fagron CZ
Acid value	<=1,0	0,92			Fagron CZ
Peroxide value	<=20	5,9			Fagron CZ
Saponification value	90 - 105	92			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	<= 1,0	0,082	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	<150	ppm		Fagron CZ
Loss on drying	<=0,5	0,05	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
Drop point	38 - 44	43,8	°C		Data Producer
Butylhydroxytoluene	calculated value	154,210	ppm		Data Producer

Quality: Excipient

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

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 11.09.2023

Conclusion: **APPROVED**

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