



## Certificate of Analysis

**Productname:** Adeps lanae

**Inspection No:** K02215/0623/536

**Batchnumber:** 22K28-T01-104359

**Expiration date:** 31.10.2024

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

**Original Manuf. Date:** 31.10.2022

**Sample Unit:** 1 x 5 g

**Batch Size:** 259 x 1 kg

**Identification of producer:** V00328

**Batch no. of vendor:** L05338/2

	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	30	ml		Fagron CZ
Acid value	<=1,0	0,87			Fagron CZ
Peroxide value	<=20	7			Fagron CZ
Saponification value	90 - 105	103			Fagron CZ
Water-soluble oxidisable substances	Conform	Conform			Fagron CZ
Paraffins	<= 1,0	0,0	%		Fagron CZ
Pesticide residues	Conform	Conform			Contract Lab
Chlorides	<=150	<150	ppm		Fagron CZ
Loss on drying	<=0,5	0,037	%	105 °C	Fagron CZ
Sulfated ash	<=0,15	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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	44	°C		Fagron CZ
Butylhydroxytoluene	calculated value	186,570	ppm		Data Producer

Quality: Excipient

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

**Performed by:** Ludmila Stochlebová

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

**Date:** 22.05.2023

**Conclusion:** **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.