

Certificate of Analysis

Product name: **Maydis amyllum**

Batch number / Weight: **22K04-B12-233424 / 1 KG**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **22K04-B12 / INS-22-9957**

Reference Code / No.: **V01176 / E3602**

Tests	Requirement	Result	Unit	Standard remark
Appearance	matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,0 - 7,0	5,51		
Foreign matter	Conform	Conform		
Oxidising substances	<=20	Conform	ppm	
Sulphur dioxide	<=50	6,4	ppm	
Iron	<=10	<10	ppm	
Loss on drying	<=15,0	12,57	%	
Sulphated ash	<=0,6	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Total aerobic microbial count (TA)	<=10 ³	5,0x10 ¹	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU/g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EI Spol, CBMiA

Release:
Dominika Sołtysik
Qualified Person

13-09-2023

Expiration: 20-11-2026

Conclusion: APPROVED

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

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl