

## **Certificate of Analysis**

Solani amylum Product name:

22F03-B04-225312 / 1 KG Batch number / Weight:

Ph. Eur. Analysed according to:

Number of analysis / Inspection Code 22F03-B04 / INS-22-5371

V01405 / VNA31 Reference Code / No.:

Tests	Requirement	Result	Unit	Standard remark
Appearance	Very fine, (almost) white powder which creaks when pressed between the fingers	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
рН	5,0 - 8,0	7,26		
Foreign matter	Conform	Conform		
Oxidising substances	<=20	0,8	ppm	
Sulphur dioxide	<=50	12,9	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<=20,0	18,46	%	
Sulphated ash	<=0,6	0,17	%	
Total aerobic microbial count (TA	· <=10^3	2,0x10^2	CFU/g	
Total yeasts and moulds (TYMC)	<=10^2	<10	CFU/g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 El Spol, CBMiA

Release: Agnieszka Pszczółka Qualified Person

23-01-2023

Expiration: 16-04-2026

Conclusion: APPROVED

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

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