

Certificate of Analysis

Productname: Maydis amylum
Number of analysis/Inspection Code: 1 / KEUR-179645B
Batchnumber: 17G12-B02-363340
Reference code / No.: 1998 / E4484
Analysed according to: PH.EUR 9.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Very fine matt, almost white to slightly yellow powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	4,0 - 7,0	5,2		5 g / 25 ml
Foreign matter	Conform	Conform		
Oxidising substances	<=20	Conform	ppm	
Sulphur dioxide	<=50	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=15,0	12,8	%	1.5 h 130 °C
Sulphated ash	<=0,6	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Total aerobic microbial count (TAMC)	<=10 ³	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	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

Analysis performed by the authorized laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/15/20

Expiration: 04-2022

Conclusion: APPROVED

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