

Certificate of Analysis

Product name: **Aluminii magnesi silicas**

Batch number / Weight: **21F14-B07-213163 / 100 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	granules or flakes (almost) white coarse powder,	Conform		
Identification A	White	Conform		
Identification B	White	Conform		
Identification C	White	Conform		
Identification F	Conform	Conform		
pH	9,0 - 10,0	9,5		
Viscosity	225 - 600	415	mPa.s	
Acid demand	<=4,0	3,5		
Arsenic	<= 3	Conform	ppm	
Lead	<= 15	Conform	ppm	
Loss on drying	<= 8,0	3,16	%	110°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Aluminium	About 5	5,49	%m/m	
Assay Magnesium	About 6	6,24	%m/m	
Ratio Al / Mg	0,5 - 1,2	0,9	%m/m	
Total aerobic microbial count (TA)	<=1000	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=100	<10	CFU/g	
E. coli	Negative / gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-01-2022

Expiration: 27-10-2025

Conclusion: APPROVED

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