

## Certificate of Analysis

**Product name:** **Sulfur**

**Batch number / Weight:** **23D21-B02-228560 / 1 KG**

**Analysed according to:** **Ph.Eur.11.1**

**Number of analysis / Inspection Code** **23D21-B02 / INS-23-4119**

**Reference Code / No.:** **V00582 / 2023125172**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (pale) yellow powder	Conform		
	The size of most of the particles is not greater than 20 µm	Conform		
	and that of almost all the particles is not greater than 40 µm			
Identification	Conform	Conform		
Identification A	Conform	Conform		
Identification B	White	Conform		
Melting point	About 120	120,3	°C	
Appearance of solution	Colourless	Conform		
Odour- / precipitation	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Chlorides	<= 100	<100	ppm	
Sulfates	<= 100	<100	ppm	
Sulfides	Conform	Conform		
Sulfated ash	<= 0,2	0,19	%	
Assay	99,0 - 101,0	99,5	%m/m	
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
Total aerobic microbial count (TA)	<= 10 <sup>3</sup>	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10 <sup>2</sup>	<10	CFU/g	

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Fagron Sp. z o.o.  
ul. Armii Krajowej 3  
32-540 Trzebinia, Poland  
e-mail:biuro@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 Soltysik  
Qualified Person

16-06-2023

Expiration: 11-03-2028

Conclusion: APPROVED

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