

Certificate of Analysis

Product name: **Saccharinum natricum**

Batch number / Weight: **21B11-B07-217730 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Appearance	or colourless crystals, efflorescent in dry air			
Identification	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear, colourless	Conform		
Acidity or alkalinity	Conform	Conform		
o- and p- Toluenesulfonamide	Conform	Conform		
o- Toluenesulfonamide	<=10	< 5	µg/g	
p- Toluenesulfonamide	<=10	0	µg/g	
Readily carbonisable substances	Conform	Conform		
Water (Karl Fischer)	<= 15,0	14,32	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,26	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

16-03-2022

Expiration: 10-10-2023

Conclusion: APPROVED

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