

Certificate of Analysis

Product name: Saccharinum natricum

Batch number / Weight: 21B11-B07-213391 / 25 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance		Conform		
Appearance				
Identification		Conform		
Identification B		Conform		
Appearance of solution		Conform		
Acidity or alkalinity		Conform		
o- and p- Toluenesulfonamide		Conform		
o- Toluenesulfonamide	<=10	< 5	μg/g	
p- Toluenesulfonamide	<=10	0	μg/g	
Readily carbonisable substance	es	Conform		
Water (Karl Fischer)		14,32	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay		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

28-01-2022

Expiration: 10-10-2023

Conclusion: APPROVED

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