

Certificate of Analysis

Product name: **Chlorobutanolum hemihydricum**

Batch number / Weight: **21J27-B04-217142 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Appearance	or colourless crystals, sublimes readily			
Identification A	Conform	Conform		
Identification B	Conform	Conform	%	
Appearance of solution	<=ref. susp. II <=BY5	Conform		
Acidity	Conform	0,15ml NaOHml		
Impurity A	<=60	1,8	ppm	
Impurity B		2,3	ppm	
Chlorides	<=100	<100	ppm	
Water (Karl Fischer)	4,5 - 5,5	4,92	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,0 - 101,0	99,81	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

05-04-2022

Expiration: 31-03-2026

Conclusion: APPROVED

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