

Certificate of Analysis

Product name: **Urea**

Batch number / Weight: **21L08-B04-219752 / 5 KG**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	132 - 135	134,4	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Alcalinity	Conform	Conform		
Biuret	$\leq 0,1$	Conform	%	
Ammonium	≤ 500	Conform	ppm	
Loss on drying	$\leq 1,0$	0,71	%	
Sulphated ash	$\leq 0,1$	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,5 (dried substance)	100,08	%m/m	
E. coli	Negative / gram	Conform		
Total aerobic microbial count (TA)	$\leq 10^3$	<1	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	<1	CFU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

10-06-2022

Expiration: 31-10-2024

Conclusion: APPROVED

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