

## Certificate of Analysis

**Productname:** Ureum  
**Number of analysis/Inspection Code:** 1 / KEUR-180648B  
**Batchnumber:** 20A08-F03-368053  
**Reference code / No.:** 1208 / 2019500204  
**Analysed according to:** PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		Slightly hygroscopic
Identification A	132 - 135	135	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		5% <i>m/V</i>
Alcalinity	Conform	Conform		
Biuret	<= 0,1	Conform	%	
Ammonium	<= 500	Conform	ppm	
Loss on drying	<=1,0	0,1	%	1 h 105 °C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Urea	98,5 - 101,5	100,3	% <i>m/m</i>	Dried
E. coli	Negative / gram	Conform		
Total aerobic microbial count (TAMC)	<=1000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=100	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

02/21/20

Expiration: 07-2022

Conclusion: APPROVED

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