

**Analysenzertifikat vom AZ00016484**  
**Artikel: 06-5232-00 Magnesii chloridum hexahydr**

Seite 1 von 2

Packungstext	25KG
Chargenr.	2018.05.0806
Ext. Chargenr.	M2857
Qualität	PHEUR
MFD	05.2018
Retest	30.05.2021
Ursprungsland	CZ
Freigabedatum	22. Juni 2018

**Hersteller**

Macco Organiques s.r.o.  
Zahnradni 46c  
792 01 Bruntal  
Tschechische Republik

Reference: PhEur, 01/2017: 0402

Characters: Colourless crystals, hygroscopic.

Storage: In an airtight container.

Residual solvents: Not subject to the PhEur 5.4 (CPMP/ICH/283/95) because no residual solvents are used for the production according to supplier information.

Labelling: The substance is not tested for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions, haemofiltration solutions or parental dosage forms.

Residues of metal catalysts or metal reagents according to EMEA/CHMP/SWP/4446/2000 are not likely to be present.

Elemental impurities: According to supplier's information results of heavy metals measured are Cd <0.5 ppm, Pb <1 ppm, As <1 ppm, Hg <0.05 ppm, V <0.1 ppm, Ni <0.1 ppm, Co <0.1 ppm, Ir <0.2 ppm, Os <0.2 ppm, Pd <0.5 ppm, Pt <0.2 ppm, Rh <0.5 ppm, Ru <0.2 ppm, Se <1 ppm, Ba <1 ppm, Cr <0.04 ppm, Cu <0.5 ppm, Li <1 ppm, Mo <0.5 ppm, Sb <0.5 ppm and Sn <0.5 ppm, which are categorized within classes 1, 2A, 2B and 3 (ICH Q3D Guideline for Elemental impurities, Step 4 version, December 2014).

Reason for change: Change to current PhEur according to CC2017.01.001.

Test	Methode	Spezifikation		Soll	Resultat
		Min.	Max.		
<b>Identification</b>					
Water (see Tests)	E-TEST A			complies	complies
Chlorides	E-TEST B			complies	complies
Reaction a					
Magnesium	E-TEST C			complies	complies
<b>TESTS</b>					
Appearance of solution	APPEARAN 2) CE			complies	complies
Clear (2.2.1) and colourless (2.2.2, II)					

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Test	Methode	Min.	Spezifikation		Soll	Resultat
				Max.		
Acidity or alkalinity	ACIDITY/AL 2) KALINITY				complies	complies
Not more than 0.3 ml of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide						
Bromides	E-IMPURITY 2)			500		<500 ppm
Sulphates	E2.4.13 2)			100		<100 ppm
Arsenic	E2.4.2 2)			2		<2 ppm
Calcium	E2.4.3 2)			0.1		<0.1 %
Iron	E2.4.9 2)			10		<10 ppm
Water	E2.5.12 2)	51.0		55.0		53.3 %
Residual solvents	E2.4.24 2)				complies	complies
Subject to the PhEur 5.4 (CPMP/ICH/283/95) according to supplier information						
<b>Assay</b>						
Assay MgCl <sub>2</sub> , 6 H <sub>2</sub> O	E-ASSAY 2)	98.0		101.0		100.7 %
<b>Remarks / Hinweise</b>						
Origin / Ursprungsland	WE22					Tschechische Republik
MFD / Herstellungsdatum	MFD					05.2018
Retest / zu überprüfen ab:	RETEST					30.05.2021

**Wir weisen darauf hin, dass der vorliegende Rohstoff als Hilfsstoff geliefert wird.**  
**Dieser Untersuchungsbericht ist ein Computerausdruck der bei uns verfügbaren Daten und ist auch ohne Unterschrift gültig.**

Herisau, 22. Juni 2018  
Hänseler AG FvP / QP  
i.v. Steve Bischof