

Analysenzertifikat vom AZ00010802
Artikel: 06-6584-01 Natrii sulfas decahydricus

Seite 1 von 2

Packungstext	500G
Chargenr.	2017.11.0665
Ext. Chargenr.	0000000009
Qualität	PHEUR
MFD	03.2017
Retest	28.02.2022
Ursprungsland	DE
Freigabedatum	1. Dezember 2017
Freigabedatum Bulk	13. November 2017

Hersteller

Chemische Fabrik GmbH
Köthenwaldstrasse 2-6
31275 Lehrte
Deutschland

Reference: PhEur 01/2017: 0100

Characters: White or almost white crystalline powder or colourless, transparent crystals

It partly dissolves in its own water of crystallisation at about 33 °C

Elemental impurities: According to manufacturer's information results of heavy metals analytically tested are Cd <0.06 ppm, Pb <0.15 ppm, As <0.5 ppm, Hg <0.09 ppm, Co <0.15 ppm, V <0.3 ppm, Ni <0.5 ppm, Tl <0.24 ppm, Au <0.5 ppm, Pd <0.3 ppm, Ir <0.3 ppm, Os <0.3 ppm, Rh <0.3 ppm, Ru <0.3 ppm, Se <0.5 ppm, Ag <0.3 ppm, Pt <0.3 ppm, Li <0.5 ppm, Sb <0.5 ppm, Ba <0.5 ppm, Mo <0.5 ppm, Cu <0.5 ppm, Sn <0.5 ppm, and Cr <0.5 ppm, which are categorized within classes 1, 2A, 2B and 3 in the ICH Guideline Q3D for Elemental impurities (EMA/CHMP/ICH/353369/2013) as well as classes 1A, 1B, 1C, 2 and 3 in the Guideline on the specification limits for residual of Metal catalysts or Metal reagents (EMA/CHMP/SWP/4446/2000).

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

Test	Methode	Spezifikation		Soll	Resultat
		Min.	Max.		
Identification					
Sulfates (2.3.1)	E-TEST			complies	complies
Sodium (2.3.1)	E-TEST 1			complies	complies
Loss on drying (see Tests)	E-TEST 2			complies	complies
TESTS					
Appearance of solution	APPEARAN CE			complies	complies
Clear (2.2.1) and colourless (2.2.2 II)					
Acidity or alkalinity	ACIDITY/AL KALINITY			complies	complies
Not more than 0.5 ml of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide					
Chlorides	E2.4.4		200		<40 ppm
Loss on drying	E2.2.32	52.0	57.0		54.4 %
Residual solvents	E2.4.24			complies	complies
Not subject to the PhEur 5.4 (CPMP/ICH/283/95) because no residual solvents are used for the productin according to supplier information					

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Test	Methode	Spezifikation		Soll	Resultat
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Assay					
Assay Na ₂ SO ₄ (dried substance)	E-ASSAY	98.5	101.0		100.3 %
Remarks / Hinweise					
Origin / Ursprungsland	WE22				Deutschland
MFD / Herstellungsdatum	MFD				03.2017
Retest / zu überprüfen ab:	RETEST				28.02.2022

We hereby certify that the above information is authentic and accurate.
This batch has been fabricated/manufactured, including packaging and quality control at the above mentioned site in fully compliance with the EU-GMP requirements of the local Regulatory Authority. The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.

This certificate is only valid for closed containers of this specific batch.

No release relevant deviation was observed.

Dieser Untersuchungsbericht ist ein Computerausdruck der bei uns verfügbaren Daten und ist auch ohne Unterschrift gültig.

Herisau, 1. Dezember 2017
Hänseler AG FvP / QP
i.v. Steve Bischof