

LOTE: 3117179

af 21/12/2022



Dr. Paul Lohmann®

High value mineral salts

Dr. Paul Lohmann GmbH & Co. KGaA - Postfach 12 20 - D 31857 Emmerthal

Batch No 3117179
Released by Dr. Sebastian Bringmann
Man./Release Date 19/05/2022
Retest Date 18/05/2024

Our. conf. No 012206809
Your order 71568
Quantity 25.0 kg
Packing Unit 25 kg
DPL-Code No 515009001
Page 1(2)
Printing Date Emmerthal, 05/10/2022

Certificate of Analysis

Zinc Sulfate 7-Hydrate

Cryst., Ph.Eur.10.Ed.

Parameters	Limits	Results
Description	crystals	crystals
Colour	colourless	colourless
Identification Zinc (Ph.Eur.)	positive	positive
Identification Sulfate (Ph.Eur.)	positive	positive
Appearance of solution (5 %)	conforms	conforms
pH (5 %)	4.4-5.6	5.3
Chloride (Cl)	max. 0.0300 %	< 0.0300 %
Iron (Fe)	max. 0.0100 %	< 0.0100 %
Cadmium (Cd, ICH-Q3D)	max. 5 ppm	< 5 ppm
Lead (Pb, ICH-Q3D)	max. 5 ppm	< 5 ppm
Nickel (Ni, ICH-Q3D)	max. 20 ppm	< 20 ppm
Thallium (Tl, ICH-Q3D)	max. 8 ppm	< 8 ppm
Assay ZnSO ₄ *7H ₂ O (Ph.Eur.)	99.0-104.0 %	101.2 %
Total aerobic count (TAMC)	max. 2000 CFU/g	< 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g	< 200 CFU/g

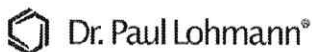
Regarding the Residual Solvents we state herewith, that the controlled production, handling and storage of this material precludes the presence of the organic solvents as specified in Ph.Eur. (ICH 283/95).

Heavy metal parameters of this spec. have been set in accordance to ICH Q3D guideline for elemental impurities on basis of a product related risk assessment. The risk assessment has been conducted considering option 1 (max. daily intake of 10g/d) for

an oral application. Unless otherwise indicated or specified, the elements of class 1-3 (classification acc.

The product has been tested and found in compliance with above stated parameters. Above information does, however, not release customer from making his own controls upon receipt of goods.

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Parameters	Limits	Results
ICH Q3D) are not likely to be present above the ICH Q3D option 1 limit in accordance to our assessment. Further elements are not intentionally added.		

Manufacturer:

Dr. Paul Lohmann GmbH & Co. KGaA, Hauptstrasse 2, D-31860 Emmerthal


 (QC Manager)

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