

Dr. Paul Lohmann GmbH KG - Postfach 12 20 - D-31857 Emmerthal

INDUKERN S.A.
Attn. Carolina Coronas
Parc Empresarial Mas Blau II
C) Alta Ribagorça, 6-8
08820 El Prat de Llobregat, Barcelona
Barcelona
SPAIN

Batch No : **3047361**
Released by : S. Bringmann
Man. /Release : 07/2019
Expiry/Retest Date : 06/2022

Our. conf. No : **O11907395**
Your order : 4500050757
Quantity : 90.0 kg
Packing Unit : 30.0 kg
DPL-Code No : 503035002
Page : 1(2)
Printing Date : Emmerthal, 25.10.2019

Certificate of Analysis Magnesium Hydroxide

Powder, Ph.Eur.9.Ed., approx. 500 g/l

Parameters	Limits	Results
Description	White powder	White powder
Identification	conforms	conforms
Appearance of solution	conforms	conforms
Soluble substances	max. 2.0 %	< 2.0 %
Acetic acid-insolubles	max. 0.1 %	< 0.1 %
Chloride (Cl)	max. 0.1 %	< 0.1 %
Sulfate (SO ₄)	max. 1.0 %	< 1.0 %
Arsenic (As)	max. 0.0004 %	< 0.0004 %
Calcium (Ca)	max. 1.5 %	< 1.5 %
Iron (Fe)	max. 0.07 %	< 0.07 %
Nickel (Ni, ICH-Q3D)	max. 55 ppm	< 55 ppm
Loss on ignition (900°C)	29.0-32.5 %	30.5 %
Assay Mg(OH) ₂	95.0-100.5 %	99.7 %
Total aerobic count (TAMC)	max. 2000 CFU/g	< 2000 CFU/g
Yeasts/moulds count (TYMC)	max. 200 CFU/g	< 200 CFU/g
Bulk density (loose)	approx. 500.0 g/l	426.8 g/l

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 specification 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. ICH Q3D) are not likely to be present above the ICH Q3D option 1 limit in accordance to our assess-

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.

This is a computer generated document and requires therefore no signature

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ment.

Further elements are not intentionally added.

The specification comprises elemental impurities based on the corresponding monograph. These elements are furthermore considered in the specification to comply with the monograph.

Manufacturer:

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