

Nº lote ACOFARMAN

22 1423

Firma y fecha:

15.03.22

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

INDUKERN S.A.

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



Dr. Paul Lohmann®

High value mineral salts

Batch No

3107014

Released by

Dr. Sebastian Bringmann

Man./Release Date

05/10/2021

Retest Date

03/10/2024

Our. conf. No

012107047

Your order

4500069636

Quantity

75.0 kg

Packing Unit

25 kg

DPL-Code No

503035002

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Printing Date

Emmerthal, 05/10/2021

Certificate of Analysis

Magnesium Hydroxide

Powder, Ph.Eur.10.Ed., approx. 500 g/l

Parameters	Limits	Results
Description	powder	powder
Colour	white	white
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 %
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 %	30.4 %
Assay Mg(OH) ₂	95.0-100.5 %	99.6 %
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 g/l	595 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 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

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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Retest Date 03/10/2024 ✓

Certificate of Analysis

Magnesium Hydroxide ✓

Powder, Ph.Eur.10.Ed., approx. 500 g/l

Our. conf. No 012107047
Your order 4500069636
Quantity 75.0 kg
Packing Unit 25 kg
DPL-Code No 503035002
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Printing Date Emmerthal, 05/10/2021

Parameters	Limits	Results
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 assessment. 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:

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

(QC Manager)

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