



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

**Batch No** : 3085968  
**Released by** : T. Poppe  
**Man. /Release** : 05/2020  
**Expiry/Retest Date** : 04/2023 ✓  
**Our. conf. No** : 012100182  
**Your order** : 4500062455  
**Quantity** : 200.0 kg  
**Packing Unit** : 25.0 kg  
**DPL-Code No** : 503035002  
**Page** : 1(2)  
**Printing Date** : Emmerthal, 11.01.2021

## Certificate of Analysis Magnesium Hydroxide

Powder, Ph.Eur.10.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 <sub>4</sub> ) | 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 %       | 32.0 %       |
| Assay Mg(OH) <sub>2</sub>  | 95.0-100.5 %      | 98.2 %       |
| 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 | 488 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

Dr. Paul Lohmann GmbH & Co. KGaA, Hauptstrasse 2, D-31860 Emmerthal / Germany, Tel. +49 5155 63-0

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## Certificate of Analysis

### Magnesium Hydroxide

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

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:

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

Nº lote ACOFARMA:

210744

Firma y fecha:

*Poppe*  
16/02/21

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