



Kuehne + Nagel (AG & Co.) KG
Betriebsstätte Schkeuditz
Paul-Thiersch-Straße 5-7
D-04435 SCHKEUDITZ

Certificate of Analysis

Date: 26 Sep 2023
Our ref. no.: 43068461 10
Your ref. LDO-172897

| | | |
|------------------------|------------|-------------------------------|
| Material: | 34538 | METHOCEL(TM) E5 Premium LV |
| Customer material no.: | ID34538P | Hydroxypropyl Methylcellulose |
| Batch No.: | 2444420354 | Retest date: 19 May 2028 |
| Quantity: | 131 DR | Production date: 21 May 2023 |

| Test | Result | Specification | Unit | Reference |
|-------------------------|-------------|---------------|---------|-------------------|
| Apparent Viscosity 1) | 5,3 | 4,0 - 6,0 | mPa sec | USP/EP/JP/CHP |
| Loss on drying | 1,4 | <= 5,0 | % | USP/EP/JP/CHP |
| Residue on ignition | 0,5 | <= 1,5 | % | USP/JP/CHP |
| Sulphated ash | 0,5 | <= 1,5 | % | CURRENT USP/EP/JP |
| pH 2) | 6,9 | 5,0 - 8,0 | | USP/EP/JP/CHP |
| Methoxyl content | 28,8 | 28,0 - 30,0 | % | USP/EP/JP/CHP |
| Hydroxypropoxyl content | 8,5 | 7,0 - 12,0 | % | USP/EP/JP/CHP |
| Opalescence | Passes test | Passes test | | CURRENT EP |
| Colour Evaluation 3) | Passes test | Passes test | | CURRENT EP |

Comments

The material property data reported in this COA are representative values obtained in laboratory tests conducted on a product sample taken from the batch produced. The undersigned certifies, that at the time of issuance of this COA, that the material property data reported are the results of the tests conducted. It is the recipient's sole responsibility to determine the suitability and legality of its proposed use of the Products.

If provided in any language other than English, the original English version will control, and the undersigned hereby disclaims responsibility for any errors caused by translation.

It is hereby certified that the material indicated above has been manufactured in accordance with excipient and food additive GMPs, was inspected and tested in accordance with current USP/Ph.Eur./JP/ChP/E464/JECFA/FCC for Hypromellose/Hydroxypropyl Methylcellulose and, unless agreed otherwise, conforms in all respects to the specification relevant thereto.



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This batch, based on audit testing and process control, is certified to be NMT 10 mg/kg heavy metals (as Pb) and also meets all specification requirements for harmonized identification tests, residual solvents and microbiological limits.

- 1) Measurement conditions: 2% in water @ 20degC
- 2) Measurement conditions: 2%in water
- 3) Measurement conditions: Solution Color

This certificate is generated automatically

Tam D. Nguyen

Quality Control Department