

Certificate of Analysis

Product name: **Maydis amylum**

Batch number / Weight: **22K04-B11-225284 / 1 KG**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22K04-B11 / INS-22-9958**

Reference Code / No.: **V01176 / E3596**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|--|---------|---------|-----------------|
| Appearance | matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| pH | 4,0 - 7,0 | 5,43 | | |
| Foreign matter | Conform | Conform | | |
| Oxidising substances | <=20 | Conform | ppm | |
| Sulphur dioxide | <=50 | 6,4 | ppm | |
| Iron | <=10 | <10 | ppm | |
| Loss on drying | <=15,0 | 13,05 | % | |
| Sulphated ash | <=0,6 | 0,10 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Total aerobic microbial count (TA) | <=10 ³ | <10 | CFU / g | |
| Total yeasts and moulds (TYMC) | <=10 ² | <10 | CFU/g | |
| E. coli | Negative / gram | Conform | | |
| Salmonella | Negative / 10 gram | Conform | | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

20-01-2023

Expiration: 18-11-2026

Conclusion: APPROVED

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