

Certificate of Analysis

Product name: **Oryzae amylum**
Batch number / Weight: **21F23-B07-213363 / 1 KG**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------------|--|---------|---------|-----------------|
| Appearance | Very fine, (almost) white powder which creaks when pressed between fingers | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| pH | 5,0 - 8,0 | 6,8 | | |
| Iron | <=10 | Conform | ppm | |
| Foreign matter | Conform | Conform | | |
| Loss on drying | <=15,0 | 8,6 | % | |
| Sulphated ash | <=0,6 | 0,3 | % | |
| Oxidising substances | <=20 | Conform | ppm | |
| Sulphur dioxide | <=50 | Conform | ppm | |
| 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 | Conform | CFU / g | |
| Total yeasts and moulds (TYMC) | <=10 ² | Conform | 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 |

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

23-12-2021

Expiration: 23-09-2024

Conclusion: APPROVED

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