

Certificate of Analysis

Productname: Solani amylum
Number of analysis/Inspection Code: 1 / KEUR-187776B
Batchnumber: 20C11-F02-373342
Reference code / No.: 1998 / VNL98
Analysed according to: PH.EUR10.0

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------------|--|---------|---------|-----------------|
| Appearance | Very fine, (almost) white powder | Conform | | |
| Identification A | Conform | Conform | | Microscopy |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| pH | 5,0 - 8,0 | 6,8 | | 5 g / 25 ml |
| Foreign matter | Conform | Conform | | |
| Oxidising substances | <=20 | 4 | ppm | |
| Sulphur dioxide | <=50 | 6 | ppm | |
| Iron | <= 10 | Conform | ppm | |
| Loss on drying | <=20,0 | 18,3 | % | 1.5 h 130 °C |
| Sulphated ash | <=0,6 | 0,3 | % | |
| Total aerobic microbial count (TAMC) | <=10 ³ | Conform | CFU / g | |
| Total yeasts and moulds (TYMC) | <=10 ² | Conform | CFU / g | |
| E. coli | Negative / gram | Conform | | |
| Salmonella | Negative / 10g | Conform | | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Pharma Cosmetic + microbieel.

Release:
Paul Hofman
Pharmacist - Qualified Person

12/18/20

Expiration: 10-2023

Conclusion: APPROVED

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