

Certificate of Analysis

Productname: Arachidis oleum raffinatum
Number of analysis/Inspection Code: 1 / KEUR-180828B
Batchnumber: 19J18-F01-367764
Reference code / No.: 1176 / 8005550002
Analysed according to: PH.EUR 9.8

| Tests | Requirement | Result | Unit | Standard remark |
|-----------------------------|--|---------|------|----------------------------|
| Appearance | Clear, (pale) yellow viscous liquid | Conform | | |
| Relative density | About 0,915 | 0,914 | | |
| Identification B | Conform | Conform | | Composition of fatty acids |
| Acid value | <= 0,5 | 0,1 | | |
| Peroxide value | <=5,0 | 0,8 | | |
| Unsaponifiable matter | <= 1,0 | 0,2 | %m/m | |
| Alcaline impurities | Conform | Conform | | |
| Composition of fatty acids | Conform | Conform | | GC |
| Saturated fatty acids < C16 | <=0,4 | <0,05 | % | |
| Palmitic acid | 5,0 - 14,0 | 6,7 | % | |
| Stearic acid | 1,3 - 6,5 | 1,9 | % | |
| Oleic acid | 35,0 - 76,0 | 72,4 | % | |
| Linoleic acid | 8,0 - 43,0 | 13,1 | % | |
| Linolenic acid | <=0,6 | 0,2 | % | |
| Arachidic acid | 0,5 - 3,0 | 0,8 | % | |
| Eicosenoic acid | 0,5 - 3,0 | 1,7 | % | |
| Behenic acid | 1,0 - 5,0 | 1,7 | % | |
| Erucic acid | <=0,5 | 0,2 | % | |
| Lignoceric acid | 0,5 - 3,0 | 0,9 | % | |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Water | <=0,1 | 0,0 | % | Karl Fischer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Quercus BE.

Release:

dr. M.J. Vincenten - van Maanen

Pharmacist - Qualified Person

02/28/20

Expiration: 05-2021

Conclusion: APPROVED

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