



Certificate of Analysis

Productname: Sorbitani sesquioleas

Inspection No: J00042/0122/536

Batchnumber: 21J29-T01-093442

Expiration date: 01.06.2023

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur. 10.0

Original Manuf. Date: 31.5.2021

Sample Unit: 1 x 5 ml

Batch Size: 54 x 250 ml

Identification of producer: V01582

Batch no. of vendor: 0001867706

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------------------|--|---------|-------|--------------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Pale yellow or slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25 °C. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| Relative density | About 0,99 | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | 180 - 215 | 189 | | Hydroxyl value | Fagron CZ |
| Identification B | 70 - 95 | 77 | | Iodine value | Fagron CZ |
| Identification C | Conform | Conform | | Composition of fatty acids, GC | Contract Lab |
| TESTS | | | | | |
| Acid value | <=16,0 | 8,3 | | | Fagron CZ |
| Hydroxyl value | 180 - 215 | 189 | | | Fagron CZ |
| Iodine value | 70 - 95 | 77 | | | Fagron CZ |
| Peroxide value | <=10,0 | 1,19 | | | Fagron CZ |
| Saponification value | 145 - 166 | 150 | | | Fagron CZ |
| Composition of fatty acids | Conform | Conform | | GC | Contract Lab |
| Myristic acid | <=5,0 | <5,0 | % | | Contract Lab |
| Palmitic acid | <=16,0 | 4,8 | % | | Contract Lab |
| Palmitoleic acid | <=8,0 | 1,0 | % | | Contract Lab |
| Stearic acid | <=6,0 | 1,5 | % | | Contract Lab |
| Oleic acid | 65,0 - 88,0 | 77,8 | % | GC | Contract Lab |
| Linoleic acid | <=18,0 | 10,7 | % | | Contract Lab |
| Linolenic acid | <=4,0 | 0,5 | % | | Contract Lab |
| Fatty acids of chain length >C18 | <=4,0 | 0,4 | % | | Contract Lab |
| Water (Karl Fisher) | <=1,5 | 0,22 | % | | Fagron CZ |
| Total ash | <=0,5 | 0,2 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 10 ³ | <10 | CFU/g | | Contract Lab |
| TYMC | <=2 x 10 ² | <10 | CFU/g | | Contract Lab |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | Data Producer |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | | Data Producer |

Quality: Excipient

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | Kontrolní laboratoř č. 536 | Post Code | 779 00 | Fax No. | +420 585 226 521 |

Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 24.03.2022

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.