

Certificate of Analysis

Productname: Propylenglycolum

Inspection No: I05647/0821/536
Batchnumber: 21E25-T03-088475
Expiration date: 12.04.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 12.4.2021

Sample Unit: 0 x
Batch Size: 6 x 25 l

Identification of producer: V00709
Batch no. of vendor: 24014556P0

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-----------------------|---|---------|-------|---------------------------------|---------------|
| CHARACTERS | | | | | |
| Appearance | A viscous, clear, colourless, hygroscopic liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | 1,035 - 1,040 | 1,037 | | Relative density | Fagron CZ |
| Identification B | 1,431 - 1,433 | 1,433 | | Refraction index | Fagron CZ |
| Identification C | 184 - 189 | 186 | °C | Boiling point | Fagron CZ |
| Identification D | 121 - 128 | 124 | °C | Melting temperature of crystals | Fagron CZ |
| TESTS | | | | | |
| Appearance | Clear / colourless | Conform | | | Fagron CZ |
| Relative density | 1,035 - 1,040 | 1,037 | | | Fagron CZ |
| Refractive Index | 1,431 - 1,433 | 1,433 | | | Fagron CZ |
| Acidity | ≤0,05 | 0,03 | ml | 0,1 mol/l NaOH | Fagron CZ |
| Oxidising substances | ≤0,2 | 0,1 | ml | 0,05 mol/l Na2S2O3 | Fagron CZ |
| Reducing substances | Conform | Conform | | | Fagron CZ |
| Water (Karl Fischer) | ≤0,2 | 0,2 | % | | Fagron CZ |
| Sulfated ash | ≤0,01 | 0 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | ≤2 x 10 ³ | Conform | CFU/g | | Contract Lab |
| TYMC | ≤2 x 10 ² | Conform | 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 |

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 23.08.2021
Conclusion: **APPROVED**

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