## SPECIFICATION

**Propylene Glycol Ph. Eur.* / USP* / JP**

Propylene Glycol USP/EP

Product code: 013

Testing specifications: Ph. Eur.*, USP*, JP*, LSM 029*/ LSM 013*

The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and (EU) No 231/2012 (E1520)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Ph. Eur.*</th>
<th>USP*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assay</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Character</strong></td>
<td>conorms</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>A / B / C / FT-IR</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Boiling point (Identification C)</strong></td>
<td>184 - 189°C</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td>clear, colourless</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Acidity</strong></td>
<td>≤ 0.05 ml 0.1 N NaOH</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Oxidising substances</strong></td>
<td>≤ 0.2 ml 0.05 N Sodium thiosulphate</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Reducing substances</strong></td>
<td>conorms</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Chloride</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Sulfate</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Relative density / Specific gravity</strong></td>
<td>d₂₀ : 1.035 – 1.040</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Refractive index</strong></td>
<td>nD : 1.431 – 1.433</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Residue on ignition</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Sulphated ash</strong></td>
<td>≤ 0.01% m/m</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td><strong>Water</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Limit of diethylene glycol and ethylene glycol:</strong></td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>- DEG</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>- EG</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 0.10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 0.10%</td>
</tr>
</tbody>
</table>

*current version

**The requirements of USP* Identification B/C, USP Assay and of JP Ethylene glycol, diethylene glycol and related substances are covered by internal validated GC method LSM 029**.

Compiled by: 16.12.2019
Approved by: 17.12.2019
Released by: 20.12.2019
Effective: 01.01.2020
Supersedes: 01.01.2017

Aug. Hedinger GmbH & Co. KG, Heiligenwiesen 26, D-70327 Stuttgart, phone:+49(0)711-402050, fax: +49(0)711-4020535
Page 1 of 3
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Propylene Glycol Ph. Eur.* / USP* / JP*
Propylene Glycol USP/EP

product code: 013

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 029*/ LSM 013*

The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and (EU) No 231/2012 (E1520)

### Parameter | Specification | Test method
---|---|---
**Identification** | conform | JP*
**Specific gravity** | $d_{20}^\circ: 1.035 – 1.040$ | JP*
**Acidity** | conform | JP*
**Chloride** | ≤ 0.007% | JP*
**Sulfate** | ≤ 0.002% | JP*
**Heavy metals** | ≤ 5 ppm | JP*
**Arsenic** | ≤ 2 ppm | JP*
**Glycerin** | conform | JP*
**Water** | ≤ 0.5% | JP*
**Residue on ignition** | ≤ 0.005% | JP*
**Distilling range** | ≥ 95% (V/V) at 184-189°C | JP*
**Ethylene glycol, diethylene glycol and related substances:**
- Ethylene glycol | ≤ 0.1% | GC, LSM 029***
- Diethylene glycol | ≤ 0.1% | GC, LSM 029***
- $\sum$ Impurities | ≤ 1.0% | GC, LSM 029***
- each other related substance | ≤ 0.1% | GC, LSM 029***

**Additional Specification**

| Parameter | Specification | Test method |
---|---|---|
**Assay** | ≥ 99.80% m/m | GC, LSM 029***
**Monoethylene Glycol** | ≤ 0.01% m/m | GC, LSM 029***
**1,2-Butanediol** | ≤ 0.01% m/m | GC, LSM 029***
**1,3-Propanediol** | ≤ 0.01% m/m | GC, LSM 029***
**Diethylene Glycol** | ≤ 0.01% m/m | GC, LSM 029***
**Di- and Tripropylene Glycol** | ≤ 0.1% m/m | GC, LSM 029***

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Dr. Katja Teufel
QA-Manager
Dr. Philipp Hoch
QA-Manager
Dr. Frank Milek
Qualified Person (GMP)

Aug. Hedinger GmbH & Co. KG, Heiligenwiesen 26, D-70327 Stuttgart, phone:+49(0)711-402050, fax: +49(0)711-4020535
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Propylene Glycol USP/EP

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 029*/ LSM 013*
The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and (EU) No 231/2012 (E1520)

Storage: It is recommended to store the material at ambient temperatures in closed containers and protected from sunlight and other sources of UV light.
Shelf life: 24 months
Manufacturer and manufacturing site: Dow Deutschland, Stade (Germany)
Manufacturing process: synthetic, key raw material: propylene oxide

Regulatory Compliance:

BSE/TSE/ GMO / Kosher status / Aflatoxins:
The material has no BSE/TSE risk, is not derived from GMO, is kosher and complies with the German “Aflatoxin Verbotsverordnung”.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):
Neither solvents of class 1 - 3 are used during manufacturing of this product, nor can they occur within the manufacturing process.

Elemental Impurities (Ph. Eur.* 5.20 / ICH Q3D*):
At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

Batch certification:
Every batch is analysed according to all parameters of Ph. Eur.* (except Characters), USP*, JP* (except Description and Identification) and the additional specification. The Certificate of Analysis (CoA) provides all results like above including date of manufacture, release date, repackaging date, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

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