



Specification

| Concerning Product: | |
|---|---|
| Article number | 25322683TPEI04 |
| Trade name / designation / denomination | Polyethylenglycol 400, Pharma |
| CAS number | 25322-68-3 |
| Other names / synonyms | •Macrogol; •Poly(ethylene oxide); •Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated; •Polyethylene glycol; •Polyethylene glycol 1500; •Polyethylene glycol 300; •Polyethylene glycol 4000; •Polyethylene glycol 6000; •ethane-1,2-diol; |
| EC number | 500-038-2 |
| Customs tariff number / CN code / TARIC | 39072011 |
| Molecular weight [g / mol] | 62.06784 |
| Formula | (C ₂ H ₆ O ₂) _n |

| Parameter | Test Method | Specification | Unit |
|---------------------------|------------------------|-------------------------------------|---------|
| Organoleptic test | | | |
| Appearance of solution | visual | (@ 25% in Water) clear | |
| Colour | visual | (@ 20 °C) clear | |
| Colour | EN 1557 | 25% a. i. in water: ≤ 15 | Hazen |
| Physical parameter | | | |
| Acidity/Alkalinity | Ph. Eur. titrimet. | 0,1M NaOH/5g: $\leq 0,1$ | ml |
| Form | visual | (@ 20°C) liquid | |
| Loss on drying | DIN 51777 | $\leq 1,0$ | % |
| Molar mass | calculated of OH value | 380 – 420 | g/mol |
| OH-value | | 267 – 295 | mgKOH/g |
| pH value | USP-NF | (5% in H ₂ O): 4,5 – 7,0 | |
| Reducing substances | Ph. Eur. | corresponding | |

| | | | |
|----------------------|-----------|--|--------------------|
| Solidification range | Ph. Eur. | 4 – 8 | °C |
| Viscosity | USP-NF | @ 98.9°C: 6,8 – 8,0 | mm ² /s |
| Viscosity | DIN 51562 | @ 20°C: 112 – 124 | mPa s |
| Impurities | | | |
| Sulphated ash | Ph. Eur. | ≤ 0,1 | % |
| Impurity | GC | Dioxane content: ≤ 1 | ppm |
| Impurity | GC | Ethylene oxide: ≤ 1 | ppm |
| Impurity | Ph. Eur. | Ethylene- and diethylene glycol: ≤ 0,20 | % |
| Impurity | Ph. Eur. | Formaldehyde: ≤ 15 | ppm |

Supplemental information:

Note: Formaldehyde content may increase during storage.

ICH-Guideline for Residual Solvents incl. Annex I (ICH/Q3C): Ethylene oxide is used as a monomer for the production of the product. It is specified to have a residual level of 1 ppm in the final product. Only class 2 solvents 1.4-Dioxane and Ethylene glycol are likely to be present, due to the nature of the production process; all are below the Option 1 limit (1.4-Dioxane max. 1 ppm, Ethylene glycol max. 500 ppm). Annex I of the above mentioned ICH guideline is not applicable.

Metal impurities according to ICH Q3D "Metal impurities" have been evaluated for the Polyglykols in a risk assessment. A separate statement on ICH Q3D metal impurity limits is available on request.

Sulphated Ash, Residue on ignition, Reducing Substances and Metal impurities according to ICH Q3D are tested in a skipped testing procedure. All other testing results given on the CoA are determined on every single batch or its precursor batch. Viscosity at 98.9°C is correlated from Viscosity at 20°C.

Complies with monographie: The product comply with all specification requirements of the current version of the Ph. Eur., USP-NF and JP. Manufactured according to IPEC-GMP (Excipients).

Regional origin: D

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 06. Mar. 2020

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