



## Specification

Concerning Product:	
Article number	25322683TPEUG3
Trade name / designation / denomination	Polyethylenglycol 300, EP/USP, GMP
CAS number	25322-68-3
Other names / synonyms	•Macrogol; •Poly(ethylene oxide); •Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -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 <sub>2</sub> H <sub>6</sub> O <sub>2</sub> ) <sub>n</sub>

Parameter	Test Method	Specification	Unit
<b>Organoleptic test</b>			
Appearance of solution	visual	(25% in H <sub>2</sub> O) clear	
Colour	EN 1557	(25% in H <sub>2</sub> O) ≤ 15	Hazen
<b>Physical parameter</b>			
Acidity/Alkalinity	Ph. Eur.	≤ 0,1	
Form		liquid	
Loss on drying	DIN 51777	≤ 1,00	%
Molar mass	of OH value	285 – 315	g/mol
OH-value	DIN EN OSO 4629	356 – 394	mgKOH/g
pH value	USP-NF	(5% in H <sub>2</sub> O) 4,5 – 7,0	
Reducing substances	Ph.Eur.	corresponding	
Viscosity	USP-NF	@ 98.9°C: 5,4 – 6,4	mm <sup>2</sup> /s

Viscosity	DIN 51562	@ 20 C°: 88 – 96	mPa s
<b>Impurities</b>			
Dioxins	Head-Space GC	≤ 1	ppm
Sulphated ash	Ph. Eur.	≤ 0,1	%
Impurity	Head-Space GC	Ethylene oxide: ≤ 1	ppm
Impurity	Ph. Eur.	Formaldehyde:	%
Related substances	Ph. Eur.	Ethylen- + Diethylenglycol: ≤ 0,20	%

### **Supplemental information:**

**Shelf life:** 2 years

**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. and USP-NF. Manufactured according to IPEC-GMP (Excipients).

**Regional origin:** D

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 01. Jul. 2020

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