



Specification

Concerning Product:	
Article number	25322683CIV4
Trade name / designation / denomination	Polyethylenglycol 4000 P
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			
Colour	EN 1557	25% a.i. in water: ≤ 30	Hazen
Physical parameter			
Acidity/Alkalinity	Ph. Eur. titrimet.	0.1M NaOH/5g: ≤ 0.1	ml
Form	visual	powder	
Loss on drying	DIN 51777	≤ 1.00	%
Molar mass	calculated of OH value	3700 – 4400	g/mol
OH-value	DIN EN ISO 4629	25 – 30	mgKOH/g
pH value	USP-NF	(5% in H ₂ O): 4.5 – 7.5	
Reducing substances	Ph. Eur.	corresponding	
Solidification range	Ph. Eur.	53 – 58	°C
Solubility	visual	a.i. in water: ≤ 25	%
Viscosity	USP-NF	@ 98.9°C: 110 – 158	mPa s
Viscosity	USP-NF	at 20°C of 50% solution: 114 – 142	mPa s
Impurities			
Dioxins	GC	≤ 1	ppm
Sulphated ash	Ph. Eur.	≤ 0.1	%
Impurity	internal	Ethylene oxide: ≤ 1	ppm
Impurity	Ph. Eur.	Ethylene- and diethylene glycol: $\leq 0,2$	%
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 of 50% solution.

Complies with monographie: The product comply with all specification requirements of the current version of the Ph. Eur. and USP-NF. Manufactured according to ICH Q7.

Regional origin: D

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 01. Jul. 2020

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