



Specification

Concerning Product:	
Article number	25322683TP3350
Trade name / designation / denomination	Polyethylenglycol 3350 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			
Appearance of solution	25% in water	clear	
Appearance	@20°C	powder	
Colour	25% a.i. in water	≤ 30	
Physical parameter			
Acidity/Alkalinity		ml 0.1M NaOH/5g; titrimetric ≤ 0,1	
Loss on drying	Karl-Fischer	≤ 1,00	%
Molar mass	HPLC	3015 – 3685	g/mol
Molar mass	calculated of OH value	3050 – 3685	g/mol
OH-value		30,0 – 37,0	mgKOH/g
pH value		5% in H ₂ O 4,5 – 7,5	
Reducing substances		complies	
Solidification range		53,0 – 57,0	°C
Viscosity		@ 98.9°C: 76 – 110	mm ² /s
Viscosity		25% in H ₂ O 85 – 105	mPa s
Identity			
Assay		HPLC: 97,0 – 103	%
Assay	Polydispersity	HPLC: 90 – 110	%
Identification		IR/HPLC complies	

Impurities			
Residue on ignition		≤ 0,1	%
Sulphated ash		≤ 0,1	%
Impurity	Ethyleneglycol	≤ 0,062	%
Impurity	Ethylene- and diethylene glycol	≤ 0,2	%
Impurity	Dioxane content Head-Space GC	≤ 1,00	ppm
Impurity	Ethylene oxide Head-Space GC	≤ 1,00	ppm
Impurity	HPLC	Formaldehyde ≤ 15	ppm
Impurity	HPLC	Sum Acetaldehyde and Formaldehyde ≤ 200	ppm

Annotation:

ICH-Guideline for Residual Solvents (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. Annex I of the above mentioned ICH guideline is not applicable.

ICH-Richtlinie für Restlösemittel (ICH/Q3C): Ethylenoxid wird als Monomer für die Herstellung des Produkts verwendet. Es wird ein Restgehalt von 1 ppm im Endprodukt angegeben.

Aufgrund der Natur des Produktionsprozesses sind wahrscheinlich nur Lösungsmittel der Klasse 2, 1,4-Dioxan und Ethylenglykol, vorhanden; alle liegen unter dem Limit von Option 1. Anhang I der oben genannten ICH-Guideline ist nicht anwendbar.

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.

Formaldehyde and Acetaldehyde content may increase during storage.

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.

Supplemental information:

Complies with monographie: EP, USP-NF, JP

Regional origin: D

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 24. Aug. 2022

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