67500 Polyethylene Glycol 1000

Product Specification

Item	Specification	Unit	Method
Country of origin	Germany		
Consistence at 20°C visual	wax-like		
Solubility 25% a.i. in water visual	clear		
Hazen color 25% a.i. in water	max. 30		EN 1557
Viscosity at 20°C of 50% solution	24 - 28	mPa·s	DIN 51562
Viscosity at 98.9°C	16 - 19	mm^2/s	USP / NF
pH Value 5% in water	5.0 – 7.5		DIN EN 1262
Water content	max. 1.00	%	Karl-Fischer DIN 51777
Ethylene oxide	max. 1	ppm	Head-Space GC
Dioxane content (calculated at 100 %)	max. 1	ppm	Head-Space GC
Reducing substances	corresponding		Ph. Eur.
OH value	107 - 118	mg KOH/g	DIN 53240
Molar mass (calculated) of OH value	950 - 1050	g/mol	
Ethylene- and Diethylene glycol	max. 0.20	%	Ph. Eur.
Solidification point	35 - 40	°C	Ph. Eur.
Acidity (ml 0.1 M NaOH/5g)	max. 0.1		Ph. Eur.
Heavy metals (Pb)	max. 5	ppm	USP/NF
Sulphated ash	max. 0.1	%	Ph. Eur.
Formaldehyde	max. 15	ppm	Ph. Eur.

Remarks
The product complies with all specification requirements of the current version of the Ph.Eur. and USP-NF.

ICH-Guideline on Residual Solvents incl. Annex I (CPMP/ICH/283/95):
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.

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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 1 of the above mentioned ICH guideline is not applicable.

ICH-Guideline for Metal Catalyst or Metal Reagent Residues (EMEA/CHMP/SWP/4446/2000 and Ph.Eur. general Chapter 5.20): Polyglykols are synthesized without the use of metal catalysts or metal reagents listed in these guidelines. Concentration limits for individual metal catalysts and metal reagents for oral and parenteral exposure are fulfilled.

Heavy Metals, Sulfated Ash, Reducing Substances and Metal Catalyst or Metal Reagent Residues 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.

Formaldeyde content may increase during storage.

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