SPECIFICATION

Propylene Glycol Ph. Eur.* / USP*

Propylene Glycol USP/EP

Product code: 029

Testing specifications: Ph. Eur.* / USP* / LSM 029*

The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC* and (EU) No 231/2012 (E1520)

Parameter	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Assay	—	—	≥ 99.5 %**	GC, LSM 029*/**
Characters	clear, colourless	Ph. Eur.*	—	—
Identification	A / B / C / FT-IR	Ph. Eur.*	A/B/C**	USP*
Boiling point	184 – 189°C	Ph. Eur.*	—	—
Appearance	clear, colourless	Ph. Eur.*	—	—
Acidity	≤ 0.05ml 0,1 N-NaOH	Ph. Eur.*	≤ 0.20ml 0,1 N-NaOH	USP*
Oxidising substances	≤ 0.2ml 0.05 N-Sodium-thiosulph.	Ph. Eur.*	—	—
Reducing substances	conforms Ph. Eur.*	Ph. Eur.*	—	—
Chloride	—	—	≤ 70 ppm	USP*
Sulfate	—	—	≤ 60 ppm	USP*
Heavy metals	—	—	≤ 5 ppm	USP*
Relative density / Specific gravity	d_{20}^{20} : 1.035 – 1.040	Ph. Eur.*	d_{25}^{25} : 1.035 – 1.037	USP*
Refractive index n_D^{20}	1.431 – 1.433	Ph. Eur.*	—	—
Residue on ignition	—	—	≤ 3.5 mg / 50 g	USP*
Sulphated ash	≤ 0.01 % m/m	Ph. Eur.*	—	—
Water	≤ 0.2 %	Ph. Eur.*	≤ 0.2 %	USP*
Limit of diethylene glycol and ethylene glycol: - DEG - EG	—	—	 ≤ 0.10 % ≤ 0.10 %	GC, LSM 029*/**
Additional Parameters				
Parameter	**Specification**	**Test method**		
Assay	≥ 99.80 % m/m	GC, LSM 029*/**		
Monoethylene Glycol	≤ 0.01 % m/m	GC, LSM 029*/**		
1,2-Butanediol	≤ 0.01 % m/m	GC, LSM 029*/**		
1,3-Propanediol	≤ 0.01 % m/m	GC, LSM 029*/**		
Diethylene Glycol	≤ 0.01 % m/m	GC, LSM 029*/**		
Di- and Tripropylene Glycol	≤ 0.1 % m/m	GC, LSM 029*/**		

** The Requirements of USP Identity B/C and Assay are covered by internal validated GC method LSM 029.
*current version

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Dr. Katja Dahms QC-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2017	15.02.2016	

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Storage:	It is recommended to store the material at ambient temperatures in closed containers and protected from sunlight and other sources of UV light.
Shelf life:	24 months
Manufacturer:	Dow Deutschland
Manufacturing Site:	Stade (Germany)

The material has no BSE/TSE risk, is not derived from GMO, is kosher and complies with the German Aflatoxinverbots -Verordnung.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / CPMP/ICH/82 260/06):
Neither solvents of class 1 - 3 are used during manufacturing the product, nor can they occur within the manufacturing process.

Every batch is analysed according to all parameters of this specification (except characters). The Certificate of Analysis (CoA) provides all results like above including release date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

*current version

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