HEDINGER 1843 A pure decision.

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*, 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	D	Ph. Eur.*	A/B/C**	USP*
Appearance	clear, colourless	Ph. Eur.*	—	—
Acidity	≤ 8.3 ml 0.01 N NaOH	Ph. Eur.*	≤ 0.20 ml 0.10 N NaOH	USP*
Oxidising substances	≤ 0.2 ml 0.05 N Sodium thiosulfate	Ph. Eur.*	—	—
Reducing substances	conforms	Ph. Eur.*	—	—
Chloride	—	—	≤ 70 ppm	USP*
Sulfate	—	—	≤ 60 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*
Ethylene glycol and diethylene glycol / Limit of diethylene glycol and ethylene glycol: - DEG - EG	 ≤ 0.10% ≤ 620 ppm	GC, LSM 029*/**	 ≤ 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 Ph. Eur.* Ethylene glycol, diethylene glycol and of USP* Identification B/C, USP* Assay are covered by internal validated GC method LSM 029*.

*current version

Effective date: 22.09.2025

Supersedes version from: 01.12.2024

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*, FCC* and (EU) No 231/2012 (E1520)

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients*
Supply chain	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP]
Primary Packaging material	Specified packaging materials from audited suppliers: 1 L Amber Glass Bottles 1 L, 5 L, 10 L, 20 L HDPE Containers 200 L HDPE-Steel Combi-drums 1000 L HDPE EVOH Intermediate Bulk Container with diffusion barrier

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 from date of manufacture
The specified shelf-life related to originally closed containers.

Manufacturer and manufacturing site: Dow Deutschland, Stade (Germany)

Regulatory Compliance:

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* and EU-GMP Part II Guidelines*.

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) is available upon request.

Batch certification:

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, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

*current version

Compiled by: 21.08.2025	Approved by: 21.08.2025	Released by: 21.08.2025	Effective:	Supersedes:
Dr. Anne Reiff Senior QA-Manager	Dr. Markus Sterk Head of QC	Dr. Frank Milek Qualified Person (GMP)	22.09.2025	01.12.2024