HEDINGER 1843 A pure decision.

SPECIFICATION

Propylene Glycol Ph. Eur.* / USP* / JP*

Propylene Glycol USP/EP **product code: 013**

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 029*/ LSM 013*

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	conforms	Ph. Eur.*	—	—
Identification	A / B / C / FT-IR	Ph. Eur.*	A / B / C**	USP*
Boiling point (Identification C)	184 - 189°C	Ph. Eur.*	—	—
Appearance	clear, colourless	Ph. Eur.*	—	—
Acidity	≤ 0.05 ml 0.1 N NaOH	Ph. Eur.*	≤ 0.20 ml 0.10 N NaOH	USP*
Oxidising substances	≤ 0.2 ml 0.05 N Sodium thiosulphate	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*
Limit of diethylene glycol and ethylene glycol: - DEG - EG	—	—	 ≤ 0.10% ≤ 0.10%	GC, LSM 029*/**

*current version

**The requirements of USP* Identification B/C, USP Assay and of JP Ethylene glycol, diethylene glycol and related substances are covered by internal validated GC method LSM 029*.

Compiled by: 16.12.2019	Approved by: 17.12.2019	Released by: 20.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2020	01.01.2017

HEDINGER 1843 A pure decision.

SPECIFICATION

Propylene Glycol Ph. Eur.* / USP* / JP*
Propylene Glycol USP/EP **product code: 013**

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 029*/ LSM 013*
The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and (EU) No 231/2012 (E1520)

JP*		
Parameter	**Specification**	**Test method**
Description	conforms	JP*
Identification	1 / 2	JP*
Specific gravity	d_{20}^{20}:1.035 – 1.040	JP*
Acidity	conforms	JP*
Chloride	≤ 0.007%	JP*
Sulfate	≤ 0.002%	JP*
Heavy metals	≤ 5 ppm	JP*
Arsenic	≤ 2 ppm	JP*
Glycerin	conforms	JP*
Water	≤ 0.5%	JP*
Residue on ignition	≤ 0.005%	JP*
Distilling range	≥ 95% (V/V) at 184-189°C	JP*
Ethylene glycol, diethylene glycol and related substances: - Ethylene glycol - Diethylene glycol - ∑ Impurities - each other related substance	 ≤ 0.1% ≤ 0.1% ≤ 1.0% ≤ 0.1%	GC, LSM 029*/**

Additional Specification		
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*/**

*current version
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Compiled by: 16.12.2019	Approved by: 17.12.2019	Released by: 20.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2020	01.01.2017

SPECIFICATION

Propylene Glycol Ph. Eur.* / USP* / JP*
Propylene Glycol USP/EP **product code: 013**

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 029*/ LSM 013*
The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and (EU) No 231/2012 (E1520)

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 and manufacturing site: Dow Deutschland, Stade (Germany)

Manufacturing process: synthetic, key raw material: propylene oxide

Regulatory Compliance:

BSE/TSE/ GMO / Kosher status / Aflatoxins:

The material has no BSE/TSE risk, is not derived from GMO, is kosher and complies with the German “Aflatoxin Verbotsverordnung”.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

Neither solvents of class 1 - 3 are used during manufacturing of this product, nor can they occur within the manufacturing process.

Elemental Impurities (Ph. Eur.* 5.20 / ICH Q3D*):

At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

Batch certification:

Every batch is analysed according to all parameters of Ph. Eur.* (except Characters), USP*, JP* (except Description and Identification) and the additional specification. The Certificate of Analysis (CoA) provides all results like above including date of manufacture, release date, repackaging date, 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
**The requirements of USP* Identification B/C, USP Assay and of JP Ethylene glycol, diethylene glycol and related substances are covered by internal validated GC method LSM 029*.

Compiled by: 16.12.2019	Approved by: 17.12.2019	Released by: 20.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2020	01.01.2017