

Product Specification

CM – Monomers Division

1,2 PROPYLENE GLYCOL USP BMBcert

PRD-No.: 30799044

1. Document information

Document name: StS_12PGUSP_BMBcert_30799044_CM_EN
Revision: 2 valid from: 2025-01-01

2. General

This product is produced by BASF SE, Ludwigshafen, Germany. BASF SE, Ludwigshafen, Germany is certified according to ISO 9001. An HACCP-Concept according (EU) 852/2004 is implemented. The requirements according to ISO 22000, ISO/TS 22002-1 and additional FSSC 22000 requirements are fulfilled. This product is certified according to EXCiPACT for pharmaceutical excipient suppliers (Good Manufacturing Practice).

Appearance: Clear and not more intensely colored than reference solution B₉ (Ph.Eur.)
Chemical Name: propane-1,2-diole (C₃H₈O₂)
CAS-Nr.: 57-55-6
EINECS-Nr.: 200-338-0

3. Properties

Parameter	Unit	Specification	Test method
Identification (IR)	-	Must conform	USP-NF
Identification (IR)	-	Must conform	Ph.Eur.
Identification (Limit of ethylene glycol and diethylene glycol)	-	Must conform (NMT 0.10% each)	PM00637QC
Purity 1,2 Propylene glycol (GC) (calculated)	g/100g (%)	Min. 99.8	PM02337QC
Specific gravity, d(20/20)	-	1.035 - 1.040	PM00379QC
Specific gravity, d(25/25)	-	1.035 - 1.037	PM00379QC
Refractive index, n(20/D)	-	1.431 - 1.433	Ph.Eur.
Acidity (calculated as acetic acid)	-	Must conform (max.4.98 mg/50 mL)	Ph.Eur.
Water	g/100g (%)	Max. 0.2	Ph.Eur. (equivalent to USP-NF and JP)
Sulphated ash	mg/kg	Max. 70	Ph.Eur. (equivalent to USP-NF and JP)
Chloride (IC)	mg/kg	Max. 70	PM/00621
Sulphate (IC)	mg/kg	Max. 60	PM/00621
Oxidizing substances (calculated as H ₂ O ₂)	mg/kg	Must conform (max. 17 mg/kg)	Ph.Eur.
Reducing substances	-	Must conform	Ph.Eur.
Sum of unspecified impurities (GC) (incl. dimers and polymers)	g/100g (%)	Max. 0.1	PM02337QC
1,3-Propanediol (GC)	mg/kg	Max. 100	PM02337QC
Halogenated organic substances, expressed as chlorine (coulometric)	mg/kg	Max. 1	PM00621

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Hazen colour	-	Max. 10	PM00914
Arsenic ¹ (AAS)	mg/kg	Max. 2	PM/01906
Heavy metals ¹ (AAS)	mg/kg	Max. 5	PM/01683
Residual Solvents ²	-	Must conform	Ph.Eur.5.4/USP<467>/ICH Q3
Ethylene glycol (GC)	mg/kg	Max. 620	PM00637QC
Diethylene glycol (GC)	mg/kg	Max. 1000	PM00637QC

¹ Tested periodically.

² Not tested since no organic solvents are likely to be present.

The product meets the specification of following monographs: "Propylene Glycol" of USP-NF (current version), of European Pharmacopoeia (current version) and of Japanese Pharmacopoeia (English current version). It fulfills the purity criteria for food additives set by Directive (EU) 231/2012 E 1520 as well as the one contained in the Food Chemical Codex.

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

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