



Dow Propylene Glycol USP/EP

General Description

Propylene Glycol USP/EP (PG USP/EP), referring to the United States and European Pharmacopeia, is a high-purity grade of monopropylene glycol for use in pharmaceutical, food, cosmetic, personal care, flavor and fragrance, plus a variety of other applications. The clear, colorless, practically odorless, slightly viscous, water-soluble and hygroscopic liquid with low vapor pressure is produced and handled in compliance with current Good Manufacturing Practice (cGMP) guidelines. PG USP/EP is tested for compliance with the current USP, EP, and Japanese Pharmacopeia (JP) specifications plus the Food Chemical Codex (FCC); it also complies with the Brazilian Pharmacopeia, and other pharmaceutical, cosmetic and food regulations in the global markets where it is sold. It is listed by the Cosmetic, Toiletry and Fragrance Association as an approved ingredient in cosmetics and its use is reviewed by the Cosmetic Ingredient Review (CIR). PG USP/EP is Kosher certified and complies with Halal requirements.

Properties¹ of Propylene Glycol USP/EP

Chemical Name	1,2-Propanediol
Formula	CH ₃ -CH(OH)-CH ₂ OH; C ₃ H ₈ O ₂
Molecular Weight	76.10
CAS Number	57-55-6
EINECS Number	200-338-0
Assay	> 99.8% by weight
Water	< 0.2% by weight
Boiling Point, 101.3 kPa (1 atm)	187°C (369°F)
Distillation Range, 101.3 kPa (1 atm)	186–189°C (367°F–372°F)
Vapor Pressure, 20°C (68°F)	0.011 kPa (0.08 mm Hg)
25°C (77°F)	0.017 kPa (0.13 mm Hg)
Freezing Point	Supercools
Pour Point	< -57°C (-71°F)
Specific Gravity 20/20°C (68/68°F)	1.038
25/4°C (77/39°F)	1.033
60/4°C (140/39°F)	1.007
Refractive Index n ₂₀ /D, 20°C (68°F)	1.4310–1.4330
Viscosity, 25°C (77°F)	48.6 centipoise (mPa.s)
60°C (140°F)	8.4 centipoise (mPa.s)
Specific Heat, 25°C (77°F)	2.51 J/g°K
Surface Tension, 25°C (77°F)	36 mN/m
Flash Point, Pensky-Martens Closed Cup	104°C (220°F)
Autoignition Temperature	371°C (700°F)
Thermal Conductivity, 25°C (77°F)	0.2061 W/m°K
Electrical Conductivity, 25°C (77°F)	10 micro S/m
Heat of Formation	-422 kJ/mol (-101 Kcal/g-mol)
Heat of Vaporization, 25°C (77°F)	67.0 kJ/mol

¹These data are laboratory results typical of the product, and should not be confused with, or regarded as specifications. For a copy of the sales specification, please contact your Dow representative or visit our web site at www.dowpg.com.

Sales Specification and Certificate of Analysis

The sales specification of Propylene Glycol USP/EP contains all original specification items listed in the current USP, EP, JP and FCC, plus a number of Dow-specific test items. Key product parameters are analyzed on every lot, and the complete set of monograph specification items are analyzed on a skip-lot basis once per quarter.

Lot-specific Certificates of Analysis (CoA) are provided for every product shipment, containing test results for all USP, EP, JP and FCC items and clearly differentiating between actual and skip-lot results.

PurityPlus

PG USP/EP is manufactured in Dow facilities in the U.S., Germany, Brazil and Australia using the same rigorous, global quality control procedures to help ensure outstanding product quality and application reliability, worldwide.

Current Good Manufacturing Practice (cGMP) principles, as published by the International Pharmaceutical Excipients Council (IPEC), are applied by Dow during all manufacturing and handling steps of PG USP/EP. This GMP program includes a number of purity standards:

- Dedicated facilities
- Extensive additional quality assurance testing
- Dedicated bulk storage
- Transportation in stainless steel or lined equipment
- Color differentiated drums
- Label management
- Sealing procedures
- Distributor and terminal qualification programs
- Personnel qualification and training programs

In support of distributors who repackage Dow PG USP/EP, Dow provides on-going clean area drumming support, including start-up assistance and clean area inspections. The supply chain operations of Dow PG USP/EP in Europe are carried out in compliance with the European Chemical Industry Council (CEFIC) Guideline for Handling and Distribution of Propylene Glycol USP/EP.

Applications

Propylene Glycol USP/EP is a widely used ingredient in pharmaceutical, food, cosmetic, personal care, flavors and animal feed applications; an overview of typical uses of PG USP/EP is given below.

It must be emphasized that it is the user's responsibility to consult area and country-specific regulations for details of approved use.

1. Pharmaceuticals - Solvent for active ingredients in oral, topical and injection drug products (excipient).
2. Cosmetics & Personal Care - Solvent, coupling agent, carrier, emulsion stabiliser, softening agent, viscosity modifier and humectant in many types of cosmetics and personal care products such as skincare, suncare, shampoo, bath/shower products, toothpastes, mouthwashes, shaving products and baby care products.
3. Flavors & Fragrances - Solvent and extraction solvent of flavors and fragrances for applications in food, beverages, perfumes and cosmetics.

4. Food - Various applications as a direct food additive (E 1520) such as a carrier or carrier solvent for colors, emulsifiers, antioxidants and enzymes (in Europe with maximum 1 g/kg in human foodstuffs), and humectant and stabilizer in fruits, vegetables and bakery goods (except in Europe). PG USP/EP is also applied in indirect contact food applications, such as a low temperature heat-transfer fluid in the brewing, dairy and ice cream industries and for food storage facilities, an equipment cleaner fluid or a solvent for printing inks.
5. Petfoods & Animal Feed - Humectant, emulsifier, preservative, solvent for additives (in Europe with different maximum contents for specific species), energy source and aid for prevention of ketosis (acetonemia) in dairy cattle.

Application-specific information for PG USP/EP is available from application overview data sheets.

Formulation Advantages

- Excellent solvent action for a variety of flavoring, fragrance and active drug ingredients
- High humectant values for providing moisture retention in products
- Low volatility
- Absence of odor and color
- Plasticizing and softening agent
- Complete water solubility
- Excellent solubility for other organic materials, e.g., fatty acids, alcohols, ketones and esters

Storage & Handling

PG USP/EP has a shelf life of two years when stored below 40°C (104°F) in closed containers away from sources of UV light.

For more details about product handling and safety information, please refer to the Dow Material Safety Data Sheet (MSDS/SDS).

Additional information is available from your Dow representative or on our web site or by calling:

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