

Technical Data Sheet Propylene Glycol USP Grade

for Pharmaceutical

< Updated in Nov. 7, 2011 >

Description

Propylene Glycol USP Grade (PG USP) for Pharmaceutical is a high purity material produced by hydrolysis of Propylene Oxide (PO) with excess water at the high temperature and pressure. PG USP is distilled product of more than 99.80% purity.

PG USP is a relatively nontoxic, hygroscopic liquid with low vapor pressure. It is practically colorless, odorless, and water soluble. It is used as an additive and solvent in pharmaceutical application.

<u>Sales</u> Specifications

Property	Specifications	Test Method
Identification , -	Pass	USP
MPG Assay , wt.%	Min. 99.80	USP
EG, wt.ppm	Max. 50	USP
DEG, wt.ppm	Max. 50	USP
Sp.Gr (25/25℃)	1.035 – 1.037	USP
Color , APHA	Max. 10	ASTM D 1209
Water , wt.ppm	Max. 700	USP
Acidity, wt.ppm as Acetic acid	Max. 30	USP
Iron , wt.ppm	Max. 0.10	ASTM E 394
Chlorides, wt.ppm	Max. 1.0	USP
Sulfate , wt.ppm	Max. 10	USP
Heavy metal (as Pb) , wt.ppm	Max. 5.0	USP
Residue , wt.ppm	Max. 20	USP
Residual Solvent, -	Pass	USP 467
Distillation Range (1atm), ℃	186 – 189	ASTM E 202

SKC's PG USP is produced in compliance with the United States Pharmacopeia (USP), meets the requirements of other Standards like the European Pharmacopeia (EP). PG USP is also registered in accordance with the regulation of Chinese Food and Drug Administration(CFDA)

Applications

PG USP offers excellent versatility and functionality in applications.

- 1. Solvent and extractant for a wide range of active ingredients, such as corticosteroids, phenol derivatives, barbiturates, vitamin A and D, most alkaloids and many local anesthetics
- 2. Emollient for softening and smoothing is complex mixtures of chemical agents specially designed to make the external layers of the skin softer and more pliable, by increasing its hydration (water content) by reducing evaporation.
- 3. Humectants are used in topical dosage forms to increase the solubility of the active ingredient, to elevate its skin penetration and increase its activity time. Humectants also elevate the hydration of the skin to minimize the dehydrating effect of some active ingredients.



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- 4. PG USP is also used additives, such as emulsion stabilizer, dispersant, coupling agent, viscosity modifier in pharmaceutical application.
- 5. Plasticizer in aqueous film coating formulation.

Items	Properties
IUPAC Name	1,2-Propanediol
Formula	CH ₃ -CH(OH)-CH ₂ OH ; C ₃ H ₈ O ₂
Molecular Weight(g/mol)	76.10
CAS Number	57-55-6
EINECS Number	200-338-0
Boiling Point, 101.3 kPa (1atm)	187℃(369°F)
Distillation Range, 101.3 kPa (1atm)	186 - 189℃(367-372°F)
Vapor Pressure, 20℃(68°F)	0.011 kPa (0.08 mmHg)
25 ℃(77°F)	0.017 kPa (0.13 mmHg)
Freezing Point	<-59℃ (<-74.2°F)
Pour Point	< -57℃(-71°F)
Specific Gravity, 20/20 ℃(68/68°F)	1.038
25/4 ℃(77/39°F)	1.033
60/4°C(140/39°F)	1.007
Refractive Index n20/D, 20 °C (68°F)	1.4310 - 1.4330
Viscosity, 25°C (77°F)	48.6 cPs (mPa.s)
60℃(140°F)	8.4 cPs (mPa.s)
Specific Heat, 25 ℃ (77°F)	2.51 J/g [°] K(0.60 Btu/lb/°F)
Surface Tension, 25°C(77°F)	36 mN/m(36 dynes/cm)
Flash Point	104℃(220°F)
Autoignition Temperature	371 ℃(700°F)
Thermal Conductivity, 25 ℃ (77°F)	0.2061 W/m°K(0.1191 Btu/hr ft°F)
Electrical Conductivity, 25 °C (77°F)	10 micro S/m
Heat of Formation	-422 KJ/mol (-101 Kcal/g-mol)
Heat of Vaporization, 25 ℃ (77°F)	67.0 kJ/mol(379 Btu/lb/°F)

Physical Properties

Viscosity Data

Temperature		Viscosity (Centipoises)
-10 ℃	14°F	700
C 0	32° F	260
10°C	5 0°F	120
20 °C	68°F	64
30 °C	86°F	35
40 °C	104°F	19
50 ℃	122°F	13
60 °C	140°F	8.7



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<u>Material</u> Safety Policy	Before handling the product, The Material Safety Data Sheet (MSDS) should always be read and understood thoroughly and adequate safety procedures should be followed. MSDS offers information on the toxicity, environmental and industrial hygiene aspect of our products
<u>Handling and</u> <u>Storage</u>	PG USP is high-purity material, which must be handled with special precautions to avoid contamination with a container tightly closed and to avoid exposure to UV light, air, heat. Under ordinary conditions, mild steel is a satisfactory material of construction; however for long term storage and where iron contamination and color are objectionable, stainless steel or aluminum vessels are recommended. Store under 40 $^{\circ}$ C with N ₂ blanketing for the inhibition of oxidization
<u>Container</u> <u>Material</u> <u>Selection</u>	Stainless Steel, aluminum, plastic or carbon steel with phenolic coating are recommended.
<u>Shipping</u>	Product is available in barges, lined tank cars and dedicated tank truck, and 215kg nonreturnable drums. DOT Label required: None Freight classification: Propylene Glycol

Additional information is available from your SKC representative, our web site or calling :

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