Technical Data Sheet

Propylene Glycol USP Grade

for Pharmaceutical

< Updated in Mar. 29, 2016 >

Description

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

PG USP is a clear, relatively nontoxic, hygroscopic liquid with low vapor pressure. According to these properties, PG USP is cleared for use in the United States in accordance with U,S. FDA requirements. PG USP is used as an excipient (non-active ingredient) in the manufacture of pharmaceutical product. SKC PG USP is produced in compliance with the United States Pharmacopeia(USP), also meets the requirements of European Pharmacopeia (EP) and other regulations and standards.

Sales Specifications

Property	Specifications	Test Method
IDENTIFICATION, by IR, GC, A, B, C	Pass	USP
ASSAY, MPG, wt. %	Min. 99.80	USP
EG, wt.ppm	Max. 50	USP
DEG, wt.ppm	Max. 50	USP
TESTS		
Residue on Ignition, mg (wt. ppm)	Max. 1 (Max. 20)	USP
Chlorides, wt.ppm	Max. 1.0	USP
Sulfate , wt.ppm	Max. 10	USP
Heavy metal (as Pb), wt. ppm	Max. 1.0	USP
SPECIFIC TESTS		
Specific Gravity, 25/25℃	1.035 – 1.037	USP
Acidity, ml, 0.1N NaOH (ppm as Acetic Acid)	Max. 0.05 (Max. 30)	USP
Water, wt. ppm	Max. 700	USP
Iron , wt.ppm	Max. 0.10	ASTM E 394
Color , APHA	Max. 10	ASTM D 1209
Distillation Range (1atm), ℃ IBP/DP	186 – 189	ASTM D 1078

Applications

PG USP offers excellent versatility and functionality in applications.

1. Solvent and provide equal distribution of the active ingredient in the formulation, so that each pill, liquid dose or cream-based application always contains the exactly prescribed amount of curing agent.

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.

Physical Properties

Items	Properties
IUPAC Name	1,2-Propanediol
Formula	CH_3-CH(OH)-CH_2OH ; $C_3H_8O_2$
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) 25℃(77°F)	0.011 kPa (0.08 mmHg) 0.017 kPa (0.13 mmHg)
Freezing Point	<-59℃ (<-74.2°F)
Pour Point	< -57℃(-71°F)
Specific Gravity, 20/20℃(68/68°F) 25/4℃(77/39°F) 60/4℃(140/39°F)	1.038 1.033 1.007
Refractive Index n20/D, 20℃(68°F)	1.4310 - 1.4330
Viscosity, 25℃ (77°F) 60℃(140°F)	48.6 cPs (mPa.s) 8.4 cPs (mPa.s)
Specific Heat, 25℃(77°F)	2.51 J/g^{o}K(0.60 Btu/lb/°F)
Surface Tension, 25℃(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^{o}K(0.1191 Btu/hr ft°F)
Electrical Conductivity, 25℃(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)

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Material 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

Handling and Storage

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 ℃ with N_2 blanketing for the inhibition of oxidization.

Container Material Selection

Stainless Steel, aluminum, plastic or carbon steel with phenolic coating are recommended.

Shipping

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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