

# TRUEGARD PROPYLENE GLYCOL

USP KOSHER 100% CONCENTRATE



## PRODUCT DESCRIPTION

**TRUEGARD PROPYLENE GLYCOL USP/EP (PG USP/EP)**, referring to the United States and European Pharmacopoeias, 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.

**TRUEGARD PG USP/EP** is tested for compliance with the current USP, EP, and Japanese Pharmacopoeia (JP) specifications plus the Food Chemical Codex (FCC); it also complies with the Brazilian Pharmacopoeia, 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.

## TYPICAL COMPONENT PROPERTIES

Chemical Name	1,2-Propanediol
Formula	CH <sub>3</sub> -CH(OH)-CH <sub>2</sub> OH; C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>
Molecular Weight (g/mol)	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	Super cools
Pour Point	< -57°C (-71°F)
Specific Gravity 20/20°C (68/68°F)	1.038
25/4°C (77/39°F)	1.033

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60/4°C (140/39°F)	1.007
Refractive Index n <sub>20</sub> /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

*1. These are typical values and should not be construed as specifications.*

## SALES SPECIFICATION & CERTIFICATE OF ANALYSIS

The sales specification of **TRUEGARD PG USP/EP** contains all original specification items listed in the current USP, EP, JP and FCC, plus a number of 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.

## PURITY PLUS

**TRUEGARD PG USP/EP** is manufactured in facilities in the U.S., Germany, Brazil, Australia and Thailand 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 during all manufacturing and handling steps of **TRUEGARD PROPYLENE GLYCOL USP/EP**.

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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
- Traceability through the whole supply chain
- Personnel qualification and training programs

The supply chain operations of **TRUEGARD 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 stabilizer, softening agent, viscosity modifier and humectant in many types of cosmetics and personal care products such as skincare, sun care, 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.

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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. Pet foods & Animal Feed - Humectant, emulsifier, preservative, solvent for additives, energy source and aid for prevention of ketosis (acetonemia) in dairy cattle. In EMEA a specific tailor made Propylene Glycol Animal Feed is offered for this application (for details see Product Technical Data Sheet).

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

## STORAGE & HANDLING

Propylene Glycol USP/EP is stable for at least two years when stored at ambient temperatures in closed containers and away from sunlight and other sources of UV light. Where product heating is utilized (i.e. for bulk storage and/or transport containers) the product temperature should be controlled to prevent unintentional overheating over extended periods as this may potentially lead to accelerated oxidative degradation of the product. As a general guide Keller-Heartt recommends heating up to not more than 40° C. For more details about product handling and safety information, please refer to the Material Safety Data Sheet (MSDS).

## SAFETY CONSIDERATIONS

Material Safety Data (MSD) sheets are available from Keller-Heartt. MSD sheets are provided to help customers satisfy their own handling, safety and disposal needs and those that may be required by locally applicable health and safety regulations. MSD sheets are updated regularly, therefore, please request and review the most current MSD sheet before handling or using any product. These are available from Keller-Heartt.

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## **CUSTOMER NOTICE**

Keller-Heartt, Inc. encourages its customers to review their application of TRUEGARD products from the standpoint of human health and environmental quality. To help ensure that TRUEGARD products are not used in ways for which they were not intended or tested, Keller-Heartt personnel will assist customers in dealing with ecological and products safety. Your Keller-Heartt sales representative can arrange the proper contacts.

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