

REGULATORY & QUALITY INFORMATION

Product Information

Product Name: Propylene Glycol USP

INCI Name: Propane-1,2-diol

Synonyms: 1,2-Propanediol, Alpha-Propylene Glycol, MPG

CAS No.: 57-55-6

EC No.: 200-338-0

Product Type: USP/EP Pharmaceutical Grade Humectant, Solvent, and Cosmetic Ingredient

Country of Origin: India

Recommended Applications:

Cosmetics and Personal Care Products

Pharmaceutical Formulations

Food Applications (where permitted)

Skin Care

Hair Care

Oral Care

Fragrance Carrier

Industrial Applications

Regulatory Status

Propylene Glycol USP is manufactured in accordance with recognized pharmaceutical quality standards and is suitable for use in cosmetic, pharmaceutical, food, and industrial applications, subject to applicable regulations.

Canada

Regulated under the Food and Drugs Act and Cosmetic Regulations administered by Health Canada.

Finished cosmetic products must comply with ingredient notification and labeling requirements.

United States

Complies with applicable United States Pharmacopeia (USP) requirements.

Cosmetic products are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Modernization of Cosmetics Regulation Act (MoCRA).

Food use is permitted where compliant with applicable FDA regulations.

European Union

Meets applicable European Pharmacopoeia (EP) standards.

Cosmetic products should comply with Regulation (EC) No. 1223/2009.

Industrial chemical requirements may fall under REACH Regulation (EC) No. 1907/2006 where applicable.

Quality Specifications

Parameter Specification

Appearance Clear, colorless viscous liquid

Odor Practically odorless

Propylene Glycol Assay $\geq 99.7\%$

Water $\leq 0.50\%$

Color (APHA) ≤ 3

Specific Gravity (25°C) 1.0350–1.0370

Refractive Index (20°C) ≤ 1.4330

Acidity (as Acetic Acid) $\leq 0.0020\%$

Neutralization Number ≤ 0.100 mg KOH/g

Chloride ≤ 60 mg/kg

Sulphated Ash ≤ 1.0 mg/kg

Heavy Metals Meets USP/EP Requirements

Quality Assurance

Every production batch is tested according to established quality control procedures before release.

Routine testing may include:

Appearance
Identity
Assay
Color
Water Content
Refractive Index
Specific Gravity
Acidity
Chloride
Heavy Metals
Purity
Packaging Inspection
Batch Traceability

A Certificate of Analysis (COA) is available for every production batch.

Good Manufacturing Practice (GMP)

This product is manufactured under quality management systems consistent with pharmaceutical and cosmetic Good Manufacturing Practices.

Manufacturing controls include:

Raw Material Qualification
Process Control
Batch Documentation
Quality Testing
Packaging Verification
Product Traceability
USP / EP Compliance

This product complies with the applicable requirements of:
United States Pharmacopeia (USP)
European Pharmacopoeia (EP)

GMO Statement

Propylene Glycol USP is not manufactured using genetically modified organisms (GMOs).

Animal Testing Statement

Botanic Planet Canada Inc. does not intentionally conduct animal testing on this product except where required by applicable law.

Vegan Statement

Propylene Glycol USP is synthetic in origin and contains no animal-derived ingredients.

Suitable for vegan formulations.

BSE/TSE Statement

This product contains no ingredients of animal origin and presents no known risk related to Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).

Allergen Statement

This product contains no intentionally added fragrance allergens or common cosmetic allergens.

Heavy Metals Statement

Heavy metals comply with applicable USP/EP requirements and are routinely controlled through quality assurance procedures.

Microbiological Quality

Due to its chemical nature and manufacturing process, microbiological contamination is not expected under normal storage conditions.

Routine microbiological testing is generally not required for this product.

Storage Conditions

Store in tightly closed original containers.

Protect from:

Excessive heat

Moisture

Direct sunlight

Strong oxidizing agents

Recommended Storage Temperature: 15–30°C (59–86°F)

Shelf Life

36 months from the date of manufacture when stored in unopened original containers under recommended storage conditions.

Traceability

Each production batch is assigned a unique lot number for complete traceability through manufacturing, testing, packaging, and distribution records.

Intended Use

For use as a pharmaceutical excipient, cosmetic ingredient, food ingredient (where permitted), humectant, solvent, carrier, and industrial raw material.

The finished product manufacturer is responsible for determining suitability for the intended application and ensuring compliance with all applicable regulations.

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