

93682-PROPYLENE GLYCOL**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation.**

Name: Propylene glycol

Bulk code: 93682

Internal code: 42661

1.2 Synonyms.

Propylene Glycol, Propane-1,2-diol, E1520

2. DESCRIPTION

Appearance: Transparent liquid free of suspended matter.

Colour: Colourless.

Odour: Practically odourless.

Geographical origin: Germany.

Origin: Synthetic.

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS number: 57-55-6

CE number: 200-338-0

INCI: Propylene Glycol

Composition:

Propylene Glycol:	$\geq 99.8\%$
Dipropylene Glycol:	$<0.1\%$
Water	$\leq 0.2\%$

Method of production:

It is made by reacting synthetic propylene oxide with water at high temperature and pressure without the use of a catalyst or solvent. This product is entirely of synthetic origin.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: The product is soluble in ether, miscible with water, acetone, alcohol, glycerine and chloroform and immiscible with petroleum ether, mineral and fixed oils, but dissolves some essential oils.



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5. PROPERTIES/USES

Excipient for pharmaceutical use.

Suitable for oral use: The product is compliant with the FCC, with Commission Regulation (EU) No 231/2012 on food additives and with 21CFR. The manufacturer has ISO FSSC 22000. The product is suitable for direct or indirect contact with food and for use in animal feed (except cat food).

Cosmetic use: The composition of the product is compliant with Regulation (EC) 1223/2009 and is not included in the list of restricted substances.

THE PRODUCT IS NOT RECOMMENDED FOR:

- Generating artificial smoke/theatrical fog/mist/artificial snow
- Producing tobacco, manufacturing tobacco products, manufacturing electronic cigarettes or manufacturing marijuana products
- Use as an active ingredient in pesticides
- Use as a thermal fluid without inhibitors, including as an ingredient in fluids for heating or cooling food or beverages or for heating an enclosed space where personnel exposure could occur
- Manufacturing ammunition or chemical weapons
- Ingredient in cat food

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; so this product IS NOT STERILE.

STORAGE:

Store in a cool, well-ventilated place away from sunlight in a full and tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

This product is made of propylene oxide and water. The ingredients and sources of these ingredients are not of animal or plant origin. The product is produced from organic and inorganic chemicals that are not derived from animals or plants. There are no additives or extracts from the brain, spinal cord, bone marrow or eyes of any animal. Therefore, this

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product does not have bovine spongiform encephalopathy (BSE)/transmissible spongiform encephalopathy (TSE) issues.

GMOs:

This product does not contain nor has it been manufactured at any stage with genetically modified organisms (GMOs).

CMR substances:

It is not classified as a hazardous substance, nor as a carcinogenic, mutagenic or toxic for reproduction (CMR) substance by Council Directive 67/548/EEC (Annex I) and its subsequent amendments, including EC Regulation No 1272/2008. Propylene glycol does not contain any CMR substances.

SVHC:

The product does not contain any substances classified as an SVHC listed in the updated candidate list of substances according to the ECHA website

(http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

above the notifiable limits based on raw material composition information.

NANOMATERIALS:

There are several definitions of nano-terms. The European Union Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial defines nanomaterial as follows: "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. The product is a liquid and no nanomaterials are used in the production process; they are not intentionally added, so they are not expected to be present.

MICROPLASTICS:

The product does not contain solid polymers. The manufacturer do not expect the product to fall within the scope of the proposed restriction: Annex XVII to Regulation (EC) No 1907/2006 amendment regarding the synthetic polymer microparticles definition:

Polymers that are solid and which either are contained in particles and constitute at least 1 % by weight of those particles, or build a continuous surface coating on particles, where at least 1 % by weight of those particles fulfil either of the following conditions:

- (a) all dimensions of the particles are equal to or less than 5 mm;
- (b) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

It remains the responsibility of the customer to comply with the final microplastic regulation for the formulated products they are placing on the market



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VOCs:

- Commission Directive 2002/42/EC: EU Directive 2002/42/EC defines a VOC as any organic compound having an initial boiling point of less than or equal to 250 degrees Celsius measured at a standard pressure of 101.3 kPa. According to these definitions, this product is considered a VOC.
- 40 CFR 51.100: As regards VOC content, a definition of VOC by the US Environmental Protection Agency (EPA) is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, and excluding compounds with negligible photochemical reactivity. For other specific exemptions, see Section 51.100(s) of the Code of Federal Regulations Title 40 and refer to recent Federal Register notices. According to this broad definition from the US EPA, this substance is considered a VOC. Volatile organic compound (VOC) rules and regulations vary widely depending on the use of the finished product, and the applicability of VOC regulations depends on the jurisdiction concerned. In some states, regulators have exempted VOCs with a vapour pressure of less than 0.1 mm Hg at 20 degrees Celsius from VOC content limitations for consumer and/or commercial products. Check local regulations to see whether this is applicable. The vapour pressure of propylene glycol is 0.08 mm Hg (0.11 mbar, 0.011 kPa) at 20 degrees Celsius. Please note that it is the user's responsibility to determine the appropriate regulatory requirements for the operation and/or use of the end product.

IRRADIATION:

This product does not contain material that has undergone irradiation nor has it been manufactured at any stage with irradiation.

PRESERVATIVES:

Preservatives are not intentionally added during the manufacturing process, so they are not expected to be present.

RESIDUAL SOLVENTS:

This product is not intentionally manufactured or formulated with Class 1, 2 or 3 solvents, as indicated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q3C Guideline for Residual Solvents; however, we do not analyse these specific chemicals.

None of the Class 1, Class 2 and Class 3 residual solvents specified in USP General Chapter <467> effective 1 December 2020 are used to manufacture this product.

CALIFORNIA PROPOSITION 65:

This product does not contain any chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

93682-PROPYLENE GLYCOL**ELEMENTAL IMPURITIES:**

This product is not intentionally manufactured or formulated with Class 1, 2A, 2B or 3 elemental impurities, as defined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q3D Guideline for Elemental Impurities. Please note that we only analyse a few specific elements that are included in the specification.

IMPURITIES:

- EU Directive 2011/65/EU (RoHS): This product satisfies the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive) (RoHS 3). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP).
- The following substances are not expected to be present in this product. The presence of these substances may not be specifically analysed. Therefore, the absence or level of these substances cannot be guaranteed at any specific limit or threshold value:
 - o Bisphenol A
 - o Bisphenol A-diglycidylether (BADGE)
 - o Biocides
 - o Chlorinated paraffins
 - o Diethylene glycol (DEG)
 - o Fragrance
 - o Insecticides
 - o Latex
 - o Melamine
 - o Nitrosamines
 - o Palm oil
 - o Parabens
 - o Perfluoroalkylated substances
 - o Monoethylene glycol (MEG)
 - o Pesticides
 - o Phthalates
 - o Polycyclic aromatic hydrocarbons (PAHs)
- EMA/CHMP/428592/2019: The products Nitrosamines, nitrites, nitrates, nitrosating agents, secondary and tertiary amines, amides, ammonium salts, are not used in the production process, it is not known if they are used to prepare the raw materials/reagents used in the manufacturing process, they are not known to be

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generated as impurities during the manufacturing process and they are not intentionally added and thus they are not expected to be present.

HEAVY METALS:

- EU 94/62/EC – Packaging and Packaging Waste: Additional materials not listed in the MSDS or Specification are not routinely analysed. Specifically, although we have not analysed the heavy metals referred to in EU Directive 94/62/EC (cadmium, hexavalent chromium, lead, mercury), they are not expected to be present in this product.
- Coalition of Northeastern Governors (CONEG): This product is compliant with the Coalition of Northeastern Governors (CONEG) toxic packaging legislation. Any incidental levels of lead, cadmium, hexavalent chromium and mercury do not exceed 100 ppm in total.

ALLERGENS:

- **Cosmetic allergens:** (Regulation (EC) 15/2003). This product is manufactured from propylene oxide derived from synthetic hydrocarbons (petroleum products) and condensed steam water, at high temperature and pressure in a closed process using dedicated equipment, without the use of additives or process aids. This includes allergens in the opinion of the European Union Scientific Committee on Cosmetic Products and Non-Food Products on fragrance allergy in consumers, SCCNFP/0017/98, listed in Annex 3 to Directive 2003/15/EC included in the specifications of this product and no specific tests are carried out for their presence. Based on the factors listed, this product is considered to be free of all known and specified allergy-triggering substances; therefore, certification or analysis of batch-specific allergens is not required.
- **Food allergens:**
 - o Regulation (EC) 1169/2011: This product is manufactured from propylene oxide derived from synthetic hydrocarbons (petroleum products) and condensed steam water, at high temperature and pressure in a closed process using dedicated equipment, without the use of additives or process aids. This includes food allergens listed in Annex II to Regulation (EU) No 1169/2011 (formerly Annex IIIa to Directive 2000/13/EC) and subsequent amendments. The allergy-triggering compounds listed herein are not included in the product specifications and no specific tests are performed for their presence. Based on the factors listed, this product is considered to be free of all known and specified allergy-triggering substances; therefore, certification or analysis of batch-specific allergens is not required.
 - o ANVISA/DC Resolution No 26: This product is manufactured from propylene oxide derived from synthetic hydrocarbons (petroleum products) and condensed steam water, at high temperature and pressure in a closed process using dedicated equipment, without the use of additives or process

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aids. This includes the food allergens listed in ANVISA/DC Resolution No 26 of 07/07/2015. The allergy-triggering compounds listed herein are not included in the product specifications and no specific tests are performed for their presence. Based on the factors listed, this product is considered to be free of all known and specified allergy-triggering substances; therefore, certification or analysis of batch-specific allergens is not required.

HALAL:

This product is Halal certified, which means that it satisfies the following conditions:

- It does not contain any ingredients of animal origin.
- It does not contain alcohol and no alcohol has been used in the manufacturing process (alcohol = methanol, ethanol).
- The equipment used in the manufacturing process, including packaging, is not also used to manufacture or package products of animal origin.

KOSHER:

The product is Kosher certified.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

NUTRITIONAL COMPOSITION:

Nutritional Information (based on 100 g)	
Calories (total)*	399
Water (g)	0.2
Ash (g)	0.005
Fat (g)	0.0
Protein (g)**	0.0
Carbohydrates (g)*	99.795
Added sugars	0.0

Additional nutritional information (based on 100 g)			
Cholesterol (mg)	0	Calcium (mg)	0
Total dietary fibre (g)	0	Total vitamin A (IU)	0
Soluble fibre (g)	0	Vitamin C (mg)	0
Insoluble fibre (g)	0	Thiamin (mg)	0
Iron (mg)	0	Riboflavin (mg)	0
Sodium (mg)	0	Niacin (mg)	0
Potassium (mg)	0	Zinc (mg)	0
Magnesium	0	Iodine (mg)	0



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*The caloric value of propylene glycol is defined as 4 calories per gram using the general definition of a carbohydrate as set forth in 21CFR 101.9(c)(1)(i)(B) and 21CFR101.9(c)(6).

**Protein and fat (including trans fat) are not used in the manufacture of propylene glycol; therefore, they are not part of the final composition of the material.

The value for all other vitamins and minerals is ZERO, based on 21CFR101.9(c)(4),(5),(8).

WADA:

Substances included in the 2020 WADA Prohibited List are not used in the production process, nor are they intentionally added and thus they are not expected to be present.

TESTED ON ANIMALS:

The product has not been tested on animals for cosmetic purposes.

ISO 16128:

Not applicable.

IFRA:

The product is listed.

REACH:

The product is compliant with REACH. All substances relevant to REACH in this product have been registered.

01-2119456809-23-XXXX

TARIFF ITEM NUMBER:

2905320000

GRAS:

Propylene glycol is "generally recognised as safe" (GRAS) by the US FDA for use in food applications in accordance with the relevant sections of Title 21 of the Code of Federal Regulations. In addition, the Flavor Extract Manufacturers Association (FEMA) lists propylene glycol as GRAS (FEMA GRAS number 2940).

Propylene glycol is authorised for food contact applications in Europe and is listed in Annex I to Commission Regulation (EU) No 10/2011 as an authorised monomer and additive for plastic materials and articles intended to come into contact with food.

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INVENTORIES:

Country	Inventory	Status
Australia	AIIC	All substances contained in this product are listed on the Australian Inventory of Industrial Chemicals, or are not required to be listed.
Canada	DSL	All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed.
China	IECSC	All intentional components are listed on the inventory, are exempt, or are supplier certified.
Japan	ENCS	All intentional components are listed on the inventory, are exempt, or are supplier certified.
Korea	KECI	All intentional components are listed on the inventory, are exempt, or are supplier certified.
New Zealand	NZIoC	There is no requirement to list components of this product on the New Zealand Inventory of Chemicals (NZIoC).
Philippines	PICCS	All intentional components are listed on the inventory, are exempt, or are supplier certified.
Switzerland	EINECS	The components of this product are on the EINECS inventory or are exempt from inventory requirements.
Taiwan	TCSI	All intentional components are either listed on the Inventory or exempted by regulations, or certified by vendors of their supply chemicals.
United States of America (USA)	TSCA	All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Propylene glycol is on China's positive list of cosmetic raw materials (2015), making it an approved raw material for cosmetic applications. It is also not included in the list of restricted or prohibited substances under China's "Technical and Safety Standards for Cosmetics" (2015).

Propylene glycol is included in Japan's list of designated food additives (#355). Designated additives in Japan are those designated by the Minister of Health, Labour and Welfare as substances that are unlikely to harm human health under Article 10 of the Food Sanitation Act. It is also an approved food additive in China GB2760(2014) – Standard for uses of food additives – for the uses described in the propylene glycol section. The reference number is CNS18.004.