

D. E. QUÍMICA – Intermediate products
Repsol Technological centre
Ctra. A-5 Km.18, 28931
Móstoles - Madrid – SPAIN

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GUARANTEE CERTIFICATE

PRODUCT: MONOPROPYLENE GLYCOL (MPG) OR PROPYLENE GLYCOL (PG) USP/EP GRADE

- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUÍMICA, is manufactured using **exclusively** Propylene Oxide and Water as raw materials with a purity bigger than 99.8 %. **Propylene glycol and its raw materials are produced in Tarragona (Spain)**. According to the components used in the production, the PG USP/EP has a synthetic origin.
- PROPYLENE GLYCOL (PG) USP/EP delivered by road trucks or IBCs (1000kg) has a expiry data of 1 year since manufacturing data. For PROPYLENE GLYCOL (PG) USP/EP delivered by drums, expiry data is 2 years since manufacturing data. Retained samples will be storage 1 year more than expiry data. All packaging materials used for MPG USP/EP transport are food grade approved.
- Based on the high temperatures (180 °C) of the manufacturing process used by REPSOL QUIMICA S.A. (reaction and purification) and our best knowledge, the microbiological presence in the product is highly unlikely.
- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUIMICA, S.A. is a petrochemical product and its manufacturing process REPSOL QUIMICA, S.A. do not include any gluten containing raw material or any of the known allergens to which a segment of the population are sensitive.
- Nutritional value is 0.4 Kcal per 100 grams of MPG or 1.67 KJ/100 gr.
- Manufacturing process of PROPYLENE GLYCOL (PG) USP/EP does not include any raw material or additive with animal or vegetal origin. As a result, it is not applicable any legislation concerning Genetically Modified Organism (GMO).
- REPSOL QUIMICA S.A. complies with the Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents EMEA/CHMP/SWP/4446/2000 and the European Pharmacopoeia, Chapter 5.20: Metal Residues and Chapter 2.4.20: Metal Catalysts or Metal Reagents.
- PROPYLENE GLYCOL (PG) USP/EP grade produced and commercialized by REPSOL QUÍMICA S.A. does not use or include any nanomaterial.
- REPSOL QUIMICA S.A. hereby confirms that the product PROPYLENE GLYCOL USP/EP is not treated with radiation.

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- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUIMICA, S.A. is a petrochemical product and it is manufactured according to Halal requirements as follows:
 - The product does not contain any animal origin ingredient.
 - The product does not contain ethyl alcohol and ethyl alcohol has not been used in the manufacturing process.
 - The equipment used for its manufacturing is exclusively and it is not used for the manufacture of animal origin products or products containing animal origin ingredients.
- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUÍMICA, S.A., no animal testing is performed in our installations after the 3rd of March of 2009.
- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUIMICA, S.A. is a petrochemical product and it is manufactured according to KOSHER requirements.
- The production of PROPYLENE GLYCOL (PG) USP/EP by REPSOL QUIMICA, S.A. does not include or it is exposed to the following components:
 - o 1,2,3-propanetriol triacetate
 - o Additives
 - o Aflatoxins
 - o Aluminium
 - o Banana
 - o BHA
 - o Biocides, herbicides and pesticides
 - o bis (2-hydroxypropyl) ether
 - o Bisphenol A
 - o BPA
 - o Chemicals in Proposition 65 list
 - o Colorants
 - o Diacetyl y/o Acetyl propionyl
 - o Diethylene glycol
 - o Dioxin
 - o Dried fruits (Almond, hazelnut..)
 - o Eggs,
 - o Estrogenic substances
 - o Ethylene glycol
 - o genotoxic products
 - o Gluten
 - o lactose
 - o latex
 - o Melamine
 - o Milk
 - o Mineral oils
 - o Musk

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- o Organic tin compounds
- o Palm oil
- o Parabens
- o Phormaldehyde and releasers
- o Phormol and releasers
- o phthalate
- o Polycyclic aromatic hydrocarbons(PHA)
- o Preservatives
- o residual solvents
- o Shellfish
- o Substances very high concern (SVHC)
- o Surfactants

for this reason, the components mentioned above, should not be present in the product.

Normatives related to Propylene glycol

Pharmacopeias

PROPYLENE GLYCOL USP/EP grade is in accordance with:

- Propylene glycol monograph of The European Pharmacopeia (EP)
- Propylene glycol monograph of The American Pharmacopeia (USP)

Additionally complies with the following parameters:

- Heavy metals specification established in 5 ppm (referred to lead)
- Volatile Organic Compound (VOC) specification, according Residual Solvent method <467> for USP and Residual Solvent method (5.4) for EP.
- The Q3D Guideline related to provide a global policy for limiting metal impurities qualitatively and quantitatively in drug products and ingredients.

European Normatives

- It is in accordance to Commission Directive 2008/84/EC amending Directive 2009/10/EC and 2010/67/EC on food specific purity criteria on food additives other than colours and sweeteners.
- PROPYLENE GLYCOL (PG) USP/EP grade produced and commercialized by REPSOL QUIMICA is a petrochemical product and it is cleared for indirect food contact under EC Council Directive 2011/10/EC and its subsequent amendments 1282/2011/EC y 321/2011/EC (relating to plastic materials and articles intended to come into contact with foodstuffs) Directive 2011/10/EC replaces Directive 2002/72/EC. PROPYLENE GLYCOL reference is 23740 (1,2-propanediol)

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- PROPYLENE GLYCOL is in accordance to Commission Directive 95/2/EC amended by Directive 96/85/EC, 98/72/EC, 2001/5/EC, 2003/52/EC, Regulation EC N° 1882/2003, Directive 2003/114/EC, 2006/52/EC and Commission Directive 2010/69/EU on food additives other than colours and sweeteners.
- PROPYLENE GLYCOL is in accordance to Regulation 231/2012, laying down specifications for food additives listed in Annexes II and III to Regulation 1333/2008.
- PROPYLENE GLYCOL is in accordance to Commission Directive 2008/84/EC amending Directive 2009/10/EC and 2010/67/EC on food specific purity criteria on food additives other than colours and sweeteners. Replace Directive 96/77/EC. PROPYLENE GLYCOL is identified with de code E1520 (1,2 propapediol)
- PROPYLENE GLYCOL is in accordance to Commission Directive 76/768/EC amending Directive 2003/15/EC on the approximation of the laws of the Member States relating to cosmetic products.
- PROPYLENE GLYCOL (PG) USP/EP grade produced and commercialised by REPSOL QUÍMICA is a petrochemical product and its manufacturing process does not include any raw material nor additive with animal or vegetal origin. As a result, no measure related with the Bovine Spongiform Encephalopathy (BSE), Transmittable Spongiform Encephalopathy (TSE) and Genetically Modified Organism (GMO) is applicable. In addition to this, the equipment used for their manufacture is exclusive and there is no possibility of contamination with animal or vegetal derived products.
- PROPYLENE GLYCOL (PG) USP/EP produced and commercialised by REPSOL QUÍMICA, S.A., is a petrochemical product and its manufacturing process does not include any raw material or additive classified as Carcinogenic, Mutagenic or Toxic for reproduction. As a result, it is not applicable any legislation concerning to these components.
- PROPYLENE GLYCOL, according to Directive EC n° 892/2010, is classified as ingredient in animal food, except, as is listed in the Directive 91/336/EEC, for cat food.
- PROPYLENE GLYCOL USP/EP grade complies with the requirements of Regulation n°183/2005/EC amending Regulation 219/2009 (and included the Annex II) referred to hygiene of feed. This performance includes the registration of the activity at the local Authorities.

Repsol Química registered number for this activity is ESP43501828

American Normatives:

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- PROPYLENE GLYCOL is listed in the Food Chemical Codex (FCC), is considered as a GRAS (Generally Recognized as Safe) product in FDA. The following applications are allowed for the Propylene glycol:

73: LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

73.30 - Annatto extract.

133: CHEESES AND RELATED CHEESE PRODUCTS

133.178 - Pasteurized Neufchatel cheese spread with other foods.

133.179 - Pasteurized process cheese spread.

136: BAKERY PRODUCTS

136.110 - Bread, rolls, and buns.

169: FOOD DRESSINGS AND FLAVORINGS

169.175 - Vanilla extract.

172: FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

72.210 - Coatings on fresh citrus fruit.

172.515 - Synthetic flavoring substances and adjuvants.

172.765 - Succistearin (stearoyl propylene glycol hydrogen succinate).

172.850 - Lactylated fatty acid esters of glycerol and propylene glycol.

172.856 - Propylene glycol mono- and diesters of fats and fatty acids.

172.858 - Propylene glycol alginate.

172.870 - Hydroxypropyl cellulose.

173: SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

173.25 - Ion-exchange resins.

173.310 - Boiler water additives.

173.340 - Defoaming agents.

173.375 - Cetylpyridinium chloride.

175: INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

175.105 - Adhesives.

175.300 - Resinous and polymeric coatings.

175.320 - Resinous and polymeric coatings for polyolefin films.

176: INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

176.170 - Components of paper and paperboard in contact with aqueous and fatty foods.

176.180 - Components of paper and paperboard in contact with dry food.

176.200 - Defoaming agents used in coatings.

176.210 - Defoaming agents used in the manufacture of paper and paperboard.



176.300 - Slimicides.

177: INDIRECT FOOD ADDITIVES: POLYMERS

177.1010 - Acrylic and modified acrylic plastics, semirigid and rigid.

177.1210 - Closures with sealing gaskets for food containers.

177.1680 - Polyurethane resins.

177.2420 - Polyester resins, cross-linked.

177.2600 - Rubber articles intended for repeated use.

177.2800 - Textiles and textile fibers.

**178: INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND
SANITIZERS**

178.1010 - Sanitizing solutions.

178.2010 - Antioxidants and/or stabilizers for polymers.

178.3300 - Corrosion inhibitors used for steel or tinplate.

178.3400 - Emulsifiers and/or surface-active agents.

178.3740 - Plasticizers in polymeric substances.

178.3910 - Surface lubricants used in the manufacture of metallic articles.

**184: DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS
SAFE**

184.1666 - Propylene glycol.

310: NEW DRUGS

310.545 - Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

349: OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

349.12 - Ophthalmic demulcents.

350: ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

350.10 - Antiperspirant active ingredients.

**352: SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE
[STAYED INDEFINITELY]**

352.70 - Standard sunscreen.

500: GENERAL

500.50 - Propylene glycol in or on cat food.

522: IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

522.234 - Butamisol hydrochloride.

522.380 - Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

522.960a - Flumethasone suspension.

522.960b - Flumethasone acetate injection.

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522.2640 - Tylosin.

524: OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

524.981b - Fluocinolone acetonide solution.

524.981d - Fluocinolone acetonide, dimethyl sulfoxide solution.

524.981e - Fluocinolone acetonide, dimethyl sulfoxide otic solution.

573: FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

573.760 - Poloxalene.

582: SUBSTANCES GENERALLY RECOGNIZED AS SAFE

582.1666 - Propylene glycol.

582.4666 - Propylene glycol.

589: SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

589.1001 - Propylene glycol in or on cat food.



Technical Service and Development Department
Intermediates products