



## GUARANTEE CERTIFICATE

### REPSOL QUIMICA S.A.

Repsol Technology Lab  
Technical Service and Development  
Intermediate Products  
C/Agustín de Betancourt s/n  
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Tel. +34917538600 Fax. +34915304517  
E-mail: [atdintermedios@repsol.com](mailto:atdintermedios@repsol.com)

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

**Company name:** REPSOL QUIMICA S.A.  
**Complete address:** C/ Mendez Alvaro 44, 28045, Madrid. SPAIN

Chemical name: 1,2-propanediol CAS#: 57-55-6 EINECS: 200-338-0  
JEFCA nº: 925 FEMA nº: 2940  
NAFTA Harmonized Tariff System (HTS) Code: 2905.32.0000  
Reach Registration Number 01-2119456809-23-0004  
INCI Name: Propylene glycol

PROPYLENE GLYCOL (PG) USP/EP produced and commercialized by **REPSOL QUÍMICA S.A.**, 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 The European Union (Spain). According to the components used in the production, this product has a synthetic origin.

Propylene Oxide (CAS: 75-56-9), is technically unavoidable in the product. Propylene oxide is not present in propylene glycol due the reaction is always in excess of water, assuring the total reaction of the oxide.

Expiry date for bulk product delivered in truck or IBCs is 1 year, and expiry date for product delivered in drums is 2 years. Retained samples will be storage 1 year more than expiry data. All packaging materials used for MPG USP/EP transport are food grade approved.

### STATEMENTS

- **MICROBIOLOGICAL.** Based on the high temperatures (180 °C) of the manufacturing process used by in the chemical process (reaction and purification) and our best knowledge, the microbiological presence in the product is highly unlikely.
- **CONEG (Coalition of Northeastern Governors).** This chemical contain <100 ppm total of Pb, Cr+6, Cd and Hg.
- **CALIFORNIA PROPOSITION 65.** This product does not contain Proposition 65 listed components January 3 rd, 2020.
- **STOCKHOLM COUNTY COUNCIL'S.** This product is in agree with the "Stockholm County Council's phase-out list for chemicals hazardous to the environment and human health 2012–2016".
- **NUTRITIONAL ALLERGENS.** This product does not include any gluten containing raw material or any of the known allergens to which a segment of the population are sensitive. The food ingredients listed in the Annex II of European Regulation 1169/2011 are not used in the manufacture or formulation of this product. This product is in accordance with Directive 2003/89/EC and 2006/142/EC Annex III and Amending Directive 2000/13/EC on allergens.
- **PROTEINS, FATS AND STARCHES.** This product is a petrochemical product and in its manufacturing process do not include proteins, fats and starches.
- **CONFLICT MINERALS.** We certify that, our product is manufactured in SPAIN and are free of "tin, tantalum, tungsten and gold and their derivatives", in compliance with the 2010 Dodd-Frank Wall Street Reform & Consumer Protection Act.

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- **GOOD MANUFACTURING PRACTICES (GMP).** REPSOL QUIMICA, S.A. follows the Good Manufacturing Practices (GMP) Guide for Bulk Pharmaceutical Excipients prepared by the International Pharmaceutical Excipients Council (IPEC) for the manufacture and distribution of this product.
- **NUTRITIONAL INFORMATION.** (EU n° 1169/2011). Propylene Glycol is considered a carbohydrate.

	Units	Value (/100g)
Energy value		1674.7 KJ = 400 Kcal
Carbohydrates	g	100
which sugars	g	0
Proteins	g	0
Lipid	g	0
Saturated fatty acids	g	0
Salt	g	0
Fibre	g	0

- **GMP+.** The production process and storage for this product at the REPSOL QUIMICA S.A. Tarragona plant including the distribution is GMP+FSA certified. Registration number GMP012797. <https://portal.gmpplus.org/cdb/certified-companies/>
- **METAL.** 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.
- **NANOMATERIALS.** This product does not use or include any nanomaterial.
- **RADIATION / IONIZATION.** This product is not treated with radiation or ionization.
- **SOLID CONTAMINATION.** This product is a liquid, produced via a continuous petrochemical process. The product is filtered at various stages in the distribution process to remove solid contaminants (strange bodies). Distribution processes are tightly controlled to prevent inadvertent contamination from prior cargoes.
- **VEGAN & VEGETARIAN.** This product complies with a vegan or vegetarian diet. They contain no animal ingredients or animal byproducts, use no animal ingredients or by-products in the manufacturing process, and are not tested on animals.
- **HALAL.** This product 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.

A copy of the Halal certificate is available on the REPSOL website at <https://www.repsol.energy/en/products-and-services/chemicals/product-range/propylene-glycol-pharmaceutical-grade/index.cshtml>

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- **KOSHER.** This product has been certified KOSHER-Parve (including Passover). A copy of the certificate is available on the REPSOL website at <https://www.repsol.energy/en/products-and-services/chemicals/product-range/propylene-glycol-pharmaceutical-grade/index.cshml>
- **ANIMAL TESTING.** For this product, no animal testing is performed in our installations after the March 3<sup>rd</sup> of 2009.
- **VERMONT.** REPSOL QUÍMICA S.A., supplier of the raw material PROPYLENE GLYCOL USP/EP GRADE (technical data sheet herewith attached) declare that Enzymes and Processing aids used in the raw material above mentioned are used in accordance with the purpose and “definitions” provided under the State of Vermont’s law entitled “Labeling of Food Produced with Genetic Engineering,” under subsections 9 V.S.A. § 3042 (4) or (18) indicated below:
  - Definitions
  - (4) “Enzyme,” as defined in 9 V.S.A. 3042, means a protein that catalyzes chemical reactions of other substances without itself being destroyed or altered upon completion of the reactions.
  - (18) “Processing aid,” as defined in 9 V.S.A. § 3042, means:
    - (a) a substance that is added to a food during the processing of the food but that is removed in some manner from the food before the food is packaged in its finished form;
    - (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; or
    - (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at levels that do not have any technical or functional effect in that finished food.
- **RESIDUAL SOLVENTS.** This product also complies with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline Q3C “Impurities: Guideline for Residual Solvents.” (Impurities: Guideline for Residual Solvents, ICH Guideline Q3C, CPMP/ICH/283/95). It is manufactured from hydrocarbon raw materials in a solventless process and does not contain any of the class 1, 2 and 3 solvents listed in this ICH guideline.
- **ECOLABEL.** The MPG USP/EP fulfills all the ecological criteria for the award of the EU ECOLABEL to --- laundry detergents (2017/1218) --- dishwashing detergents (2017/1216) --- hand dishwashing detergents (2017/1214) --- all-purpose cleaners and sanitary cleaners (2011/383/EU) --- industrial and institutional laundry detergents (2017/1219) --- industrial and institutional automatic dishwasher detergents (2017/1215) --- Rinse-off cosmetic products (2014/893/EU). The MPG is listed in the Detergents Ingredients Database (DID-list) Part A. List of ingredients version 2016, with the number **2581**.
- **BLUE ANGEL.** The MPG USP/EP fulfills all the ecological criteria for the award of the BLUE ANGEL label to --- Hand dishwashing detergents, all-purpose, sanitary and glass cleaners RAL-UZ 194 January 2015 --- Detergents for dishwashers RAL-UZ 201 January 2016 --- Laundry detergents RAL-UZ 202 January 2016 --- Shampoos, shower gels, soaps and further so-called „Rinse-off“ cosmetic products RAL-UZ 203 January 2016.

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- **PHARMACOPEIAS.** PROPYLENE GLYCOL USP/EP grade is in accordance with:
  - Monograph of The European Pharmacopoeia (EP) 9<sup>th</sup> Edition.
  - Monograph of The American Pharmacopoeia (USP) 39<sup>th</sup> Edition.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.Our MPG USP/EP comply with the United States Pharmacopoeia and the European Pharmacopoeia, but in any case, before using our product, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.
- **FOOD CONTACT PLASTIC (European Normative).** This 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, 321/2011/EC and 2017/752 (relating to plastic materials and articles intended to come into contact with foodstuffs) Directive 2011/10/EC replaces Directive 2002/72/EC. PROPYLENE GLYCOL is authorized as an additive or polymer production aid (reference number is 23740) (1,2-propanediol); and as a monomer or other starting substance (reference number is 81840), without restrictions or specific migration limits (SML).
- **FOOD ADDITIVE (European Normative).** This product 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.

This product is in accordance to Regulation 231/2012, laying down specifications for food additives listed in Annexes II and III to Regulation 1333/2008.

This product 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 colors and sweeteners. Replace Directive 96/77/EC. This product is identified with de code E1520 (1,2-propanediol).
- **COSMETIC.** This product 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. It is also in accordance to REGULATION (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products.

The customer should determine that the properties of the final product are appropriate for their desired end-use.
- **ISO 16128-1:2016.** Refers to the natural and organic content of raw materials and cosmetic products. According to ISO 16128: 2016 (E) part 1, the MPG USP / EP propylene glycol is defined as a Non-Natural Ingredient (Fossil Part > 50%).
- **BSE/TSE/GMO.** This product 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), Transmissible 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.

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- **CARCINOGENIC, MUTAGENIC OR TOXIC FOR REPRODUCTION (CMR).** This 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.
- **ANIMAL FEED INGREDIENT.** This product, according to Directive EC nº 892/2010, is classified as ingredient in animal feed, except for cat feed, as is listed in the Directive 91/336/EEC. This product complies with the requirements of Regulation nº183/2005/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.  
This product is listed in the Catalogue of Approved Feed Materials (EU Regulation 2017/1017, no. 13.11.1) and in the Register of Feed Materials.  
Prior to October 2010, propylene glycol was only approved as feed additive.  
Propylene glycol USP/EP (pharmaceutical grade) is used as feed grade and is the appropriate grade for this application due to its handling practices.
- **IOFI (International Organization of the Flavor Industry).** The IOFI Global Reference List (GRL) is an open ended, global, positive list of flavoring materials that are considered to be safe for their intended use by one or more internationally recognized assessment bodies: the European Food Safety Authority (EFSA), the Council of Europe (COE), the Scientific Committee on Food (SCF), the U.S. Food and Drug Administration (FDA), the Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Japanese Food Safety Commission (FSC). FEMA number 2940; JECFA number 0925.
- **FLAVOURINGS.** The use of carriers as co-solvents are legally approved for the dilution of flavourings. Flavourings may contain food additives as permitted by Regulation 1333/2008 and/or other food ingredients incorporated for technological purposes (Article 3(4) of Regulation 1334/2008) Propylene glycol may be needed as a carrier for flavourings.
- **WATER CONTAMINATING CLASS (Germany).** WGK 1 slightly water endangering.
- **ODS (Ozone-Depleting Substances).** This product does not contain or was produced with ODS, Directive 1005/2009 EC.
- **VOC, 1999/13/EC.** If the VOC definition is “Volatile organic compound (VOC) defined in the 1999/13/EC as any organic compound having at 293.15 K a vapor pressure of 0.01 kPa or more”, and taking into account that the MPG at 293.15K has a Vapour Pressure of 0.009 kPa, the only VOC is the water content, with a maximum of 0.1 weight %.
- **VOC, EPA.** Propylene Glycol is a Volatile Organic Compound (VOC) as defined by EPA - 40 CFR 51.100 (s)(l) with a VOC content of 8.65 lbs./gal (1,036 g/cm<sup>3</sup>) at 25°C.
- **VOC, The Swiss Federal Council.** According to the “Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC), of 12 November 1997 (Status as of 1 March 2013). The Swiss Federal Council”. We hereby CERTIFY that, the product MPG is not in the list set out in Annex 1 “Positive List of Substances (Volatile Organic Compounds (VOCs) subject to the Tax)”. We do not introduce or use volatile organic compounds mentioned in the list above for the manufacture of MPG. The reaction of

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the process itself, it could generate low molecular weight compounds, assimilated to VOCs\*, whose average of the total amounts found in our evaluations are below of 2%.

\* For the purpose of this Ordinance: Volatile organic compounds (VOCs), are organic compounds with a vapour pressure of at least 0.1 mbar at 20 °C or a boiling point of maximum 240 °C at 1013.25 mbar.

- **PALM OIL.** This product do not proceed from palm oil, and does not contain 2-Chloroacetamide (CAS:79-07-2), Tagetes Minuta extract (CAS:91770-75-1), Tagetes Patula extract (CAS:91772-29-1), Furfural (CAS:98-01-1), Cyclopentasiloxane (D5) (CAS: 541-02-6).
- **JATROPHA-FREE\***. This product does not contain Jatropha oil.  
\* The Federal Ministry of Food, Agriculture and Consumer Protection wishes to draw attention to the following warning issued by the Food and Drug Administration (FDA): "Products using oils, glycerin or protein that were derived from the Jatropha plant may have toxic effects". The Jatropha plant belongs to the spurge family and is used for the production of bio-diesel fuel. It contains "Phorbol esters", which pose both an acute and a chronic risk for humans and animals alike. The FDA identifies a danger by the possible use of oils, glycerin, or proteins deriving from the Jatropha plant in foods, animal feed, pharmaceutical products, cosmetics etc. In addition to the deliberate use of the Jatropha plant, the FDA refers to a possible falsification in foods and animal feed because the protein content of the Jatropha plant is similar to that found in soya beans.
- **GERMAN BfR.** Recommendations of the Federal Institute for Risk Assessment on Plastics intended to Come into Contact with Food.  
Are all components in your product listed on the German Recommendations of the Federal Institute for Risk Assessment on Plastics intended to Come into Contact with Food?  
XIV. Plastic Dispersions Yes  No   
XXXVI. Paper and board for food contact Yes  No   
IX. Colorants for Plastics and other Polymers Used in Commodities Yes  No
- **FDA (American Normative).** This product 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

172.210 - Coatings on fresh citrus fruit.

172.515 - Synthetic flavoring substances and adjuvants.

172.765 - Succinestearin (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.

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#### 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.

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 (except in cat food).

582.4666 - Propylene glycol. Animal food.

#### 589: SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

589.1001 - Propylene glycol in or on cat food.

- **NOT INCLUDED PRODUCTS.** This product does not include or it is exposed to the following components:

- 1,2,3-propanetriol triacetate
- 1,4-dioxane
- 2,4-pentanedione
- 2-chloroacetamide
- 2-Methoxy-1-propanol
- 4-methylbenzophenone
- 4,5-Epoxy- dec-2(trans)-enal
- Additives
- Aflatoxins
- Aluminium
- Anthraquinone
- Asbestos
- Azo colourants
- Azodicarbonamide (CAS n°123-77-3)
- Acetylacetone (CAS n°123-54-6)
- Acrylamide
- Aromatic amines
- Azo dyes
- Banana
- Benzene
- Benzophenone
- BHA
- Biocides, herbicides and pesticides
- Bis (2-hydroxypropyl) ether
- Bisphenol A (BPA)
- Bromine
- Bronopol

- Carcinogenic & Mutagenic Compounds
- Chemicals in Proposition 65 list
- Chlorhexidine
- Chlorine
- Chlorophenols (Tetrachloropehnol - Pentachlorophenol)
- Chlorpyrifos (CHP)
- Chlorpyrifos-methyl (CHP-methyl)
- Cocamidopropyl betaine
- Colophonium
- Colorants
- Cyclopentasiloxane (D5)
- DEAB (4,4' bis (diethylamino)benzophenone)
- Diacetyl y/o Acetyl propionyl
- Diethylene glycol
- Dioctyl adipate (DOA) (CAS: 103-23-1)
- Dioxin
- Dried fruits (Almond, hazelnut..)
- Eggs
- Enzymes
- Estrogenic substances
- Ethylene glycol
- Ethylene oxide
- Ethyleneimine
- Fats
- Fluorine
- Formaldehyde and releasers
- Formaldehyde donors

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

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>○ Formol and releasers</li><li>○ Furfural</li><li>○ Genotoxic products</li><li>○ Gluten</li><li>○ Gold</li><li>○ Iodine</li><li>○ Lactose</li><li>○ Lanolin</li><li>○ Latex</li><li>○ Melamine</li><li>○ Methyl dibromoglutaronitrile</li><li>○ Methylchloroisothiazolinone</li><li>○ Methylisothiazolinone</li><li>○ Michlef's ketone</li><li>○ Milk</li><li>○ Mineral Oil Aromatic Hydrocarbons-MOAH</li><li>○ Mineral Oil Saturated Hydrocarbons-MOSH</li><li>○ Musk</li><li>○ Myroxylon pereirae (Balsam of Peru)</li><li>○ NETSA (N'ethyl toluene sulfonamide)</li><li>○ Organic tin compounds</li><li>○ Palladium</li><li>○ Palm oil</li><li>○ Parabens</li><li>○ Phthalate</li><li>○ Phthalic acid in adhesives polyesters based Perchlorate</li><li>○ Pigment colourants based on and compounds of antimony</li><li>○ Polycyclic aromatic hydrocarbons(PAH)</li><li>○ Polyolefin oligomer with saturated hydrocarbon</li></ul> | <ul style="list-style-type: none"><li>○ Polysorbate 60</li><li>○ Preservatives</li><li>○ Processing aids</li><li>○ Proteins</li><li>○ Quaternium 15</li><li>○ Residual solvents</li><li>○ Rhodamine-based pigments</li><li>○ Semicarbazide (CAS n°57-56-7)</li><li>○ Shellfish</li><li>○ Silicone and Labs paint wetting disruptive substances</li><li>○ Sorbitan isostearate</li><li>○ Sorbitan Oleate</li><li>○ Sorbitol</li><li>○ Starches</li><li>○ Substances very high concern (SVHC). Last update on 16/07/2019</li><li>○ Sulfur</li><li>○ Surfactants</li><li>○ Tagetes Minuta extract</li><li>○ Tagetes Patula extract</li><li>○ Tantalum</li><li>○ Tea tree oil</li><li>○ Tert-butylhydroquinone</li><li>○ Thimerosal</li><li>○ Thiuram-Mix</li><li>○ Tin</li><li>○ Titanium Acetyl Acetonate (TAA)</li><li>○ Tungsten</li></ul> |
|--|--|

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

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- GLOBAL INVENTORY STATUS.** The ingredients of this product are compliant with the following chemical inventory requirements or exemptions.

Country/Region	Inventory	Status Description
Australia	AICS	Compliant
Canada	DSL	Compliant
China	IECSC	Compliant
Europe	REACH	Compliant
Japan	ENCS	Compliant
Korea	KECL	Compliant
Malaysia	EHSNR	Compliant
New Zealand	NZIoC	Compliant
Philippines	PICCS	Compliant
United States of America	TSCA	Compliant
Taiwan	TCSCA	Compliant

### GENERAL QUESTIONS

	Yes	No
Do you have a certified quality system (i.e. ISO 9001)?	X	
Do you have a certified / registered environmental management system ((i.e. ISO 14001)?	X	
Is the operation of the company controlled by an environmental permit and do you fulfil the requirements set on the permit?	X	
Have you made LCA/Carbon foot print analysis from your products?	X	
Do you have a certified food safety / hygiene management system ((i.e. ISO 22000, BRC, IFS, GFSI)?		X
Can you guarantee a full traceability of your products (i.e. EC regulation 1935/2004)?	X	
Does the facility have a Hazard Analysis Critical Control Point (HACCP) plan?	X	
Is there a product recall procedure in place?	X	
Is the product supplied free from allergens listed in EU directive 2003/89/EG annex III a?	X	
Does facility have a documented Allergen Control Program?		X
Can you confirm that the products and ingredients used comply with European legislation or legislation in relevant country(ies) to which they are sold?	X	
Is the company a member of some Ethical Trading Program (i.e. ETI)?	X	
Do you have a policy of ethical standards or social responsibility?	X	
Do you have a certified occupational health and safety system (i.e.OHSAS 18001)?	X	
Do you notify your customers in writing prior implementation of major changes in your process?	X	
Are you or your suppliers importing any substance from non-EEA manufacturer to EEA (European Economic Area = EU + Norway + Iceland)?		X
Are you planning in the near future to import into the EEA from a non-EEA manufacturer?		X
CLP. Have you or your suppliers notified the substances in your product as required by REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006?	X	

Does the raw material contain any components of the following sort?	No	Yes (information about CAS# and concentration is attached)
IARC <sup>1</sup> Group 1 (proven human carcinogens)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IARC Group 2A: the substance is probably carcinogenic to humans (limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in test animals)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NTP <sup>2</sup> known carcinogens	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NTP reasonably anticipated to be human carcinogen	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EU <sup>3</sup> category 1 carcinogenic, mutagenic and reprotoxic (proven human CMR)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EU category 2 CMR (should be regarded as if they are CMR to humans)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
vP/vB very Persistent/very Bio accumulative <sup>4,5</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
PBT Persistent/Bio accumulative/Toxic <sup>4,5</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Potential PBT <sup>5</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
SVHCs Substances of Very High Concern <sup>6</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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Does the raw material contain any components of the following sort?	No	Yes (information about CAS# and concentration is attached)
Preservatives (incl. Biocides or Fungicides) (If yes, please specify the actual dosage; if a range is given, the maximum value will be taken)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Alkylphenoethoxylates (APEO) or alkyl phenols	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Pentachlorophenol (PCP)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Phthalates	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Isocyanates	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Residual free monomers	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Formaldehyde (If yes, please specify the actual dosage; if a range is given, the maximum value will be taken)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Substances with formaldehyde as part of the cross linking structure (only applicable for dispersion products)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Silica dust (part of grain size <10µm)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Glycol, Glycol ether and Glycol ether acetate	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Lindane	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Arsenic (CAS Nr. 74430-38-2)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NOGE (Novolac glycidyl ether), BADGE (Bisphenol-A-diglycidyl ether), BFDGE (Bisphenol-F-diglycidyl ether)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Aminoethylethanolamine (AEEA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>

1 International Agency for Research on Cancer

2 National Toxicology Program

3 European Union Classification scheme

4 Not deliberately added to the raw material and may only occur in impurities of concentration less than 0,01 percent by weight

5 See MSDS for explanation

6 See "Candidate List of Substances of Very High Concern for authorisation" at

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

#### Ingredients/substances/preparations/mixtures as well as any additional functional ingredients and known impurities that are present at concentrations in the product of greater than 0,010%. (Regulation (EC) n°66/2010)

Criteria	Title	Present		If YES, precise substance-CAS number-content
		YES	NO	
4.	<b>Volatile Organic Compounds (VOC)'s content (%)</b> <i>Article 2, définition 13 of the decision 2014/312/UE</i> <i>Directive 2004/42/EC</i>	X		MPG - 57-55-6 - > 99.8% DPG - 25265-71-8 - < 0.1% Water - 7732-18-5 - < 0.1%
4.	<b>Semi Volatile Organic Compounds (SVOC)'s content (%)</b> <i>Article 2, définition 14 of the decision 2014/312/UE</i>		X	
5.b)	<b>Substances of Very High Concern according to the procedure described in Article 59(1) of the REACH Regulation</b>		X	
5. 1.iii)	<b>Isothiazolinone compound content</b> 2-méthyl-2H-isothiazol-3-one; 1,2-benzisothiazol-2(2H)-one 2-octyl-2H-isothiazol-3-one; 5-chloro-2-méthyl-4-isothiazolin-3-one / 2-méthyl-4-isothiazolin-3-one		X	
5. 1.	<b>3-iodo-2-propynyl butylcarbamate (IBPC) content</b>		X	
5. 1.	<b>Zinc pyrithione content</b>		X	
5. 1.	<b>N-(3-aminopropyl)-N-dodécylpropane-1, 3-diamine content</b>		X	
5.1.d)	<b>Zinc oxide content</b>		X	
5.4.b)	<b>Alkylphenoethoxylates (APEO) content and their derivatives</b>		X	
5.4.c)	<b>Long chain perfluorinated surfactants :</b> <b>Perfluorocarboxylic acids content</b> with carbon chain lengths ≥C8 including perfluorooctanoic acid (PFOA) <b>Perfluoroalkylesulfonates content</b> with carbon chain lengths ≥C6 including perfluorohexane sulfonic acid (PFHxS) and perfluorooctanesulfonate (PFOS) <b>Related compounds that may degrade to the substances identified above</b>		X	

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Ingredients/substances/preparations/mixtures as well as any additional functional ingredients and known impurities that are present at concentrations in the product of greater than 0,010%. (Regulation (EC) n°66/2010)

Criteria	Title	Present		If YES, precise substance-CAS number-content
		YES	NO	
5.5.a)	<b>Silicon resin emulsion H412(R52/53), H413 (R53) content</b>		X	
5.5.b)	<b>Metals and their compounds content</b> Cadmium, lead, chromium VI, mercury, arsenic, barium, selenium, antimony and cobalt		X	
5.5.c)	<b>Crystalline silica and leucophyllitemineralscontaining crystalline silica H373 (R48/20) content</b>		X	
5.6.b)	<b>Phthalates content</b> DEHP (Bis-(2-éthylhexyl)-phthalate); BBP (Butylbenzylphthalate) DBP (Dibutylphthalate); DMEP (Bis2-méthoxyéthyl) phthalate DIBP (Diisobutylphthalate); DIHP (dialkylphthalates ramifiés en C6-8) DHNUP (dialkylphthalates ramifiés en C7-11); DHP (Di-n-hexylphthalate)		X	
5.7.a)	<b>Free formaldehyde content</b>		X	
5.7.c)	<b>Unreactedmonomers content</b> present from binders including acrylic acid		X	
5.7.c)	<b>Volatil AromaticHydrocarbons content</b>		X	
5.7.c)	<b>Halogenatedsolvents content</b>		X	

<b>Presence of substances or mixtures labeled hazard statements and risk phrases below (see SDS)</b>	Yes	No
H300 (R28), H310 (R27), H301 (R25), H311 (R24), H330 (R23/26), H304 (R65), ,H331(R23), EUH070 (R39/41)		X
H370 (R39/23, R39/24, R39/25, R39/26), R39/27, R39/28), H372 (R48/25, R48/24, R48/23), H371 (R68/20, R68/21, R68/22), H373 (R48/20, R48/21, R48/22)		X
H317 (R43), H334 (R42)		X
H340 (R46), H350 (R45), H350i (R49), H360F (R60), H360D (R61), H360FD (R60/61), H360fd (R60/63) H360Df (R61/62), H341 (R68), H351 (R40), H361f (R62), H361d (R63), H361fd (R62/63), H362 (R64)		X
H400 (R50), H410 R50/53), H411 (R51/53), H412 (R52/53), H413 (R53)		X
EUH059 (R59)		X

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#### RISK EXCIPIENT CHECKLIST FOR EXCIPIENT SUPPLIERS

Based on the Guidelines 2015/C 95/02 of 19 March 2015 on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use obliges the manufacturing authorization holder to incorporate a risk management for excipients used.

#### The excipient risk profile

- Is there the risk of transmissible spongiform encephalopathy? Yes  No
- Are the excipients from animal or human origin? Yes  No
- Is there any potential for viral contamination? Yes  No
- Are the excipients derived from cell cultures or other biochemical processes? Yes  No
- Is there any potential for microbiological or endotoxin/pyrogen contamination? Yes  No
- Does the excipient contain any possible allergen? Yes  No

The materials listed in the table below are included based on the current allergen legislation in the U.S., EU and Japan and other materials of interest. Mark all that included:

This product contains ingredients derived from and/or may come in to contact with this material during manufacturing, packaging or storage.			
	Yes/No		Yes/No
Cereals containing gliadin gluten (wheat, rye, barley, oats)	No	Mustard	No
Milk/dairy products	No	Sesame seeds	No
Eggs	No	Lupin	No
Fish/crustacean/molluscs/shellfish including abalone and squid	No	Buckwheat, oranges, kiwifruit, peaches, apples, yams	No
Peanuts	No	Sulphur dioxide/sulphites at concentrations greater than 10 mg/kg as SO <sub>2</sub>	No
Tree nuts	No	BHT (E321/BHA (E320)	No
Soybeans	No	Benzoates (E210-E213)	No
Celery	No	p-hydroxybenzoates (parabens) (E214-E219)	No

- Is latex used in the manufacturing or packaging of the excipient? Yes  No
- Are elemental impurity levels present in excipients known, documented, and available upon request? Yes  No
- Does the excipient contain any material derived from genetic modification, or has it come into contact with GM materials during its manufacture, packaging or storage? Yes  No
- Is there any potential, for any impurity originating from the raw materials, e.g. aflatoxins or pesticides, or generated as part of the process and carried over, e.g. residual solvents and catalysts? If Yes, describe briefly Yes  No
- Is there sterility assured for excipients claimed to be sterile? Yes  No
- How the sterility is assured? Not apply
- Are there dedicated production lines and or/facility? Yes  No
- Is there any potential for any impurities carried over from other processes, in absence of dedicated equipment and/or facilities? Yes  No
- Describe briefly the environmental control and storage/transportation conditions including cold chain management, if appropriate.  
The production process is a chemical synthesis in a continuous closed plant. The product is stored in a dedicated tank and transported by tanker truck with food approval and previously inspected before the load in our plant.
- Describe briefly the supply chain complexity.  
The product is sent from our plant directly to the customers.
- Describe briefly the stability process followed for each excipient. Are any stability results available? Yes  No   
A stability study has been conducted according to the "Guideline ICH Q1A (R2): Stability testing of new drug substances and products. Guideline IPEC: The IPEC Excipient Stability Program Guide".
- Describe briefly the packaging and labelling process followed by the company. How the packaging integrity is assured?  
The integrity is assured using numbered seals, and the seals number is reported with the documentation of the product.

#### The following controls are required to maintain the quality and safety of the excipient.

#### Quality system

- Is there an established and implemented pharmaceutical quality system in place? Yes  No
- Is there sufficient competent and appropriately qualified personnel? Yes  No

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## GUARANTEE CERTIFICATE

### REPSOL QUIMICA S.A.

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

- Can you provide organizational charts and number of employees, including list of staff qualification.re there defined job descriptions for managerial and supervisor staff responsible for manufacturing and quality activities? Yes  No
- Is there a list of consultants with qualification and service provided? Yes  No
- Are available training programs for all staff involved in manufacturing and quality activities? Yes  No
- Are available training programs related to health, hygiene and clothing as identified as necessary to the intended operations? Yes  No
- Is there any provision and maintenance of premises and equipment appropriate to the intended operations? Yes  No
- Is there a documentation system available covering all processes and specifications for the various manufacturing and quality operations? Yes  No
- Are there implemented SOPs for the identification, collection, indexing, filing, storage, maintenance and disposition of the controlled documents? Yes  No
- Are there implemented SOPs for the identification, collection, indexing, filing, storage, maintenance and disposition of records? Yes  No
- Is there a system for coding and identifying starting materials, intermediates and excipients to allow full traceability? Yes  No
- Is there a qualification program for suppliers? Yes  No
- Is the retention of records for incoming materials and excipients and retention of samples of excipients for the periods performed as required by the regulations? Yes  No
- Is there a system to ensure that any activity contracted out is subject to a written contract? Yes  No
- Is an effective system where by complaints are reviewed and excipients may be recalled, applied? Yes  No
- Are available change management and deviation management systems? Yes  No
- Is there a system in place for monitoring Corrective/Preventive actions? Yes  No
- Is a self-inspection program in place? Yes  No
- Are internal audits conducted regularly? Yes  No
- Are the environmental conditions and storage conditions controlled? Yes  No
- Please provide details of water purification system  
[The water is obtained from the Public Service of the city, who is responsible of the water quality.](#)
- Please provide details regarding work environment, air handling, controlled environments and pest controls.  
[We have a contract with an external company for pest control.](#)
- Is there a system (SOPs & programs) for equipment calibration, qualification and maintenance? Please provide a list with key equipment including materials of construction and a list of utilities. Yes  No
- Is there a computer system management in place? Yes  No
- Is there a system of monitoring and measurement of customer satisfaction? Yes  No

#### Production/ Testing / Release

- Is there an SOP in place for purchasing and planning operations?and development of product realization Yes  No
- Are there production instructions and records in place? Yes  No
- Are there cleaning procedures in place? Yes  No
- Is there a solvent recovery procedure in place? Yes  No
- Is there an SOP for in process controls in place?/ Yes  No
- Is there a validation of manufacturing processes program available? Yes  No
- Is there a system in place for identification and traceability? Yes  No
- Are there SOPs in place for packaging and labeling of the material(s)? Yes  No
- Are there SOPs in place Storage and handling of the material(s)? Yes  No
- Are there SOPs in place for delivery and distribution? Yes  No
- Is there a system for quality control of the excipient and a responsible person independent from production to release of batches? Yes  No
- Is there an SOP in place for handling Out-of-specification test results? Yes  No
- Do you keep retain samples for each batch manufactured? Yes  No
- Do you issue a Certificate of Analysis for each batch manufactured? Yes  No
- Is there a stability testing program in place? Yes  No

#### RISK EXCIPIENT CHECKLIST FOR EXCIPIENT SUPPLIERS (END)

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

#### ICH Q3D GUIDELINE FOR ELEMENTAL IMPURITIES: IDENTIFICATION OF POTENTIAL ELEMENTAL IMPURITIES

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, 16 December 2014  
[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q3D/Q3D\\_Step\\_4.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3D/Q3D_Step_4.pdf)

Excipient name:	MONOPROPYLENE GLYCOL (MPG) USP/EP
Trade name:	MONOPROPYLENE GLYCOL (MPG) USP/EP
Name of supplier:	REPSOL QUIMICA S.A.
Name of manufacturer: (if different from supplier)	
Address of manufacturer:	CALLE MENDEZ ALVARO 44. 28045 MADRID. SPAIN

#### Source/type of Excipient

Mineral	Mineral derived	Plant	Plant derived	Synthetic	Fermentation	Other (explain)
				X		

Please identify the elemental impurities naturally present, intentionally added and/or potentially present

Class	Elemental Impurities	Intentionally added (e.g., Catalysts, Reagents)	Not intentionally added		
			Naturally present (e.g. Mined Excipient)	Potentially derived from Manufacturing equipment	Potentially leached from Container closure system
1	As, Cd, Hg, Pd	0	0	0	0
2A	Co, Ni, V	0	0	0	0
2B	Ag, Au, Ir, Os, Pd, Pt, Rh, Ru, Se, Tl	0	0	0	0
3	Ba, Cr, Cu, Li, Mo, Sb, Sn	0	0	0	0

#### ICH Q3D GUIDELINE FOR ELEMENTAL IMPURITIES: IDENTIFICATION OF POTENTIAL ELEMENTAL IMPURITIES (END)



Technical Service and Development Department  
Intermediate Products

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