

	Dossier technique et réglementaire / <i>technical and regularoty document</i> <b>POLYGLYCOL 400</b>	Janvier 2019 / <i>January 2019</i>
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INCI: **PEG-8**  
N°CAS: 5117-19-1 / 25322-68-3  
N°EINECS/ELINCS: 225-856-4

#### DESCRIPTION / DESCRIPTION:

Le polyglycol 400 est un mélange de polymères provenant de l'oxyde d'éthylène, de formule générale  $H-(OCH_2-CH_2)_n-OH$ . Sa masse moléculaire moyenne est égale à 400 environ (correspondant à la valeur nominale n) / *Polyglycol 400 is a mixture of polymers derived from ethylene oxide, of general formula  $H-(OCH_2-CH_2)_n-OH$ . Its average molecular weight is about 400 (corresponding to the nominal value n)*  
Matière première conforme à la Pharmacopée Européenne en vigueur (monographie 1444: MACROGOLS type 400) / *Raw material conforming to the European Pharmacopoeia in force (monography 1444: MACROGOLS type 400)*

#### CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect à 20°C / <i>aspect at 20°C</i>	Liquide limpide et incolore / <i>clear, colourless liquid</i>	1BAL02
Couleur / <i>color</i>	$\leq 25$ PtCo	1BAL05
Poids moléculaire moyen / <i>average molecular weight</i>	380 – 420 g.mol <sup>-1</sup>	1BAL01
Viscosité cinématique à 20°C / <i>kinematic viscosity at 20°C</i>	94 – 116 mm <sup>2</sup> .s <sup>-1</sup>	1BAL16
Viscosité cinématique à 99°C / <i>kinematic viscosity at 99°C</i>	6.8 – 8 mm <sup>2</sup> .s <sup>-1</sup>	1BAL16
pH (solution aqueuse à 5%) / <i>pH (5% aqueous solution)</i>	4.5 – 7	1BAL06
Cendres sulfuriques / <i>sulfuric ashes</i>	$\leq 0.1$ %	1BAL10
Teneur en eau / <i>water content</i>	$\leq 0.5$ %	1BAL08
Acidité (en acide acétique) / <i>acidity (as acetic acid)</i>	$\leq 0.015$ %	1BAL11
Teneur en MEG+DEG / <i>MEG+DEG content</i>	$\leq 0.2$ %	1BAL12
Teneur en oxyde d'éthylène / <i>oxide ethylene content</i>	$\leq 1$ ppm	1BAL09
Teneur en dioxane / <i>dioxane content</i>	$\leq 5$ ppm	1BAL09
Teneur en métaux lourds (en Pb) / <i>heavy metals content (as Pb)</i>	$\leq 5$ ppm	1BAL14
Teneur en formaldéhyde / <i>formaldehyde content</i>	$\leq 15$ ppm	1BAL44
Substances réductrices / <i>reducing substances</i>	Conforme / <i>compliant</i>	1BAL40
Indice d'hydroxyle / <i>hydroxyl value</i>	270 – 291 mg KOH/g	1BAL01

**Ces éléments seront repris sur nos BA / these elements will be on our CoA**

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**CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:**

Aliments chimiques codex: conforme / *Food chemicals codex: conform*

Pharmacopée USP/NF: conforme / *USP/NF pharmacopoeia: conform*

Directives EEC et ICH: conforme / *EEC and ICH guidelines: conform*

**APPLICATIONS:**

Produits pharmaceutiques, cosmétiques, textile, plastiques et résines, industrie du papier, imprimerie, industrie du métal, produits chimiques intermédiaires / *Pharmaceuticals, cosmetics, textile, industry, plastics ans resins, paper industry, printing, metal industry, chemical intermediates*

**CONDITIONNEMENT STANDARD / STANDARD PACKAGING:**

IBC de 1100 kg – fût de 220 kg – tonnelet de 60 kg / *1100 kg IBC – 220 kg drum – 60 kg keg*

Matière première non classifiée comme substance dangereuse / *Raw material not classified as dangerous substance*

A conserver au sec dans un emballage hermétiquement fermé / *Keep in a dry place in a tightly closed container*

<b>Additives</b>	It is reasonable to assume that the following impurities: sulphur compounds, residual propylene oxide and ethylene oxide, acrylic compounds and derivates, aromatics compounds and derivates – polycyclic aromatic compounds, bacteriologic or enzymatic compounds, carboxylic acids, fipronil, halogenated compounds, inorganic and organic, mineral oil derivates (MOSH and MOAH), nitrogen compounds inorganic and organic, paraffin wax, radioactive compounds are not present in the product
<b>Allergen</b>	The products listed as allergenic are not present in this product according to regulation No 1223/2009 on cosmetic products (and amendments), regulation No 1169/2011 on the provision of food information to consumers (and amendments), ALBA list, version August 2001, page 10 from 13, §26 of allergenic components
<b>Animal Testing</b>	No animal testing for cosmetic purposes (regulation No1223/2009/EC) has been performed on the product. Animal testing will only be performed for REACH purposes
<b>BSE - Bovine Spongiform Encephalopathy</b>	This product is free from BSE
<b>California Prop 65</b>	This product is not listed under Proposition 65 State Drinking Water and Toxic Enforcement act but following contaminants or by-products are known to the State of California to cause cancer or reproductive toxicity: Ethylene oxide (CAS:75-21-8-) < 1ppm, 1,4-dioxane (CAS:123-91-1) < 5 ppm, monoethylene glycol (CAS:107-21-1) < 0.2 %, formaldehyde (CAS:50-00-0) < 15 ppm, acetaldehyde (CAS:75-07-0) < 100ppm
<b>Carcinogenic, Mutagenic and Reprotoxic (CMR)</b>	This product is not tested on a routine basis for the impurities listed as CMR for reproduction under European regulation 1272/2008/EC, it is reasonable to assume that only following impurities are likely to be present: dioxane < 5 ppm, ethylene oxide < 1 ppm, formaldehyde < 15 ppm
<b>Composition</b>	(CAS:25322-68-3): Polyethylene glycol > 99.5 % + (CAS:75-21-8): ethylene oxide < 1mg/kg + (CAS:107-21-1): monoethylene glycol < 620 mg/kg + (CAS:111-46-6): diethylene glycol < 0.15% + (CAS:127-09-3): sodium acetate 0.15% + (CAS:123-91-1): dioxane < 5 mg/kg
<b>Cosmetic</b>	This product is compliant with cosmetic regulation (EC) No 1223/2009
<b>Cosmos / Ecocert</b>	This product is synthetic – not accepted by Cosmos
<b>Danger</b>	This product is not classified as dangerous according to CLP and ADR
<b>Dioxane</b>	Dioxin is likely to be present at concentration < 5 ppm
<b>Ecolabel</b>	<i>No data available</i>
<b>European Pharmacopeia</b>	This product is compliant with the current European Pharmacopeia 9.0 (Ph. Eur, 9 <sup>th</sup> edition, United States Pharmacopoeia 40 – National Formulary 35 (USP 40 – NF 35) and Food Chemicals Codex, FCC 9 (9 <sup>th</sup> edition, 2004)

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<b>Food</b>	This product is cleared as food additive as E1521 following the European Regulation 1333/2008, amended by regulation (EC) No 1129/2011 establishing a Union list of food additives. This product do not comply with Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in annex II and III of regulation (EC) No 1333/2008, since the residual amount of ethylene oxide on the specifications is 1 ppm, which is higher than the 0.2 ppm required
<b>Genetically Modified Organisms (GMO)</b>	This product is free from GMO
<b>Inventories</b>	Compliant with China IECSC, USA TSCA (UVCB; XU), New Zealand NZIoC, Korea KECI and ECL (KE-20228), Philippines PICCS, Australia AICS, Canada DSL, Taiwan CSNN, Japan ENCS/MITI (7-129)
<b>Geographic origin (for plant)</b>	Not concerned
<b>Glycol ether</b>	<i>No data available</i>
<b>Halal</b>	This product do not have a formal Halal certification, but meet the basic requirements of Halal (no material of animal origin or biological origin are used)
<b>Heavy Metals</b>	Heavy metals including catalyst residues: Aluminium (Al), Arsenic (As), Barium (Ba), Berillium (Be), Boron (B), Cadmium (Cd), Calcium (Ca), Cobalt (Co), Chromium (Cr), Copper (Cu), Iron (Fe), Lead (Pb), Manganese (Mn), Mercury (Hg), Molybdenum (Mo), Nickel (Ni), Selenium (Se), Silver (Ag), Tin (Sn), Titanium (Ti), Vanadium (V), Zinc (Zn) are not present in the product, if present the limit is $\leq 5$ ppm
<b>HS code</b>	39072011
<b>Irradiation / ionization</b>	This product has not been treated with / has not been exposed to ionizing radiation of any type (including radioactive radiation)
<b>Kosher</b>	This product is Kosher and Parev certified
<b>Latex</b>	Latex is not present in this product
<b>Manufacturing location</b>	Belgium / Germany
<b>Microbiological data</b>	This product doesn't contain yeast, enzyme and bacteria
<b>Nanomaterials</b>	This product doesn't contain nanomaterials (nanoparticles, substances at nanoscale)
<b>Nutritional data</b>	<i>No data available</i>
<b>Origin</b>	Petrochemical and synthetic
<b>Pesticide</b>	Pesticides are not present in this product
<b>Phthalate</b>	
<b>Preservative</b>	No preservatives are used for the production of this product
<b>Process</b>	This product is produced by reaction of polymerization of ethylene oxide with either water, monoethylene glycol or diethyleneglycol as starting materials: (propylene oxide + water) -> reaction -> evaporation (crude glycol) -> distillation -> purified glycol
<b>REACH</b>	This product is a polymer – exempted from REACH (the monomers are registered)

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<b>Residual Solvents</b>	No Class 1 solvents are used in the manufacturing process and are not likely to be present, solvents of Class 2 that are likely to be present are ethylene glycol < 620 mg/kg; 1,4 dioxane, solvents of Class 3 that are likely to be present are acetic acid < 0.015 %wt, no Class 4 solvents are used in the manufacturing process and are not likely to be present in the final product according to EMA/CHMP/ICH/82260/2006 (March 2011) guideline for residual solvents
<b>RSPO</b>	This product doesn't contain palm derivatives – not concerned
<b>Shelf Life before re-check</b>	4 years
<b>Substances of Very High Concern (SVHC)</b>	This product is not listed or contain substances mentioned on the "Candidate List of Substances of very High Concern"(SVHC) published 27/06/2018 in concentrations ≥ 0.1%
<b>Volatiles organic compounds (VOC)</b>	This product doesn't contain VOC (directive 2010/75/EU)

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Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancel and replace all technical and regulatory previous documents.*