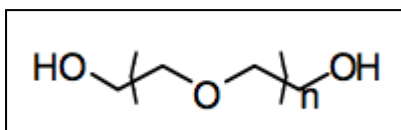


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INCI: **PEG - 180**
N°CAS: 25322-68-3
N°EINECS/ELINCS: –

DESCRIPTION / DESCRIPTION:

Le polyglycol 8000 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 8000 environ (correspondant à la valeur nominale n) / *Polyglycol 6000 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 8000 (corresponding to the nominal value n)*
Matière première conforme à la pharmacopée Européenne en vigueur (monographie : MACROGOLS type 8000) / *Raw material conforming to the European Pharmacopoeia in force (monography MACROGOLS type 8000)*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect à 20°C / <i>Aspect at 20°C</i>	Ecailles blanches / <i>White scales</i>	Visuel / <i>Visual</i>
Couleur / <i>Color</i>	≤ 25 PtCo	1BAL05
Poids moléculaire moyen / <i>Average molecular weight</i>	7000 – 9000 g.mol ⁻¹	1BAL01
Viscosité à 20°C (sol.aqueuse à 50%) / <i>Viscosity at 20°C (50% in aq.solution)</i>	240 – 472 mm ² .s ⁻¹	1BAL16
pH (solution aqueuse à 5 %) / <i>pH (5% aqueous solution)</i>	4.5 – 7	1BAL06
Cendres sulfuriques / <i>Sulfuric ashes</i>	≤ 0.1 %	1BAL10
Teneur en eau / <i>Water content</i>	≤ 0.5 %	1BAL08
Acidité (en acide acétique) / <i>Acidity (as acetic acid)</i>	≤ 0.015 %	1BAL11
Teneur en MEG + DEG / <i>MEG + DEG content</i>	≤ 0.2 %	1BAL12
Teneur en oxyde d'éthylène / <i>Oxide ethylene content</i>	≤ 1 ppm	1BAL09
Teneur en dioxane / <i>Dioxane content</i>	≤ 5 ppm	1BAL09
Teneur en métaux lourds (comme Pb) / <i>Heavy metals content (as Pb)</i>	≤ 5 ppm	1BAL14
Teneur en formaldéhyde / <i>Formaldehyde content</i>	≤ 15 ppm	1BAL44
Indice d'hydroxyle / <i>Hydroxyl content</i>	12 – 16 mg KOH /g	1BAL01

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

Ces caractéristiques sont conformes aux précédentes spécifications datées de Novembre 2014 / These features are in accordance with previous specifications dated on November 2014

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Matière en suspension: substantiellement libre / *Suspended matter: substantially free*
Solubilité dans l'eau (25% aqueux): exempté de brume et de turbidité / *Water solubility (25% aqueous): free from haze and turbidity*
Impuretés réduites: test passé / *Reducing impurities: pass test*
Viscosité à 99°C / *Viscosity at 99°C*: 470 – 900mm².s⁻¹ (1BAL16)
Point de congélation / *Freezing range*: 55 – 62°C (1BAL49)
Antioxydant BHT (E321) / *Antioxidant BHT (E321)*: 30 – 60 ppm (1BAL35)
Pharmacopée USP/NF: conforme / *USP/NF Pharmacopoeia: conform*

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

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

APPLICATIONS:

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

CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Sac de 25 kg / *25kg bag*

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*

Additives	It is reasonable to assume that the following impurities: sulphur compounds, residual propylene oxide and residual ethylene oxide (<1ppm), mycotoxins, 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
Allergen	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
Animal Testing	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
BSE - Bovine Spongiform Encephalopathy	This product is free from BSE
California Prop 65	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
Carcinogenic, Mutagenic and Reprotoxic (CMR)	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
Composition	(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:72-17-3): sodium lactate 0.15% + (CAS:123-91-1): dioxane < 5 mg/kg + (CAS:128-37-0): BHT < 100mg/kg
Cosmetic	This product is compliant with cosmetic regulation (EC) No 1223/2009
Cosmos / Ecocert	This product is synthetic – not accepted by Cosmos
Danger	This product is not classified as dangerous according to CLP and ADR
Dioxane	Dioxane is likely to be present at concentration < 5 ppm and dioxin are not present in this product
Ecolabel	No data available
European Pharmacopeia	This product is compliant with the current European Pharmacopeia 9.0 (Ph. Eur, 9th edition, United States Pharmacopoeia 40 – National Formulary 35 (USP 40 – NF 35) and Food Chemicals Codex, FCC 9 (9th edition, 2014)

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Food	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
Genetically Modified Organisms (GMO)	This product is free from GMO
Inventories	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)
Geographic origin (for plant)	Not concerned
Glycol ether	<i>No data available</i>
Halal	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)
Heavy Metals	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 ≤ 5 ppm
HS code	34042000
Irradiation / ionization	This product has not been treated with / has not been exposed to ionizing radiation of any type (including radioactive radiation)
Kosher	This product is Kosher and Parev certified
Latex	Latex is not present in this product
Manufacturing location	Belgium / Germany
Microbiological data	This product doesn't contain yeast, enzyme and bacteria
Nanomaterials	This product doesn't contain nanomaterials (nanoparticles, substances at nanoscale)
Nutritional data	<i>No data available</i>
Origin	Petrochemical and synthetic
Pesticide	Pesticides are not present in this product
Phthalate	<i>No data available</i>
Preservative	This product contain BHT ($< 100\text{mg/kg}$)
Process	This product is manufactured by reaction of diethylene glycol and ethylene oxide
REACH	This product is a polymer – exempted from REACH (the monomers are registered)
Residual Solvents	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
RSPO	This product doesn't contain palm derivates – not concerned
Shelf Life before re-check	4 years

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Substances of Very High Concern (SVHC)	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 concentration $\geq$ 0.1%
Volatiles organic compounds (VOC)	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.*