INTERCHIMIE	Dossier technique et réglementaire / *technical and regulatory document* **POLYGLYCOL 400**	octobre 2025 / *october 2025*

INCI: **PEG-8**
N°CAS: 25322-68-3
N°EINECS/ELINCS:

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: MACROGOLS type 400) */ Raw material conforming to the European Pharmacopoeia in force (monography: MACROGOLS type 400)*

CARACTERISTIQUES GARANTIES / *GUARANTEED SPECIFICATIONS:*

CARACTERISTIQUES	**SPECIFICATIONS**	**METHODES / *METHODS***
Aspect à 20°C */ aspect at 20°C*	Liquide limpide et incolore */ clear, colourless liquid*	1BAL02
Poids moléculaire moyen */ average molecular weight*	385 – 415 $g.mol^{-1}$	1BAL01
Indice d'hydroxyle */ hydroxyl value*	270 – 291 mg KOH/g	1BAL01
Couleur */ color*	≤ 25 PtCo	1BAL05
pH (solution aqueuse à 5%) */ pH (5% aqueous solution)*	4.5 – 7	1BAL06
Cendres sulfuriques */ sulfuric ashes*	≤ 0.1 %	1BAL10
Teneur en eau */ water content*	≤ 0.5 %	1BAL08
Oxyde d'éthylène résiduel */ Residual ethylene oxide*	≤ 1 ppm	1BAL09
Teneur en dioxane */ dioxane content*	≤ 5 ppm	1BAL09
Viscosité cinématique à 99°C */ kinematic viscosity at 99°C*	6.8 – 8 $mm^2.s^{-1}$	1BAL16
Acidité (en acide acétique) */ acidity (as acetic acid)*	≤ 0.015 %	1BAL11
Teneur en MEG+DEG */ MEG+DEG content*	≤ 0.2 %	1BAL12
Teneur en métaux lourds (en Pb) */ heavy metals content (as Pb)*	≤ 5 ppm	1BAL14
Teneur en formaldéhyde */ formaldehyde content*	≤ 15 ppm	1BAL44

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

CARACTERISTIQUES A TITRE D'INFORMATION / *ADDITIONAL INFORMATION*:
Pharmacopée USP/NF: conforme */ USP/NF pharmacopoiea: conform*
Directives EEC et ICH: conforme */ EEC and ICH guidelines: conform*
Viscosity at 20°C */ Viscosity at 20°C*: 94 – 116 mm^2/s

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*

Additives	It is reasonable to assume that the following impurities: sulphur compounds, acrylic compounds, aromatics compounds, halogenated compounds, mineral oil derivates (MOSH, MOAH POSH, POAH), nitrogen compounds are not present in the product
Allergen	We have every reason to expect that these products are free of food allergens (1169/2011) and cosmetics allergen (1223/2009 & 2023/1545)
Animal Testing	We have not conducted, commissioned, or been party to any animal testing for any purpose for the material in reference, and its component ingredients since March 11th, 2013.
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. Polyethylene glycol is manufactured by polymerization of ethylene oxide with either water, monoethylene glycol or diethylene glycol as starting materials. Following contaminants or byproducts are known to the State of California to cause cancer or reproductive toxicity: - Ethylene oxide (CAS 75-21-8) < 1 ppm - 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) < 100 ppm The Proposition 65 List of 11th of August 2023 was taken into account for this declaration.
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 < 300 mg/kg + (CAS:111-46-6): diethylene glycol < 0.1% + (CAS:127-09-3): sodium acetate 0.15% + (CAS:123-91-1): dioxane < 5 mg/kg
Cosmetic	Following specifications are valid for Polyethylene Glycol, mentioned in Annex II of Cosmetics Regulation (EC) No 1223/2009: - Formaldehyde: 15 ppm maximum - Ethylene oxide: 1 ppm maximum

	- 1,4-dioxane: 5 ppm maximum According to Article 14 of the Cosmetics Regulation (EC) No 1223/2009, substances classified as CMR substances shall be prohibited. However, according to Article 17, the non-intended presence of traces of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3. The product Polyethylene Glycol is not analyzed on a routine basis for substances listed in Annex III of EC No 1223/2009. However, diethylene glycol is present as an impurity < 0.1%. As a consequence, 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	
Ecolabel	*No data available*	
European Pharmacopeia	This product is compliant with the current European Pharmacopeia, USP/NF Pharmacopoeia, EEC & ICH guidelines	
Food	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 (& 2023/2108), since the residual amount of ethylene oxide on the specifications is 1 ppm, which is higher than the 0.1 ppm required	
Genetically Modified Organisms (GMO)	This product is free from GMO	
Inventories	Listed in China IECSC, USA TSCA, New Zealand NZIoC, Korea ECL (KE-20228),	Philippines PICCS, Australia AICS, Canada DSL, Thailand (TECI, 2012) 55-1-02846 Japan ENCS/MITI (7-129)
Geographic origin (for plant)	Not concerned	
Glycol ether	*No data available*	
Halal	This product doesn't have a formal Halal certification, but meets the basic requirements of Halal (no material of animal origin or biological origin are used)	
Heavy Metals	Heavy metals not expected to be present	
HS code	3907291190	
Irradiation / ionization	This product has not been treated with ionizing	
Kosher	This product is Kosher certified	
Latex	Latex is not expected in this product	
Manufacturing location	Belgium / Germany	
Microbiological data	*No data available*	
Microplastics	This restriction does not apply if one of the following requirements is fulfilled: - The substance is not a polymer - The polymer is a liquid (melting point or initial melting point of 20°C or less at a standard pressure of 101.3 kPa) - The polymer is biodegradable - The polymer is soluble: >2 g/L PEG-series (CAS 25322-68-3) - Polyethylene glycols with a molecular weight below 600 Da are considered liquid. PEG 600 Da is borderline and PEGs with a molecular weight above 600 Da are considered solid polymers. - All PEG grades are water soluble >>> 2 g/L	

	=> The microplastics restriction is not applicable for PEG grades
Nanomaterials	Not expected
Nitrosamines	Though PEGs are not tested on a routine basis for nitrosamine impurities, the production route for does not entail the use of these products in any stage of the manufacturing process, nor have they been seen to be produced within the process, and from this, it is reasonable to assume that nitrosamines are not present and meet the following guidelines: • EMA/409815/2020 • EMA/369136/2020
Nutritional data	*No data available*
Origin	Petrochemical
PAH/PFAS	Not been tested for the presence of PFAS (per- and polyfluoroalkyl substances), we hereby confirm that our products do not contain any intentionally added PFAS.
Pesticide	Not expected
Phthalate	*No data available*
Preservative	This product doesn't contain BHT no colorants (Annex IV), conservatives (Annex V) nor UV filters (Annex VI) are used for the production of Polyethylene Glycol.
Process	This product is produced 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 : - ethylene glycol < 300 mg/kg - 1,4 dioxane < 380 mg/kg, solvents of Class 3 that are likely to be present : -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
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 21/01/2025 in concentration ≥0.1%
Volatiles organic compounds (VOC)	- Vapour pressure: < 0.001 kPa (20°C) - Boiling point: > 200°C (calculated; decomposes) 0% VOC according to : -2010/75/EU -2004/42/CE -SR814018; 01/01/2017 -2015/886/EEU -2011/383/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.*