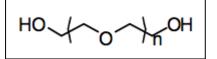


Dossier technique et réglementaire / technical and regularoty document

Janvier 2019 / January 2019

POLYETHYLENE GLYCOL 200



INCI: **Peg-4** N°CAS: 25322-68-3 N°EINECS/ELINCS: –

DESCRIPTION / DESCRIPTION:

Le polyglycol 200 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 200 environ (correspondant à la valeur nominale n) / Polyglycol 200 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 200 (corresponding to the nominal value n)

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

| CARACTERISTIQUES | SPECIFICATIONS | METHODES / METHODS |
|--|--|--------------------|
| Aspect produit pur à 23°C / Pure product aspect at 23°C | Liquide limpide et incolore / Clear, colourless liquid | |
| Poids moléculaire moyen / Average molecular weight | 190 – 210 g.mol ⁻¹ | 1BAL01 |
| Indice d'hydroxyle / Hydroxyl value | 535 – 590 mg KOH/ g | 1BAL01 |
| Couleur / color | ≤ 30 PtCo | 1BAL05 |
| pH à 5 % dans eau distillée / pH at 5% in distilled water | 4.5 – 7.5 | 1BAL06 |
| Teneur en eau / Water content | ≤ 0.5 % | 1BAL08 |
| Teneur en oxyde d'éthylène / Oxide ethylene content | ≤1 ppm | 1BAL09 |
| Teneur en dioxane / Dioxane content | ≤ 5 ppm | 1BAL09 |
| Viscosité cinématique à 99°C / Kinematic viscosity at 99°C | 3.9 – 4.8 mm ² /s | 1BAL16 |
| Cendres sulfuriques / Sulfuric ashes | ≤ 0.2 % | 1BAL10 |
| Teneur en métaux lourds / Heavy metals content | ≤ 5 ppm | 1BAL14 |

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:

Indice de réfraction / Refractive index: 1.458

Complètement soluble dans l'eau / Completely soluble in water

Point éclair / Flash point: > 170°C

Nombre moyen de -OH / Average OH-number: 561

Densité / Density: 1.124 g /cm³

APPLICATIONS:

Produits pharmaceutiques, cosmétiques, détergents, industrie du textile et du cuir, plastiques et résines, industrie du papier, imprimerie, céramique/verre, mines, industrie du caoutchouc, industrie pétrolière, industrie du métal, bois, produits chimiques intermédiaires / Pharmaceuticals, cosmetics, detergents, textile and leather industry, plastics ans resins, paper industry, printing, ceramics/glass, mining, rubber industry, petroleum industry, metal industry, wood, chemical intermediates



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CONDITIONNEMENT STANDARD / STANDARD PACKAGING:

Fûts de 220 kg, tonnelet de 60 kg / 220 kg drums, 60 kg keg

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

| Additives | It is reasonable to assume that the following impurities: sulphur compounds, residual |
|--------------------------------|--|
| Additives | 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 |
| 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 | This product is free from BSE |
| Encephalopathy | |
| 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 | This product is not tested on a routine basis for the impurities listed as CMR for |
| and Reprotoxic (CMR) | reproduction under European regulation 1272/2008/EC, it is reasonable to assume |
| and Reprotoxic (civility | 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 |
| Composition | <pre>1 (CAS:23322-08-5): Polyethylene glycol > 93.5 % + (CAS:73-21-8): ethylene date 1 < 1mg/kg + (CAS:107-21-1): monoethylene glycol < 620 mg/kg + (CAS:111-46-6):</pre> |
| | diethylene glycol < 3.5% + (CAS:127-09-3): sodium acetate 0.15% + (CAS:123-91-1): |
| | |
| Commetic | dioxane < 5 mg/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 |
| Ecolabel | No data available |
| European Pharmacopeia | This product is compliant with the current European Pharmacopeia 9.0 (Ph. Eur, 9 th |
| | edition, United States Pharmacopoeia 40 – National Formulary 35 (USP 40 – NF 35) |
| | and Food Chemicals Codex, FCC 9 (9 th edition, 2004) |
| 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 | This product is free from GMO |
| Organisms (GMO) | F |
| Inventories | Compliant with China IECSC, USA TSCA (UVCB; XU), New Zealand NZIoC, Korea KECI |
| 311101100 | and ECL (KE-20228), Philippines PICCS, Australia AICS, Canada DSL, Taiwan CSNN, |
| | Japan ENCS/MITI (7-129) |
| | Jupan E1400/141111 (7 120) |



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| Geographic origin (for plant) | Not concerned |
|-------------------------------|--|
| Glycol ether | No data available |
| 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 | 39072019 |
| 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 | No data available |
| Origin | Petrochemical and synthetic |
| Pesticide | No data available |
| Phthalate | No data available |
| Preservative | This product doesn't contain BHT |
| Process | This product is produced by reaction of polymerization of ethylene oxide with either water, monoethylene glycol or diethyleneglycol as starting materials: (ethylene oxide + water) -> reaction -> evaporation -> distillation -> purified glycol |
| 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 |
| Substances of Very High | No data available |
| Concern (SVHC) | TI: 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 |
| Volatiles organic | 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.