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## PEG1500 PHARMA

### SALES SPECIFICATION

| Inspection Characteristic                                                                                             | Units                        | Lower | Upper  | Method |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------|-------|--------|--------|
| Average molecular weight                                                                                              |                              | 1400  | 1600   | 1BAL01 |
| Hydroxyl number                                                                                                       | mg KOH/g                     | 70    | 80     | 1BAL01 |
| Clarity at 80°C                                                                                                       | Free from haze and turbidity |       |        | 1BAL02 |
| Water solubility (25% aqueous)                                                                                        | Free from haze and turbidity |       |        | 1BAL03 |
| Suspended matter                                                                                                      | Substantially free           |       |        | 1BAL04 |
| Colour (25% aqueous)                                                                                                  | PtCo                         |       | 25     | 1BAL05 |
| pH (5% aqueous)                                                                                                       |                              | 4,5   | 7,0    | 1BAL06 |
| Sulphated ash                                                                                                         | % wt                         |       | 0,10   | 1BAL10 |
| Water                                                                                                                 | % wt                         |       | 0,5    | 1BAL08 |
| Residual ethylene oxide                                                                                               | ppm                          |       | 1      | 1BAL09 |
| Dioxane                                                                                                               | ppm                          |       | 5      | 1BAL09 |
| The product also meets the following which whilst not determined on a routine basis is guaranteed by process control. |                              |       |        |        |
| Acidity (as acetic acid)                                                                                              | % wt                         |       | 0,0150 | 1BAL11 |
| Ethylene and diethylene glycol                                                                                        | % wt                         |       | 0,20   | 1BAL12 |
| Heavy Metals                                                                                                          | ppm                          |       | 5      | 1BAL14 |
| Reducing Impurities                                                                                                   | Pass test                    |       |        | 1BAL40 |
| Formaldehyde                                                                                                          | ppm                          |       | 15     | 1BAL44 |
| Viscosity at 20°C(50% aqueous)                                                                                        | mm <sup>2</sup> /s           | 31    | 46     | 1BAL16 |
| Viscosity at 99°C                                                                                                     | mm <sup>2</sup> /s           | 26    | 33     | 1BAL16 |
| Freezing range                                                                                                        | °C                           | 42    | 48     | 1BAL49 |
| Antioxidant BHT (E321)                                                                                                | ppm                          | 30    | 60     | 1BAL35 |
| Expiry date                                                                                                           | Years                        |       | 4      | 1BAL50 |
| Food chemicals codex                                                                                                  | Conform                      |       |        |        |
| European pharmacopeia                                                                                                 | Conform                      |       |        |        |
| USP/NF pharmacopeia                                                                                                   | Conform                      |       |        |        |
| EEC and ICH guidelines                                                                                                | Conform                      |       |        |        |



INCI: **PEG 32**  
N°CAS: 25322-68-3  
N°EINECS/ELINCS: –

**DESCRIPTION / DESCRIPTION:**

Le polyglycol 1500 est un mélange de polymères provenant de l'oxyde d'éthylène, de formule générale  $H-(O-CH_2-CH_2)_n-OH$ . Sa masse moléculaire moyenne est égale à 1500 environ (correspondant à la valeur nominale n) / *Polyglycol 1500 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 1500 (corresponding to the nominal value n)*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie: MACROGOLS) / *Raw material conforming to the European Pharmacopoeia in force (monography MACROGOLS)*

**CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:**

| CARACTERISTIQUES                                                           | SPECIFICATIONS                          | METHODES / METHODS       |
|----------------------------------------------------------------------------|-----------------------------------------|--------------------------|
| Aspect / <i>aspect</i>                                                     | Ecailles blanches / <i>White scales</i> | Visuelle / <i>visual</i> |
| Couleur (aqueuse à 25%) / <i>color (25% aqueous)</i>                       | $\leq 25$ PtCo                          | 1BAL05                   |
| Poids moléculaire moyen / <i>average molecular weight</i>                  | 1400 – 1600 g.mol <sup>-1</sup>         | 1BAL01                   |
| Indice d'hydroxyle / <i>hydroxyl content</i>                               | 70 – 80 mg KOH /g                       | 1BAL01                   |
| pH (à 5 % dans eau distillé) / <i>pH (5% in distilled water)</i>           | 4.5 – 7.5                               | 1BAL06                   |
| Cendres sulfuriques / <i>sulfuric ashes</i>                                | $\leq 0.1$ %                            | 1BAL10                   |
| Teneur en eau / <i>water content</i>                                       | $\leq 0.5$ %                            | 1BAL08                   |
| 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 (comme Pb) / <i>heavy metals content (as Pb)</i>   | $\leq 5$ ppm                            | 1BAL14                   |
| Acidité (en acide acétique) / <i>acidity (as acetic acid)</i>              | $\leq 0.015$ %                          | 1BAL11                   |
| Viscosité à 20°C (aqueuse à 50°C) / <i>viscosity at 20°C (50% aqueous)</i> | 31 – 46 mm <sup>2</sup> /s              | 1BAL16                   |
| Teneur en formaldéhyde / <i>formaldehyde content</i>                       | $\leq 15$ ppm                           | 1BAL44                   |
| Teneur en Ethylene glycol / <i>Ethylene glycol content</i>                 | $\leq 0.062$ %                          | 1BAL12                   |
| Teneur en Diethylene glycol / <i>Diethylene glycol content</i>             | $\leq 0.1$ %                            | 1BAL12                   |

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

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

Viscosité à 99°C / *Viscosity at 99°C*: 26 – 33mm<sup>2</sup>.s<sup>-1</sup> (1BAL16)  
Point de congélation / *Freezing range*: 42 – 48°C (1BAL49)  
Antioxydant BHT (E321) / *Antioxidant BHT (E321)*: 30 – 60 ppm  
Pharmacopée USP/NF: conforme / *USP/NF pharmacopoeia: conform*  
Directives EEC et ICH: conforme / *EEC and ICH guidelines: conform*

|                                                                                  |                                                                                                                  |                                |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------|
|  | Dossier technique et réglementaire / <i>technical and regularoty document</i><br><b>POLYETHYLENE GLYCOL 1500</b> | Octobre 2025 /<br>October 2025 |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------|

#### 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:

Sac de 25 kg / 25 kg bag

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

|                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Additives</b>                                    | It is reasonable to assume that the following impurities: sulphur compounds, acrylic compounds, aromatics compounds, halogenated compounds, mineral oil derivatives (MOSH, MOAH POSH, POAH), nitrogen compounds are not present in the product<br>Contain BHT                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Allergen</b>                                     | We have every reason to expect that these products are free of food allergens (1169/2011) and cosmetics allergen (1223/2009 & 2023/1545)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Animal Testing</b>                               | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <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.<br><br>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:<br>- Ethylene oxide (CAS 75-21-8) < 1 ppm<br>- 1,4-dioxane (CAS 123-91-1) < 5 ppm<br>- Monoethylene glycol (CAS 107-21-1) < 0.2%<br>- Formaldehyde (CAS 50-00-0) < 15 ppm<br>- Acetaldehyde (CAS 75-07-0) < 100 ppm<br><br>The Proposition 65 List of 11th of August 2023 was taken into account for this declaration. |
| <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:<br>dioxane < 5 ppm,<br>ethylene oxide < 1 ppm,<br>formaldehyde < 15 ppm                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Composition</b>                                  | (CAS:25322-68-3): polyethylene glycol > 99.5 %<br>+ (CAS:75-21-8): ethylene oxide < 1mg/kg<br>+ (CAS:107-21-1): monoethylene glycol < 300 mg/kg<br>+ (CAS:111-46-6): diethylene glycol < 0.15%<br>+ (CAS:72-17-3): sodium lactate 0.15%<br>+ (CAS:123-91-1): dioxane < 5 mg/kg<br>+ (CAS:128-37-0): BHT < 100mg/kg                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Cosmetic</b>                                     | Following specifications are valid for Polyethylene Glycol, mentioned in Annex II of Cosmetics Regulation (EC) No 1223/2009:<br>- Formaldehyde: 15 ppm maximum<br>- Ethylene oxide: 1 ppm maximum<br>- 1,4-dioxane: 5 ppm maximum<br>According to Article 14 of the Cosmetics Regulation (EC) No 1223/2009, substances                                                                                                                                                                                                                                                                                                                                                                                       |


**POLYETHYLENE GLYCOL 1500**

|                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                     |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
|                                             | <p>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.</p> <p>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 &lt; 0.1%.</p> <p>As a consequence, this product is compliant with cosmetic regulation (EC) No 1223/2009</p>                                                                                             |                                                                                                                     |
| <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>                              | Dioxane 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, USP/NF Pharmacopoeia, EEC & ICH guidelines                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                     |
| <b>Food</b>                                 | 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>                          | Listed in<br>China IECSC,<br>USA TSCA,<br>New Zealand NZIoC,<br>Korea ECL (KE-20228),                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Philippines PICCS,<br>Australia AICS,<br>Canada DSL,<br>Thailand (TECI, 2012) 55-1-02846<br>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 does 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 not expected to be present                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                     |
| <b>HS code</b>                              | 3907291190                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| <b>Irradiation / ionization</b>             | This product has not been treated with ionizing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                     |
| <b>Kosher</b>                               | This product is Kosher certified see certificate in our website                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                     |
| <b>Latex</b>                                | Latex is not expected in this product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                     |
| <b>Manufacturing location</b>               | Belgium / Germany                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                     |
| <b>Microbiological data</b>                 | This product doesn't contain yeast, enzyme and bacteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                     |
| <b>Microplastics</b>                        | <p>This restriction does not apply if one of the following requirements is fulfilled:</p> <ul style="list-style-type: none"> <li>- The substance is not a polymer</li> <li>- The polymer is a liquid (melting point or initial melting point of 20°C or less at a standard pressure of 101.3 kPa)</li> <li>- The polymer is biodegradable</li> <li>- The polymer is soluble: &gt;2 g/L</li> </ul> <p><u>PEG-series (CAS 25322-68-3)</u></p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- All PEG grades are water soluble &gt;&gt;&gt; 2 g/L</li> </ul> <p>=&gt; The microplastics restriction is not applicable for PEG grades</p> |                                                                                                                     |
| <b>Nanomaterials</b>                        | Not expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                     |
| <b>Nitrosamines</b>                         | Though PEGs are not tested on a routine basis for nitrosamine impurities, the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                     |

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|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------|
|  | Dossier technique et réglementaire / <i>technical and regulatory document</i><br><b>POLYETHYLENE GLYCOL 1500</b> | Octobre 2025 /<br>October 2025 |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------|

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|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               | 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: <ul style="list-style-type: none"> <li>• EMA/409815/2020</li> <li>• EMA/369136/2020</li> </ul>                                                                                                                                                     |
| <b>Nutritional data</b>                       | <i>No data available</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Origin</b>                                 | Petrochemical                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>PAH/PFAS</b>                               | 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.                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Pesticide</b>                              | Not expected                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Phthalate</b>                              | <i>No data available</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Preservative</b>                           | This product contains BHT (< 100mg/kg)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Process</b>                                | This product is manufactured by reaction of diethylene glycol and ethylene oxide                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>REACH</b>                                  | This product is a polymer – exempted from REACH (the monomers are registered)                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Residual Solvents</b>                      | No <u>Class 1</u> solvents are used in the manufacturing process and are not likely to be present,<br>solvents of <u>Class 2</u> that are likely to be present :<br>- ethylene glycol < 300 mg/kg<br>- 1,4 dioxane < 380 mg/kg,<br>solvents of <u>Class 3</u> that are likely to be present :<br>-acetic acid < 0.015 %wt,<br>No <u>Class 4</u> 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 21/01/2025 in concentration ≥0.1%                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Volatiles organic compounds (VOC)</b>      | - Vapour pressure: < 0.001 kPa (20°C)<br>- Boiling point: > 200°C (calculated; decomposes)<br><br>0% VOC according to :<br>-2010/75/EU<br>-2004/42/CE<br>-SR814018; 01/01/2017<br>-2015/886/EEU<br>-2011/383/EU                                                                                                                                                                                                                                                                                                                        |

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