

**TECHNICAL DATA SHEET**

1461-TDS-ENG-2026

<b>POLIETILENGLICOL 4000 POLVO (EUR. PH.)</b>		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 25322-68-3	EC Nº: 500-038-2	AEMPS CODE: ---
MOL. WEIGHT: 4000	MOL. FORMULA: HO-(CH <sub>2</sub> -CH <sub>2</sub> O) <sub>n</sub> -H	ARTICLE CODE: 1461

<b>ATTRIBUTES</b>	<b>SHOULD BE</b>
Appearance	White or almost white solid with a waxy or paraffin-like appearance
Solubility	Very soluble in water and in methylene chloride, practically insoluble in alcohol, in fatty oils and in mineral oils
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY6
Acidity or alkalinity	=< 0.1 mL of 0.1 M NaOH
Viscosity	110 - 170 mPa·s
Freezing point	53 - 59 °C
Hydroxyl value	25 - 32
Reducing substances	Not more intensely coloured than ref. sol. R3
Formaldehyde	=< 30 ppm
Ethylene oxide and dioxan	
Ethylene oxide	=< 1 ppm
Dioxan	=< 10 ppm
Water	=< 2.0 %
Sulfated ash	=< 0.2 %

**COMPLIES WITH**

European Pharmacopoeia 12.2

**STORAGE**

Tightly closed. Store at a dry place. At room temperature. Protect from water and moisture.

**REMARKS**

Product intended for pharmaceutical purposes.

**BSE/TSE (CPMP/BWP/1230/98 REV 1)**

This product was prepared without using Materials of animal origin for which a BSE-risk exists. A BSE-risk estimation is therefore not necessary.

**GMO (Regulation (EC) No. 1829/2003 and 1830/2003)**

For above product there is no obligation of GMO-labelling. It can be labelled as "without genetechnology".

**Residual solvents (Guideline CPMP/ICH/283/95)**

 This product contains solvents. It complies with this guideline because the concentrations are below the limits:  
 1,4-Dioxane (Class 2): < 1 ppm

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Ethylene glycol (Class 2): < 500 ppm

**Allergens (1223/2009/EG)**

This product does not contain any allergens listed in above mentioned directive.

**Nitrosamines Risk Evaluation**

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

**Elemental impurities (EMA/CHMP/SWP/4446/2000, ICH-Q3D)**

This product does not contain any metal residues listed in above mentioned directives.