



TECHNICAL DATA SHEET

1461-TDS-ENG-2024

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

ATTRIBUTES	SHOULD BE
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 11.0

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

Ethylene glycol (Class 2): < 500 ppm

Allergens (1223/2009/EG)

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



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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.