



TECHNICAL DATA SHEET

006056-TDS-ENG-2023

| POLIETILENGLICOL 400 Ph.EurUSP | | | | |
|--------------------------------|------------------------------------|------------------|----------------------|--|
| DESCRIPTION DCI: | | DESCRIPTION DOE: | | |
| CAS N°: 25322-68-3 | EC N°: 500-035-2 | | AEMPS CODE: | |
| MOL. WEIGHT: | MOL. FORMULA: C2nH4n+2On+1 (n=8.2- | | ARTICLE CODE: 006056 | |

| ATTRIBUTES | SHOULD BE | |
|---------------------------------------|---|--|
| Appearance | Clear, viscous, colourless or almost colourless, hygroscopic liquid | |
| Solubility | Miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils | |
| Identification A | Complies | |
| Identification B | Complies | |
| Identification C | Complies | |
| Appearance of solution | Clear and not more intensaley coloured than ref. sol. BY6 | |
| Acidity or alkalinity | =< 0.1 mL of 0.1 M NaOH | |
| Viscosity | 105 - 130 mPa·s | |
| Freezing point | 4 - 8 °C | |
| Hydroxyl value | 264 - 300 | |
| Reducing substances | Not more intensely coloured than ref. sol. R3 | |
| Formaldehyde | =< 30 ppm | |
| Ethylene glycol and diethylene glycol | =< 0.4 % | |
| 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

Store it in a fresh, dry and well-ventilated place.

REMARKS

Polyethylenglycol 400 is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.