

TECHNICAL DATA SHEET

009740-TDS-ENG-2024

POLIVINILPIRROLIDONA K 30 (EUR. PH. / E 121)			
DESCRIPTION DCI:		DESCRIPTION DOE:	
CAS Nº: 9003-39-8	EC Nº: 618-363-4		AEMPS CODE:
MOL. WEIGHT:	MOL. FORMULA: C6nH9n+2NnOn		ARTICLE CODE: 009740

ATTRIBUTES SHOULD BE

Appearance White or yellowish-white, hygroscopic powder or flakes

=< 0.1 %

11.5 - 12.8 %

Solubility Freely soluble in water, in ethanol (96 per cent) and in methanol, very slightly

soluble in acetone

Identification ACompliesIdentification DComplies

Appearance of solution Clear and not more intensely coloured than ref. sol. B6, BY6 o R6

рΗ 3.0 - 5.028.0 - 32.0 Viscosity, expressed as K-value Aldehydes =< 500 ppm Peroxides =< 400 ppm Formic Acid =< 0.5 % Limit of hydrazine =< 1 ppm Impurity A =< 10 ppm =< 3.0 % Impurity B Water =< 5.0 %

COMPLIES WITH

Riqueza (N content)

European Pharmacopoeia 11.0

STORAGE

Sulfated ash

Keep the container tighly closed in a dry, cool and well-ventilated place.

REMARKS

Povidone K30 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.