



TECHNICAL DATA SHEET

46433159-TDS-ENG-2025

POLICRESULEN API		
DESCRIPTION DCI: POLICRESULEN		DESCRIPTION DOE: POLICRESULENO
CAS Nº: 9011-02-3	EC Nº: 685-372-8	AEMPS CODE: 90962A
MOL. WEIGHT: ---	MOL. FORMULA: (C ₁₅ H ₁₆ O ₈ S ₂) _n	ARTICLE CODE: 46433159

ATTRIBUTES	SHOULD BE
Appearance	Reddish-brown viscous liquid, strong acid
Solubility	Freely soluble in water or ethanol, insoluble in trichloromethane or ether
Identification (1)	Complies
Identification (2)	Complies
Related substances	
m-cresol-4,6-disulfonic acid ammonium	=< 1.5 %
m-cresol-4-sulfonic acid ammonium	=< 17.0 %
m-cresol-6-sulfonic acid ammonium	=< 7.0 %
double cresol sulfonic acid ammonium	=> 1.9 %
Relative density	1.10 - 1.30 g/mL
Sulfates	=< 2.0 %
Barium	Complies
Residue on ignition	=< 0.2 %
Heavy metals	=< 20 ppm
Assay	45.0 - 55.0 %
Residual solvents	
Methylene Chloride	=< 0.06 %
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
S. Aureus	Absence/1g
E. Coli	Absence/1g
C. Albicans	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

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

REMARKS

Policresulen is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".



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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.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.