

TECHNICAL DATA SHEET

1805-TDS-ENG-2026

TIOPRONINA		
DESCRIPTION DCI: tiopronin		DESCRIPTION DOE: TIOPRONINA
CAS Nº: 1953-02-2	EC Nº: 217-778-4	AEMPS CODE: 1157A
MOL. WEIGHT: 163,19	MOL. FORMULA: C5H9NO3S	ARTICLE CODE: 1805

ATTRIBUTES	SHOULD BE
Appearance	White crystalline powder, special smell
Solubility	Freely soluble in water or ethanol, very slightly soluble in ether or chloroform, soluble in ammonia and pH 5.0 acetic acid-sodium acetate buffer solution
Identification A	Complies
Identification B	Complies
Identification C	Complies
Melting point	96 - 99 °C
Appearance of solution	Clear and colourless
Sulfates	=< 0.048 %
Iron	=< 0.0005 %
Arsenic	=< 2 ppm
Related substances	=< 2.0 %
Loss on drying	=< 0.50 %
Residue on ignition	=< 0.10 %
Heavy metals	
Lead	=< 20 ppm
Mercury	=< 20 ppm
Cadmium	=< 20 ppm
Residual solvents	
Ethyl acetate	=< 5000 ppm
Assay	=> 98.0 %

COMPLIES WITH

Manufacturer Specifications

STORAGE

Keep container tightly sealed between 2 - 8 °C. Protect from light.

REMARKS

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

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.

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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.