

TECHNICAL DATA SHEET

1505-TDS-ENG-2026

PROPILTIOURACILO (EUR. PH.)		
DESCRIPTION DCI: propylthiouracil		DESCRIPTION DOE: PROPILTIOURACILO
CAS Nº: 51-52-5	EC Nº: 200-103-2	AEMPS CODE: 5016A
MOL. WEIGHT: 170,23	MOL. FORMULA: C ₇ H ₁₀ N ₂ O ₅	ARTICLE CODE: 1505

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or crystals
Solubility	Very slightly soluble in water, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides
Identification B	Complies
Impurity A	=< 0.05 %
Related substances	
Impurity B	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.8

STORAGE

Keep the container tightly closed, in a cool and dry place and protected from light.

REMARKS

Propylthiouracil 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".

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.