



TECHNICAL DATA SHEET

002393-TDS-ENG-2024

DITRANOL (ANTRALINA) (EUR. PH.)		
DESCRIPTION DCI: dithranol		DESCRIPTION DOE: DITRANOL
CAS Nº: 1143-38-0	EC Nº: 214-538-0	AEMPS CODE: 1386A
MOL. WEIGHT: 226,23	MOL. FORMULA: C ₁₄ H ₁₀ O ₃	ARTICLE CODE: 002393

ATTRIBUTES	SHOULD BE
Appearance	Yellow or brownish-yellow, crystalline powder.
Solubility	Practically insoluble in water, soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides.
Identification A	Complies
Identification B	Complies
Melting point	178 - 182 °C
Related substances	
Impurity A	=< 1.0 %
Impurity B	=< 1.0 %
Impurity C	=< 1.0 %
Impurity D	=< 2.5%
Total impurities	=< 3.0 %
Chlorides	=< 100 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1%
Assay	98.5 % -101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Dithranol 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.