



## TECHNICAL DATA SHEET

001124-TDS-ENG-2023

ICHTHAMOL EP (Ictiol - Amonio Tumenol)		
DESCRIPTION DCI: ICHTHAMMOL		DESCRIPTION DOE: ICTAMOL
CAS N°: 8029-68-3	EC N°: 232-439-0	AEMPS CODE: 531A
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 001124

ATTRIBUTES	SHOULD BE
Appearance	Dense, blackish-brown liquid
Solubility	Miscible with water and with glycerol, slightly soluble in ethanol (96 per cent), in fatty oils and in liquid paraffin. It forms homogeneous mixtures with wool fat and soft paraffin
Identification A	Complies
Identification B	Complies
Identification C	Complies
Acidity or alkalinity	=< 0.2 mL of 0.02 M HCl or NaOH
Relative density	1.040 - 1.085
Sulfated ash	=< 0.3 %
Assay	
Dry matter	50.0 - 56.0 %
Total ammonia	4.5 - 7.0 %
Organically combined sulfur	=> 10.5 %
Sulfur in the form of sulfate	=< 20.0 %

### COMPLIES WITH

European Pharmacopoeia 10.0

### STORAGE

Keep the product in tightly closed containers.

### REMARKS

Ichtammol 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.