

## **TECHNICAL DATA SHEET**

32405-TDS-ENG-2025

INDOL-3-CARBINOL			
DESCRIPTION DCI: INDOLE-3-CARBINOL		DESCRIPTION DOE: INDOLE-3-CARBINOL	
CAS Nº: 700-06-1	EC Nº: 211-836-2		AEMPS CODE:
MOL. WEIGHT: 147,18	MOL. FORMULA: C9H9NO		ARTICLE CODE: 32405

ATTRIBUTES SHOULD BE

Appearance Off white to white or orange-yellow, crystalline powder, which may show

agglomerations

Particle size 98 % through 80 mesh

Identification IR Complies Melting point 92 - 99 °C Loss on drying =< 1.0 % Assay => 98.0 % Heavy metals =< 10 ppm Arsenic =< 2 ppm Lead =< 2 ppm =< 0.5 ppm Cadmium Mercury =< 0.5 ppm

Residual solvents [In-house] No toluene or benzene

Microbial contamination

TAMC = < 1000 CFU/gTYMC = < 100 CFU/gEscherichia coli Absence/1g

Salmonella Absence/1g

Staphylococcus aureus Absent/1g

## COMPLIES WITH

Manufacturer Specifications

## STORAGE

Store in a cool dark place away from light.

## **REMARKS**

According to Regulation (EU) 2015/2283, Indole-3-Carbinol is classified as a NOVEL FOOD and its use as food excipient is NOT permited.

Indole-3-Carbinol complies 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.