



## TECHNICAL DATA SHEET

001319-TDS-ENG-2023

<b>SODIO BICARBONATO (Ph.Eur.) (Sodio Hidrogenocarbonato)</b>		
DESCRIPTION DCI: SODIUM BICARBONATE		DESCRIPTION DOE: SODIO BICARBONATO
CAS N°: 144-55-8	EC N°: 205-633-8	AEMPS CODE: 125BI
MOL. WEIGHT: 84.01	MOL. FORMULA: NaHCO <sub>3</sub>	ARTICLE CODE: 001319

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	Clear and colourless
Carbonates	
pH	= < 8.6
Chlorides	= < 150 ppm
Sulfates	= < 150 ppm
Ammonium	= < 20 ppm
Calcium	= < 100 ppm
Iron	= < 20 ppm
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

In tightly closed container, protected from light and heat.

### REMARKS

Sodium Bicarbonate 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.

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.