

## TECHNICAL SPECIFICATIONS

# SODIUM CYCLAMATE HYDRATED

Sweetener for food E-952

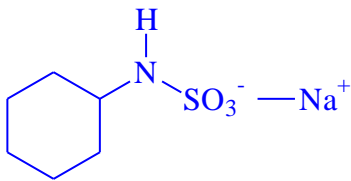
**Product Code:** 1121 (boxes 25 kg); 1123 (drums 50 kg); 1125 (big bags 500 kg); 1127 (big bags 1.000 kg).

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CHARACTERISTIC	SPECIFICATION	METHOD
Formula	C <sub>6</sub> H <sub>12</sub> NSO <sub>3</sub> Na  	
Chemical name	Sodium N-cyclohexylsulphamate, hydrated.	
CAS Number	[139-05-9]	
Ph. Eur. Monograph	Nr 0774	
Relative molecular mass	201.2 (anhydrous) 237.2 (di-hydrated)	
Appearance	White or almost white crystalline powder or colourless crystals, odourless.	
Taste	Very sweet.	
Appearance of solution	Clear and colourless.	Eur. Ph.
Identification	A. IR spectrophotometry. E. Reaction of sodium.	Eur. Ph.
Solubility	Freely soluble in water, slightly soluble in ethanol.	
Loss on drying	≤ 15.0 %	PRO.27
Content (dry basis)	98.5 – 101.0%	PRO.28
pH (solution 10% in water)	5.5 – 7.5	Eur. Ph.
Absorbance at 270 nm	≤ 0.1	Eur. Ph.

CHARACTERISTIC	SPECIFICATION	METHOD
Sulphates	≤ 0.1 %	Eur. Ph.
Elemental impurities: conform	ICH Guideline Q3D	ICP-MS
Lead	< 0.5 ppm	ICP-MS
Selenium	< 15 ppm	ICP-MS
Arsenic	< 1.5 ppm	ICP-MS
Cyclohexylamine	≤ 8 ppm	Eur. Ph.
N,N-dicyclohexylamine	≤ 0.5 ppm	Eur. Ph.
(1) N,N'-dicyclohexylsulfamide	≤ 1 ppm	Eur. Ph.
Aniline	≤ 0.5 ppm	Eur. Ph.
Sulphamic acid	≤ 0.1%	Eur. Ph.
Microbiology Total aerobic mesophilic bacteria Total coliform bacteria Salmonella spp. Mould and yeast	< 1000 cfu/g Absence / 0.1 g Absence / 25 g < 100 cfu/g	Eur. Ph.
Residual solvents: conform Xylene	ICH Guideline Q3C < 1.0 ppm (ICH ≤ 2170 ppm)	GC Headspace
Shelf life	Five years	

(1) *European Pharmacopoeia: no limit.*

USE: FOOD and DRINKS according to the Regulation (EU) 1333/2008 and Regulation (EU) 1129/2011, and subsequent modifications. PHARMACY according to European Pharmacopoeia 10th edition.

PURITY Conform to European Pharmacopoeia 10<sup>th</sup> edition, to ICH Guidelines Q3C on Residual Solvents and Q3D on Elemental Impurities, and to Regulation (EU) 231/2012 on Specifications for Food Additives and amendments.