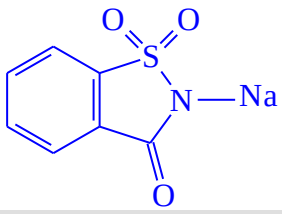
TECHNICAL SPECIFICATIONS

SODIUM SACCHARIN HQ 15% HYDRATED

Sweetener for food E-954

Product Code: 2021 *(boxes 25 kg);* ***2023*** *(drums 50 kg).*

Issued: February 03 ***Version:*** 17 (30/06/2020)

CHARACTERISTIC	SPECIFICATION	METHOD
Formula	$C_7H_4NO_3SNa \cdot 2\ H_2O$ 	
Chemical name	1,2-benzisothiazolin-3-one-1,1-dioxide, sodium salt dihydrate	
CAS Number	[128-44-9]	
Eur Ph monograph	Nr 0787	
Relative molecular mass	241.2 (hydrate) 205.2 (anhydrous salt)	
Appearance	White or almost white, odourless micro crystals.	
Taste	Intensely sweet.	
Appearance of solution	Clear and colourless	Eur. Ph.
Identification	B. IR Spectrophotometry E. Reaction of sodium	Eur. Ph. Eur. Ph.
Solubility	Freely soluble in water, sparingly soluble in ethanol.	
Water:	≤ 15.0%	PRO.047
Content (dry basis)	99.0 – 101.0%	Eur. Ph.
pH (10% solution in water)	6.0 – 7.5	PRO.49 .

CHARACTERISTIC	SPECIFICATION	METHOD
Acidity or alkalinity	Pass the test.	Eur. Ph.
Benzoates and salicylates	No detectable	Regulation 231/2012/CE
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.
Readily carbonizable substances	Pass the test.	Eur. Ph.
p-TSA (toluenesulphonamide) o-TSA (toluenesulphonamide) 1,2-benzisothiazolin-3-one (BIT) Methyl anthranilate p-sulphonamidobenzoic acid	≤ 10 ppm ≤ 10 ppm ≤ 5 ppm ≤ 1 ppm ≤ 10 ppm	Eur. Ph. Eur. Ph. PRO.87 PRO.87 PRO.103
Organic Volatiles Impurities	Passes the test	U.S.P.
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	ICH Guideline Q3C	GC Headspace
Shelf life	Five years	

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

PURITY according to European Pharmacopoeia 10th ed, to ICH Guidelines Q3C(R1) on Residual Solvents and Q3D(R6) on Elemental Impurities, and to Regulation (EU) 231/2012 on Specifications for Food Additives, and subsequent amendments.