

TECHNICAL SPECIFICATIONS

ACID SACCHARIN E - 954

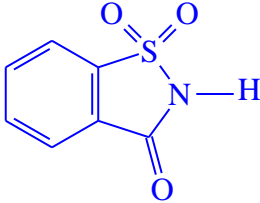
Product Code : 2221 (boxes 25 kg); 2223 (drums 50 kg);

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CHARACTERISTIC	SPECIFICATION	METHOD
Formula	C ₇ H ₅ NO ₃ S 	
Chemical name	1,2 Benzisothiazol-3-(2H)-one 1,1-dioxide	
CAS Number	[81-07-2]	
Ph. Eur. Monograph	Nr 0947	
Relative molecular mass	183.2	
Appearance	White or almost white crystals or crystalline powder, odourless.	
Taste	Intensely sweet.	
Appearance of solution	Clear and colourless	Ph. Eur.
Identification	C. IR absorption spectrophotometry.	Ph. Eur.
Solubility	Sparingly soluble in boiling water and in ethanol, slightly soluble in cold water. Soluble in dilute solutions of alkali hydroxides and carbonates.	
Loss on drying	≤ 1.0 %	PRO.110
Content (dry substance)	99.0 – 101.0 %	Ph. Eur.

CHARACTERISTIC	SPECIFICATION	METHOD
Sulphated Ash	≤ 0.2 %.	Ph. Eur.
(¹) Benzoates and salicylates	Not 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.	Ph. Eur.
p-TSA (toluenesulphonamide) o-TSA (toluenesulphonamide) 1,2-benzisothiazolin-3-one (BIT)	≤ 10 ppm ≤ 10 ppm ≤ 5 ppm	Ph. Eur. Ph. Eur. PRO.87
Methyl anthranilate p-sulphonamidobenzoic acid	≤ 1 ppm ≤ 10 ppm	PRO.87 PRO.103
Organic Volatiles Impurities	Pass the test	U.S.P.
Residual Solvents: conform	ICH Guideline Q3C	GC Head Space
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	Ph. Eur.
Shelf life	Five years	

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

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