



Specification

Concerning Product:	
Article number	35300
Raw material description / name	Saccharin Na, Dihydrat (15%) 450 fach 40-80 mesh, EP/USP/JP
CAS-No.	6155-57-3
EC Number	204-886-1 (612-173-5)
Other information	E-954 Chemical name: 1,2-benzisothiazolin-3-one-1,1-dioxide, sodium salt dihydrate sodium; 1,1-dioxo-1,2-benzothiazol-2-id-3-one;dihydrate Relative molecular mass: 241.2 Chemical Fomular: C ₇ H ₄ NO ₃ SNa·2 H ₂ O
EU customs tariff number	29251100
Origin	Europe

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph.Eur.	clear and colourless	
Appearance		White crystalline powder or colorless crystals.	
Flavor and taste		intensely sweet (aprox. 450 times than sucrose)	
Odour		odourless	
Physical parameter			
Acidity/Alkalinity	Ph.Eur.	complies	
Loss on drying	PRO.47	≤ 15,0	%
pH value	PRO.49	(10% in H ₂ O): 6,0 – 7,5	
Solubility		freely soluble in water sparingly soluble in alcohol	
Identity			
Assay	Ph.Eur.	99,0 – 101,0	%
Identification	Ph.Eur.	E. Reaction of sodium: positive	
Infrared absorbtion spectrometry	Ph.Eur.	Identification B.: positive	

Impurities			
Heavy Metals (as Pb)	Ph.Eur. ⁽¹⁾	≤ 10	ppm
Readily carbonizable substances	Ph.Eur.	complies	
Impurity	PRO.87 ⁽¹⁾	1,2-benzisothiazolin-3-one (BIT): ≤ 5	ppm
Impurity	Regulation 231/2012/CE ⁽¹⁾	Benzoates & Salicylates: not detectable	
Impurity	PRO.87 ⁽¹⁾	Methyl anthranilate ≤ 1	ppm
Impurity	Ph.Eur.	o-TSA (toluenesulphonamide): ≤ 10	ppm
Impurity	PRO.103 ⁽¹⁾	p-sulphonamidobenzoic acid ≤ 10	ppm
Impurity	Ph.Eur.	p-TSA (toluenesulphonamide): ≤ 10	ppm
Elemental Impurities			
Arsenic (As)	ICP-MS. ⁽¹⁾	≤ 2	ppm
Lead (Pb)	ICP-MS. ⁽¹⁾	≤ 1	ppm
Selenium (Se)	ICP-MS. ⁽¹⁾	≤ 30	ppm
Organic volatile impurities			
Org. volat. Imp. Total	USP ⁽¹⁾	complies	
Microbiological data			
Aerobic microorganisms	Ph.Eur. ⁽¹⁾	≤ 100	CFU/g
Coliform bacteria	Ph.Eur. ⁽¹⁾	absence	/ 0.1 g
Salmonella	Ph.Eur. ⁽¹⁾	absence	/ 25 g
Yeast and Mould	Ph.Eur. ⁽¹⁾	≤ 100	CFU/g

Annotation:

⁽¹⁾: Limit of the European Pharmacopoeia: higher or not defined.

Regulatory information:

Residual solvents (Ph.Eur.⁽¹⁾):

- Methanol: ≤ 5 ppm
- Toluene: ≤ 1 ppm

Supplemental information:

Released by manufacturer: 2017-03-14

Shelf life: 5 years

Complies with monographie: PURITY according to Regulation (EU) 231/2012 and subsequent amendments (**E-954**), European Pharmacopoeia 9th ed., USP 40 (2017), FCC and JP XVI.

Packing: card boxes 25 kg, drums 25 kg, drums 50 kg, big bags 500 kg, big bags 1.000 kg

Regional origin: EU

Usage: FOOD and DRINKS, according to the Regulation (EU) 1333/2008, Regulation (EU) 1129/2011, and subsequent modifications. PHARMACY according to European Pharmacopoeia 9th edition. Any other applicable regulation must be observed. Sweetener for food E-954.

Version of manufacturer: 16

Chemische Werke Hommel GmbH & Co.KG



T.-R. Volki

Waltrop, 23. Jan. 2019

Version: V2016.10

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