



Specification

Concerning Product:	
Article number	35330
Trade name / designation / denomination	Saccharin 550-fach 60-100 Mesh
CAS number	81-07-2
Other names / synonyms	•1,2-benzisothiazol-3(2H)-one 1,1-dioxide; •Saccharin Acid 20 mesh; •Saccharin Acid 60-100 mesh; •o-benzoicsulfimide;
EC number	201-321-0
Customs tariff number / CN code / TARIC	29251100
Molecular weight [g / mol]	183,18
Formula	C ₇ H ₅ NO ₃ S

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph.Eur.	clear and colourless	
Colour		White or almost white	
Flavor and taste		Intensely sweet (approx. 550 times sweeter than sucrose)	
Odour		odourless	
Physical parameter			
Form		micro crystals or crystalline powder	
Loss on drying	PRO.110	≤ 1,0	%
Solubility		Slightly soluble in cold water, soluble in diluted alkaline solutions.	
Identity			
Assay	Ph.Eur.	99,0 – 101,0	%
Identification	Ph.Eur.	(IR Spectrum): positive	
Impurities			
Readily carbonizable substances	Ph.Eur.	complies (*)	
Sulphated ash	Ph.Eur.	≤ 0,2	%
Impurity	PRO.87	1,2-benzisotiazoline-3-one (BIT) ≤ 5	ppm
Impurity	Regulation 231/2012/CE	Benzoates and salicylates (*): pass the test	
Impurity	PRO.87	Methyl anthranilate: ≤ 1	ppm
Impurity	Ph.Eur.	o-Toluenesulphonamide: ≤ 10	ppm
Impurity	PRO.103	p-sulphonamidobenzoic acid: ≤ 10	%
Impurity	Ph.Eur.	p-Toluenesulphonamide: ≤ 10	ppm
Residual Solvents			
Residual solvents	GC	according to ICH Guideline Q3C (*)	

Elemental Impurities			
Arsenic (As)	ICP-MS.	(*) ≤ 1,5	ppm
Lead (Pb)	ICP-MS.	(*) ≤ 0,5	ppm
Selenium (Se)	ICP-MS.	(*) ≤ 15	ppm
Organic volatile impurities			
Org. volat. Imp. Total	USP	complies (*)	
Microbiological data			
Aerobic microorganisms	Ph.Eur.	(*) ≤ 1000	CFU/g
Coliform bacteria	Ph.Eur.	absence (*)	/ 0,1 g
Salmonella	Ph.Eur.	absence (*)	/ 25 g
Yeast and Mould	Ph.Eur.	(*) ≤ 100	CFU/g

Annotation:

*: Periodically tested every 6 month

Regulatory information:

Elemental Impurities (ICP-MS.): according to ICH Guideline Q3D (*)

Registration status: This product is manufactured according to the Good Manufacturing Practices (GMP) for excipients.

Supplemental information:

Shelf life: 5 years

Complies with monographie: Ph. Eur. Monograph No. 0947

PURITY according to Ph. Eur. 11th edition, Regulation (EU) 231/2012 on Specifications for Food Additives and amendments, USP 40, FCC and JP XVI.

Packing: 25 kg cardbox, 50 kg drum

Regional origin: EU

Usage: USE according to the European Pharmacopoeia 11th edition, to Regulation (EC) 1333/2008 and Regulation (EU) 1129/2011 on Food Aditives, and amendments, FDA Title 21, Paart 180, 180.37.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 16. Feb. 2026

LF-Basis: 18 (2024-04-02)

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