



## Specification

Concerning Product:	
Article number	35300
Trade name / designation / denomination	Saccharin Na, Dihydrat (15%) 450 fach 40-80 mesh, EP/USP
CAS number	6155-57-3
Other names / synonyms	•1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt, dihydrate; •sodium 1,1-dioxo-1,2-benzothiazol-2-id-3-one dihydrate;
EC number	204-886-1
Customs tariff number / CN code / TARIC	29251100
Molecular weight [g / mol]	241.2 (Di hydrated)
Formula	C <sub>7</sub> H <sub>4</sub> NNaO <sub>3</sub> S · 2H <sub>2</sub> O

Parameter	Test Method	Specification	Unit
<b>Organoleptic test</b>			
Appearance of solution	Ph.Eur.	clear and colourless	
Colour		white or almost white	
Flavor and taste		intensely sweet (aprox. 450 times than sucrose)	
Odour		odourless	
<b>Physical parameter</b>			
Acidity/Alkalinity	Ph.Eur.	complies	
Form		crystalline powder	
Loss on drying	PRO.332	≤ 15,0	%
pH value	PRO.332	(10% in H <sub>2</sub> O): 6,0 – 7,5	
Solubility		freely soluble in watersparingly soluble in ethanol (96 per cent).	
<b>Identity</b>			
Assay	Ph.Eur.	99,0 – 101,0	%
Identification	Ph.Eur.	(E) - Reaction of sodium: positive	
Infrared absorbtion spectrometry	Ph.Eur.	Identification (B): positive	
<b>Impurities</b>			
Readily carbonizable substances	Ph.Eur.	complies	
Impurity	PRO.332 <sup>(1)</sup>	1,2-benzisothiazolin-3-one (BIT): ≤ 5	ppm
Impurity	Regulation (EU) 231/2012 <sup>(1)</sup>	Benzoates & Salicylates: pass the test	
Impurity	PRO.332 <sup>(1, 2)</sup>	Methyl anthranilate ≤ 1	ppm
Impurity	Ph.Eur.	o-TSA (toluenesulphonamide): ≤ 10	ppm
Impurity	PRO.103 <sup>(1, 2)</sup>	p-sulphonamidobenzoic acid ≤ 10	ppm
Impurity	Ph.Eur.	p-TSA (toluenesulphonamide): ≤ 10	ppm
<b>Residual Solvents</b>			

Residual solvents	GC	conform to ICH Guideline Q3C	
<b>Elemental Impurities</b>			
Arsenic (As)	ICP-MS <sup>(1)</sup>	≤ 1,5	ppm
Lead (Pb)	ICP-MS <sup>(1)</sup>	≤ 0,5	ppm
Selenium (Se)	ICP-MS <sup>(1)</sup>	≤ 15	ppm
<b>Organic volatile impurities</b>			
Org. volat. Imp. Total	USP <sup>(1, 2)</sup>	complies	
<b>Microbiological data</b>			
Aerobic microorganisms	Ph.Eur. <sup>(1)</sup>	≤ 1000	CFU/ g
Coliform bacteria	Ph.Eur. <sup>(1)</sup>	absence	/ 0.1 g
Salmonella	Ph.Eur. <sup>(1)</sup>	absence	/ 25 g
Yeast and Mould	Ph.Eur. <sup>(1)</sup>	≤ 100	CFU/ g

**Annotation:**

<sup>(2)</sup>: This substance is not expected to be present in the final product. It is originated in a different route of synthesis and therefore not expected to be present and not tested. It is just listed in respect to the monography.

\* n.d. = not detectable / nicht messbar

<sup>(1)</sup>: Limit of the European Pharmacopoeia: higher or not defined.

**Regulatory information:**

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

**Registration status:** PURITY according to European Pharmacopoeia 11th ed., to ICH Guidelines Q3C on Residual Solvents and Q3D on Elemental Impurities, to Regulation (EU) 231/2012 on Specifications for Food Additives, and subsequent amendments, and USP (43)

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

**Supplemental information:**

**Shelf life:** 5 years

**Complies with monographie:** Ph.Eur. 11th edition, monograph No. 0787

**Packing:** card boxes 25 kg, drums 50 kg

**Regional origin:** EU

**Usage:** FOOD and DRINKS according to the Regulations (EC) 1333/2008 and (EU) 1129/2011, and amendments. PHARMACY according to European Pharmacopoeia 11th edition.

Sweetener for food E-954

Chemische Werke Hommel GmbH & Co.KG

*This document was generated electronically and is valid without signature.*

Waltrop, 19. Jul. 2024

LF-Basis: 21 (2024-04-02)

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