



Specification

Concerning Product:	
Article number	6155573JEP
Trade name / designation / denomination	Saccharin Na 40-80 (JEP)
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 ₇ H ₄ NNaO ₃ S · 2H ₂ O

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution		clear and colourless	
Appearance		White or almost white crystalline powder	
Physical parameter			
Acidity/Alkalinity	EP/USP	complies	
Loss on drying	EP/USP	≤ 15	%
Solubility		in ethanol (96%): sparingly soluble	
Solubility		in water: freely soluble	
Identity			
Assay	USP	98,0 – 102,0	%
Assay	EP	99,0 – 101,0	%
Identification	EP	derivation to fluorescent substances: complies	
Identification	EP	derivation to salicylic acid: complies	
Identification	EP	Test for sodium (Nonluminous flame test): yellow color	
Identification	EP/USP	Test for sodium (Potassium Pyroantimonate Solution test): a dense precipitate is formed	
Infrared absorption spectrometry	EP/USP	complies	
Melting Point (identity)	EP	226 – 230	°C
Impurities			
Readily carbonizable substances	EP/USP	absent	
Impurity	GC	all other organic impurities: n.d. *	
Impurity	USP	Benzoate and Salicylate: complies	
Impurity	on dry weight basis	Benzoic acid p-sulphonamide ≤ 25	mg/kg
Impurity	on dry weight basis	o-Toluenesulphonamide ≤ 10	mg/kg

Impurity	on dry weight basis	p-Toluenesulphonamide ≤ 10	mg/kg
Residual Solvents			
Residual solvents		n.d. *	
Elemental Impurities			
Arsenic (As)	on dry weight basis	≤ 2	mg/kg
Lead (Pb)	on dry weight basis	≤ 1	mg/kg
Selenium (Se)	on dry weight basis	≤ 0,003	% (w/w)
Microbiological data			
Aerobic microorganisms		≤ 100	CFU/g
Escherichia Coli.		neg.	
Pseudomonas aeruginosa		neg.	
Salmonella		neg.	
Staphylococcus Aureus		neg.	
Yeast and Mould		≤ 100	CFU/g
Particle size distribution			
Particles		< 180 µm:	%

Annotation:

* n.d. = not detectable / nicht messbar

Arsenic/Selenium/Lead/Residual solvents/Other organic impurities(by GC)/Microbes results are quarterly based on statistics.

Supplemental information:

Shelf life: 5 years

Note: Free from allergen, irradiation, pesticides, GMO, BSE/TSE, DEHP, DINP, DBP, Gluten, Latex, lactose and CMR.

Storage conditions: Preserve in well-closed containers (USP/FCC); Store at room temperature (USP); In a airtight container (PH. EUR)

Complies with monographie: EP11.0, USP/NF, JP, KP, E 954, FCC, JECFA

Regional origin: RK

Conclusion: The above specification and analytical method conform to the Pharmaceutical grade (Ph. Eur., USP/NF, JP, KP, etc.) and Food grade (E954, FCC, JECFA, etc.).

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 26. Oct. 2023

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