

**SACARINA SODICA (EUR. PH.)**

PRODUCT CODE: 1534	CAS Nº: 6155-57-3	ANALYSIS Nº: 105/24
MANUFACTURER BATCH:	CERTIFICATE ID: 41.903	
SUPPLIER BATCH: W0146701	MANUFACTURING DATE: 22/11/2023	
METAPH BATCH: 0170424	EXPIRY DATE: 21/11/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals, efflorescent in dry air	White crystalline powder, efflorescent in dry air
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)	Complies (*)
Identification B	Complies	Complies
Identification E	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity or alkalinity	Complies	Complies (*)
o-and p-toluensulfonamide		(*)
o-toluenesulfonamide	=< 10 ppm	Not Detected
p-toluenesulfonamide	=< 10 ppm	Not Detected
Readily carbonisable substances	Complies	Complies (*)
Water	=< 15.0 %	14.7 %
Assay	99.0 - 101.0 %	100.7 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Active ingredient allowed as a food additive according to the specifications for food additives (Reg. EU n. 231/2012).

Sodium Saccharin is subject to the provisions of the ICH Q3D guide "Elemental impurities" and complies with the provisions of the EMA / CHMP / ICH / 82260/2006 - ICH Q3C (R6) "Residual solvents" guidelines.

(\*) Data adapted from the supplier's certificate of analysis.

The product is not of animal origin and no animal product is used in its production, so it does not present a risk of BSE / TSE.

The product is not derived from GMOs. No genetically modified organism is used in its production and no GMO product comes into contact with the product during any stage of production.

**STORAGE**

Store in the original container in a cool and dry place.

Analysis date: 07/05/2024

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40000598