

TECHNICAL DATA SHEET

1534-TDS-ENG-2024

| SACARINA SODICA (EUR. PH.) | | | |
|----------------------------|--------------------------|------------------|--------------------|
| DESCRIPTION DCI: | | DESCRIPTION DOE: | |
| CAS Nº: 6155-57-3 | EC Nº: 612-173-5 | | AEMPS CODE: |
| MOL. WEIGHT: 205.2 | MOL. FORMULA: C7H4NNaO3S | | ARTICLE CODE: 1534 |

ATTRIBUTES SHOULD BE

Appearance White or almost white, crystalline powder or colourless crystals, efflorescent in dry

air

Solubility Freely soluble in water, sparingly soluble in ethanol (96 %)

Identification BCompliesIdentification EComplies

Appearance of solution Clear and colourless

Acidity or alkalinity Complies

o-and p-toluensulfonamide

o-toluenesulfonamide =<10 ppmp-toluenesulfonamide =<10 ppmReadily carbonisable substances Complies
Water =<15.0 %Assay 99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

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.

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.