



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

28.10.2022

Version:

4.0

91603-SUCROSE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1. Identification of the substance or preparation

Name: Sucrose

Bulk code: 91603

Internal code: 405148

1.2. Synonyms

Sugar, cane sugar, refined sugar.

2. DESCRIPTION

Appearance: Crystalline powder

Colour: White or almost white

Odour: Odourless

Geographical origin: France, Czech Republic and Romania

Origin: Plant (beet)

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS: [57-50-1]

EC: 200-334-9

Formula: $C_{12}H_{22}O_{11}$

Molecular weight: 342,3 g/mol

Method of production: This product is obtained through diffusion, purification, evaporation and crystallisation.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: It is soluble in water; slightly soluble in alcohol, absolute alcohol, propanol, methanol, glycerine and pyridine. Practically insoluble in chloroform and ether.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.



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The product satisfies the requirements of European legislation, in particular those of amended Directive (EC) 2001/111 relating to certain sugars intended for human consumption, transposed into French legislation by Decree 2003-586 of 30 June 2003.

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Sucrose should be stored in a cool, dry place, protected from sunlight in a tightly closed container, avoiding variations in moisture and temperature.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

No animal products are used nor are they likely to be used in the manufacturing process. Therefore, sucrose is compliant with the EMEA/410/01 guideline "Guidance for minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products". The product is derived from plant-based raw materials and the product does not come into contact with animal derivatives during the manufacturing process.

GMOs:

The sucrose we manufacture does not come from genetically modified organisms and, consequently, under current European regulations (Regulations (EC) 1829/2003 and 1830/2003), it is not necessary to label GMOs.

CMR:

The product is not considered a CMR substance.

NANOPARTICLES:

The product is not included in the following definitions, neither of artificial nanomaterials as set forth in Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers and in Regulation (EU) 2015/ 2283 of 25 November 2015 on novel foods, nor of nanomaterials as set forth in Regulation (EU) 1223/2009 of 30 November 2009 on cosmetic products. In addition, with regard to the specific national legislation in force in France, French Decree 2012-232 of 17 February 2012 establishes the content and conditions of the annual declaration of nanoscale substances pursuant to Article R. 523-4 of the Environmental Code. Therefore, the products are not affected by this French regulation and this mandatory declaration of nanoscale substances does not apply.



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IONISATION:

The product is not treated with ionisation/irradiation during the manufacturing process. Decree 2001-1097.

PRESERVATIVES/SWEETENERS:

The product is free of additives such as preservatives and sweeteners.

PESTICIDES:

The product is compliant with the requirements of the European Pharmacopoeia. Analyses performed on the final product show the absence of pesticides.

RESIDUAL SOLVENTS:

The concentration levels of residual solvents in the product comply with the European Pharmacopoeia, the ICH Q3C (R8) EMA/CHMP/ICH/213867/2020 Guideline for residual solvents and with the USP <467> on Residual Solvents.

ELEMENTAL IMPURITIES:

The finished product is not expected to contain the elemental impurities specified in ICH Q3D of 22/03/2019.

CONTAMINANTS:

- Mycotoxins: Manufacturing is subject to a Hazard Analysis Critical Control Point (HACCP) risk assessment. The results of the monitoring of the products and/or intermediates demonstrate that all mycotoxins tested, including aflatoxins and ochratoxin A, are below the regulatory limits defined in current European food legislation.
- Latex: The product is free of latex.
- Dioxins: Not expected to be present.
- Glycol ether: The product is free of glycol ether.
- Phthalates: Not expected to be present.
- Melamine: These are not used in the manufacturing process and thus are not expected to be present.
- Quaternary ammonium residues: The product is compliant with the limits set forth by the SCoFCAH in its latest version.
- Bisphenol A: The product does not contain bisphenol A according to Regulation (EU) 2018/213 of 12 February 2018.
- Nitrosamines: Due to the manufacturing process and the origin of the raw materials, these are not expected to be present.
- Antibiotics: No antibiotics are used in the manufacturing process.
- Heavy metals: The analyses performed on the final product show that the levels of heavy metals are below the maximum limits set forth by Regulation (EC) 1881/2006.
- Processing aids/technical aids: The final product may have the involuntary but technologically unavoidable presence of residues of technological aids or derivatives.
- Genotoxic impurities: The product does not contain genotoxic impurities.

CALIFORNIA PROPOSITION 65:

The product does not contain nor is it exposed to any of the chemicals listed in the Proposition.

91603-SUCROSE**ALLERGENS:**

Food allergens: European Union Regulation R1169/2011 on food information for consumers (INCO) specifies in its Annex II a list of substances or products that cause allergies or intolerances. The substances or ingredients listed must be mentioned and labelled in accordance with the terms of Article 21 of the aforementioned regulation.

Given this information, sucrose does not contain allergenic ingredients that require labelling.

HALAL:

The product is Halal compliant.

KOSHER:

The product is Kosher certified.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

NUTRITIONAL COMPOSITION:

Parameter	Per 100 g
Energy value	1700 KJ (400 kcal)
Saturated fat	0 g 0 g
Sugar carbohydrates	100 g 100 g
Protein	0 g
Salt	0 g

WADA:

The product does not contain or come into contact with any of the substances listed on the WADA list.

TESTED ON ANIMALS:

The product has not been tested on animals.

REACH:

Exempt.