PHARMASUGAR®
SUCRE SEMOULE TAMISÉ
"SIEVED POWDERED SUGAR"

DESCRIPTION

PHARMASUGAR® SUCRE SEMOULE TAMISÉ ("SIEVED POWDERED SUGAR") is obtained by successive sieving of sugar belonging to European Pharmacopeia Sucrose 01/2016 monograph. This high quality product with a small grain size spread is characterized by the size of its crystals. The screening does not alter the product complies with the European Pharmacopoeia. It is produced from French sugar beets, in French manufacturing site which is IPEC certified.

USES

PHARMASUGAR® SUCRE SEMOULE TAMISÉ is suitable for used every applications as excipient, for which sugar is used as sweet bulking agent.
For specific requirements for size, qualities PHARMASUGAR® SUCRE CALIBRES are recommended.

CHARACTERISTICS

PHYSICAL & CHEMICAL ACCORDING TO THE EUROPEAN PHARMACOPEIA

Parametres	Specifications	Analysis methode
Appearance	White cristals	ICUMSA GS2-13*
IR Identification spectrophotometre	Identical to the reference	European Pharmacopeia methode 2.2.24
Solubility	In water and ethanol	European Pharmacopeia methode
Appearance of the solution	Limpid	ICUMSA GS2/3-18*
Conductivity	≤ 35 µS.cm-1	ICUMSA GS2/3-17*
Optical rotation	+ 66,3 à + 67,0	ICUMSA GS2/3-1*
Color value	≤ 45 UI	ICUMSA GS2/3-10*
Reducing sugars	Absence	ICUMSA GS2/3/9-5*
Sulfites	≤ 10 ppm	ICUMSA GS2/3-35*
Loss on drying	≤ 0,1 %	ICUMSA GS2/1/3/9-15*

INDICATIVE GRAIN SIZE

(Indicative) Mean Aperture	0,30 to 0,50 mm	ICUMSA GS2/9-37*
Max on/sieve (%/mm)	2 / 0,8	-
Max under/sieve (%/mm)	5 / 0,125	

MICROBIOLOGY

Mesophilic bacteria	< 200 cfu/10g	ICUMSA GS 2/3-41*
Yeasts	< 10 cfu/10g	ICUMSA GS 2/3-47*
Moulds	< 10 cfu/10g	ICUMSA GS 2/3-47*

NUTRITIONNAL CHARACTERISTICS (PER 100g)

Energy	1700 kJ ; 400 kcal	Proteines	0 g
Carbohydrates	100 g	Fat	0 g
Carbohydrates of which Sugar	100 g	Fat of which Saturated Fatty Acids	0 g
		Salt	0 g

*Analysis methodes are adapted from the European Pharmacopeia (ICUMSA methodes equivalent or correlated with respect to Sucrose monograph).

COMPOSITION/INGREDIENTS

100% Sucrose

LABELLING

PHARMASUGAR® SUCRE SEMOULE TAMISÉ is to be included in the list of ingredients under the designation "sucrose".

www.cristalco.com

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S.A.S. au capital social de 2 558 700 euros – R.C.S. Paris B 348 119 728 – SIRET 348 119 728 00015 – N° T.V.A. – Intracommunautaire : FR 63 348 119 728

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BATCHES IDENTIFICATION

For packaged products it corresponds to the date of packaging and is composed as follows: **A U 7 SS J** (A = year, U = delivery centre, 7 = invariable figure, SS = week, J = 1 Monday, 2 Tuesday …or 0 = whole week).

PACKAGING

Bag	25 Kg net	Pallet of 900 Kg net	12 layers of 3 bags

Soft container (Big Bag with internal bag)	1000 Kg net
	1200 Kg net

PRESERVATION & USE CONDITIONS

Optimal storage is at a temperature of 15 to 25°C and a relative humidity below 65%.
Avoid all thermic shocks, contact with humid surfaces and strong-smelling products. Fine grain sugars are more subject to lumping.

SHELF LIFE / DATE OF MINIMUM DURABILITY

According to Directive 2000/13/EC on labelling, dry sugar is not subject to a "Best Before" (DLUO), nor a “date of minimum durability” (DDM) expiry date.

A stability study was carried out on three batches of PHARMASUGAR® SUCRE SEMOULE TAMISÉ. None non-compliance was detected during these analyses.

REGULATION / QUALITY GUARANTEES

PHARMASUGAR® SUCRE SEMOULE TAMISÉ:

- Is compliant to **European Pharmacopeia**; Sucrose monograph 01/2016: 0204
- Is a conventional product, not derived from **GMOs** according to regulations 1829/2003 and 1830/2003
- Has not undergone any **irradiation** treatment
- Is free of any ingredient in the form of manufactured **nanomaterials**
- Does not contain any of the **allergens** listed in the European regulation INCO UE N°1169/2011, ALBA, Ph.Eur. Monographie 1063
- Is compliant to regulation 396/2005 about maximum limits applicable to **pesticide** residues in or on foodstuffs
- Is compliant to Ph.Eur. 5.2.8: no risk of **TES-BSE** (bovine spongiform encephalopathy)

CERTFICATIONS

Cristal Union group manufacturing sites have set up a risk analysis according to HACCP method (based on *Codex Alimentarius*) and hold FSSC 22000, ISO 9001, ISO 14001, and ISO 50001 certifications.

Cristal Union group declared Sucrose substance as a Raw Material for Pharmaceutical Use to the ANSM (French agency for medicine and health products security). Cristalco has declared itself as a distributor of its raw material for pharmaceutical use to the ANSM. These statements are renewed every year.

PHARMASUGAR ® range products are produced and packaged on both sites of Bazancourt (FR) and Erstein (FR), IPEC certified.

Last update: 2018/09/10
The information found in this document is provided in good faith. In spite of efforts to ensure accuracy, we cannot accept legal responsibility for this information. This document may be updated without warning.

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