



CASTER SUGAR N°1 400
SUCROSE EP/USP-NF/JP

Definition α -D-Glucopyranoside, β -D-Fructofuranosyl
 $C_{12} H_{22} O_{11}$

CAS number [57-50-1]

Geographical origin France

Plant origin Beet root (*Beta vulgaris*)

Physical and chemical characteristics according to the harmonized “sucrose” monographs of currently applicable European Pharmacopoeia (EP), United States Pharmacopoeia (USP-NF) and Japanese Pharmacopoeia (JP)

Parameter	Unit	Pharmacopoeia standard	Tereos standard	Method
Characters				
Aspect	-	White or almost white crystalline powder or lustrous, colorless or white or almost white crystals		EP JP
Solubility	-	Very soluble in water, sparingly soluble in ethanol 96%, practically insoluble in anhydrous alcohol		EP JP
Identification: First identification, method A	-	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with the reference spectrum of sucrose CRS		EP 2.2.24 USP <197> JP 2.25
Assay				
Appearance of solution	-	Solution S is clear		EP 2.2.1
	-	Opalescence of solution \leq Opalescence of reference suspension 1		USP, JP
Conductivity	μ S/cm	Maximum 35 at 20 °C		EP 2.2.38 USP JP 2.51

P H A R M A C E U T I C A L E X C I P I E N T



Physical and chemical characteristics according to the harmonized “sucrose” monographs of currently applicable European Pharmacopoeia (EP), United States Pharmacopoeia (USP-NF) and Japanese Pharmacopoeia (JP) - *continued*

Parameter	Unit	Pharmacopoeia standard	Tereos standard	Method
Specific optical rotation	-	+ 66,3 to + 67,0		EP 2.2.7 USP <781> JP 2.49
Color value	ICUMSA	Maximum 45	Maximum 22,5	EP 2.2.25 USP JP 2.24
Reducing sugars	-	The blue color does not disappear completely		EP, USP, JP
Sulfites	ppm	Maximum 10 ppm calculated as SO ₂	Maximum 5 ppm calculated as SO ₂	EP, USP, JP
Loss on drying	%	Maximum 0,1	Maximum 0,06	EP 2.2.32 USP <731> JP 2.41

Physical and chemical characteristics according to Directive 2001/111/CE

Parameter	Unit	Standard	Method
Aspect/Type of color	Color-type unit	< 2	ICUMSA GS2-11 ou GS2-13
	European points	< 4	Conversion ICUMSA / European points
Coloration	ICUMSA	< 22,5	ICUMSA GS2-10
	European points	< 3	Conversion ICUMSA / European points
Ash	%	< 0,01	ICUMSA GS2-17
	European points	< 6	Conversion ICUMSA / European points
Total	European points	< 8	Total European points: aspect, coloration, ash parameters
Loss on drying	g%g	≤ 0,06	ICUMSA GS2-15
Polarization	g%g	≥ 99,7	ICUMSA GS2-1
Invert sugar	%	≤ 0,04	ICUMSA GS2-4 ou GS2-5
SO ₂	mg/kg	< 5	ICUMSA GS2-33 ou GS2-35

ICUMSA: International Commission for Uniform Methods of Sugar Analysis.

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Sieve characteristics

Mean aperture	microns	300 to 500	EP 2.9.12, USP <786>, JP 3.04 (ICUMSA GS2-37)
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ICUMSA: International Commission for Uniform Methods of Sugar Analysis.

Microbiological characteristics

Parameter	Unit	Standard	Method
Total plate count	CFU/10g	≤ 200	ICUMSA GS2 – 41
Yeasts	CFU/10g	≤ 10	ICUMSA GS2 – 47
Moulds	CFU/10g	≤ 10	ICUMSA GS2 – 47
Escherichia coli	CFU/g	< 1	NF ISO 16649 – 2

ICUMSA: International Commission for Uniform Methods of Sugar Analysis.

Nutritional characteristics

	For 100 g
Energy value	1700 kJ 400 kcal
Fat	0 g
of which saturates	0 g
Carbohydrates	100 g
of which sugars	100 g
Protein	0 g
Salt	0 g

Packaging

Bags (25 kg, 50kg) Big Bag Bulk

Pallets : ISPM15 treated (heat treatment) pallets

- . 80x120 lost pallets (non-returnable)
- . 100x120 lost pallets (non-returnable)



Storage conditions

Caster sugar n°1 400 must be stored avoiding moisture and temperature variations.

It is worthwhile to remind that crystallised sugar is considered as a very stable raw material and therefore is exempted from any date of minimum durability indication, according to European regulation 1169/2011, annex X.

Quality guarantees

RESIDUAL SOLVENTS Caster sugar n°1 400 complies with the requirements of the EMEA guide CPMP/ICH/283/95 "*Impurities: Guideline for Residual Solvents*" and with the requirements of currently applicable European, United States and Japanese pharmacopoeia.

METAL TRACES Caster sugar n°1 400 complies with the EMEA guide CHMP/SWP/4446/2000 "*Guideline on the specification limits for residues of metal catalysts or metal reagents*" and with the requirements of currently applicable European and United States pharmacopoeia.

GMO The caster sugar n°1 400 which we manufacture does not come from genetically modified organisms and consequently, by virtue of current European regulation (Regulations 1829/2003/CE and 1830/2003/CE), no labeling regarding GMOs is necessary.

GENOTOXIC IMPURITIES The caster sugar n°1 400 which we manufacture does not contain genotoxic impurities and is in full compliance with the requirements of the FDA guide "*Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches*" and with the requirements of the EMEA guide "*Guideline on the Limits of Genotoxic Impurities*".

BSE/TSE No product of animal origin is used or is likely to be used in the caster sugar n°1 400 which we manufacture. Therefore, caster sugar n°1 400 complies with the EMEA/410/01 guide "*Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*".



SAFETY DATA SHEET

We inform you that we do not establish any safety data sheet for caster sugar n°1 400. Indeed, this sheet requested by European and French regulations (REACH regulation 1907/2006/CE) specifically concerns toxic or dangerous substances or chemical preparations.

Caster sugar n°1 400 is therefore not concerned by these provisions, which was confirmed by the French Office of Technological Risks and of Chemical and Oil Industries, following a request made by our trade association, SNFS (French Sugar Manufacturer Union).

ALLERGENS

European Union regulation R1169/2011 on food information to consumers (INCO) specifies in annex II the list of substances or products causing allergies or intolerances. Substances or ingredients which are listed must be mentioned and labelled according to the terms of article 21 of the above mentioned regulation.

Considering this information, we declare that caster sugar n°1 400 does not contain allergenic ingredients requiring labelling.

TRACEABILITY

Our traceability management system respects GS1 standards. Each of the pallets we send bears at least one standard EAN 128 label with a Serial Shipping Container Code which makes the link with our production, storage and shipping operations.

This information is based on our knowledge at the date of issue of this document and is provided in good faith. This document supersedes all previous versions and is valid without signature. This product, its ingredients and its additives comply with French and European regulation. The conditions of use of this product can be limited in certain applications. It is the user's responsibility to ensure that the conditions for the use of the product are met, especially in view of legal and regulatory provisions in force.

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