

VIVASTAR® CS 200 Glucose

INCI: Glucose

PRODUCT REGULATORY INFORMATIONⁱ

Additives

VIVASTAR® CS 200 Glucose is free of any additive. It is not preserved, nor blended, flavoured, coloured, stabilized or diluted by any additive.

Aflatoxins

VIVASTAR® CS 200 Glucose complies with the European Food Law. VIVASTAR® CS 200 Glucose has been periodically tested for aflatoxins. Results are consistently less than 0.1 µg/kg.

Allergens / Fragrance

VIVASTAR® CS 200 Glucose is not made from and does not come in contact with the 26 potentially sensitizing fragrance ingredients in Annex III to Regulation (EC) No. 1223/2009 and its modifications during the manufacturing and packaging process.

Present	Absent	Allergen (Regulation (EC) No. 1169/2011, Annex II as amended) (FALCPA for USA)
	X	Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
	X	Crustaceans and products thereof
	X	Eggs and products thereof
	X	Fish and products thereof
	X	Peanuts and products thereof
	x	Soybeans and products thereof
	X	Milk and products thereof (including lactose)
	X	Nuts i.e. Almond (<i>Amygdalus communis</i>), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis</i>), Brazil nut (<i>Bertholletia excelsa</i>), Pistachio nut (<i>Pistacia vera</i>), Macadamia nut and Queensland nut (<i>Macadamia ternifolia</i>) and products thereof
	X	Celery and products thereof
	X	Mustard and products thereof
	X	Sesame seeds and products thereof
	X	Sulphur dioxide and sulphites at concentrations of more than 10 mg / kg or 10 mg / litre expressed as SO ₂
	X	Lupines and products thereof
	X	Molluscs and products thereof

Allergen (LeDa List 2.0 2011), absent (Recipe without / Does not intentionally contain):					
x	Milk	x	Chicken meat	x	Sesame
x	Lactose	x	Fish	x	Sesame oil
x	Egg	x	Crustaceans	x	Glutamate (E620 - E625)
x	Soy		Corn/maize	x	Sulphur dioxide and sulphites (E220 – E228) at concentrations of more than 10 mg/kg or 10 mg/L, expressed as SO ₂
x	Soy oil	x	Cocoa	x	Coriander
x	Gluten	x	Legumes	x	Celery
x	Wheat	x	Nuts	x	Carrot
x	Rye	x	Nut oil	x	Lupin
x	Beef	x	Peanuts	x	Mustard
x	Pork	x	Peanut oil	x	Molluscs

Animal Origin

The raw material of VIVASTAR® CS 200 Glucose is only from plant origin.

There is no contact with material of animal origin during manufacturing and packaging process.

Furthermore, no animal based processing aids are used during the production of VIVASTAR® CS 200 Glucose.

Batch Code

ENB20C10B

EN = product code
B = packaging type
20 = year of manufacture (2020)
C = month of manufacture (A-M, Skip I / C = March)
10 = week of manufacture
B = consecutive lot within campaign

Biodegradability

VIVASTAR® CS 200 Glucose is biodegradable. It is only from plant origin. The origin of the raw materials used for manufacturing dextrates is corn.

BSE / TSE

VIVASTAR® CS 200 Glucose is not made from and does not come into contact with products of human or animal origin. VIVASTAR® CS 200 Glucose and the starting materials do not come into contact with material of bovine, ovine or caprine origin during the manufacturing process. Therefore, VIVASTAR® CS 200 Glucose is free of any rich forms of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). VIVASTAR® CS 200 Glucose complies with the requirements of EMA/410/01.

California Proposition 65

VIVASTAR® CS 200 Glucose is tested for lead on a periodic basis using ICP-MS. The detection limit is 0.05 ppm. Results are typically less than the detection limit.

This information is intended to be used as a foundation of understanding upon which additional testing may be necessary. The data provided is for informational purposes only and is not meant to be a guarantee or specification.

Carbohydrates

VIVASTAR® CS 200 Glucose contains digestible carbohydrates.

CITES

(Convention on International Trade in Endangered Species of Wild Fauna and Flora)

VIVASTAR® CS 200 Glucose does not originate from any endangered plants and/or animals. The origin of the raw material used for manufacturing VIVASTAR® CS 200 Glucose is corn.

Colors

VIVASTAR® CS 200 Glucose does not contain any colors. It is not colored.

Composition and Origin

VIVASTAR® CS 200 Glucose is derived from plant sources. VIVASTAR® CS 200 Glucose is comprised mainly of dextrose with small amounts of starch oligosaccharides.

Country of Manufacture

VIVASTAR® CS 200 Glucose is manufactured in the USA.

Declaration

Food

VIVASTAR® CS 200 Glucose is recommended for declaration as “dried glucose syrup.” Please consider country-specific regulations for food.

Pharma

According to US FDA's Inactive Ingredients Database, VIVASTAR® CS 200 Glucose is recommended for declaration as “dextrates.” Please consider country-specific regulations for pharma.

Cosmetic

The INCI name of VIVASTAR® CS 200 Glucose is Glucose. Please consider country-specific regulations for cosmetic.

Dyes

VIVASTAR® CS 200 Glucose does not contain any dyes.

Enzymes

VIVASTAR® CS 200 Glucose is not processed with enzymes. Raw materials may be processed with enzymes.

Fats and Fatty Acids

VIVASTAR® CS 200 Glucose does not contain any kind of fats and fatty acids including any kind of plant or animal derived oil like ricinus oil (castor oil).

Flavors

VIVASTAR® CS 200 Glucose does not contain any flavor additives and/or flavor enhancers (e.g. glutamate, nucleotides). It is not flavored.

Food Compliance

Europe

The European Council classifies different kinds of sugars in Council Directive 2001/111/EC, including glucose syrup and dried glucose syrup. VIVASTAR® CS 200 Glucose is consistent with the Directive's definition of dried glucose syrup. Please consider country-specific regulations for food.

USA

VIVASTAR® CS 200 Glucose is considered to be Generally Recognized as Safe (GRAS) by the US Food and Drug Administration.

JECFA

Dextrates is defined as a food and not a food additive, therefore a JECFA (WHO) specification does not exist for VIVASTAR® CS 200 Glucose.

Fumigation

The raw material used for VIVASTAR® CS 200 Glucose production does not undergo any fumigation with ethylene oxide or methyl bromide during production.

Genotoxic Impurities

VIVASTAR® CS 200 Glucose does not fall under the scope of the Guideline on the limits of genotoxic impurities (ICH M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk) for new active substances or new applications for existing active substances, where assessment of the route of synthesis, process control and impurity profile does not provide reasonable assurance that no new or higher levels of genotoxic impurities are introduced as compared to products currently authorised in the EU containing the same active substance.

No known or potential genotoxic impurities have been identified.

Gluten

VIVASTAR® CS 200 Glucose does not contain gluten. VIVASTAR® CS 200 Glucose can be declared as gluten free according to EU classification reg. EC No. 1169/2011 based on reg. EC No. 178/2002.

GMO

Information for customers whose products comply with the European Union's food and feed regulations:

VIVASTAR® CS 200 Glucose is derived from corn that is not genetically modified. There is no labeling requirements for VIVASTAR® CS 200 Glucose according to the European Union Regulation on genetically modified food and feed (EU 1829/2003) and European Union Regulation concerning traceability and labeling of food and feed products from genetically modified organisms (EU 1830/2003).

GMP Compliance

The Quality System of the manufacturing sites is based on the

- GMP regulations issued by WHO and/or
- GMP regulations for Excipients issued by IPEC Europe and IPEC USA, and published in the USP.

The system is described in documents. The manual contains e.g.:

- organization and job descriptions,
- GMP training for employees,
- internal audit program,
- specifications and test methods for raw materials, IPC, and finished products,
- manufacturing procedures and general SOPs for cleaning, calibration, maintenance, sanitation and housekeeping,
- programs for validation, change control, OOS,
- environmental related SOPs and pest control program.

The execution of all programs and SOPs is documented.

Every year several international customers audit the manufacturing sites.

Because the GMP regulations for excipients have no mandatory character in the European Union, USA and China, governmental authorities are not obliged to inspect the site. There is no regulatory GMP guideline or directive in the European Union, USA and China that applies to excipients; therefore, certification by health authorities is not possible in these countries.

GRAS

Dextrates is considered GRAS (Generally Recognized as Safe).

Halal

VIVASTAR® CS 200 Glucose is halal approved for JRS Pharma LP, USA by IFANCA.

Heavy Metals

Elemental impurities analysis of VIVASTAR® CS 200 Glucose is conducted periodically, and includes analysis for arsenic, cadmium, lead and mercury. A standard elemental impurities statement is available upon request.

Hormones

VIVASTAR® CS 200 Glucose does not contain any active hormones.

Impurities

VIVASTAR® CS 200 Glucose is free of:

Diethylene glycol

Dioxin

Gelatin

Metal catalysts

Polycyclic aromatic hydrocarbons

Rubber

Inactive Ingredients Database

VIVASTAR® CS 200 Glucose is listed as dextrates in the Inactive Ingredients Database published by the United States Food and Drug Administration.

Irradiation

There is no irradiation associated with the manufacture, packaging, or storage of VIVASTAR® CS 200 Glucose including the raw materials and the packaging materials.

Kosher

VIVASTAR® CS 200 Glucose is certified as kosher for JRS Pharma LP, USA by OK Kosher.

Latex

VIVASTAR® CS 200 Glucose does not contain any latex.

Manufacturing Authorization / Licence

A manufacturing authorization/license to manufacture excipients is not required in USA. Manufacturing licences and GMP Certifications are only issued to drug manufacturing facilities. As a result, JRS Pharma LP does not have a manufacturing license.

Melamine

It can be assumed that due to internal production processes and the properties of the raw material, VIVASTAR® CS 200 Glucose does not contain melamine.

Microplastic

According to the European Chemicals Agency (ECHA), Annex XV Restriction Report (Proposal for a Restriction: Substance Name(s): intentionally added microplastics) of 20 March 2019, we hereby confirm that VIVASTAR® CS 200 Glucose does not fall under the definition of "microplastics."

Mycotoxins

Due to the knowledge of the raw material, production process and equipment of VIVASTAR® CS 200 Glucose we consider the risk for a contamination with aflatoxins and mycotoxins is very low. VIVASTAR® CS 200 Glucose complies with the Commission Regulation (EC) No 1881/2006, as amended. Individually products are not necessarily tested.

Nagoya Protocol

VIVASTAR® CS 200 Glucose is in compliance with Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

Nanomaterial

According to EU Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers VIVASTAR® CS 200 Glucose does not contain "nanomaterials." According to the Recommendation of the 18 October 2011 (EU) No 2011/696 "nanomaterial" means a natural, incidental or manufactured

material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm.

Nitrosamines

Due to the knowledge of the raw material, production process and equipment of VIVASTAR® CS 200 Glucose, we consider the risk for a contamination with nitrosamines can be excluded.

Nutritional Values

EU Regulation

According to the Regulation (EC) No. 1169/2011 the nutritional labelling requires the following data:

For VIVASTAR® CS 200 Glucose the following values apply*¹:

VIVASTAR® CS 200 Glucose (values per 100 g):

Calorific value	381 kcal or 1594 kJ/100 g* ³
Protein	<0.781 g
Usable carbohydrate* ²	94.3 g
Sucrose	< 0.1 g
Glucose	93.7 g
Fructose	<0.1 g
Fat	0.01 g
Saturated fatty acids	0.01 g
Unsaturated fatty acids	0.0 g
Dietary fiber* ⁴	1.4 g
Sodium	< 0.003 g

*¹ As it is a natural product the values can slightly vary.

*² Calculated

*³ Within the European Union due to directive 2008/100/EC dietary fibers have to be calculated with 2 kcal/g - 8 kJ/g.

From 31 October 2012 no trade is allowed with products which do not comply with this directive.

*⁴ The dietary fiber content in the dried matter is min 1.4%.

Organization and calculation of the nutrition declaration is based on the European law Regulation (EU) No 1169/2011 with Annex XV – Expression and Presentation of Nutrition Declaration – and Annex XIV – Conversion Factors (dietary fibers calculated with 8 kJ/g or 2 kcal/g).

For nutrition claims made on foods in the European Union please consider Regulation (EC) No 1924/2006 – Annex “Nutritional claims and conditions applying to them.”

Source of fiber: 3 g/100 g or 1.5 g/100 kcal

High fiber: 6 g/100 g or 3 g/100 kcal

The above-displayed data are based on JRS monitoring following the regulatory requirements of regulation (EU) No 1169/2011 and the EC Publication / December 2012 “Guidance to the setting of tolerances for nutrient values declared on a label.”

US Regulation

Calories are calculated per 21 CFR 101.9(c)(1)(i)(C).

VIVASTAR® CS 200 Glucose (Avg. Units per 100 g):

Carbohydrates	91.2%
Carbohydrates, Available	90.2%
Calories	365 calories/100 g
Calories from Fat	0 calories/100 g
Calories from Saturated Fat	0 calories/100 g
Calories (Insoluble Fiber Subtracted)	361 calories/100 g
Calcium	<1.00 mg/100 g
Iron	<1.00 mg/100 g
Sodium	<3.00 mg/100 g
Potassium	<3.00 mg/100 g
Ash	<0.012%
Moisture	8.761%
Total Fat	0.01%
Saturated Fat	0.01%
Monounsaturated Fat	0.00%
cis-cis Polyunsaturated Fat	0.00%
trans Fat	0.00%
Protein	<0.781%
Insoluble Fiber	1.0%
Soluble Fiber	0.4%
Total Fiber	1.4%
Fructose	Less than 0.1%
Glucose	93.7%
Sucrose	Less than 0.1%
Maltose	0.167%
Total Sugars	93.9%

Note: The nutritional values reported are calculated based on the newest available data at the time of calculation. This information is provided for preliminary calculation only. The finished product should be analyzed for accurate labeling purposes.

Packaging

VIVASTAR® CS 200 Glucose is supplied in packaging which complies with the current food law requirements. The packaging corresponds with the regulations (EC) No 1935/2004, No 10/2011 as amended, and US 21 CFR 174.

Palm Oil and Palm Derivatives

Palm oil or palm derivatives are not used for the production of the raw materials or for further process steps.

Pesticides

Pesticide levels in VIVASTAR® CS 200 Glucose are below the statutory requirements regarding the guidance levels and limits of pesticides according to regulation (EC) No 396/2005 as amended.

Phthalates

Phthalates are not used or produced in the manufacture of VIVASTAR® CS 200 Glucose.

Preserving Agents

VIVASTAR® CS 200 Glucose does not contain any preserving agents (e.g. sorbic acid, benzoic acid) and/or antioxidants (e.g. BHA/BHT). It is not preserved.

Process Description

VIVASTAR® CS 200 Glucose is spray crystallized dextrates containing small amounts of starch oligosaccharides. The macroporous spheres have a median particle size of 190 to 220 µm.

Proteins and Amino Acids

VIVASTAR® CS 200 Glucose does not contain any proteins or amino acids such as leucine, phenylalanine, cysteine, glutamic acid or aspartic acid.

Quality Management Certificates

Manufacturing site JRS Pharma LP, USA is ISO 9001:2015 and FSSC 22000 certified.

REACH

J.Rettenmaier & Söhne recognizes the requirements on substances used in medicinal products according to the REACH legislation.

Article 2.5 (a) of the regulation stipulates that –

“The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used: (a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.”

Based on the above article, it is our understanding that both active and inactive ingredients (excipients) are within the scope of this exemption.

If there is a change in the REACH Status of the above product, we will keep you informed and will register the product if it is then necessary.

Re-evaluation / Expiration

When stored as recommended, VIVASTAR® CS 200 Glucose has a recommended re-evaluation period of 3 years from the date of manufacture. An additional year can be added if the results for loss on drying and pH are within specifications and will remain within specification throughout the specified extension interval based on product trends.

Residual Solvents and Organic Volatile Impurities

The raw materials, manufacturing process and product do not contain any of the Class 1, Class 2 or Class 3 solvents listed in Residual Solvents USP<467>, Ph. Eur. <5.4> and ICH Q3C.

Site of Manufacture and Storage

VIVASTAR® CS 200 Glucose is manufactured, finally packed and tested for J.Rettenmaier & Söhne GmbH + Co.KG by:

JRS Pharma LP
A member of the JRS Group
725 41st Ave Dr SW
Cedar Rapids, IA, 52404
USA

VIVASTAR® CS 200 Glucose is owned by J.Rettenmaier & Söhne GmbH + Co.KG and therefore we reserve the rights to provide all relevant documents to our customers.

The labeling includes the following information:

- J.Rettenmaier & Söhne GmbH + Co.KG name and address
- INCI name and brand name
- Lot number
- Manufacturing date
- Re-evaluation date
- Gross and net weight
- Manufacturing location

J.Rettenmaier & Söhne GmbH + Co.KG issues a CoA based on a final quality control and release by the Quality department of the plant.

VIVASTAR® CS 200 Glucose is stored at:

JRS Pharma LP
A member of the JRS Group
725 41st Ave DR SW
Cedar Rapids, IA, 52404
USA

JRS Distribution Centre
Microcellulose Weissenborn GmbH & Co KG
A member of the JRS Group
Freiberger Str. 7
09600 Weissenborn
Germany

VIVASTAR® CS 200 Glucose is not re-packaged, or re-labeled.

Stabilizer

VIVASTAR® CS 200 Glucose does not contain any stabilizers. It is not stabilized.

Starches and Starch Derivatives

VIVASTAR® CS 200 Glucose is a derivative of starch.

Storage Recommendations

VIVASTAR® CS 200 Glucose should be stored in original, unopened, well-closed containers protected from excessive heat and moisture.

Bags should be sealed and drum tightly secured when the entire contents of the package are not used.

Substances of Very High Concern (SVHC)

VIVASTAR® CS 200 Glucose does not contain any substances of very high concern above 0.1%, substances listed on annex XIV, submitted to authorization, or listed on the candidate list published by ECHA, which we regularly follow the updates.

Sugars and Sugar Derivatives

VIVASTAR® CS 200 Glucose contains mono- and disaccharides such as sugar, lactose, glucose, maltose, fructose.

Suitability for Vegan and Ovo-Lacto-Vegetarians

VIVASTAR® CS 200 Glucose is suitable for vegans and ovo-lacto-vegetarians.

Test on Animals

VIVASTAR® CS 200 Glucose has not been tested on animals and no animal testing is planned.

Toxic, Narcotic and Psychotropic Status

VIVASTAR® CS 200 Glucose does not contain any toxic, narcotic or psychotropic sources and does not contain any additive/excipient obtained from toxic, narcotic or psychotropic sources.

TUP (Technically Unavoidable Particles) According to Guidance from IPEC 2015

Burnt/charred particles can occur during the manufacturing of dextrates. Product accumulates on the wall of the spray dryer; it browns/chars in the heat and can potentially break free from the spray dryer wall. These dark particles are cosmetic defects only and have no detrimental effect on final product quality.

Viral Safety

Potential sources of virus contamination (ICH Q5A (R1) - Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin):

Viral contamination of biotechnology products may arise from the original source of the cell lines or from adventitious introduction of virus during production processes.

VIVASTAR® CS 200 Glucose is not a biotechnology product, therefore there is no risk for viral contamination.

WADA

VIVASTAR® CS 200 Glucose is not contaminated with banned substances and does not come into contact with banned substances.

VIVASTAR® CS 200 Glucose is a registered trademark of J. Rettenmaier & Söhne GmbH & Co. KG.

ⁱ Disclaimer:

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however, we do not assume any liability whatsoever for the accuracy and completeness of the above information.

VIVASTAR® CS 200 Glucose is not a cosmetic product in the sense of 1223/2009/EC. It is within the responsibility of the producer of a cosmetic product to proof the suitability of an ingredient for the final application.