

C☆PharmSorbitol NC 16205

DESCRIPTION

Aqueous solution of D-sorbitol, containing also hydrogenated oligosaccharides.

RAW MATERIAL

Corn (Maize)

PRODUCT LABEL

Package labelling Sorbitol syrup

FOR PHARMACEUTICAL USE

NOT FOR RETAIL SALE WHEN USED AS FOOD ADDITIVE

PRODUCT CLASSIFICATION

CN Code (Valid for EU 28) 3824 60 19

E No E 420 (ii)

Country of Origin

Germany

Italy

SPECIFICATIONS

Chemical/physical specifications

Parameter		Unit	Min	Typical	Max	Text
Dry substance	-	%	69.8		70.9	
Mannitol	on d.b.	%	2		6	
Sorbitol	on d.b.	%	74		79	
Reducing sugars	on d.b.	%			0.2	

European Pharmacopoeia

Parameter		Unit	Min	Typical	Max	Text
Identification A	Ph.Eur. HPLC					pass test
Identification B	Ph.Eur. angle of rot.	°	1.5		3.5	
Identification C	Ph.Eur. vis.aspect					pass test
Appearance of solution	Ph.Eur.					pass test
Conductivity	Ph.Eur.	µS/cm			10	
Reducing sugars	Ph.Eur.	ml	12.8			
Red.sugars after hydrolysis	Ph.Eur.	ml	8			
Water	Ph.Eur.	%	28		32	
Sorbitol, assay	Ph.Eur. on d.b.	%	72		92	
Tot. aerobic microbial count	Ph.Eur. /g				1000	
Tot. combined yeasts/moulds coun	Ph.Eur. /g				100	
E. coli	Ph.Eur. /g					absent
Lead	Ph.Eur.	ppm			0.5	
Nickel	Ph.Eur.	ppm			1	

United States Pharmacopoeia / National Formulary

Parameter		Unit	Min	Typical	Max	Text
Identification A	USP/NF catechol					pass test
Identification B	USP/NF HPLC					pass test
Identification C	USP/NF DEG and EG	%			0.1	
pH	USP/NF		5		7.5	
Water	USP/NF	%	28.5		31.5	
Residue on ignition	USP/NF on d.b.	%			0.1	
Red. sugars	USP/NF on d.b.	%			0.3	
Sorbitol, assay	USP/NF	%	45			
Tot. aerobic microbial count	USP/NF /g				1000	
Tot. combined yeasts/moulds count	USP/NF /g				100	
E. coli	USP/NF /g					absent
Nickel	USP/NF on d.b.	ppm			1	

Allergens (Legal directives)
Allergen information

	Presence	Comment
Wheat and products thereof	No	
Cereals containing gluten and products thereof	No	
Crustaceans and products thereof	No	
Eggs and products thereof	No	
Fish and products thereof	No	
Peanuts and products thereof	No	
Soybeans and products thereof	No	
Milk and products thereof (including lactose)	No	
Nuts and products thereof	No	
Celery and products thereof	No	
Mustard and products thereof	No	
Sesame seeds and products thereof	No	
Sulphur dioxide and sulphites	No	** SO2 <10 ppm
Lupins and products thereof	No	
Molluscs and products thereof	No	

The above list of allergens is in accordance with Annex II of Regulation (EU) n° 1169/2011 on food information to consumers

The above list of allergens is in accordance with Food Allergen Labeling and Consumer Protection Act (FALCPA)

The above list of allergens is in accordance with Health Canada, the Canadian Food Inspection Agency (CFIA)

** Sulphur dioxide <10ppm allergen labelling not required according to Annex II of Regulation (EU) n° 1169/2011 on food information to consumers.

Dietary information

Suitable for		Certified	Comment
Halal	Yes	Yes	
Kosher	Yes	Yes	
Lacto-vegetarian	Yes	No	
Ovo-vegan	Yes	No	
Vegan	Yes	No	
Vegetarian	Yes	No	

GMO statement

For its operations in Europe, Cargill complies with the EU GMO requirements as principally laid down under EC Regulation No 1829/2003 on 'genetically modified food and feed' and EC Regulation No 1830/2003 on 'the traceability and labelling of food and feed products produced from GMO's'. By ensuring the supply of conventional ingredients in the EU, Cargill thus ensures that there is no need to label its products under either 1829/2003 or 1830/2003.

Legal requirements

Zusatzstoff-Verkehrsverordnung

The current United States Pharmacopoeia / National Formulary version

Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008.

Where manufactured in the EU this product is in compliance with Regulation (EC) 1333/2008 and subsequent amendments - on food additives.

Directive 94/35/EC and their amendments - sweeteners for use in foodstuffs

Current JECFA Monograph

Commission Regulation (EU) No 724/2013 amending Regulation (EU) No 231/2012 as regards specifications on several polyols.

INCI: Sorbitol or Hydrogenated Starch Hydrolysate

This product is in compliance with:

Aflatoxin VerbotsV

Rückstandshöchstmengenverordnung (RHmV)

The current European Pharmacopoeia version

Current Food Chemical Codex

STANDARD PACKAGING

Bulk

Drums

Intermediate Bulk Container (IBC)

RECOMMENDED STORAGE CONDITIONS

Store above 5°C to prevent crystallization

SHELF LIFE FOR PACKED PRODUCT

Shelf life after production date (months): 24

Minimum remaining shelf life after delivery (months): 6

FUNCTIONALITY

Clear and colourless non-crystallising sorbitol syrup with a pleasant sweet taste. It is a reduced calorie and non-cariogenic bulk sweetener and has humectant and bodying characteristics.

Excessive consumption may produce laxative effects.

APPLICATION

Liquid dosage formulations:

- Non-cariogenic bulking agent for sugar-free solutions and syrups
- Anti-crystallising agent
- Stabiliser for drugs and vitamins in suspensions

Medicated confectionery:

- Chewing gum

Topical preparations:

- Emollient and humectant in emulsions

Humectant and plasticiser in toothpaste and gels

Plasticiser in capsules

Country of origin definition:

Country of Origin or product origin is defined as the country where the material was manufactured/produced/cultivated.

When the material undergoes substantial transformation in a second country, the country in which the transformation is performed shall be considered the country of origin.

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C★PharmSorbidex NC 16205

Nutritional Information					
Average values per 100g	Unit	EU	US	Japan	Comment
Energy (kcal)	kcal	169			
Energy (kJ)	kJ	704			
Protein	g	0			
Carbohydrates	g	70			
of which sugars	g	0			
of which starch	g	0			
of which polyols	g	70			
of which dietary fibre	g	0			
Fat	g	0			
of which saturated	g	0			
of which Trans Fat	g	0			
Cholesterol	mg	0			
Sodium	mg	0			
Salt	mg	0			
Calcium	mg	0			
Iron	mg	0			
Potassium	mg				
Vitamin C	mg	0			
Water	g	30			
Ash	g	0			

The list comprises relevant nutritional components only.

Values are calculated based on the average of product specifications. In those cases where only a minimum or a maximum value is specified, these values were taken respectively.

The EU column lists the nutritional values in accordance with Regulation (EU) n° 1169/2011 on food information to consumers.

The US column lists the nutritional values in accordance with Code of Federal Regulations (CFR 21).

The Japan column lists the nutritional values in accordance with the Japanese Legislation.

The energy values may differ per region because of different calculations.



Allergen control

Maize & sugar derived products

Starches & Sweeteners Europe

Krefeld - Germany

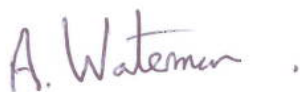
Herewith we confirm that our Cargill location located at Krefeld, in Germany, processes maize and sugar as raw materials.

Maize and sugar based products are not subject to EU allergen labelling requirements, as set under EU Regulation 1169/2011, as neither material is identified as gluten containing cereals under EU food law.

Product integrity is assured through manufacturing policies, including process HACCP evaluations, and process control mechanisms. These policies and processes cover all stages of product manufacture from raw material through to finished product storage and customer delivery.

The only allergen, based upon Regulation 1169/2011, used at Krefeld, is sulphur dioxide. Sulphur dioxide is used as a processing aid in the processing of maize and can also, at customer request, be added to the glucose and/or glucose-fructose syrups manufactured at this location. To ensure the sulphur dioxide content of our glucose and glucose-fructose starches and syrups are controlled, all loads of food grade starch, glucose and glucose-fructose syrups are positively released to either the customer specified sulphur dioxide range or have a maximum level of 10 mg/kg. Where the sulphur dioxide content is higher than 10 mg/kg, this will be recorded on the product Certificate of Analysis and included in the product specification.

This statement will be reviewed within 15 months.



Andrew Waterman
Food Safety, Quality & Regulatory

Claims: The labeling, substantiation and decision making of all claims for your products is your responsibility. We recommend you consult regulatory and legal advisors familiar with all applicable laws, rules and regulations prior to making labeling and claims decisions.

Contact

Cargill Starches & Sweeteners Europe

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February 2017

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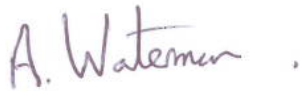


Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE)

Starches & Sweeteners Europe

Cargill Starches & Sweeteners Europe can confirm that there is no use of any raw materials of animal origin in its production processes, either through the source raw materials, or through the use of processing aids. Neither is it expected, on the basis of Cargill's current scientific and technical understanding, that materials of animal origin would be present in Cargill SSE products, be it as a result of external contamination nor as a by-product of the production process. Cargill SSE does not specifically test its products to determine the remote possibility that trace amounts of animal raw materials may be present as a result of extraneous environmental contamination as the company is not aware of any data indicating that such testing is warranted today.

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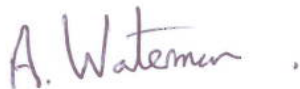


Latex

Starches & Sweeteners Europe

Cargill SSE can confirm that there is no direct use of latex in its production process for its products, either through the source raw materials, or through the use of processing aids. Neither is it expected, on the basis of Cargill's current scientific and technical understanding, that latex would be present in Cargill SSE products, be it as a result of external contamination nor as a by-product of the production process. Cargill SSE does not specifically test its products to determine the remote possibility that trace amounts of latex may be present as a result of extraneous environmental contamination as the company is not aware of any data indicating that such testing is warranted today.

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Latex
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