

C☆PharmSorbitol NC 16205

DESCRIPTION

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

This product is produced from maize in Italy and Germany until autumn 2021. From autumn 2021 onwards product from Germany will only be produced from wheat.
Product from Italy will continue to be produced from maize.

RAW MATERIAL

Corn (Maize)

Wheat

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 count	Ph.Eur. /g				100	
E. coli	Ph.Eur. /g					absent

Above mentioned European Pharmacopoeia parameters are not measured for every lot, but on monitoring basis. When tested, results are within the specified limits listed.

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	

Above mentioned United States Pharmacopoeia / National Formulary parameters are not measured for every lot, but on monitoring basis. When tested, results are within the specified limits listed

Allergens (Legal directives)
Allergen information

	Presence	Comment
Cereals containing gluten and products thereof	No	* gluten <20 mg/kg
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	** SO ₂ <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.

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

* Wheat-based glucose syrups including dextrose, wheat-based maltodextrins and products thereof (such as polyols) are exempted from allergen labelling 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

The current version of ICH guideline Q3D on elemental impurities (INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE)

The current European Pharmacopoeia version

The current United States Pharmacopoeia / National Formulary version

Zusatzstoff-Verkehrsverordnung

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

Rückstandshöchstmengenvorordnung (RHmV)

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

Current Food Chemical Codex

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

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

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.

Disclaimer:

This document is provided for your information and convenience only. All information, statements, recommendations and suggestions are believed to be true and accurate under local laws but are made without guarantee, express or implied. WE DISCLAIM, TO THE FULLEST EXTENT PERMITTED BY LAW, ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE and FREEDOM FROM INFRINGEMENT and disclaim all liability in connection with the storage, handling or use of our products or information, statements, recommendations and suggestions contained herein. All such risks are assumed by you/user. The labeling, substantiation and decision making relating to the regulatory approval status of, the labeling on and claims for your products is your responsibility. We recommend you consult regulatory and legal advisors familiar with applicable laws, rules and regulations prior to making regulatory, labeling or claims decisions for your products. The information, statements, recommendations and suggestions contained herein are subject to change without notice.

C★PharmSorbidex NC 16205

Nutritional Information					
Average values per 100g	Unit	EU	US	Japan	Comment
Energy (kcal)	kcal	169	144		
Energy (kJ)	kJ	704	612		
Protein	g	0	0		
Carbohydrates	g	70	70		
of which sugars	g	0	0		
of which starch	g	0	0		
of which polyols	g	70	70		
of which dietary fibre	g	0	0		
Fat	g	0	0		
of which saturated	g	0	0		
of which Trans Fat	g	0	0		
Cholesterol	mg	0	0		
Sodium	mg	0	0		
Salt	mg	0	0		
Calcium	mg	0	0		
Iron	mg	0	0		
Potassium	mg		0		
Vitamin C	mg	0			
Vitamin D	mcg		0		
Water	g	30	30		
Ash	g	0	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.