

C☆PharmGel 03302

DESCRIPTION

Maize starch in the form of an odourless and tasteless, intense white-coloured powder obtained from a special white maize hybrid.

RAW MATERIAL

Corn (Maize)

PRODUCT LABEL

Package labelling Maize starch

Ingredients [Listed in Descending Order] Starch

PRODUCT CLASSIFICATION

CN Code (Valid for EU 28) 1108 12 00

Country of Origin

Netherlands

SPECIFICATIONS

Chemical/physical specifications

Parameter		Unit	Min	Typical	Max	Text
Bulk Density	loose	g/l	440		560	
Bulk Density	packed	g/l	610		730	

European Pharmacopoeia

Parameter		Unit	Min	Typical	Max	Text
Identification A	Ph.Eur. microsc.					pass test
Identification B	Ph.Eur. boil test					pass test
Identification C	Ph.Eur. Iodine					pass test
Foreign matter	Ph.Eur.					pass test
Loss on drying	Ph.Eur.	%			15	
pH	Ph.Eur.		4		7	
Sulphated ash	Ph.Eur.	%			0.6	
Sulphur dioxide	Ph.Eur.	ppm			50	
Oxidising substances	Ph.Eur.	ppm			20	
Tot. aerobic microbial count	Ph.Eur. /g				1000	
Tot. combined yeasts/moulds count	Ph.Eur. /g				100	
E. coli	Ph.Eur. /g					absent
Salmonella	Ph.Eur. /10g					absent
Iron	Ph.Eur.	ppm			10	

United States Pharmacopoeia / National Formulary

Parameter		Unit	Min	Typical	Max	Text
Identification A	USP/NF microsc.					pass test
Identification B	USP/NF boil test					pass test
Identification C	USP/NF Iodine					pass test
Loss on drying	USP/NF	%			15	
Oxidizing substances	USP/NF	µg/g			20	
pH	USP/NF		4		7	
Residue on ignition	USP/NF	%			0.6	
Sulfur dioxide	USP/NF corn starch	µg/g			50	
Tot. aerobic microbial count	USP/NF /g				1000	
E. coli	USP/NF /g					absent
Tot. combined yeasts/moulds count	USP/NF /g				100	
Iron	USP/NF corn starch	µg/g			10	

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	Internal specification SO2 <10mg/kg
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

The current European Pharmacopoeia version

The current United States Pharmacopoeia / National Formulary version

This product is in compliance with:

The current Japanese Pharmacopoeia version

STANDARD PACKAGING

Paper Bags

Polyethylene bags

RECOMMENDED STORAGE CONDITIONS

Store inside, under dry conditions

SHELF LIFE FOR PACKED PRODUCT

Shelf life after production date (months): 36

Minimum remaining shelf life after delivery (months): 6

FUNCTIONALITY

- acts as a hydrophilic polymer that swells on contact with water
- When heated in an aqueous environment, gelatinises and forms a smooth gel with excellent binding properties.
- is compatible with most excipients and drugs.

APPLICATION

Solid dosage formulations:

- Diluent in direct compression and wet and dry granulation
- Diluent in capsule and powder formulations
- Binder for wet granulation (cooked at 5 - 25 % w/w)
- Disintegrating agent at 3 -15 % w/w

Topical preparations:

- Base for dusting powders
- Protective covering in ointment formulations

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:

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C★PharmGel 03302

Nutritional Information					
Average values per 100g	Unit	EU	US	Japan	Comment
Energy (kcal)	kcal	353	353	353	
Calories from Fat	kcal		0		
Energy (kJ)	kJ	1500	1500	1500	
Protein	g	0.3	0.3	0.3	
Carbohydrates	g	88	88	88	
of which sugars	g	0	0	0	
of which starch	g	88	88	88	
Dietary Fiber	g				
Fat	g	0.1	0.1	0.1	
of which saturated	g	0	0	0	
of which Trans Fat	g	0	0	0	
Cholesterol	mg	0	0	0	
Sodium	mg	10	10	10	
Salt	mg	25	25	25	
Calcium	mg	5	5	5	
Iron	mg	0.2	0.2	0.2	
Vitamin A	IU	0	0	0	
Vitamin C	mg	0	0	0	
Water	g	12	12	12	
Ash	g	0.1	0.1	0.1	

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.



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

Cargill Texturizing Solutions – Starches & Derivatives

Cargill can confirm that there is no use of any raw materials of animal origin in the production processes of its starches and derivatives 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 materials of animal origin would be present in Cargill starchy products, be it as a result of external contamination nor as a by-product of the production process. Cargill 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.

This statement will be reviewed within 15 months.

Food Safety, Quality & Regulatory Management

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 Texturizing Solutions

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BSE/TSE – Starches & Derivatives
July 2016

Page 1 of 1
Version 4





Latex

Starches & Derivatives

CTS Starches Europe can confirm that there is no direct use of latex in its production process, 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 CTS Starches products, be it as a result of external contamination nor as a by-product of the production process. CTS Starches Europe 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.

This statement will be reviewed within 15 months.

Food Safety, Quality & Regulatory Management

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.*

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Latex – Starches & Derivatives - EMEA
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Page 1 of 1
Version 12

