

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 | |

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

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)

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

Status pursuant to USDA 7 CFR Part 66 National Bioengineered Food Disclosure Standard ("BE" status):

The product has been sourced from a non-bioengineered source and the inadvertent presence of BE is less than 0.9%.

The current United States Pharmacopoeia / National Formulary version

The current Japanese Pharmacopoeia version

This product is in compliance with:

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

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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