# 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 coun | 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 coun | USP/NF /g | | | | 100 | |
| Iron | USP/NF corn starch | µg/g | | | 10 | |

## Allergens (Legal directives)

### Allergen information

| | Presence | Comment |
|---|---|---|
| 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 the European Food Labeling Directive 2000/13/EC as amended.

## 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.

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