

## FARMAL™ 2I T

### 1. Product identity

<b>INCI Name</b>	TAPIOCA STARCH
<b>Chemical name</b>	Mixture of amylose and amylopectin
<b>Description</b>	Bleached native tapioca starch
<b>Intended function</b>	Carrier for actives; Mitigates oiliness; Aesthetic enhancer
<b>Appearance</b>	White fine powder
<b>CAS number</b>	9005-25-8
<b>EC number</b>	232-679-6
<b>Source</b>	Tapioca tuber
<b>Manufacturing Country of Origin</b>	Thailand
<b>Manufacturing process</b>	General description: Milling of tapioca tuber to extract starch Manufacturing process flow available on request
<b>Manufacturing Quality System</b>	FFC 22000 and ISO 9001
<b>Shelf life/Storage</b>	2 years from manufacture. Store in a clean, dry, well ventilated warehouse away from odorous materials. Store at ambient temperature. Store away from heat, sparks, or other flame sources. Keep product dry.

### 2. Composition and Impurities

The composition given below illustrates the typical composition of this product and should not be considered to be a formulation specification:

CAS Number	INCI Name	Chemical Name	Typical concentration	Function	Origin
9005-25-8	TAPIOCA STARCH	Mixture of amylose and amylopectin	87-91%	Key	Natural
7732-18-5	AQUA	Water	9-13%	Residual moisture	Natural
7681-57-4	SODIUM METABISULPHITE	Disodium disulphite	<0.001% SO <sub>2</sub>	Residual processing aid	Synthetic
7722-84-1	HYDROGEN PEROXIDE	Hydrogen peroxide	<0.002% Residual oxidants	Residual processing aid	Synthetic

Effective Date: 01.06.2016 [1]

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### 3. Regulatory Status

#### EU Cosmetics Regulation (EC) No 1223/2009:

**Annex II:** Not expected to contain prohibited substances listed in Annex II of this Regulation

**Annex III:** Not expected to contain restricted substances listed in Annex III of this Regulation, including the 26 allergens as defined in the 7th Amendment of the European Cosmetics Directive (2003/15/EC)

This product does not contain colorants or UV filters. Sodium metabisulphite and hydrogen peroxide are used as processing aids during the extraction of the starch. The maximum residuals of sulphur dioxide and oxidants in this product are 10 ppm (0.001%) and 20 ppm (0.002%) respectively.

Additionally, this product does not contain substances classified as Carcinogenic, Mutagenic or toxic to Reproduction (CMR) according to CLP Regulation (EC) No 1272/2008.

#### Allergens

As stated above, this product is not expected to contain the 26 allergens defined in the 7th Amendment of the European Cosmetics Directive (2003/15/EC). Additionally, we can confirm that this product is not expected to contain 'Substances or Products causing allergies or intolerances' as defined in Annex II of Regulation (EU) No 1169/2011 on Food Information to Consumers. With regards to the residual sulphur dioxide, Regulation (EC) 1333/2008 on food additives<sup>1</sup> states that an SO<sub>2</sub> content of less than 10ppm is not considered to be present.

#### REACH Regulation (EC) No 1907/2006

Starch is listed on Annex IV of the REACH Regulation, which lists substances that are exempted from registration under the REACH Regulation on the basis that "sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties"- set out in Article 2.7. Additionally we can confirm that this product does not contain any substances of very high concern (SVHC).

#### CLP Regulation (EC) No 1272/2008

This product is not classified as hazardous according to (EC) No 1272/2008. However this product can produce a nuisance dust which should be maintained below a time weighted average of 10 mg/m<sup>3</sup> (total inhalable) or 4 mg/m<sup>3</sup> (respirable).

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<sup>1</sup> Regulation (EC) 1333/2008 on food additives, Annex II, Part E, 06.2.2.

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#### 4. Chemical Inventory Status

The information provided below is intended to provide inventory status for various geographies, it is not intended to be a complete regulatory assessment.

Substance identifier	CAS: 9005-25-8
Europe - EINECS	Listed
US - TSCA	Listed
Australia - AICS	Listed
Canada – DSL/NDSL	Listed
China - IECSC	Listed
Japan - MITI	Listed
Korea - ECL	Listed
Phillipines - PICCS	Listed

#### 5. Microbiological Data

Typical microbiological results for this product are summarised below. While this information is typical of FARMAL™ 2IT it should not be considered as a specification.

Total Viable Count	<500 cfu/g
Yeast & Mould	<100 cfu/g
<i>Escherichia coli</i>	Negative/1 g
<i>Salmonella</i>	Negative/25 g
Coliforms	< 10 cfu/g
<i>Staphylococcus aureus</i>	Negative/10 g
<i>Pseudomonas aeruginosa</i>	Negative/10 g
<i>Klebsiella</i>	Negative/10 g
Gram negative bacteria	Negative/10 g

#### 6. Animal testing statement

This product has not been tested on animals.

#### 7. Nanomaterial status

Based on the EU Cosmetics Regulation (1223/2009/EC) and the European Commission Recommendation on the definition of nanomaterial (2011/696/EU), Ingredion EMEA Companies confirm that this product is not produced via nanotechnology.

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### 8. Heavy metals

Typical values for heavy metals found in an equivalent starch product are summarised below. While this information is typical it should not be considered as a specification.

Metal	Level detected	Reporting Limit
Arsenic	Not detected	0.005 ppm
Cadmium	<0.03 ppm	0.003 ppm
Lead	Not detected	0.01 ppm
Mercury	Not detected	0.01 ppm
Copper	<0.05 ppm	0.005 ppm
Aluminium	0.36 ppm	0.03 ppm

### 9. Biologics Information

#### Genetically Modified Organisms

This product is derived from tapioca, which is not genetically modified (GM). This product meets the requirements of Regulation (EC) 1829/2003 on genetically modified food and animal feed and Regulation (EC) 1830/2003 on the traceability and labelling of GMO.

#### Animal Derived Ingredients

This product does not contain any ingredients of animal origin.

#### Natural Rubber/Latex

This product is not formulated with latex derived from the rubber tree, *Hevea Brasiliensis*.

#### Palm oil

This product is not formulated with palm oil.

### 10. Natural/Organic Certification

This product has not been certified against EU standards for Cosmetics as Natural or Organic.

### 11. Toxicological summary:

Starch is the glucide reserve in plants and is the main carbohydrate in the human diet. Starch, from all botanical origins, is listed on Annex IV of the REACH Regulation (EC) No 1907/2006. This Annex lists products exempted from REACH requirements on the basis that “sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties”. Starch is a permitted food ingredient in the EU, with specifications laid down in the Food Chemicals Codex Starch and is also included on the US FDA's list of substances considered Generally Recognized As Safe (GRAS).

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**Systemic toxicity:**

The US Cosmetic Ingredient Review<sup>2</sup> reviews the safety of multiple polysaccharides used as cosmetic ingredients. Tapioca starch is included in the polysaccharides which are considered safe in the present practices of use and concentration in cosmetics, as described in the assessment.

**Local toxicity:**

The product itself can produce a nuisance dust which should be maintained below a time weighted average of 10 mg/m<sup>3</sup> to avoid respiratory irritation, similarly the particles may irritate the eyes and skin. A similar product derived from corn has been tested for skin irritation potential using a Repeated Insult Patch Test in 50 human volunteers and no potential for dermal irritation or sensitisation was observed.

**12. Sustainability**

Please find Ingredion’s Sustainability Update at the link below.

<http://www.ingredionincorporated.com/CorporateResponsibility/sustainability.html>

This document is issued on behalf of the Ingredion EMEA Company which is supplying the product. The Ingredion EMEA Companies are part of the Ingredion group of companies. The respective details of each of the Ingredion EMEA Companies are as follows:

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<sup>2</sup> CIR (2015). US Cosmetic Ingredient Review. Safety assessment of polysaccharide gums as used in cosmetics.

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