

FARMAL™ CS 3757

1. Product identity

INCI Name	ZEA MAYS (CORN) STARCH
Chemical name	Starch, mixture of amylose and amylopectin
Description	Native maize (corn) starch
Intended function	Carrier for actives; Mitigates oiliness; Aesthetic enhancer
Appearance	White powder
CAS number	9005-25-8
EC number	232-679-6
Source	Maize/corn
Manufacturing Country of Origin	USA
Manufacturing process	General description: Maize is milled to extract starch Manufacturing process flow available on request
Manufacturing Quality System	US 21CFR Part 110, ISO 9001, and FSSC 22000 standards
Shelf life/Storage	2 years from manufacture, if stored correctly. 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
56780-58-6	ZEA MAYS (CORN) STARCH	Starch, mixture of amylose and amylopectin	86- 91%	Key	Natural
7732-18-5	AQUA	Water	9-14%	Residual moisture	Natural
7681-57-4	SODIUM METABISULFITE	Disodium disulphite	<0.008% SO ₂	Residual processing aid	Synthetic
7722-84-1	HYDROGEN PEROXIDE	Hydrogen peroxide	<0.018% residual oxidants	Residual processing aid	Synthetic

Effective Date: 01.06.2016 [1]

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3. EU 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 Metabisulfite 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 80 ppm (0.008%) and 180 ppm (0.018%) 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 the majority of 'Substances or Products causing allergies or intolerances' as defined in Annex II of Regulation (EU) No 1169/2011 on Food Information to Consumers, the exception to this is the residual sulphur dioxide (<80 ppm SO₂) from use of sodium metabisulphite as a processing aid.

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/m³ (total inhalable) or 4 mg/m³ (respirable).

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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™ CS 3757 it should not be considered as a specification.

Standard Plate Count	<100 cfu/g
Yeast	<50 cfu/g
Mould	<50 cfu/g
<i>Escherichia coli</i>	Negative/1 g
<i>Salmonella</i>	Negative/25 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 metals found in this product are summarised below. While this information is typical of FARMAL™ CS 3757 it should not be considered as a specification.

Metal	Level detected	Reporting Limit
Arsenic (total)	Not detected	0.1 ppm
Cadmium (total)	Not detected	0.02 ppm
Lead (total)	Not detected	0.1 ppm
Mercury (total)	Not detected	0.01 ppm

9. Biologics Information

Genetically Modified Organisms

This product is derived from GM maize.

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 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:

Starch derived from maize (Zea mays starch) has been reviewed by the US Cosmetic Ingredient Review who concluded that starch derived from maize is safe for use in cosmetics based on current uses¹.

Local toxicity:

The product itself can produce a nuisance dust which should be maintained below a time weighted average of 10 mg/m³ to avoid respiratory irritation, similarly the particles may irritate the eyes. Local effects on the skin have been investigated in a Repeated Insult Patch Test in 50 human volunteers, no potential for dermal irritation or sensitisation was observed.

Study	Test item	Result
Repeated Insult Patch Test	FARMAL™ CS 3757	Under the conditions of the study the test item did not indicate potential for dermal irritation or sensitisation

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:

Ingredion UK Limited
 Ingredion House,
 Manchester Green
 339 Styal Road
 Manchester M22 5LW
 England

P: +44 (0) 161 435 3200
 F: +44 (0) 161 435 3300

Registered in England No. 07315745

Ingredion Germany GmbH
 Grüner Deich 110
 20097 Hamburg
 Germany

P: +49 (0) 40 23 91 50
 F: +49 (0) 40 23 91 51 70

Amtsgericht Hamburg HRB 105432

**Russia Ingredion Holding LLC
 Representative Office**
 Vernadskogo Prospect
 39, office 501
 Moscow
 Russia
 119415

P: +7 (0) 495 786 81 43

Ingredion South Africa (Pty) Ltd
 Infinity Office Park, Suite 6, Block C,
 2 Robin Close, Meyersdal, 1448,
 Gauteng
 RSA

P: +27 (0) 11 867 9260
 F: +27 (0) 11 867 9271

Registration number 2010/013219/07

**Ingredion Middle East
 Branch**
 Office 03B Dubai
 Dubai Biotechnology and Research
 Park
 Dubai
 United Arab Emirates

P: +971 44 53 4288

Kenya Ingredion Holding LLC
 5th Floor-Tulip House
 Mombasa Road
 P.O Box 1952-00606
 Nairobi
 Kenya

P: +254 20 36 28 000

Rafhan Maize Products Co. Ltd.
 Rakh Canal East Road
 PO Box 62
 Faisalabad 38060
 Punjab
 PAKISTAN

T: 92-41-854-0121
 F: 92-41-871-1016

¹ CIR (2011). Final report of the Safety Assessment of Cosmetic Ingredients Derived from Zea Mays (Corn)

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