

## FARMAL® MS 6135

### 1. Product identity

<b>INCI Name(s)</b>	CALCIUM STARCH OCTENYLSUCCINATE
<b>Chemical Name(s)</b>	Starch, hydrogen octenylbutanedioate, calcium salt
<b>Description</b>	Chemically modified maize starch
<b>Intended function</b>	Rheology modifier and Aesthetic Enhancer
<b>Appearance</b>	White to off white powder
<b>CAS number(s)</b>	374539-60-3
<b>EC number(s)</b>	-
<b>Source</b>	Maize starch (chemically modified)
<b>Manufacturing Country of Origin</b>	Brazil
<b>Manufacturing process</b>	ISO 9001 and FSSC 22000
<b>Shelf life/Storage</b>	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 standard for the product FARMAL® MS 6135. However, this should not be considered a formulation specification.

CAS Number	INCI Name	Typical concentration	Function	Origin
374539-60-3	CALCIUM STARCH OCTENYLSUCCINATE	100% for cosmetic labelling purposes	Key	Naturally Derived / Synthetic (biopolymer from modified natural maize starch)

Note: Natural extracts vary in content throughout the year, however specific batch analysis is available upon request.

### 3. EU Regulatory Status

**EU Cosmetics Regulation (EC) No 1223/2009, as amended<sup>1</sup>:**

**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.

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

<sup>1</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

Effective Date: 21.04.2022

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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 residual of sulphur dioxide is 50 ppm (0.005%) and residual oxidants are qualitatively confirmed as Negative using a KI test.

### Allergens

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 1169/20112 on Food Information to Consumers. The exception to this is residual sulphur dioxide (<50 ppm SO<sub>2</sub>) from use of sodium metabisulfite as a processing aid.

This product does not contain gluten and any unavoidable presence of gluten in the product is below 20 ppm.

### REACH Regulation (EC) No 1907/2006<sup>2</sup>

This product is classed as a polymer and is therefore exempt from REACH. However, the product is a chemically modified polymer consisting of >2 % of a modifying substance. Ingredion's suppliers have REACH registered this substance and have agreed to be our Only Representative(s), covering tonnage supplied by Ingredion Germany GmbH within their registration(s).

Additionally, we can confirm that this product does not contain any Substances of Very High Concern (SVHCs) present on the Candidate List of Substances above the 0.1% threshold.

### CLP Regulation (EC) No 1272/2008<sup>3</sup>

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). Please refer to the Safety Data Sheet for further information

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency

<sup>3</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

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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: 374539-60-3
Europe – EC Number	CAS number not listed INCI name is present on the EU Commission Cosmetic Ingredient Database (CosING)
US – TSCA	CAS number not listed – Cosmetic use is exempt INCI name is present on the PCPC (Personal Care Products Council) Database
Australia – AICS	CAS number not listed
Canada – DSL/NDSL	CAS number not listed
China – IECSC	CAS number not listed
China – IECIC (Cosmetic Inventory 2015)	INCI name listed
Japan – ENCS	CAS number not listed
Japan – ISHL	CAS number not listed
Korea – KECL	CAS number not listed
Philippines – PICCS	CAS number not listed
New Zealand – NZLoC	CAS number not listed
Taiwan – TCSI	CAS number not listed

#### California Safe Water and Toxic Enforcement Act of 1986 (Proposition 65)

We can affirm that FARMAL® MS 6135 does not contain chemicals known to the State of California to cause cancer or toxicity at levels above the "no significant risk levels"

#### 5. Microbiological Data

Typical microbiological results for this product are summarised below. While this information is typical of the FARMAL® MS 6135, it should not be considered a specification.

Standard Plate Count	≤500 cfu/g
Yeast and Mould	<100 cfu/g
Escherichia coli	Negative/10g
Salmonella	Negative/25g

#### 6. Animal testing statement

No animal testing has been conducted on this product for use in cosmetics, in line with the Cosmetics Regulation (1223/2009/EC). For more information, please refer to our animal testing statement.

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**7. Nanomaterial status**

Based on the EU Cosmetics Regulation (1223/2009/EC), as amended 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.

**8. Heavy metals**

Typical values for metals found in this product are summarised below. While this information is typical of the FARMAL®MS 6135 product, it should not be considered as a specification.

Metal	Value	Unit
Arsenic (total)	< 0.03	mg/kg
Cadmium (total)	< 0.03	mg/kg
Lead (total)	< 0.03	mg/kg
Mercury (total)	< 0.01	mg/kg
Iron	3.3	mg/kg
Copper	< 0.03	mg/kg
Aluminium	4.1	mg/kg

**9. Biologics Information**

**Genetically Modified Organisms**

This product is not derived from or produced using GM organisms.

**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**

Not Available

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**11. Toxicological summary:**

Starch is the glucide reserve in plants and is the main carbohydrate in the human diet. Calcium Starch Octenyl Succinate is a chemically modified starch. While this modified starch is not approved as a food additive in the EU, it is the calcium salt equivalent of the food additives E 1450 (Starch Sodium Octenyl Succinate) and E 1452 (Starch Aluminium Octenyl Succinate). The document ‘US Cosmetic Ingredient Review: Safety assessment of polysaccharide gums as used in cosmetics’<sup>4</sup> reviews the safety of a large number of polysaccharide gums including Calcium Starch Octenylsuccinate and concluded that this ingredient was safe based on the expected use in cosmetics.

Systemic toxicity:

Systemic toxicity via use in cosmetics is not expected.

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. Local effects on the skin have been investigated for FARMAL® MS 6135 in a Repeated Insult Patch Test in 110 human volunteers, no potential for dermal irritation or sensitisation was observed.

**12. Sustainability**

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

<https://www.ingredion.com/na/en-us/company/meet-ingredion/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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4 CIR (2015). Final report of Safety Assessment of Polysaccharide Gums as Used in Cosmetics

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