

FARMAL® AF 1100

1. Product identity

INCI Name	CALCIUM STARCH OCTENYLSUCCINATE
Chemical name	Starch, hydrogen octenylbutanedioate, calcium salt
Description	Calcium Starch Octenylsuccinate is the calcium salt of the reaction product of octenylsuccinic anhydride with Corn Starch
Intended function	Free -flowing bio-based polymer with hydrophobic properties and can help improve sensorial properties.
Appearance	White to off white powder
CAS number	374539-60-3
EC number	-
Source	Maize/corn starch (chemically modified)
Manufacturing Country of Origin	Brazil
Manufacturing process	General description: Modification of maize starch with chemical reagents Manufacturing process flow available on request
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 standard for the product FARMAL™ AF 1100. However, this should not be considered a formulation specification.

CAS Number	INCI Name	Chemical Name	Typical concentration	Function	Origin
374539-60-3	CALCIUM STARCH OCTENYLSUCCINATE	Starch, hydrogen octenylbutanedioate, calcium salt	100% for cosmetic labelling purposes	Key	Naturally Derived / Synthetic (biopolymer from modified natural maize starch)
7732-18-5	AQUA	Water	≤14%	Residual moisture	Natural
7681-57-4	SODIUM METABISULFITE	Disodium disulphite	≤0.001% SO ₂	Residual processing aid	Synthetic

Effective Date: 01.03.2022

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3. EU Regulatory Status

EU Cosmetics Regulation (EC) No 1223/2009, as amended¹:

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.

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 10 ppm (0.001%) 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 (<10 ppm SO₂) from use of sodium metabisulfite as a processing aid.

REACH Regulation (EC) No 1907/2006³

This product is classed as a polymer and is therefore exempt from EU REACH. However, the product is a chemically modified polymer consisting of >2 % of a modifying substance. This modifying chemical is EU REACH registered by our suppliers and agreements are in place which ensure the tonnage imported by Ingredion Germany GmbH are covered by our supplier(s) 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 1272/2008⁴

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

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

² Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

³ 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

⁴ 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	Polymer INCI name is present on the EU Commission Cosmetic Ingredient Database (CosING) and the PCPC (Personal Care Products Council) Database
US - TSCA	CAS number not listed – Cosmetic use is exempt
Australia - AICS	CAS number not listed
Canada – DSL	CAS number not listed
Canada – 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

5. Microbiological Data

Typical microbiological results for this product are summarised below. While this information is typical of the FARMAL™ AF 1100 product, it should not be considered a specification.

Standard Plate Count	≤500 cfu/g
Yeast and Mould	≤100 cfu/g
Escherichia coli	Negative/1g
Salmonella	Negative/10g

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[™] AF 1100 product, it should not be considered as a specification.

Metal	Value
Arsenic	<0.01 ppm
Cadmium	<0.01 ppm
Lead	<0.03 ppm
Mercury	<0.004 ppm
Iron	<1.00 mg /100g
Copper	<1.00 mg /100g
Aluminium	<3 ppm

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*.

10. Natural/Organic Certification

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

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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 chemically modified starch. Whilst 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'⁵ reviews the safety of a large number of polysaccharide gums including Calcium Starch Octenyl Succinate 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. The mutagenic potential of FARMAL[™] AF 1100 was evaluated using a bacterial reverse mutation assay performed according to OECD Test Guideline No. 2020, and found to be negative for mutagenicity under the study conditions used.

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.

An *in vitro* study performed according to OECD Test Guideline No. 492 found that FARMAL[™] AF 1100, tested both neat as a powder and suspended at 30% in water, is 'Non-Irritant' and does not require classification for eye irritation or serious eye damage.

Local effects on the skin have been investigated for FARMAL[™] AF 1100 using an occlusive repeated insult patch study in 112 human volunteers (50% normal skin and 50% self-perceived sensitive skin), no evidence for dermal sensitisation was observed and no evidence of clinically meaningful skin irritation was observed.

Study	Test item	Result
OECD TG 492; Reconstructed human Cornea-like Epithelium (RhCE) test	FARMAL [™] AF 1100	Non Irritant
Repeated Insult Patch Test	FARMAL [™] AF 1100	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.

[Sustainability \(ingredionincorporated.com\)](https://www.ingredion.com/sustainability)

⁵CIR (2015). Final report of Safety Assessment of Polysaccharide Gums as Used in Cosmetics

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