

NATIVACARE™ 9360

1. Product identity

INCI Name	TAPIOCA STARCH
Chemical name	Starch
Description	Physically treated tapioca starch
Intended function	Viscosity controller; Skin feel enhancer
Appearance	White powder
CAS number	9005-25-8
EC number	232-679-6
Source	Organic tapioca
Manufacturing Country of Origin	Germany
Manufacturing Quality System	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
9005-25-8	TAPIOCA STARCH	Starch, mixture of amylose and amylopectin	85- 90%	Key	Natural
7732-18-5	AQUA	Water	10-15%	Residual moisture	Natural

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

Effective Date: 01.04.2017 [1]

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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 any of the ‘Substances or Products causing allergies or intolerances’ as defined in Annex II of Regulation (EU) No 1169/2011 on Food Information to Consumers.

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).

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

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5. Microbiological Data

Typical microbiological results for this product are summarised below. While this information is typical of NATIVACARE™ 9360 it should not be considered as a specification.

Standard Plate Count	<1000 cfu/g
Yeast	<100 cfu/g
Mould	<100 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.

8. Heavy metals

Typical values for metals found in this product are summarised below. While this information is typical of NATIVACARE™ 9360 it should not be considered as a specification.

Heavy Metals	Value	Unit
Total Heavy Metals	10	mg/kg
Arsenic	1	mg/kg
Lead	1	mg/kg
Cadmium	0.1	mg/kg
Mercury	0.05	mg/kg

9. Biologics Information

Genetically Modified Organisms

This product is derived from non-GM tapioca. Traceability/identity preservation (IP) system in place.

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*.

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Palm oil

This product is not formulated with palm oil.

10. Natural/Organic Certification

The product is produced in compliance with Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products, as certified by LACON GmbH.

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). NATIVACARE™ 9360 meets the Food Chemicals Codex (FCC) monograph definition and requirements for food starch, unmodified.

Systemic toxicity:

Starch derived from tapioca has been reviewed by the US Cosmetic Ingredient Review who concluded that starch derived from tapioca 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 not been investigated for NATIVACARE 9360, however native maize starch has been studied 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	Native maize starch	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>

¹ CIR (2015). Safety Assessment of Polysaccharide Gums as Used in Cosmetics

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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

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