

# PRODUCT INFORMATION SHEET

## CELLULOSE GEL (MICROCRYSTALLINE CELLULOSE)

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## 1 PRODUCT INFORMATION

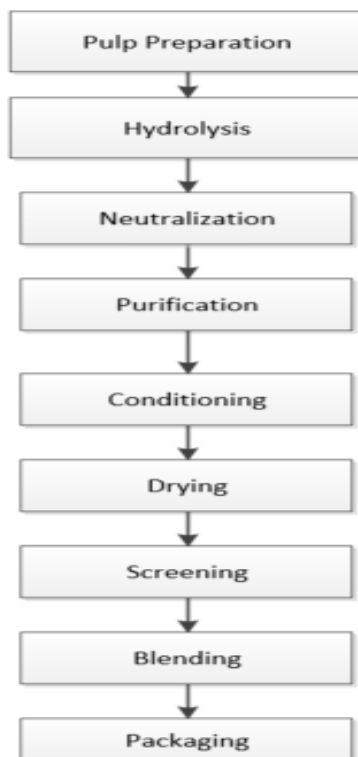
### 1.1 PRODUCT DESCRIPTION

This document applies to single ingredient cellulose gel (microcrystalline cellulose) products.

Cellulose gel occurs as a fine, white or almost white powder. It is purified, partially depolymerized cellulose prepared by treating alpha-cellulose, obtained as a pulp from fibrous plant material, with mineral acids. It consists of free-flowing, nonfibrous particles that may be compressed into self-binding tablets that disintegrate rapidly in water. It is insoluble in water, in dilute acids, in dilute sodium hydroxide solutions, and in most organic solvents - Food Chemicals Codex Description.

### 1.2 PRODUCTION PROCESS

Cellulose gel is manufactured from cellulose pulp which is hydrolyzed using hydrochloric acid, filtered, separated, washed, neutralized, dried, sieved, buffered and blended.



### 1.3 INGREDIENT DECLARATION

Cellulose gel

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#### 1.4 COUNTRY OF ORIGIN / HARMONIZED TARIFF SYSTEM (HTS)

See Country of Origin Statement for COO / HTS code

#### 1.5 CHEMICAL ABSTRACT SERVICES (CAS) NUMBER

Cellulose gel: 9004-34-6

#### 1.6 INTERNATIONAL NUMBERING SYSTEM (INS) NUMBER / E NUMBER (EUROPEAN UNION)

INS: 460

E\*: 460(i)

\*E number is provided for informational purposes only and does not imply all cellulose gel Ingredion sells conforms to EU regulations. If you need product that conforms to EU regulations, please reach out to your account owner, and make a request.

#### 1.7 LOT NUMBERING SYSTEM

Each production batch is assigned a unique identifying 8-digit lot number. The lot number is randomly generated and is printed on the product label and/or bag.

#### 1.8 PACKAGING COMPLIANCE

We are pleased to affirm that all packaging material used by Ingredion Incorporated complies with U.S. Food, Drug, and Cosmetic Act regulations for food contact packaging.

#### 1.9 RESIDUAL SOLVENTS

We have reviewed our products for the use of residual solvents as listed in USP General Chapter <467>, Residual Solvents and the ICH Q3C (R8) Guideline for Residual Solvents. No class one, two, three or other solvents per USP <467> are used during the manufacturing or handling process of our cellulose gel products.

#### 1.10 CHLORPYRIFOS

Ingredion Inc. companies, at our global manufacturing operations, perform routine analyses on either in-coming raw materials or finished products on an audit basis. Chlorpyrifos is included in these residue surveys and results are historically not detected (using <0.01 ppm as Limit of Detection).

Further, we have been working with our supply chain partners to ensure our raw material and purchased ingredient suppliers are aware of the new USA EPA guidance revoking the tolerance limits for chlorpyrifos and are aware that this pesticide is banned for use in products sold into the US effective February 22, 2022. Based on this analysis we can advise that food products supplied to you by Ingredion Inc. will meet the 2021 USA EPA Final Tolerance Rule for Chlorpyrifos.

### 1.11 HEAVY METAL ANALYSIS

Cellulose gel has been demonstrated to conform to current Food Chemical Codex (FCC) requirements, and will therefore meet FCC's heavy metal standards for

- Lead – no more than (NMT) 2 mg/kg

### 1.12 MELAMINE

Ingredion Incorporated does not intentionally add melamine or melamine-related compounds during the manufacturing process for our cellulose gel products.

### 1.13 PALM OIL

We are pleased to affirm that our cellulose gel products are not manufactured using palm oils.

### 1.14 PARTIALLY HYDROGENATED OILS

We can confirm that no partially hydrogenated oils are used in the production of our cellulose gel products.

## 2 REGULATORY / LEGAL REQUIREMENTS

### 2.1 REGULATORY COMPLIANCE

We are pleased to affirm that our cellulose gel products are food grade products and meet the applicable current Food Chemical Codex standards. Our cellulose gel products are produced under Good Manufacturing Practices (GMPs.)

Cellulose gel conforms to the following regulations

- Generally Recognized as Safe (GRAS - 21 CFR 182.1) by the US Food and Drug administration. Cellulose gel (microcrystalline cellulose) is listed in the U.S. FDA Food Additive Status List as GRAS.

## 2.2 ALLERGEN & SENSITIZING AGENT INFORMATION

The table below provides information concerning the presence of allergens and sensitizing agents in cellulose gel products:

<b>Material</b>	<b>Contained as ingredient?</b>
Milk <sup>1,2,3</sup>	No
Eggs <sup>1,2,3</sup>	No
Fish <sup>1,2,3</sup>	No
Crustacean shellfish <sup>1,2,3</sup>	No
Molluscs <sup>2,3</sup>	No
Tree Nuts <sup>1,2,3</sup>	No
Peanuts <sup>1,2,3</sup>	No
Legumes	No
Soybeans <sup>1,2,3</sup>	No
Wheat <sup>1,2</sup>	No
Gluten-containing Grains <sup>2,3,4</sup>	No
Sesame seeds <sup>1,2,3</sup>	No
Celery <sup>3</sup>	No
Mustard <sup>2,3</sup>	No
Lupin <sup>3</sup>	No
Sulfites <sup>2,3</sup>	No
Monosodium glutamate (MSG)	No
Hydrolyzed vegetable protein (HVP)	No
Butylated hydroxyanisole (BHA)	No
Butylated hydroxytoluene (BHT)	No
Tertiary butylhydroquinone (TBHQ)	No
Colorings <sup>5</sup>	No

<sup>1</sup>Allergens identified by the FDA as causing serious allergic reactions in some individuals

<sup>2</sup>Priority Food Allergens identified by Health Canada

<sup>3</sup>Allergenic foods identified in Annex IIIa of the EU Labeling Directive

<sup>4</sup>Gluten-containing grains include barley, oats, rye, triticale, wheat, kamut, spelt, or their hybridized strains.

<sup>5</sup>FD&C certified (including Yellow 5 & 6), titanium dioxide, carmine, artificial colorings

All facilities that manufacture or package cellulose gel have Allergen Control Programs in place to manage the risks associated with allergens.

## 2.3 GLUTEN

We are pleased to affirm that our cellulose gel products do not contain gluten containing grains<sup>2,3,4</sup>

## 2.4 NATURAL STATUS

The FDA has not established a regulatory standard for what is considered natural outside of flavors, synthetic substances, and colors. Rather, it follows a policy that the term “natural” may be used provided it is not false and misleading. The FDA’s policy states:

“The agency will maintain its current policy not to restrict the use of the term ‘natural’ except for added color, synthetic substances and flavors as provided in 21 CFR 101.22. Additionally, the agency will maintain its policy regarding the use of ‘natural’ as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.” (58 Federal Register 2302, January 6, 1993).

Due to the lack of regulatory standard from the FDA regarding hydrocolloids, food additives and other ingredients that may be used in systems; it is up to the customer to determine if the product they purchase meets their internal requirements for natural. In addition, each customer is solely responsible for compliance with all pertinent legal requirements worldwide; this includes decision making regarding the use of "natural" or "all natural" in product claims.

## 2.5 BIOENGINEERED (BE) STATUS

Cellulose gel does not require Bioengineered Food Disclosure Labelling.

Under the National Bioengineered Food Disclosure Standard (NBFDS,) the USDA Agricultural Marketing Service has developed a List of Bioengineered Foods to identify crops that are commercially available in a bioengineered form. Cellulose gel is not on this list and does not require Bioengineered Food Disclosure Labelling.

## 2.6 ORGANIC STATUS / ORGANIC COMPLIANT STATUS

Cellulose gel (microcrystalline cellulose) is prohibited from use in organic products.

## 2.7 IRRADIATION/ SEWAGE SLUDGE

Our sourcing and manufacturing processes do not include treatment with radiation nor do our cellulose gel products contain sewage sludge.

## 2.8 ETHYLENE OXIDE

Ethylene Oxide (ETO) is not utilized in the production, storage, or transport of cellulose gel.

Regarding presence of ETO due to other factors, such as creation of ethylene oxide during the processing or potential cross contamination, Ingredion Inc. has chosen to align with the European Union Regulation amending the Annex to Commission Regulation (EU) No 231/2012 as regards the presence of ETO in food additives, to increase the MRL for ETO in additives, sum from 0.01ppm to 0.1ppm, with effect from August 2022.

## 2.9 ANIMAL DERIVATIVES

Based on information from our suppliers, our knowledge about the raw materials and the manufacturing process; we can confirm that no animal derivatives or by-products are used in the production of our cellulose gel products.

## 2.10 DIETARY FIBER SOURCE

USA: Cellulose gel does not qualify as a dietary fiber.

CANADA: Cellulose gel does not qualify as a dietary fiber.

## 2.11 BSE /TSE STATEMENT

Our cellulose gel products are derived from botanical sources and are not manufactured using materials of bovine, sheep, goat, or human origin. These products do not come into contact with any animal origin material in which transmissible spongiform encephalopathies (TSE) or bovine spongiform encephalopathy (BSE) have been found.

## 2.12 NANOTECHNOLOGY

Nanotechnology is not used during the manufacture of our cellulose gel products.

## 2.13 PROPOSITION 65

California Proposition 65: Safe Drinking Water and Toxic Enforcement Act of 1986 provides a chemical list of substances known to the State of California to cause cancer or reproductive toxicity.

Ingredion Inc. food systems and hydrocolloids business does not intentionally add any Proposition 65 Chemicals of concern to cellulose gel. Ingredion Incorporated complies with FCC requirements and the United States of America Food and Drug Administration Requirements. The finished food manufacturer should confirm that its products do not expose consumers to listed chemicals in amounts that exceed “safe harbor” levels.”

We have reviewed our cellulose gel products and to our knowledge these products do not contain chemicals known to the State of California to cause cancer or toxicity at levels above the “no significant risk levels”.

## 2.14 PESTICIDE STATEMENT

Ingredion Incorporated’s contaminant and pesticide monitoring program consists of regular monitoring of our incoming raw materials and finished products. Ingredion also performs pesticide, contaminants, and heavy metals testing on random finished products from each of our manufacturing locations on an annual basis. Based on the raw material monitoring, product processing and annual reviews we can state this product is fully compliant with United States of America requirements set forth in 40 CFR Part 180.



## 2.15 WADA, NFL/ NFLPA AND NSF PROHIBITED INGREDIENTS

We are pleased to affirm our cellulose gel products do not contain any substances that appear on the WADA, NFL/NFLPA or NSF prohibited lists. We do not handle any substances banned by these agencies and the risk that our products could come into contact with these prohibited substances is minimal.

## 2.16 ANIMAL TESTING

Please follow the link below to review Ingredion's Animal Testing Policy.

<https://www.ingredion.com/content/dam/ingredion/pdf-downloads/corporate/sustainability-documents/Animal-Testing-Policy-05-11-21.pdf>

## 2.17 CALIFORNIA TRANSPARENCY IN SUPPLY CHAINS ACT 2010

Ingredion Incorporated is committed to conducting business in compliance with all applicable laws and regulations, including the California Transparency in Supply Chain Act. Consistent with our Policies on Business Conduct and Core Values, we neither accept nor support the use of illegal or enforced labor.

## 2.18 CONFLICT MINERALS

Our cellulose gel products do not originate in the Democratic Republic of the Congo (DRC) where minerals are mined in conditions of armed conflict and human rights abuses. Conflict minerals including tantalum, tin, gold, or tungsten are not used during the production of these products.

## 2.19 FDA FACILITY REGISTRATION

Ingredion Incorporated has registered all of our manufacturing facilities worldwide as required by the Public Health & Bioterrorism Preparedness & Response Act of 2002 and FSMA 2011 (Food Safety Modernization Act).

We consider the FDA registration number of each facility to be confidential information which will be shared only when required by law or on a case-by-case basis under a non-disclosure agreement.

## 2.20 FSMA (FOOD SAFETY MODERNIZATION ACT) COMPLIANCE

Ingredion Incorporated considers product safety to be of utmost importance and maintains robust quality, food safety, and food defense systems at all of our manufacturing facilities. Our facilities are GFSI certified.

Certified Preventive Control Qualified Individuals (PCQIs) are in place at all Ingredion manufacturing sites producing goods for sale to US and Canada customers. PCQIs have overseen the transition of our risk-based food safety management systems to align with the requirements of the Food Safety Modernization Act (FSMA) Preventive Control Rules. All have established GMP procedures and use a risk-based approach in our hazard analysis.

Food Defense Qualified Individuals (FDQIs) are in place at all Ingredion manufacturing sites producing goods for sale to US and Canada customers. FDQIs have developed robust food defense programs that comply with the requirements of the Food Safety Modernization Act (FSMA) Intentional Adulteration (IA) Rule.

### 3 FOOD SAFETY PROGRAMS

#### 3.1 FOOD SAFETY PROGRAMS

Ingredion Incorporated is committed to the manufacture and sale of food, healthcare, nutritional, and pharmaceutical ingredients that are fit for use and safe to consume. All facilities owned or contracted by Ingredion Incorporated that manufacture, process, handle, or distribute food, healthcare, nutritional, or pharmaceutical ingredients for Ingredion have documented Food Safety and GMP procedures in place that provide for the safety of our products. Each facility's food safety management systems are comprehensive, and science based.

The food safety management systems drive continuous improvement and encompass a food safety risk assessment and preventive measures, good manufacturing practices, and employee training.

#### 3.2 FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

Ingredion Inc. continues to enhance and support its Supplier Verification Program which includes foreign supplier verifications. For incoming raw materials or ingredients, our program identifies all known or reasonably foreseeable hazards with each food received/ imported. An evaluation of the risk is based on our hazard analysis and the supplier's performance. Reevaluation occurs at least every three years or when new information comes to light about a potential hazard or a change in supplier's performance. We conduct onsite audits of our foreign affiliates. Non-affiliate suppliers are audited when there is a reasonable probability that exposure to a hazard will result in an adverse health consequence.

Ingredion values its commitment to Food Safety and considers itself to be a strategic contributor to everyday products used in the food and beverage industries.

#### 3.3 RECALL POLICY / TRACEABILITY EXERCISES

Ingredion Incorporated's "Product Recall Program" sets requirements for each Ingredion manufacturing facility regarding the procedures and training needed to effectively handle a potential recall situation. The index of the Standard includes the following topics:

- Introduction (Purpose, scope, responsibilities, definitions, references)
- Detection of a possible recall situation
- Notification of Corporate Quality Assurance
- Initial Investigation and Problem Assessment
- Recall Strategy
- Recall Notifications (authorities, customers, 3rd party auditors)

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- Recall Completion and Follow-Up Activities
- Product Recall Simulation (Traceability Exercises)

North America Quality Assurance initiates traceability exercises at each Ingredion facility at least annually. The results of the traceability exercises are reviewed by NA Quality for effectiveness and analyzed for improvement opportunities.

Any report related to food safety concern of any Ingredion product should be made to our 24-hour Customer Service line at 1-800-692-3417 or 1-800-859-8569.

### 3.4 SUPPLIER APPROVAL PROGRAM

Ingredion's Supplier Management Program is managed by multiple departments within Ingredion who are responsible for ensuring approved suppliers do not contribute to any risk and conform to all specified requirements.

Ingredion only uses approved suppliers who have been evaluated to conform to Ingredion's specifications. Throughout the year, Ingredion determines and applies criteria for the evaluation, selection, monitoring of performance, and the re-evaluation based on their ability to continuously provide such specified requirements. A risk-based analysis is performed on all suppliers to determine the depth of the evaluation and thus suppliers are categorized into tiers based on their ability to meet requirements, the effect on product realization, and the impact of food safety and/or product quality.

The Supplier Management Program also applies to outside contracted facilities, transportation and all other facilities which are not operated by Ingredion but are contracted to provide a service. In the absence of categorizing them by tiers, they are approved for use by meeting all the necessary documented requirements.

Supplier food safety preventative controls are evaluated by a PCQI trained individual. This determination is based on the assessment of the food safety risk from the material and from the supplier. The PCQI trained assessor verifies that there are adequate and sufficient programs, practices and procedures in place for food safety and food security.

## 4 OTHER

### 4.1 BUSINESS CONTINUITY

Ingredion Incorporated recognizes that an uninterrupted supply of purchased materials is a vital business issue for our customers. Ingredion Incorporated has an extensive network of manufacturing facilities that provide flexibility and redundancy in our ability to supply our customers. This network supports our goal which is to minimize the impact that an event might have on the supply of products to our customers. Our Business Continuity Management Program is comprised of three critical elements: Emergency Response Program, Crisis Management Program and Business Continuity Plans.

Ingredion Incorporated has conducted a general risk assessment of its operations, including the impact of natural disasters which may impact our ability to meet customer expectations. The details of this assessment are confidential and cannot be shared outside the company. The Company has robust programs to address developing and emerging issues including a crisis management program and emergency response procedures that are reviewed and exercised on a regular basis. On a regular basis each site conducts emergency response drills, reviews their crisis communication plans, and assesses potential business risks and, when appropriate, establishes plans designed to mitigate these risks.

While Ingredion Incorporated cannot guarantee that forces outside our control will never affect our ability to fulfill a supply agreement, we believe that we are well positioned to minimize the effect on major disruptions.

#### 4.2 STATEMENT OF CODE OF CONDUCT

Please follow the link below to review Ingredion's Policies on Business Conduct (the "Policies"). The Policies are a statement of how Ingredion operates its business and lives its values. The Policies provide general guidance on legal or ethical choices our employees may face in the course of doing business and in interacting with one another.

<https://www.ingredion.com/content/dam/ingredion/pdf-downloads/corporate/code-of-conduct/COM-en.pdf>

Our employees are all stewards of our company's culture and reputation. We are responsible for protecting the interests of the company by acting in accordance with laws, regulations, and our company values of safety, quality, integrity, respect, excellence, and innovation.

At Ingredion, nothing is more important to us than the trust of our customers. As a result, we operate and will continue to operate under these Policies in the future in all our business and community relationships.

#### 4.3 SUSTAINABILITY

Please follow the link below to review Ingredion's latest sustainability report. <https://www.ingredion.com/na/en-us/company/meet-ingredion/sustainability.html>

#### 4.4 DOCUMENT CONTROL PROGRAM

Ingredion North America maintains the documented Information necessary to operate an effective quality and food safety management system. Our program is documented in the standard operating procedure, Control of Documented Information, USCN-QA-SOP-003. The Ingredion Document Control Process contains controls to ensure that Documented Information is:

- Identified and formatted
- Reviewed and approved
- Available for use
- Protected

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- Version and access controlled

Identification and Formatting: Documents are identified by title and where applicable by product name and product code. Documents are prepared on approved Ingredion templates. In the case of records such as certificates or audit reports these records are prepared by the issuer on their template.

Review and Approval: Documents are reviewed by identified Ingredion subject matter experts prior to being issued for use. The approver's name and approval date are recorded in the document metadata.

Review frequency is defined when a document is posted in the document database. Documents are reviewed and posted as changes occur or at the expiration date. Standard documents are reviewed every 3 years or as changes occur. The exception is the Safety Data Sheet (SDS) which does not expire and is updated only when changes occur. In the case of records such as certificates the review date is set according to the expiration date on the certificate.

Version control: Version control is maintained in the document database and document metadata. Electronic documents contain an effective date.

Available for use: Documents are posted to the document database for internal use. Documents which are approved for public view are available on our Technical Document website. Please press control + click on the link below to access our website or to submit a document request.

