



A HUBER COMPANY

# PRODUCT INFORMATION

## XANTHAN GUM

Does not apply to xanthan gum blended with other components

# PRODUCT INFORMATION



## XANTHAN GUM

Document No.: PRD-01

Effective Date: 25 Jan 2017

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### 1. Supplier Information

Name: CP Kelco U.S., Inc.  
Address: Cumberland Center II  
3100 Cumberland Boulevard, Suite 600  
Atlanta, GA 30339 USA  
Main Phone: 1-800-535-2687  
Main Fax: 1-678-247-2752  
Parent Company: J.M. Huber Inc  
E-mail: Customer.request@cpkelco.com

### 2. Manufacturing Site

	Okmulgee Plant	San Diego Plant	Wulian Plant	Packaging Site
Address:	1200 West 20th Street Okmulgee, OK 74447 USA	2025 E. Harbor Dr. San Diego, CA 92113 USA	140 Yanhe Rd, Wulian County 262300, Shandong, P.R. China	PacMoore* 1844 Summer Street Hammond, IND 46320 USA
Main Phone:	+1 (918) 758 2600	+1 (800) 535 2687	+011 (86) 63 3531 2999	+1 (866) 610-2666
Main Fax:	+1 (918) 756 2926	+1 (619) 652 5352	+011 (86) 63 3532 2199	+1 (219) 932-0879
Products	All Grades	All Grades except Excipients	Food, Industrial, and Oilfield	Food, Personal Care

\* Product is not manufactured at PacMoore; product is packaged into final product packaging.

### 3. Manufacturing Site Contacts/Emergency Contacts

Refer to Plant Information Sheet for the site.

### 4. Facility Registration - Bioterrorism Act

Refer to Plant Information Sheet for the site.

### 5. Product Description

Chemical Name: Xanthan Gum  
CAS Number: 11138-66-2  
EINECS Number: 234-394-2  
Appearance: Powder  
Color: White to tan  
Odor: No off odor  
Taste: Bland

### 6. Product Composition

Xanthan gum

This information is not applicable to products containing xanthan gum blended with other components.

### 7. Product Source

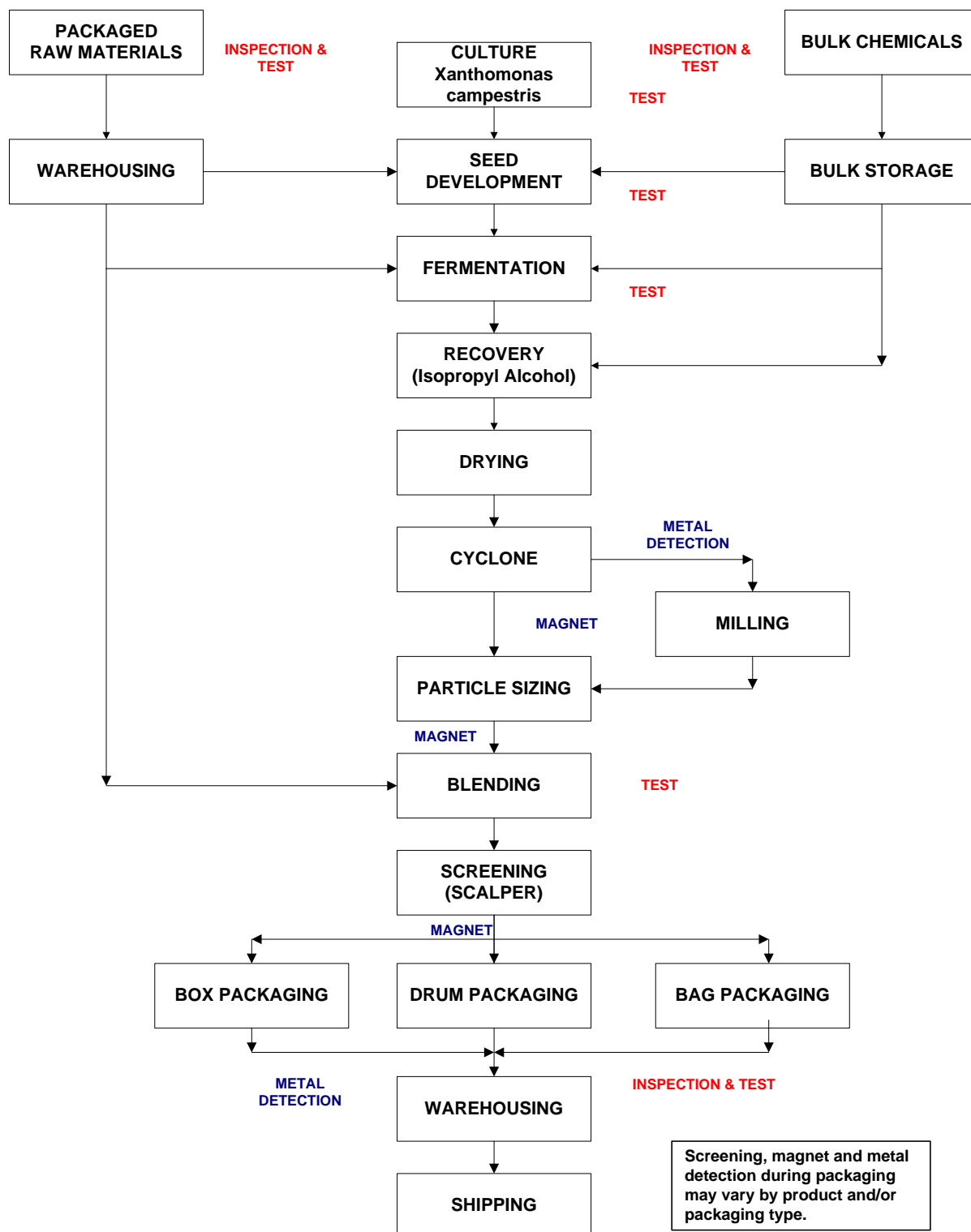
Xanthan gum is a polysaccharide produced by fermentation of a pure culture *Xanthomonas campestris*.

### 8. Production Process

The production of xanthan gum involves a multi-step inoculum preparation, followed by fermentation in large stainless steel tanks and, finally, product recovery (see process flow, below). Fermentation equipment is sterilized before use, and strict aseptic techniques are followed to ensure a pure culture. Media composition, as well as fundamental requirements such as aeration, agitation, pH, and temperature, are precisely controlled to guarantee optimal results and reproducibility. After fermentation is complete, the organisms are killed before the product is recovered. Typically, xanthan gum is recovered from the fermentation broth by alcohol precipitation. The alcohol is then removed, and the resulting product dried, milled, tested, and packaged.

## XANTHAN GUM

### XANTHAN GUM PROCESS FLOW



## XANTHAN GUM

### 9. Quality Systems (HACCP/HARPC, ISO)

CP Kelco products are produced at production facilities with quality systems which are certified to the ISO 9001 quality standards and Global Food Safety Initiative (GSFI) standards. HACCP/HARPC plans are in place at xanthan gum production facilities. Facilities are audited by an approved certification body.

### 10. current Good Manufacturing Practices (cGMP)

Food-grade xanthan gum products, and xanthan gum products for cosmetic and personal care applications, are manufactured and sold by CP Kelco USA, Inc., and are produced in compliance with the current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food as defined in the United States Code of Federal Regulations, Title 21, Part 110. Excipient-grade xanthan gum products are manufactured under cGMPs, as defined in USP <1078> "Good Manufacturing Practices Guidelines for Bulk Pharmaceutical Excipients."

### 11. General Standard Packaging/Shipping Information

Product packed in a standard 25-kg boxes

#### Primary Packaging

Description	2.0 mil clear polyethylene liners (21 CFR §177.1520) FDA approved
Dimensions:	19.25" x 33"
Weight:	N/A
Closing System:	Heat sealed

#### Secondary Packaging

Description:	Double walled corrugated boxes
Dimensions:	11.75" (W) x 15.5" (L) x 14.5" (H)
Weight:	1.4 kg (3.0 lb) tare 25 kg (55.1 lb) net 26.4 kg (58.1 lb) gross
Closing System:	Tamper evident tape

#### Tertiary Packaging

Description:	Four way entry pallets that meet ISPM No. 15 standards
Dimensions:	40.0" (W) x 48.0" (L) x 4.0" (H)
Weight:	25 kg (55.1 lb)

#### Unitized Packaging:

Description:	30 units per pallet (3 layers of 10) Bottom and top cardboard tray with protective corner boards on top
Dimensions:	40.0" (W) x 48.0" (L) x 48.0" (H)
Weight:	750 kg (1650 lb) net 816 kg (1799 lb) gross
Closing System:	Stretch wrapped with polyethylene

#### Labeling

Unit:	Company Name, Address, Product Name, Lot Number, CAS, Regulatory Information Country of Origin
-------	---

#### Shipping Capacity

20' Cargo box container:	10 pallets
40' Cargo box container:	20 pallets

All packaging material complies with relevant UK, EU and US food contact legislation.

For information only, i.e. not packaging specifications

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## XANTHAN GUM

Product packed in a standard 25-kg Leverpak drums (or their equivalent) with polyethylene liners (21 CFR § 177.1520)

### Primary Packaging

Description	0.003 mil clear polyethylene liners (21 CFR §177.1520) FDA approved
Dimensions:	28" x 49"
Weight:	N/A
Closing System:	Tied

### Secondary Packaging

Description:	Type: Leverpak drums (or equivalent) with lid and ring lock Lid: Hot dipped galvanized metal, pre-coat varnished metal, or polypropylene.
Dimensions:	16.375" (D) x 24.25" (H)
Weight:	3.6 kg (7.9 lb) tare 25 kg (55.1 lb) net 28.6 kg (63.0 lb) gross
Size:	19 Gallons
Closing System:	Tamper evident tape

### Tertiary Packaging

Description:	Four way entry pallets that meet ISPM No. 15 standards
Dimensions:	40.0" (W) x 48.0" (L) x 4.0" (H)
Weight:	25 kg (55.1 lb)

### Unitized Packaging:

Description:	16 units per pallet (2 layers of 8)
Dimensions:	40.0" (W) x 48.0" (L) x 52.5" (H)
Weight:	400 kg (882 lb) net 482 kg (1063 lb) gross
Closing System:	Stretch wrapped with polyethylene

### Shipping Capacity

20' Cargo box container:	10 pallets
40' Cargo box container:	20 pallets

Shipping Documents: Bill of Lading, Certificate of Analysis (COA)

First In First Out (FIFO): Company policy is to practice FIFO and we cannot guarantee less than three lots per shipment .

All packaging material complies with relevant UK, EU and US Food contact legislation

For information only; these are not specifications.

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## XANTHAN GUM

Product packed in a standard 25-kg multiwalled, valve-filled bags

### Primary Packaging

Description: 4 ply multi-walled White or Kraft paper bag (21 CFR §177.1520) FDA approved  
Dimensions: 20" (W) x 23.5" (L) x 6.25" (H)  
Weight: 0.25 kg (.55 lb) tare  
25 kg (55.1 lb) net  
25.25 kg (55.7 lb) gross  
Closing System: Valve filled, heat sealed (tamper evident), folded and tucked  
Multi-wall properties:\* Wall 1: 49 lb TK (Tea Kraft)  
Wall 2: .05 mil HDPE (High Density Polyethylene – Film)  
Wall 3: 49 lb TK (Tea Kraft)  
Wall 4: 58 lb TK (Tea Kraft)  
*\*From inside out*

### Secondary Packaging

Description: Four way entry pallets that meet ISPM No. 15 standards  
Dimensions: 40.0" (W) x 48.0" (L) x 4.0" (H)  
Weight: 25 kg (55.1 lb)

### Unitized Packaging:

Description: 40 units per pallet (8 layers of 5)  
Bottom and top cardboard tray  
Dimensions: 40.0" (W) x 48.0" (L) x 54.0" (H)  
Weight: 1000 kg (2205 lb) net  
1035 kg (2282 lb) gross  
Closing System: Stretch wrapped with polyethylene

### Labeling

Unit: Company Name, Address, Product Name, Lot Number, CAS, Regulatory Information  
Country of Origin

### Shipping Capacity

20' Cargo box container: 10 pallets  
40' Cargo box container: 20 pallets

Shipping Documents: Bill of Lading, Certificate of Analysis (COA)

First In First Out (FIFO): Company policy is to practice FIFO and we cannot guarantee less than three lots per shipment

All packaging material complies with relevant UK, EU and US food contact legislation

For information only; these are not specifications

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## XANTHAN GUM

### 12. Transportation Information and Storage Conditions

Transportation: Product is not regulated by the US DOT, IATA, IMDG or ADR. For more information see Safety Data Sheet (Section 14)

Storage Conditions: See Product Data Sheet

For Food Grade materials, CP Kelco products cannot be commingled with any poisonous classifications either in warehouses, terminals or transit.

### 13. Product Labels

Labels on each unit contain the Company Name, Address, Product Name, Lot Number (Batch Number), CAS, Regulatory Information, and Country of Origin. Refer to Product Data Sheet for additional information.

### 14. Lot Numbering System

The lot number is seven digits in length. The first digit is the year, the second digit is the month, the next four digits are sequential number, and the last digit is the plant.

Example Lot Number: 4E0231K where 4=year, E=month (A=Jan, B=Feb, etc.), 0321 = sequential number, K=Manufacturing site (e.g, A=San Diego, K=Okmulgee, W=Wulian, H=PacMoore)

6	E	0	3	2	1	K
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Packaged in May of 2016 at  
Okmulgee plant, 321<sup>st</sup> lot packed.

### 15. Country of Origin (COO) / Harmonized Tariff System (HTS)

Country of Origin statements and Harmonized Tariff System (HTS) are available upon request by material number.

### 16. Chemical/Physical/Microbiological Analysis

See Product Data Sheet for each product.

### 17. Heavy Metal Analysis

Refer to the report for annual skip-lot test results for each site.

### 18. Certificate of Analysis (COA)

Certificates of Analysis contain test method number, test parameters and results, specifications, units of measure for each parameter, company name, address, product name, lot number (batch number), producing location, production date, shelf life/best before date.

Also for our food-, personal care-, and excipient-grade biogum products (KELTROL®, KELDENT®, and XANTURAL® lines): The COA indicates which characteristics have been tested on the actual lot. Many of the compendia parameters for which we have process capability are tested on a skip-lot basis, or tested only on a representative product, to ensure we are maintaining process capability. Therefore results for these parameters may or may not appear on every COA.

Below is a typical COA for your information.



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CP Kelco U.S., Inc.  
Cumberland Center II  
3100 Cumberland Boulevard, Suite 600  
Atlanta, GA, USA 30339  
1-800-535-2687

### CERTIFICATE OF ANALYSIS

<b>Ship to:</b>		<b>Date:</b> July 14, 2016	
		<b>Order Number:</b>	
		<b>Shipped From:</b>	
		<b>Customer Order:</b>	
		<b>Delivery:</b>	
		<b>Date Shipped:</b>	
		<b>Bill Of Lading:</b>	
<b>Sold to:(If different from Ship to)</b>		<b>Packaging:</b>	
		<b>Pick Quantity:</b> 0.00	
<b>Product Name:</b> KELTROL® GM		<b>Manufacturing Date:</b> Jan 31, 2016	
<b>Product Description:</b> XANTHAN GUM		<b>Shelf Life/Best Before Date:</b> Jan 29, 2019	
<b>Material Number:</b> 10040696		<b>Lot:</b> 6A0576K	
Characteristic	Test Result	Specification	Test Method
Particle Size, % thru 42 mesh (355 µm)	100	Not less than 95	KTM004
Particle Size, % thru 100 mesh (150 µm)	5	Not more than 25	KTM004
Loss on Drying, %	13	6 - 14	KTM003
Powder Color, %	76	Not less than 67	KTM006
Appearance	Pass	Pass	
Viscosity (1% KCl solution),cP	1315	1200 - 1600	KTM017
pH (1% Solution)	8.0	For Information Only	KTM005
pH (0.25% solution, STW)	6.7	For Information Only	KTM005
Isopropyl Alcohol (NMT 500 ppm for EC)	202	Not more than 750	KTM520
Bacteria (Viable Mesophilic), cfu/g	100	Not more than 2000	KTM800
Yeast, cfu/g	< 50	Not more than 100	KTM803
Mold, cfu/g	< 50	Not more than 100	KTM803
Coliform	Negative	Negative by MPN	KTM801
E. coli	Absent	Absent in 25g	KTM802
Salmonella spp.	Absent	Absent in 25g	KTM804
The Company guarantees that, at the time of shipment, the lot of product meets specification # 107-X and conforms to the requirement of the current edition of the Food Chemical Codex (FCC) and defined in the current EC Directives. Where a guaranteed parameter has been tested on this lot, the result is shown below.			
Total Heavy Metals, ppm	< 20.0	Not more than 20.0	KTM514
Lead, ppm	< 2.0	Not more than 2.0	KTM514
Arsenic, ppm	< 3.0	Not more than 3.0	KTM514
Mercury, ppm	< 1.0	Not more than 1.0	KTM514
Cadmium, ppm	< 1.0	Not more than 1.0	KTM514
S. aureus	Absent	Absent in 1.0g	KTM806
P. aeruginosa	Absent	Absent in 1.0g	KTM807
<b>Signature:</b> <i>Keth Curtis</i>		<b>Material was produced in:</b>	
KETH CURTIS - QUALITY MANAGER		OKMULGEE, OKLAHOMA UNITED STATES	

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## XANTHAN GUM

### 19. Shelf Life

Containers should be stored in a roofed, well-ventilated area in the unopened original package. Functional properties of the product are guaranteed to conform to the stated sales specifications as stated in the Product Data Sheet from the date of manufacture for the specified shelf life when stored under these conditions.

### 20. Safety Data Sheet (SDS)

Available upon request.

### 21. Regulatory and Compendial Information/Legal Requirements

See Product Data Sheet – Regulatory Information section

### 22. Global/International Inventories

See Safety Data Sheet (available upon request)

### 23. Proposition 65

CP Kelco's xanthan gum products sold to you, either within or for sale or distribution within the State of California, are in compliance with California's Proposition 65. No exposure to a listed chemical occurs within the meaning of Prop 65. For Product-specific Prop 65 statement, please refer to the product-specific SDS, Section 15.

### 24. EU Regulations on Hazardous Substances

CP Kelco xanthan gum products have been reviewed under EC 1272/2008 and are not classified as hazardous.

### 25. Genetically Modified Organisms (GMO)

#### [Food-grade xanthan gum products]

CP Kelco's xanthan gum line of products comply with all appropriate U.S. standards and specifications, including the general U.S. regulations governing food ingredients. These products, which are derived from a microbial fermentation process, are not considered "bioengineered foods" as defined by the Food and Drug Administration's proposed rule governing such foods.

CP Kelco's xanthan gum line of products intended for EU comply with the European Council Directive 2001/18/EC concerning the deliberate release of genetically modified organisms and EC Directives 1829/2003 and 1830/2003 concerning traceability of raw materials and labeling, unless otherwise stated on the Product Data Sheet.

CP Kelco's manufacturing facilities employ strict manufacturing standards that comply with all relevant requirements in the United States and the European Union for food products.

#### [ For industrial and oilfield uses]

CP Kelco's xanthan gum is the product of fermentation. Our xanthan gum products comply with the European Council Directive 2001/18/EC concerning the deliberate release of genetically modified organisms. CP Kelco's manufacturing facilities employ strict manufacturing standards that comply with all relevant requirements in the United States and the European Union for industrial and oilfield products.

### 26. Transmissible Spongiform Encephalopathies (TSE)/ Bovine Spongiform Encephalopathy (BSE)

CP Kelco's xanthan gum products do not contain, nor are they derived from specified risk material as defined in the FDA Interim Final Rule (Prohibiting the Use of Certain Cattle Materials that May Carry the Risk of BSE in Human Foods and Cosmetics. Docket Number 2004N-0081 July 14, 2004) and as defined in Regulation (EC) 999/2001, as amended. CP Kelco's xanthan gum products contain no by-products of animal origin of specified risk material, additives, preservatives, or colors. No products of bovine origin are used in the manufacture of xanthan gum; therefore there is no source for BSE (bovine spongiform encephalopathy) or TSE (transmissible spongiform encephalopathy) materials or to contaminate our xanthan gum products.

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### 27. Nutritional Information

[For food uses]

Available upon request

### 28. Suitability for Specific Diets (Vegetarian, Vegan, Muslim, Jewish)

Vegetarian: Suitable

Vegan: Not suitable, unless otherwise specified on the PDS and label

Kosher: Suitable (see Kosher status on the PDS for each product)

Halal: Suitable (see Halal status on the PDS for each products)

### 29. Kosher Status/ Halal Status

Food-, cosmetic-, personal care-, and excipient-grade xanthan gum products are certified as Kosher. CP Kelco xanthan gum is a product of fermentation.

Xanthan gum products produced by CP Kelco are certified Halal.

### 30. Allergen

[For food uses]

CP Kelco Regulatory Affairs has, as part of our ongoing regulatory review of changing requirements in the global marketplace, reviewed the labeling of our food grade products in accordance with:

- The Food Allergen Labeling and Consumer Protection Act (FALCPA), in effect January 1, 2006, require clear labeling of food containing the eight (8) allergen classes: Peanuts, Soybeans, Milk, Eggs, Fish, Crustacea Tree Nuts, and Wheat.
- EU Directive 1169/2011, as amended, requires the labeling of foods containing allergenic substances: Cereals containing gluten, Crustaceans, Eggs, Fish, Peanuts, Soybeans, Milk and dairy products (including lactose), Nuts, Celery, Mustard, Sesame seeds, Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter, Lupin, Molluscs.
- The Brazilian National Health Surveillance Agency ANVISA RDC 26/2015, in effect July 2016, requiring mandatory allergenic labeling.

CP Kelco's xanthan gum products do not contain allergens from the above lists. See below for more detailed information.

Allergenic foods and derivatives	Material supplied contains:	The material supplied is produced:		Cross-contact with the material supplied
		On the same equipment with:	In the same factory with:	
Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and mandelona nuts etc. Peanut may also be known as ground nut.	No	No	No	No
Crustaceans and products thereof (including crab, crayfish, lobster, prawn and shrimp)	No	No	No	No
Fish or its derivatives, (fish protein, extracts, etc.)	No	No	No	No
Eggs or its derivatives, (frozen yolk, egg white powder, egg protein isolates, etc.)	No	Yes	Yes	No
Tree Nuts (almonds, Brazil nuts, cashews, chestnuts, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, pistachios and walnuts or their derivatives, e.g., nut butters and oils etc.	No	No	No	No
Milk and products thereof (inc. lactose)	No	No	No	No*

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Soybeans and products thereof (lecithin, oil, tofu and protein isolates etc.)	No	Yes	Yes	No
Cereals containing gluten and products thereof	No	No	No	No
Sulphur dioxide and sulphites	No	Not applicable	Not applicable	Not applicable
Celery and products thereof	No	No	No	No
Sesame seeds and products thereof	No	No	No	No
Mustard and products thereof	No	No	No	No
Lupin and products thereof	No	No	No	No
Molluscs and products thereof	No	No	No	No
SENSITIVITIES /OTHER INFORMATION FOR LABELING PURPOSES				
Animal and Animal By Products	No	No	No	No
Antioxidants	No	No	No	No
Artificial Colors, Preservatives, Flavorings	No	No	No	No
Barley, Rye, Oats, Spelt, Kamut, Triticale	No	No	No	No
Bee pollen	No	No	No	No
Caffeine	No	No	No	No
Corn (Maize) or its derivatives	No	Yes	Yes	No
Latex	No	No	No	No
Gluten	No	No	No	No
Hydrolyzed Vegetable or Plant Protein (HVP/HPP)	No	No	No	No
MSG	No	Yes*	Yes*	No
Propolis	No	No	No	No
Royal jelly	No	No	No	No
Seeds ( Poppy, Sunflower)	No	No	No	No
Spices, Spice extracts, Herbs	No	No	No	No
Wheat or its derivatives, e.g., flour, starches and brans etc.	No	No	No	No
Yeast	No	No	Yes	No

\*There are no ingredients with allergenic properties used in the packaging areas. The only use of allergen materials is at an early stage in the manufacturing process and they are not present in the final product. These materials are stored in dedicated storage areas and are not handled in areas where finished products would become exposed to contamination. Additionally, warehouses may hold CP Kelco's Simplese products, which is milk based. Proper GMPs are followed to prevent cross contamination.

CP Kelco's xanthan gums also have the following allergen information according to the ALBA databank:

Cow's milk protein	-	Chicken	-	Sesame	-
Lactose	-	Fish	-	Sesame oil	-
Chicken's egg	-	Shellfish and crustaceans	-	Glutamate	-
Soy protein	-	Maize	-	Sulfite	-
Soy lecithin	-	Cocoa	-	Lupine	-
Gluten	-	Legumes/pulses	-	Coriander	-
Wheat	-	Nuts	-	Celery	-
Rye	-	Nut oil	-	Carrot	-
Beef	-	Peanuts	-	Mustard	-
Pork	-	Peanut Oil	-		

+ present      - absent      ? unknown

[For cosmetic uses]

CP Kelco's xanthan gums do not contain any fragrance allergens as listed in the EU Cosmetic Directive 2003/15/EC.

## XANTHAN GUM

### 31. Cosmetic Status

#### [For cosmetic uses]

CP Kelco's xanthan gum products (CAS No: 11138-66-2):

- Are not prohibited for use in cosmetic products in accordance with Regulation (EC) 1223/2009 and its amendments
  - Are not listed as a prohibited substance in Annex II or a restricted substance in Annex III
  - Are not subject to the allowable colorants, preservatives, or UV filters listings in Annexes IV, V, and VI because they do not perform those functions
  - Are not a CMR substance nor do they contain CMR substances as described in Part 3 of Annex VI to Regulation (EC) No 1272/2008, except as allowable per Article 17 of Regulation (EC) 1223/2009.<sup>1</sup>
- Do not contain any substances likely to cause allergic reactions as cited in Regulation (EC) 1223/2009
- Listed as Xanthan Gum in INCI (International Nomenclature of Cosmetic Ingredients)
- Complies with US FDA 21 CFR §172.695 and Purity criteria of current EC directives. (EINECS No. 234-394-2)
- Listed in The Japan Comprehensive Licensing Standards Of Cosmetics By Category 1997, xanthan gum; registered as: Serial Number: 2590; Ingredient Name: Xanthan Gum; Ingredient Code: 109058; Standard Code: 42 [Standard Code 42 means, ingredients other than those which are listed in JSCI and which the Ministry of Health, Labor and Welfare stipulated as the specifications of cosmetic ingredients, The Japanese Cosmetic Ingredients Codex (JCIC).]

<sup>1</sup> Presence of traces of prohibited substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practices and conforms with Article 3. CP Kelco products may contain residual heavy metals, which are an inherent part of the process and complies with the purity criteria of current EC Directives. See Product Data Sheet for more information.

### 32. Organic Status

Xanthan gum is listed as an allowable ingredient, per the following:

- United State's guidelines established by the National Organic Standards Board<sup>1</sup>.
- European Communities of Council Regulation (EC) 834/2007 and Commission Regulation (EC) 889/2008<sup>2,3</sup>.
- Agriculture and Agri-Foods Canada by the guidelines established by Canada General Standards Board CAN/CGSB 32.311-2006, Section 6.4.1<sup>4</sup>.
- Internationally by the guidelines established by the Codex Alimentarius Commission<sup>5</sup>.

Products manufactured in a manner consistent with the provisions of the above referenced citations and the intended end-use can be produced using the ingredient **xanthan gum**<sup>6</sup> without excluding the organic claim on the label per the organic laws of the US, EU, and Canada.

- It is not required to certify xanthan gum as organic per the US, EU, and Canada organic laws.
- Xanthan gum food additive is defined in US 21 CFR & the EU directives.
- CPK manufactures xanthan gum to the compendia and regulatory requirements of the market (US, EU & Canada) and the end use (food).

No ionizing radiation or sewage sludge is used in the production of this product. The product does not require any GMO label<sup>7</sup> in the EU, US or Canada.

<sup>1</sup> Xanthan gum [7 CFR 205.605(b), per 7 CFR 205.105 (c)(e)(f)(g)]

<sup>2</sup> Repealing Regulation (EEC) No 2092/91

<sup>3</sup> Xanthan gum (E 415)

<sup>4</sup> Water extracts, for fat products, fruit and vegetables, cakes and biscuits, and salads. Note: Comments are in process to CGSB to correct "water extract". Xanthan gum is a product of fermentation and is "de-watered", not water extracted

<sup>5</sup> Xanthan gum in Fat products, fruit and vegetables, cakes & biscuits, salads (INS 415)

<sup>6</sup> Does not apply to Keltrol 630 series or xanthan gum blends

<sup>7</sup> Refer to Product Data Sheet, Regulatory and labeling sections and GMO status letter.

### 33. Natural Status

#### [For food uses]

US FDA and EU do not have a regulatory definition of "natural" that applies to regulated food additive products. Canada has labeling guidelines on "natural" foods.<sup>1</sup> We leave to the customer's judgment and legal counsel, the decision regarding the

## XANTHAN GUM

use of the term “natural” in customer-specific advertising or labeling for those products.

<sup>1</sup> Canadian 2003 Guide to Food Labeling and Advertising – Chapter 4, Section 4.7

### [For cosmetic uses]

A definition for the term “natural” in cosmetics has not been established in the US or EU regulations, standards, or guidelines. Since there is no regulatory definition of “natural” that applies to FDA or EU regulated cosmetic ingredients, we leave it to the customer’s judgment and legal counsel, the decision regarding the use of the term “natural” and in the customer’s advertising or labeling for those products.

### 34. Animal Testing

CP Kelco does not conduct testing for any other purposes than worker, environment or consumer safety. CP Kelco Regulatory Affairs, in accordance with guidance from the US FDA, OSHA, EU, and other international regulatory agencies, may be required to perform tests to assess the safety and regulatory compliance of our products. These tests are performed in accordance with US and international test standards. If animal testing is required, it is conducted in accordance with these test standards. An OECD approved alternative to animal testing will be evaluated.

In accordance with and pursuant to Article 11, 2. (e) of Regulation (EC) 1223/2009 on cosmetic products, the most recent safety study using **xanthan gum test articles** analogous to the CP Kelco **xanthan gum** commercial product was conducted prior to 1980.

Please note that this information does not apply to all products. Please see Animal Testing Policy Letter, available upon request

### 35. Residual Solvents/ Organic Volatile Impurities (OVI)

With the exception of IPA (2-propanol, iso-propanol, isopropyl alcohol) organic volatile chemicals (solvents) are not used in our manufacture, handling or storage of xanthan gum.

Subsequently CP Kelco does not test for the presence of other solvents. The NF monograph for xanthan gum lists an isopropyl alcohol requirement of not more than 750 mg/kg (ppm). This solvent is listed under Class 3 in the ICH guidelines and the current USP/NF Residual Solvents Section <467>. CP Kelco uses isopropyl alcohol (2-propanol, IPA) in the manufacture of xanthan gum that it tested to comply with the purity criteria of the NF. No other Class 3 solvent and no solvents from Class 1, Class 2, or “other” solvents from Table 4 are used in the production of these xanthan gum products.

### 36. Irradiation

CP Kelco xanthan gum products do not undergo irradiation unless otherwise stated on the product data sheet and labeled.

### 37. Pesticide Residue Analysis

Pesticide use in CPKelco manufacturing plants is restricted to the external grounds. Pesticides are not stored on site and are applied by external certified pest control providers. For additional confirmation, CPKelco performs a Multi-Residue Analysis (Organohalides, Organonitrogen, Organophosphates and N-methyl Carbamates) on an annual basis. Results are included in the report for annual skip-lot testing results.

### 38. Aflatoxin Screening

Aflatoxin screening (B1, B2, G1 and G2) is conducted on an annual basis. Results are included in the report for annual skip-lot testing results.

### 39. FDA Continuing Guarantee

[For food, pharmaceutical, and cosmetic uses]

Available upon request

### 40. REACH Status

Available upon request