CPKelco

Presentation to the National Organic Standards Board November 28-30, 2007

Handling Committee:
205.605b: Gellan gum

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RE: Federal Register, Vol. 72, No. 197
Doc. No. AMS–TM–07–0118; TM–07–09

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- CP Kelco, a Huber Company, thanks the United States Department of Agriculture, Agricultural Marketing Service (AMS) and the National Organic Standards Board (NOSB) for the opportunity to comment at the Meeting of the National Organic Standards Board," on behalf of the **Handling Committee: 205.605b: Gellan gum**.

- CP Kelco especially appreciates the NOSB providing another opportunity for the review of **Gellan gum** this meeting.

Gellan Gum Reviews: USDA NOP/TAP and NOSB Materials Handling Committee

- **Gellan gum** received a positive scientific review from the **USDA TAP**.
  - **USDA TAP REVIEW:** "Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21)): Thus, gellan gum is produced by a naturally-occurring biological process, and a chemical process is used to extract the gellan gum from the fermentation medium and to formulate the desired thickness of the gum. The extraction and formulation steps do not alter the identity of the gellan gum produced by the microbial culture, but they do manipulate functional properties (i.e., the thickness and hardness) of the substance."

- **Gellan gum received a positive recommendation from NOSB Materials Handling Committee that was carried to the March 2007 NOSB meeting.**
  - *Yes: __5___ No: ___0__ Absent: __0_____ Abstain: _0*
  - The **Materials Handling Committee** found **Gellan gum** to be:
    - Not harmful to human health or the environment.
    - Necessary because of the unavailability of alternatives
    - Consistent and compatible with organic practices.

What is Gellan Gum?

Gellan gum is:

- A water soluble high-molecular weight polysaccharide (gum) that is composed of repeating monosaccharide units. The four monosaccharides are rhamnose (a sugar found in a variety of plants), Glucuronic acid (an oxidized glucose molecule), and two glucose units (a component of sucrose, which is common sugar).
  - Molecular weight greater than 70,000 Daltons with 95 percent above 500,000 Daltons.
- Produced by the pure-culture fermentation the non-genetically modified, non-pathogenic and nontoxic microorganism, *Sphingomonas elodea* (ATCC 31461) in a medium with protein and carbohydrate source and other nutrients.
  - Pasteurization is used to kill viable cells prior to 'recovery' or separation of the gum from the broth.
  - The gum is recovered from the broth with isopropyl alcohol. The isopropyl alcohol, some cell debris, and the water are then removed and the remaining gum is then dried and milled to a fine powder.

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Is Gellan Gum Safe? ISO, Purity, GMP

- Food grade Gellan gum is tested to meet the specifications identified in the monographs of
  - The Food Chemical Codex and
  - The current EU Gellan gum specification for purity criteria
- All test methods used to analyze Gellan gum are
  - Either official methods from the Food Chemicals Codex, the AOAC, FDA's BAM or
  - Have been validated by CP Kelco
- Gellan gum is manufactured by CP Kelco according to
  - A Quality System registered to ISO 9001 and
  - FDA's Food Good Manufacturing Practice (GMP) (21 CFR Part 110).

USDA TAP: Evaluation Question #12: Does the petitioned substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? (From 7 CFR § 205.600 (b) (5))

- Gellan gum does not contain residues of heavy metal or other contaminants in excess of FDA tolerances. 21 CFR 172.665 requires that residual isopropyl alcohol is not to exceed 0.075 percent in gellan gum used as a direct food additive. The gellan gum also must be produced by a process that renders it free of viable cells of *P. elodea*.

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Is Gellan Gum Safe?

- Other gums currently on the National List are recovered with isopropyl alcohol in a similar manner, such as pectin, xanthan, and carrageenan.
  - Many other substances listed on the National list contain isopropyl alcohol , such as xanthan. The FDA limit is 750 ppm (0.075%). However the actual IPA in any final product would be much lower.
  - Typical Gellan gum use level is **0.025-2.0%.** Therefore, even if ALL of the 750 ppm residual IPA remained in a final food product after preparation, that level would be **1.8 ppm -15 ppm**.
- Gellan gum has been tested in animals and humans and no toxic effects were observed.

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Is Gellan Gum Safe? Environmental

- The manufacture procedure of and in using Gellan gum results in an insignificant impact on the environment.
  - A recovery procedure is used to reclaim the isopropyl alcohol (i.e., it is continually reused and environmental emissions are controlled).
  - During the manufacturing process any waste is discharged to the municipal sewage treatment plant and is only present in trace amounts.
  - Waste materials from finished food grade Gellan gum product is either composted, sent to land fills, or treated in waste water treatment plants which does not result in an adverse effect on the environment.

Is Gellan Gum Safe? Environmental

- Gellan gum has no toxic effect to the environment.
- Being a polysaccharide it is biodegradable and does not persist in the environment.
  - ***USDA TAP: Evaluation Question #6: Are there adverse effects on the environment from the petitioned substance's manufacture, use, or disposal? (From 7 CFR § 205.600 (b) (2))*** There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of gellan gum. Due to its low toxicity, EPA exempted gellan gum from the requirement for a tolerance limit when used as an inactive ingredient in pesticide formulations. According to the petitioner (CP Kelco, 2004), gellan gum readily biodegrades into its four naturally-occurring constituent sugars. Although isopropyl alcohol waste is generated when producing gellan gum, there is no information to indicate that this would cause environmental problems.
- No adverse effect from gellan gum has been reported on human health or environmental.

Gellan Gum Offers Distinctive Qualities to the Growing Organic Industry

Gellan gum

- Presents distinctive qualities to formulators of products across various application segments.
  - A wide variety of products currently unavailable to the health conscious organic consumer can be made available by the addition of this unique material, Gellan gum, to the National List.
- Will give new functionalities to product developers and formulators in the growing organic industry for organic consumer products to be labeled organic or made with organic.
  - Such as: Aspics; frostings; brownies and bakery fillings; confectionery, gelatins and puddings; water gels; nonstandardized jams and jellies; dairy drinks and soy milks; nutritional products; beverages (fruit drinks, drinking jellies, coffee and tea, meal replacements and nutritional beverages, acidified protein drinks, novelty drinks); yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; pourable and spoonable dressings; and diary desserts.

Why Gellan Gum?

Gellan gum

- Provides **processing flexibility for organic food manufactures**
  - It can be used in standard processing without additional steps such as in the preparation of gelled confections where no special handling or modification of the process is required.
- **Unique "fluid gels**" are very good at suspending particulant matter
  - Protein, minerals (e.g, calcium), milk solids, vitamins, fiber and pulpin products.
- Suspensions will **remain stable**.
  - Utilization in **soy, rice, and almond organic beverages** would ensure consumption of key nutritional ingredients such as proteins and, while maintaining excellent sensory characteristics.
- **Imparts very little mouth feel while holding particles**
  - Which makes Gellan gum particularly effective in beverages for suspension of fruit pulp or jelly pieces.

Why Gellan Gum?

Gellan gum

- Can be used at a significant lower concentration than other gums.
- Provides the most firm and brittle texture than any gelling agent currently on the National List .
- Is heat stable and does not break down in acid systems.
- Will hydrate in cold systems.
- Can stabilize oil in water emulsions.
- Is an excellent suspension agent but it is shear thinning and can be applied by spraying.
- Can form films.
- Acts as a rheology modifier.

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Gellan Gum Functionality in Food Applications

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What is Gellan Gum?

- A stabilizer produced by fermentation, in a process similar to that used to produce xanthan gum. As such, it is animal-free and sustainable.
- At very low use levels, gellan gum forms a unique “fluid gel,” a weakly structured network, which can suspend insoluble particles such as fruit pulp and minerals in beverages, while maintaining a light and refreshing mouthfeel.
- At higher use levels, gellan gum forms true gels which can add texture to create novel products, enhance existing products, provide heat stability, and control water.
- Like all stabilizers, gellan gum has its own unique “fingerprint” in terms of functionality and “best fit” applications.
- Growing area of interest: Suspension of particulates in beverages.

Need for Suspension in Beverages

Suspension of cocoa, insoluble minerals, soy protein, fruit pulp, fruit pieces, insoluble fibers, novelty inclusions in:

- Juice drinks
- Neutral protein beverages
- Coffee and tea beverages
- Meal replacement and nutritional beverages
- Acidified protein drinks and smoothies

Why Suspend? Uneven Distribution of Calcium in Soymilk or Rice Drinks

"Not All Calcium-fortified Beverages Are Equal"

Nutrition Today [40(1):39-44, January/February 2005].

In the article, researchers showed all of the soy and rice beverages tested had most of their calcium in a separated, particulate form, in amounts ranging from 82% to 89% of the total calcium of the beverage.

Gellan Gum vs. Carrageenan vs. Pectin in Beverages

Function	Suspend cocoa in chocolate milk	Suspend cocoa and minerals in coffee beverages	Suspend pulp in fruit drinks and teas	Suspend minerals in soy milk	Suspend minerals in rice milk	Suspend particulates in acidified protein drinks and yogurt smoothies	Add mouthfeel to beverages
Gellan Gum	Excellent: Light mouthfeel	Excellent: Light mouthfeel	Excellent: Light mouthfeel	Excellent: Light mouthfeel	Excellent: Light mouthfeel	Yes, in combination with pectin	No
Carra-geenan	Excellent: Full mouthfeel	No	No	Fair: Medium mouthfeel	No	No	Yes, especially in dry mix beverages
Pectin	No	No	No	No	No	Yes, in combination with gellan gum	Yes, in ready-to-drink beverages

Gellan Gum vs. Carrageenan vs. Pectin in Food Applications

Function	Ice Cream and Dairy Desserts	Confectionery	Water Dessert Gels	Fruit Bakery Fillings, Yogurt Fruit Preps, Jams/Jellies	Yogurt White Mass	Meat
Gellan Gum	Very limited	Firm, short texture. Adds heat stability to gummy candies.	Adds heat stability – does not melt when heated. Range of textures.	Excellent flavor, texture, and heat stability, alone or in combination with starch.	Yes	No
Carra-geenan	Prevents whey-off, controls ice crystal growth, thickens, gels.	Elastic texture similar to gelatin, with increased heat stability.	Melts when heated. Range of textures.	Limited	No	Yes
Pectin	No	Tender, short texture. Adds heat stability to gummy candies.	No	Excellent flavor, texture, and heat stability, alone or in combination with starch. Standard of Identity jams/jellies.	Yes	No

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Conclusions

- Gellan gum has unique properties which lend themselves to specific food applications such as suspension of particulates in beverages, and providing heat stability to confections and water gels.
- Utilization of gellan gum “fluid gels” in organic soy, rice, and almond beverages would ensure consumption of key nutritional ingredients such as proteins and calcium, while maintaining excellent sensory characteristics.
- The properties of gellan gum complement those of other stabilizers such as carrageenan, xanthan gum, and pectin, and when used alone and in combination with existing stabilizers, will deliver functionality currently unavailable to the organic industry.
- **In summary, the availability of gellan gum for use in organic foods, by itself as well as in combination with other stabilizers, will bring new functionalities to product developers of organic foods, and allow those producers to better serve this important, growing market.**

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Why Gellan Gum?

Gellan gum

- Could provide the organic community with another non-animal gel source.
  - Is a sustainable product of fermentation versus an animal extract that requires far more resources to produce than Gellan gum.
  - Can be substituted for gelatin (animal based gelling agent) as a non-animal source gelling system.
  - Is suitable for vegetarians and people with religious dietary restrictions (Kosher/Halal).
  - Can be used without the concerns about BSE.
- Can serve to **compliment the properties of other stabilizers already on the National List**
  - Such as carrageenan, xanthan gum, and pectin when used in combination. Together, functionality will be delivered that is currently unavailable to the organic industry.

The Organic Industry has expressed a strong interest in Gellan gum

- Letters of support for gellan gum were sent to the Public Comment site in response to FR docket.
  - **AMS-TM-07-0118**
    - http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AMS-TM-07-0118
- Additional letters of support were sent to CP Kelco after the docket closed for comment.
- All letters received to date are attached.
- Again, CP Kelco thanks the National Organic Standards Board for the opportunity to speak
  and
- Asks that the NOSB consider recommending *205.605b: Gellan gum* to the NOP List.