Gellan Gum

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Gellan gum

Other Name:
None identified

Trade Names:
Kelcogel®
Gelrite
Phytagel
Gel-Gro

CAS Numbers:
71010-52-1

Other Codes:
2751175 (European Union register number and European Inventory of Existing Commercial Chemical Substances (EINECS) number)
KE-17592 (Korean Gazette number)

Characterization of Petitioned Substance

Gellan gum is a high molecular weight polysaccharide (i.e., complex sugar) gum produced as a fermentation product by a pure culture of the microbe *Sphingomonas elodea*[1]. The production organism is an aerobic, well-characterized, non-pathogenic, gram-negative bacterium (JECFA, 1990). The general chemical structure of gellan gum is presented in Figure 1. Its structure consists of four linked monosaccharides (i.e., simple sugars), including one molecule of rhamnose (a sugar found in various plants), one molecule of glucuronic acid (an oxidized glucose molecule), and two molecules of glucose (a component of sucrose, which is common sugar). The exact molecular formula of gellan gum may vary slightly (e.g., depending on the degree to which the glucuronic acid is neutralized with various salts [see "Properties of the Substance" and Evaluation Question 1]).

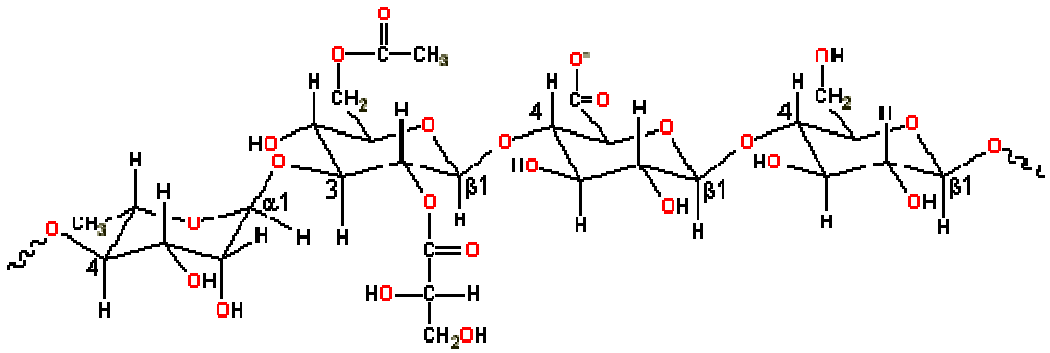

Figure 1. Gellan Gum Structure (Chaplin, Date Unknown)

There are three basic forms of gellan gum products, which are distinguished by their polysaccharide content, the percent substitution of o-acetyl functional groups, and/or the protein content (including nucleic residues and other organic nitrogen sources) (JECFA, 1990).

Properties of the Substance:
Gellan gum is a water soluble, off-white powder. It has a molecular weight greater than 70,000 daltons with 95 percent above 500,000 daltons. It forms gels when positively charged ions (i.e., cations) are added. Thus, the thickness and texture of gellan gum in various products can be controlled by manipulating the addition of potassium, magnesium, calcium, and/or sodium salts. In the same way, its melting temperature can be modified to either be below or above 100° C (Chaplin, Date Unknown).

[1] *Sphingomonas elodea* was formerly known as *Pseudomonas elodea* (Donner and Douds, 1995).

Specific Uses of the Substance:
Gellan gum is a food additive that acts as a thickening or gelling agent, and can produce gel textures in food products ranging from hard and brittle to fluid. Types of products that typically contain gellan gum include: bakery fillings, confections, dairy products, dessert gels, frostings, icings and glazes, jams and jellies, low-fat spreads, microwavable foods, puddings, sauces, structured foods, and toppings (Duxbury, 1993).

According to the petitioner's Internet site[2], gellan gum also can be used in lotions and creams, make-up, face masks and packs, hair care products, toothpaste, and air freshener gels. Gellan gum also may be used in canned cat and dog food (CP Kelco, 2004).

Approved Legal Uses of the Substance:
According to EPA, gellan gum is exempt from the requirement for a pesticide tolerance when used as an inert ingredient in pesticide formulations (EPA, 2004). Approval for the use of gellan gum as an inert ingredient in pesticide formulations is promulgated at 40 CFR 180.950.

According to FDA, gellan gum may be safely used as a direct food additive for human consumption as long as its use is in accordance with 21 CFR 172.665. According to 21 CFR 172.665, gellan gum is produced from *P. elodea* (now known as *S. elodea*) by a pure culture fermentation process and purified by recovery with isopropyl alcohol. Residual isopropyl alcohol in the gellan gum must not exceed 0.075 percent. Additionally, it is exempt from the threshold of regulation (21 CFR 170.39) for its use as a coating or sizing agent on food contact articles.

According to the petitioner, gellan gum may be used in canned cat and dog food at a level not exceeding 0.4 percent. In canned pet food, gellan gum is to function as a stabilizer and thickener and must meet the requirements of 21 CFR 172.665. This use is published in the Official Publication of the American Association of Feed Control Officials.

Action of the Substance:
Gellan gum acts as a thickening or gelling agent and can produce textures in the final product that vary from hard, non-elastic, brittle gels to fluid gels. Gellan gum is produced from *S. elodea* by a pure-culture fermentation process and then recovered with isopropyl alcohol. The gellan gum obtained from the microbial culture includes acetyl and L-glycerate groups that are removed (i.e., the gellan gum is de-acylated) to some extent with the addition of an alkali. The gellan gum is then precipitated from the fermentation medium with isopropyl alcohol (Doner and Douds, 1995). The gel thickness for specific products can be controlled by manipulating the addition of alkali cations (i.e., by adding potassium, magnesium, calcium, and/or sodium salts).

Status

International:
Gellan gum is approved, registered, or filed as a food additive in the following countries: Argentina, Brazil, Canada, Chile, Columbia, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, Venezuela, Egypt, Hungary, Israel, Jordan, Morocco, Norway, Pakistan, Poland, South Africa, Switzerland, Tunisia, Turkey, Australia, China, Hong Kong, India, Indonesia, Japan, Malaysia, Malta, New Zealand, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, the Philippines, and Vietnam (EPA, 2003). In the European community, gellan gum has approval (E–418) as a food additive.

Additionally, in April 2004, the Joint FAO/WHO Food Standards Programme 6th Session listed gellan gum as a food additive that can be used in fermented milk products under Good Manufacturing Practice (GMP) levels of use. This Committee also proposed draft revised standards for use in dairy spreads, including

[2] http://www.cpkelco.com/personalcare/

cream cheese, with gellan gum being listed as one of the ingredients that can be used under GMP levels of use.

Gellan gum is not specifically listed for the petitioned use (i.e., as a thickening or gelling agent) or other uses in the following international organic standards websites:

- Canadian General Standards Board: http://www.pwgsc.gc.ca/cgsb/032_310/32.310epat.pdf
- CODEX Alimentarius Commission: ftp://ftp.fao.org/docrep/fao/005/Y2772e/Y2772e.pdf
- European Economic Community (EEC) Council Regulation 2092/91: http://europa.eu.int/eur-lex/en/consleg/pdf/1991/en_1991R2092_do_001.pdf
- International Federation of Organic Agriculture Movements: http://www.ifoam.org/standard/norms/cover.html
- Japan Agricultural Standard for Organic Production: http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21))

Gellan gum is produced by a microbial culture and then further processed for commercial applications. Gellan gum is produced from *S. elodea* by a pure-culture fermentation process. It is recovered from the fermentation culture with isopropyl alcohol (Doner and Douds, 1995). The thickness and hardness of the gellan gum is determined by acetyl groups present in the gellan gum obtained from the microbial culture. With acetyl groups present, the gel is soft and elastic. Firmer gels are obtained by removing the acetyl groups to some extent by adding potassium, magnesium, calcium, and/or sodium salts).

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.

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21))

See Evaluation Question 1. The formulation and manufacturing process involves partial removal of acetyl groups, which in-turn affects the thickness and hardness of the gel.

Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21))

Gellan gum is produced by inoculating a carefully formulated fermentation medium with the microorganism *Pseudomonas elodea*.

Evaluation Question #4: Is there a natural source of the petitioned substance? (From 7 CFR § 205.600 (b) (1))

Although gellan gum may be produced in nature by *Pseudomonas elodea,* there is no evidence that natural sources produce gellan gum in quantities sufficient for commercial uses.

Evaluation Question #5: Is there an organic agricultural product that could be substituted for the petitioned substance? (From 7 CFR § 205.600 (b) (1))

No organic agricultural products were identified that could be substituted for gellan gum. However, similar substances listed as non-synthetic non-agricultural (non-organic) substances allowed as ingredients in or on processed products (7 CFR § 205.605(a)) include agar-agar and carrageenan. Synthetic substances allowed for the same purposes (7 CFR § 205.605(b)) include alginates, pectin (low-methoxy), and xanthan gum. Like gellan gum, carrageenan, pectin, alginate, and agar are all gelling agents (Wanous, 2004). Other thickeners used in foods include arabic (gum acacia), gum carob, gum karaya, and gum tragacanth (Iqbal, 1993). Gums approved by the FDA include arabinogalactan and carrageenan. Determining which gum to use in an application greatly depends on the type of functionality needed and the application's processing parameters.

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.

Evaluation Question #7: Does the petitioned substance have an adverse effect on human health as defined by applicable Federal regulations? (From 7 CFR § 205.600 (b) (3))

There are no known harmful effects on human health after exposure to gellan gum. However, it may have a laxative effect at high intakes (JECFA, 1990).

JECFA (1990) summarized one clinical trial in which five males and five females consumed 175 mg/kg/day of gellan gum for 7 days after a 7-day control period. Participants were then exposed to 200 mg/kg/day of gellan gum for an additional 16 days. There were no adverse dietary or physiological effects in any of the volunteers. Additionally, there were no allergenic or other subjective untoward manifestations reported by or observed in any of the human subjects. It was noted, however, that gellan gum acted as a fecal bulking agent, increased fecal bile acid, decreased fecal neutral sterols, and decreased serum cholesterol (JECFA, 1990).

Evaluation Question #8: Is the nutritional quality of the food maintained when the petitioned substance is used? (From 7 CFR § 205.600 (b) (3))

The authors of a human consumption trial summarized by JECFA (1990) concluded that ingestion of gellan gum at the given dose level (200 mg/kg/day) had no adverse dietary effects. No other information on potential nutritional effects was found.

Evaluation Question #9: Is the petitioned substance to be used primarily as a preservative? (From 7 CFR § 205.600 (b) (4))

Gellan gum is added to foods to modify thickness or enhance texture.

Evaluation Question #10: Is the petitioned substance to be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? (From 7 CFR § 205.600 (b) (4))

Gellan gum is a food additive that acts as a thickening or gelling agent, and can produce textures in the final product that vary from hard, non-elastic, brittle gels to fluid gels. It could be used to enhance textures in a variety of products. It is uncertain whether any potential uses of gellan gum would be to recreate textures lost in processing.

Evaluation Question #11: Is the petitioned substance generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices? (From 7 CFR § 205.600 (b) (5))

Gellan gum is not GRAS. According to FDA, gellan gum may be safely used as a direct food additive for human consumption as long as its use is in accordance with 21 CFR 172.665. Additionally, it is exempt from the threshold of regulation (21 CFR 170.39) for its use as a coating or sizing agent on food contact articles.

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*.

References:

Chaplin, M. Date Unknown. Water Structure and Behavior. Available at: http://www.lsbu.ac.uk/water/index.html.

CP Kelco. 2004. Petition for Evaluation of Gellan Gum for Inclusion on the National List of Substances Allowed in Organic Production and Handling (7 CFR 205.605(b)). Available at: http://www.ams.usda.gov/nop/NationalList/GellanGum.pdf.

Donner, L.W. and D.D. Douds. 1995. Purification of commercial gellan to monovalent cation salts results in acute modification of solution and gel-forming properties." Carbohydrate Research 273 (1995) 225-233. Available at: http://wyndmoor.arserrc.gov/Page/1995/6198.pdf.

Duxbury, D.D. 1993. Multi-functional gum gets final FDA approval: gellan gum offers formulators low use levels and high versatility. Food Processing. Issue February 1993. Available at: http://www.allbusiness.com/periodicals/article/356776-1.html.

EPA. 2004. Gellan Gum; Exemption from the Requirement of a Tolerance. *Federal Register* Volume 69, Pages 9958-9963. March 3, 2004.

EPA. 2003. Gellan Gum; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food. *Federal Register* Volume 68, Pages 42026-42030. July 16, 2003.

Iqbal, M. 1993. International trade in non-wood forest products: An overview. FO: Misc/93/11 - Working Paper. Available at: http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/x5326e/x5326e08.htm.

JECFA. 1990. Gellan Gum. Available at: http://www.inchem.org/documents/jecfa/jecmono/v28je17.htm.

Wanous, M. 2004. Texturizing and Stabilizing, by Gum! Available at: http://www.preparedfoods.com/CDA/ArticleInformation/features/BNP__Features__Item/0,1231,117073,00.html.