Petition for Evaluation of Low Acyl Gellan Gum for Inclusion on the National List of Substances Allowed in Organic Production and Handling (7 CFR 205.605 (b)

Submitted by:

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Date:

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List of Appendices

Item A.1 — Section of National List

CP Kelco U.S., Inc. is petitioning to have Gellan Gum (low acyl) added to the National List per § 205.605(b): Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’

Item A.2 — OFPA Category - Crop and Livestock Materials

The OFPA categories referenced in 7 U.S.C. § 6517(c)(1)(B)(i) do not apply to materials petitioned for use in organic handling or processing.

Item A.3 — Inert Ingredients

This section does not apply to this petition.

The purpose of this petition is to request the USDA National Organic Program and National Organic Standards Board allow low acyl gellan gum to the existing 7 CFR §205.605. The current National List states: Gellan gum (CAS # 71010–52–1)—high acyl form only.

1. Substance Name

Common Name: Gellan Gum

2. Petitioner and Manufacturer Information

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3. Intended or Current Use

High Acyl Gellan gum is currently allowed at 7 CFR 205.605(a) as a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products
Gellan gum (low acyl) is intended for use by organic product formulators as a stabilizer and gelling agent as outlined in 4.1 and 4.2 below.

4. Intended Activities and Application Rate

4.1. Food uses

Gellan gum (low acyl and high acyl), an approved food additive, is used in various food formulations, such as aspics; frostings; brownies and bakery fillings; gelatins and puddings; nonstandardized jams and jellies; dairy drinks and soy milks; nutritional products; beverages (dairy alternative milks, dairy drinks, fruit drinks, drinking jellies, novelty drinks); beverage mixers; kefir; yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; marinades; pourable and spoonable dressings; and dairy desserts.

The mode of action is as a suspending or gelling agent with film-forming and texturizing attributes [Appendix 1]. Gellan gum forms gels in the presence of ions when heated and cooled. The gum is stable under normal storage conditions.

The typical amount of gellan gum used does not exceed 0.5% of the processed food because of the self-limiting nature of the gum, which is the concentration of gellan gum above at which will result in an unappealing or undesirable product because of too much texture.

- Appendix 2a: Provides typical gellan gum use levels in various food product.
- Appendix 2b: Provides testimonials from formulators who require or are using the low acyl gellan gum and are restricted from the organic certifications needed to expand their reach to customers who use organic certified products.

4.2. Animal and Canned Pet Food

Gellan gum is approved in animal food and canned pet food. Gellan gum is not to exceed 0.4% in canned dog or cat food.

4.3. Consumer Products, Cosmetics and Personal Care

Gellan gum is also used in personal care products, such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. Additional uses of gellan gum are found in consumer products, such as ophthalmics, air care gels, agricultural suspensions, paints, coatings, liquid detergents, cleaners, suspensions and films.

5. Manufacturing Process

Gellan gum is a high-molecular weight polysaccharide, produced by the pure-culture fermentation of a carbohydrate with the non-genetically modified, non-pathogenic and nontoxic microorganism, *Sphingomonas elodea* (ATCC 31461), formerly known as *Pseudomonas elodea*. The structure of high acyl gellan gum consists of a 4-sugar repeating units with acetate and glycerate side chains. Removing the acetate and glycerate groups results in a linear molecule with unique properties. See Appendix 3a for additional information.

The following steps produce gellan gum:

- The first step of producing the gum is by inoculating a carefully formulated fermentation medium with this organism.
- The medium contains a bio-based glucose syrup carbon source, phosphate, organic and inorganic nitrogen sources, and appropriate trace elements.
- The fermentation is carried out under sterile conditions with strict control of aeration, agitation, temperature, and pH.
- Deacylation of the gum develops the required functionality. A strong base is used to deacylate gellan gum. This additional step does not change the polysaccharide backbone of the molecule. After deacylation, acid is used to neutralize the gellan gum solution.
    - High acyl gellan gum is treated with potassium hydroxide and heated. This produces low acyl gellan gum and potassium acetate and potassium glycerate. The potassium acetate and potassium glycerate are removed from the low acyl gellan gum during the precipitation and recovery of the low acyl gellan gum with isopropyl alcohol.
- The gum is recovered by precipitation with isopropyl alcohol.
- The precipitate is then dried and milled to a fine powder.
- The powdered form of the product is packaged.

Production, including fermentation, takes place at CP Kelco's facility in San Diego, CA.

Gellan gum is manufactured according to a Quality System registered to ISO 9001, Certificate No. FM28961, and food GMPs (21 CFR Part 117).

5.1. Manufacturing Process

The manufacturing process for gellan gum is a typical industrial fermentation process. The process for making low acyl gellan gum consists of fermentation, deacylation, clarification, recovery and testing. Each of these steps is discussed in more detail below and shown in a diagram [Appendix 3b].

5.1.1. Seed Development

The S-60 organism (S. elodea) is maintained as lyophilized stock and is revived in broth culture before freezing aliquots at –80°C for intermediate storage up to five years.

Seed development begins by inoculating 4 L of media with a frozen aliquot and shaking at 30° C for 20-36 hours. This flask is used to inoculate a 1000-5000 gallon seed vessel that undergoes the same type of fermenting and culturing to make sure purity is maintained. Sterile airflow and agitation are provided to ensure adequate oxygen supply and mixing.

5.1.2. Fermentation

A 10,000-50,000 gallon fermentor is inoculated with 1 or 2 of the 1000-5000 gallon seed vessels, fermented and cultured for 40 to 100 hours until the carbon source is exhausted. Final viscosity is dependent on the actual carbon charge but varies between 1000 and 100,000 cP. Sterile airflow and agitation are provided to ensure adequate oxygen supply and production.

5.1.3. Deacylation (for production of deacylation type product)

After the fermentation is completed, the fermented media is adjusted to pH 10.0 to 13.0 using a strong base. Deacylation is accomplished at high pH, usually at a temperature between 150° F and 280° F for 1 to 10 minutes. The pH is then adjusted to between 4 and 9 with a strong acid.

5.1.4. Clarification (for production of clarified type product)

Deacylated gellan broth is filtered to remove insoluble material.

5.1.5. Recovery

Gellan gum is precipitated using isopropyl alcohol. Glycerate and acetate, the biproducts of deacylation remain in the alcohol after precipitation and are removed from the product completely. The remaining low acyl fibers are pressed, dried, and milled to specification. [See Appendix 3a]

5.1.6. Testing

Gellan gum is held in quarantine until completion of testing and release by Quality Control and meets specifications identified in the Food Chemicals Codex monograph [Appendix 4].

5.1.7. Packaging

Gellan gum is packaged in bags and Leverpak drums or their equivalent) with polyethylene liners.: 25-kg, 50-lb, 50-kg and 100-lb (All packaging materials comply with relevant United States food contact regulations.

6. Ancillary Substances

No ancillary substances are in the gellan gum products.

7. Previous Reviews

All reviews of gellan gum have been for both the low acyl and high acyl. There is no differentiation between the two types made by regulatory authorities.

- Non-GMO Project (Certification):
  - Gellan gum (CAS # 71010-52-1) - The following low acyl gellan gum products are currently certified by NGP:
    - Kelcogel [E] - Certified 27 May 2017
    - Kelcogel F [E] - Certified 27 May 2017
    - Kelcogel CG-LA [E] - Certified 27 May 2017

8. Regulatory Authority

All Regulatory Approvals listed below are for both the low acyl and high acyl form of gellan gum. No differentiation between the two types is made in the regulatory approvals.

Gellan gum was approved by the US Food and Drug Administration in the 1990s as a food additive for use as a stabilizer and thickener under GMP levels of use in all food except where specific standards of identity preclude its use.

- USFDA FAP 7A4022, approved 11-25-1992 (Gellan Gum at 21 CFR 172.665)

FDA also approved an exemption for gellan gum under 21 CFR 170.39 thresholds of regulation, for its use as a coating or sizing agent on food-contact articles.

- USFDA: Approval from Department of Health and Human Services, Blondell Anderson, February 19, 1998.

Gellan gum may be used in pet foods (canned dog and cat food) at a level not to exceed 0.4%, functioning as a stabilizer and/or thickener and meeting the requirements of 21 CFR 172.665. This use is published in the Official Manual of the American Association of Food and Feed Control Officials.

Food grade gellan gum (low acyl and high acyl) meets the requirements of the *Food Chemicals Codex (FCC)*.

Gellan gum may be used in pesticide formulations as an inert, meeting requirements of 40 CFR 180.950 [Appendix 6].

Gellan gum is approved for food use by the Canadian government and listed in the Canadian Food and Drug Act (Division 16, Table IV, G.2)

Gellan gum is also approved for food use in Japan and found in Japanese Specifications and Standards for Food Additives.

The EU lists gellan gum (E418) in the European Community Directive EC/95/2, Annex 1.

Gellan gum has a safe history of use as a food additive worldwide and is recognized by the World Health Organization Joint Expert Committee for Food Additives as safe. JECFA, as well as the European Community Scientific Committee for Food, have established an Acceptable Daily Intake (ADI) of 'not specified (NS),' the highest rating given to an ingredient for which no toxic effects were observed [Appendix 7 and Appendix 8].

The Joint FAO/WHO Food Standards Programme 6th Session in April 2004 lists gellan gum as a food additive that can be used in fermented milk products under GMP level of use. This Committee also proposed draft revised standards for dairy spreads with gellan gum one of the ingredients listed under GMP level of use. Finally, the same Committee proposed a revised standard for cream cheese and gellan gum is listed as one of the ingredients that can be used under GMP level of use [Appendix 9, Appendix 10, and Appendix 11].

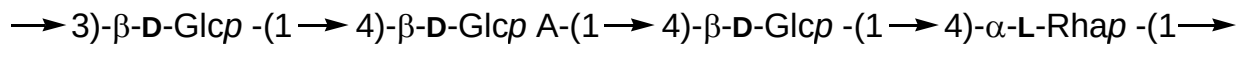
9. Chemical Abstracts Service (CAS) Number and Product Labels

- The CAS Registry number for gellan gum (both low acyl and high acyl) is 71010-52-1.
- The EU Registry Number for gellan gum (both low acyl and high acyl) is 2751175
- The EINECS Inventory Number for gellan gum (both low acyl and high acyl) is 2751175
- The Korean Gazette Number for gellan gum (both low acyl and high acyl) is KE-17592

See Appendix 12 for Product Labeling Information. Information has been included for low acyl gellan gum, trade name KELCOGEL®.

10. Physical and Chemical Properties

Low acyl gellan gum is a water soluble, high molecular weight polysaccharide that is composed of a regularly repeating, linear tetrasaccharide unit:



The four monosaccharides of the repeating unit 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). The glucuronic acid is neutralized by a mixture of potassium, sodium, calcium and magnesium salt ions. The native, high acyl polysaccharide is substituted with two acyl groups on the 3-linked glucose, namely: L-glyceryl, positioned at O(2) and acetyl at O(6). On average, there is one glycerate per repeating unit and one acetate per every two repeating units. These groups are removed and not present on low acyl gellan gum.

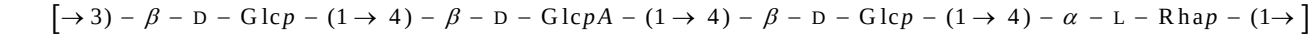
The molecular weight of low acyl gellan gum is 2-5 x 10^5 Daltons as determined by light scattering measurements.

10.1. Chemical interactions with other substances, especially substances used in organic production;

There are no known interactions with ingredients typically used in food and personal care products, including organic production.

Physical Form	Off-white powder that is soluble in hot water, partially soluble in cold water and insoluble in non-polar organic solvents
Odor or Taste	None
Melting Pont	Decomposes without Melting >150° C
Structural Form	See Below

Gellan gum, low acyl gellan gum Molecular Formula



Relative Molecular Mass	95% of the polymer is greater than 500,000 Daltons
Particle Size	Tyler Standard Screen Scale, Ro-Tap
28 mesh(600 μm)	≥ 99% through
42 mesh (355 μm)	≥ 98 % through
Loss on Drying	≤ 14%
Solution pH	4.5 – 6.5
Isopropyl alcohol	≤ 750 ppm
Heavy Metals (as Pb)	≤ 20 ppm
Lead	≤ 2 ppm
Arsenic	≤ 2 ppm
Total Plate Count	≤ 10,000 cfu/g
Fungal (Yeast & Mold) Count	≤ 400 cfu/g
Coliform	Negative by Most Probable Number
Escherichia coli	Absent in 25 g
Salmonella spp	Absent in 25 g
Staphylococcus aureus	Absent in 1.0 g
Pseudomonas aeruginosa	Absent in 1.0 g

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 developed by CP Kelco.

10.2. Toxicity and environmental persistence

There is no toxic effect of low acyl gellan gum. The safety information is discussed in items below. Low acyl gellan gum is biodegradable and being a polysaccharide will be degraded by microorganisms found in the water and soil. Therefore, the gum does not persist in the environment.

10.3. Environmental impacts from its use and/or manufacture

In the manufacturing process of low acyl gellan gum, any waste from the fermentation media will be discharged to the municipal sewage treatment plant and will be present in only trace amounts. A recovery procedure is used to reclaim isopropyl alcohol. There is insignificant impact on the environment from this manufacturing procedure. As far as the waste materials from the finished food product, they will be either composted, sent to landfills or treated in waste water treatment plants. These actions will not result in an adverse effect on the environment.

10.4. Effects on human health

As noted in section 11, low acyl gellan gum has been tested both in animals and humans and no toxic effects were observed. The gum has been marketed worldwide with no adverse effects reported that were attributed to the gum.

10.5. Effects on soil organisms, crops, or livestock.

Gellan gum (both low acyl and high acyl) is a direct food additive and is also used in the production of pet food. There have been no recorded adverse effect on livestock. Because gellan gum is a polysaccharide, it is broken down by microorganisms found in the soil and therefore, would have a beneficial effect soil organisms which in turn would benefit crops.

11. Safety Information

Gellan gum (low acyl and high acyl) has been tested extensively under Good Laboratory Practices and in accordance with FDA Redbook I guidelines. A report providing abstract summaries of the various studies is appended [Appendix 13]. In summary gellan gum has been tested in the following types of toxicological studies: acute (rats), short-term study (28-days) (monkeys) subchronic (90-day) (rats); long-term (1 year) dog; carcinogenicity (2 year) (mice and rats); reproductive (rats); teratology (developmental) (pregnant rats) and absorption, distribution and excretion (rats). There were also several cytogenetic short-term studies performed; all of which were negative. Based on these data, FDA found that there was an adequate level of safety to approve gellan gum's use as a food additive under GMP levels of use in a wide variety of fabricated food products.

Gellan gum (low acyl and high acyl) is poorly absorbed and does not present any adverse effects in any of the studies conducted. The dose levels given in the animal studies were in g/kg not mg/kg body weight as is done for most other ingredients tested in animals.

There were limited studies in humans on tolerance to gellan gum, the results of which demonstrated that there were no effects, including no allergenic responses, other than gellan gum acting as a faecal bulking aid (fiber).

The Safety Data sheet is appended [Appendix 14]. A substance report from the National Institute of Environmental Health Studies was not found.

12. Research Information

Literature searches have been conducted on gellan gum though 2018. Appended is a bibliography list of relevant literature associated with this gum's safety and technical effect [Appendix 15]. As noted, there was only one non-clinical study reported in abstract regarding the effect of gellan gum on lipid metabolism, cecal fermentation and fecal bile acid excretion in rats. Shimizu et al (1999) reported that gellan gum shortened the gastrointestinal transit time in rats, suggesting the promotion of evacuation. The remaining published literature reports are on the chemical/physical/mechanical aspects, the rheological properties as well as functional effects of this gum. Several of the published studies listed in the bibliography point to the synergism between gellan and other gums, such as carrageenan and to the improvement in food textures using gellan gum alone or with other gums, such as in combination with gelatin. As previously noted, many of the articles to not distinguish between low acyl and high acyl gellan gum. Both low acyl and high acyl gellan gum are the same CAS number and are considered the same substance under the compendia, monographs, and agency approvals.

13. Petition Justification Statement

Hydrocolloids like gellan gum, carrageenan, xanthan, locust bean gum (also known as carob bean gum) and others on the NOP list, each have a unique set of functionalities and properties. Some ingredients like locust bean and xanthan gum are thickeners, capable of providing viscosity and water control to the products they are used in. Others, like gellan gum and carrageenan, can create gelled, free-standing textures that used in many food and consumed products like capsules. These ingredients are not easily interchangeable due to the unique functionalities, processing requirements and textures. Table 13:1 addresses thickening ingredients. It was developed as an alternative to Table 1: Summary: General Properties of Gums, USDA Technical Report on Gums 2018, p. 6. Table 13:2 addresses gelling agents including low and high acyl gellan gum.

Table 13:1

Property	Gum Arabic	Tragacanth Gum	Guar Gum	Locust Bean Gum	Gellan Gum High Acyl*	Xanthan Gum
Low viscosity up to 50% solution	X					
Provides significant functionality at 1%		X	X	X	X	X
Provides suspension					X	X
Surface active ingredient	X	X				
Consistent viscosity with shear	X					
Shear thinning rheology		X	X	X	X	X
Forms thermo-reversible gels				When blended with xanthan	X	When blended with locust bean gum
Solution thins with heat		X	X	X	X	X
Insoluble in ethanol	X	X	X	X	X	X
Stable at pH >3	X	X		X	X	X
Controls syneresis		X	X	X	X	X

* High acyl gellan gum is unique in this table as it is a gelling ingredient while all of the others are thickeners.

Table 13:2

Properties	Agar	Alginates	Gelatin	High Ester Pectin	Low Ester Pectin	Kappa Carrageenan	Iota Carrageenan	High Acyl Gellan	Low Acyl Gellan[1]
Cold solubility		X							
Suitable for softgel capsules			X		X	X	X	X	X
Heat stable gels		X		X	X				X
Functionality is independent of solids in product	X	X	X			X	X	X	X
Suitable for vegetarians/ vegans	X	X		X	X	X	X	X	X
Unique texture	Firm	Range of Textures	Elastic	Firm, spreadable	Firm, spreadable	Firm	Elastic	Elastic	Firm

Gellan gum in both low and high acyl forms presents unique qualities as compared to the other gums currently on the National Organic list. For example, gellan gum fluid gels are very good at suspending particulate matter since the suspension will remain stable. These fluid gels use very low levels of gellan gum which results in low viscosity in the mouth which give very little mouthfeel making them particularly effective in beverages for suspension of fruit pulp or jelly pieces. Low acyl gellan gum offers clarity while high acyl is not available in a clarified form. Other gums on the National Organic List present an undesirable mouthfeel and limited suspension in these types of products.

Another unique quality of a low acyl gellan gum is that it is heat stable in acid systems unlike carrageenan (non-synthetic list), which breaks down under acid conditions. Gellan gum, unlike carrageenan, can be used in fruit fillings, retorted gels, or low pH beverages.

Low acyl gellan gum use provides processing flexibility for food manufacturers because it can be used in standard processing without additional steps. For example, in the preparation of gelled confections, low acyl gellan gum can be used without process modification whereas pectin requires special handling such as preparation of concentrated gum solutions.

Use of low acyl gellan gum in hard and soft capsules gives a functionality that cannot be achieved with most materials currently on the National List. Carrageenan is the only material currently listed which offers producers of hard and soft capsules the necessary technical function/properties. Consumers are putting pressure on manufacturers to deliver options that are not animal or carrageenan based. Without low acyl gellan gum, manufacturers don't have technical solutions.

In summary, the unique qualities of low acyl gellan gum are that it can be use at a significantly lower level (≤20%) than other gums on the National List. The strength of water dessert gels is increased. It provides the most firm and brittle texture of any gelling agent.

The benefits of low acyl gellan gum are unique to those gums already approved and listed on the National Organic List.

Gellan gum has been extensively reviewed by the FDA under the food additive petition process and found to safe for its intended use in a wide variety of food products. Gellan gum is used worldwide and has had no adverse effects reported. There is a wide margin of safety as noted by the decision of JECFA and EU Scientific Committee to establish an ADI (acceptable daily intake level), not specified (NS).

The addition of low acyl gellan gum's unique attributes listed above will allow producers of products currently containing carrageenan to continue to be marketed as organic using low acyl gellan gum. CP Kelco offers the position that it would be in the best interest of the organic program producers to amend 7 CFR 205.605 (a) Gellan Gum with the addition of low acyl gellan gum.

Appendix 1 – 21 CFR 172.665

for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., ''sodium carrageenan'', ''potassium carrageenan'', etc.

§ 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

§ 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of § 172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., ''sodium furcelleran'', ''potassium furcelleran'', etc.

§ 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a high molecular weight polysaccharide gum produced from *Pseudomonas elodea* by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters.

(b) The strain of *P. elodea* is nonpathogenic and nontoxic in man and animals.

(c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.

(d) The additive meets the following specifications:

(1) Positive for gellan gum when subjected to the following identification tests:

(i) A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.

(ii) To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in

the ''Gellan gum'' monograph in the Food Chemicals Codex, 7th ed. (2010), pp. 425–426, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter. The additive may be used in foods where standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the name of the additive and the designation ''food grade''.

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[55 FR 39614, Sept. 28, 1990, as amended at 57 FR 55445, Nov. 25, 1992; 64 FR 1758, Jan. 12, 1999; 78 FR 71463, Nov. 29, 2013]

§ 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 °F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 °F and 150 °F is in the range of 1.02 to 1.45.

(3) Positive for xanthan gum when subjected to the following procedure:

LOCUST BEAN GUM GEL TEST

Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide to be tested. Add the blend slowly (approximately ½ minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80 °C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60 °C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40 °C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80 °C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as ''positive'' for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as ''negative'' for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

Appendix 2a – Organic Products Application Use Levels

GELLAN GUM – USE IN PRODUCTS TO BE LABELED ORGANIC

UNIQUE GELLAN GUM FUNCTIONALITIES - GENERAL

- High viscosity at low polymer concentrations
- Can be used to thicken, suspend and gel water based systems
- Unique particle suspension properties - (e.g beads)
- High clarity
- Range of textures from firm and brittle to soft and elastic with different gellan gum types
- Process flexibility - will hydrate in cold systems with appropriate processing
- Can stabilize oil in water emulsions
- Excellent suspension but is shear thinning and can be applied by spraying
- Can form films

UNIQUE GELLAN GUM FUNCTIONALITIES - FOOD

- Suspension without mouthfeel- all other systems currently used provide viscosity and mouthfeel- examples would be guar, xanthan and carrageenan; with gellan you can get suspension and stability with very little mouthfeel
- Heat stability in acid systems- gellan holds up and provides functionality in systems where other ingredients like pectin and carrageenan fall apart due to heat and acid
- Heat stability in low solids, low pH heated systems- for example, in a bakery filling, gellan provides bake stability in systems while carrageenan and pectin don't
- Processing flexibility- some ingredients such as pectin require special handling, gellan can be used in standard processing without additional steps

TYPICAL GELLAN GUM USE LEVELS - FOODS

- Beverage applications: 0.025-0.05%
  - Dairy drinks and soy milks
  - Nutritional products
  - Beverages (fruit drinks, drinking jellies, novelty drinks)
- Gelled applications: 0.2-0.4%
  - Confections (gummies, aerated products)
  - Dessert gels,
- “Thickened” applications: 0.1-0.2%
  - Bakery (fillings, brownies, icings)
  - Yogurt, sour cream, cheese
  - Fruit (yogurt fruit, sauces, spreads- jams & jellies)
  - Pourable and spoonable dressings
  - Dairy desserts

GELLAN GUM – USE IN PRODUCTS TO BE LABELED ORGANIC

UNIQUE GELLAN GUM FUNCTIONALITIES – PERSONAL CARE

- Heat stability in oil-in-water emulsions such as sunscreens. Gellan can provide a gel-like structure giving excellent emulsion stability. The structure is easily sheared, yet can be formulated to resist melting even at boiling temperatures.
- Suspension without significant viscosity under shear allows suspension of active ingredients while allowing a spray pattern very similar to water. This is useful for skin hydration sprays, bug repellants, and cosmetics.
- Water binding-gellan in clear gel toothpaste provides good water binding, excellent clarity, and non-stringy flow that is not attainable with other common toothpaste binders such as carrageenan, xanthan, and CMC.
- Compatibility range-gellan can be used in high surfactant environments such as body washes, low pH environments such as alphahydroxy-acid formulations, and high pH environments such as depilatories.

TYPICAL GELLAN GUM USE LEVELS - PERSONAL CARE

- Body Washes: 0.05-0.25%
- Sunscreen/Lotions: 0.05-0.4%
- Skin hydration Sprays 0.05-0.2%
- Oral care -
- Toothpaste: 0.05-0.4%
- Mouthwash 0.05-0.15%

UNIQUE GELLAN FUNCTIONALITIES - OTHER

- Films-gellan is an excellent film former producing crystal clear films that can be made to be soluble or insoluble in water.
- Suspension-gellan provides suspension for mineral suspensions, agricultural suspension, and paints and coatings.
- High Pseudoplasticity-gellan's low viscosity at high shear rates allows a wide spray pattern for agricultural treatments such as pesticides.
- Acid stability-gellan's compatibility and stability with organic acids make it useful in hard surface cleaners.
- Compatibility with surfactants enable gellan to be used in laundry and dishwashing detergent formulations to provide suspension of actives.

TYPICAL GELLAN GUM USE LEVELS - OTHER

- Liquid detergents: 0.05-0.6%
- Cleaners: 0.05-0.6%
- Suspensions: 0.05-0.4%
- Films: 0.2-2%

Appendix 2b – Customer Letters

Capsugel Letter

Ferrara Pan Gellan Letter

Capsugel

Now a **Lonza** Company

October 17th, 2017

Ms. Cheryl Van Dyne
CP KELCO Global Regulatory Director
3100 Cumberland Blvd, Suite 600
Atlanta, GA 30339
USA

Re : Low Acyl Gellan Gum

We thank you for the opportunity to exchange with your company about the use of low acyl gellan gum in our hard capsules applications.

Capsugel has been engaged in research and development of vegetarian/vegan capsule shells to be compliant with organic regulations since several years. A variety of setting agents were screened for their effectiveness in producing vegetarian/vegan capsule shells that would be compliant with USDA Organic regulations, however all but carrageenan were rejected as viable, effective options. The recent decision from the NOSB Handling Subcommittee to remove carrageenan from the National List of Allowed Substances (205.605) is jeopardizing our project and our customers' expectations.

The low acyl form of gellan gum is another viable and effective option but unfortunately only the high acyl form of gellan gum is currently listed on the National List of Allowed Substances (205.605) and the high acyl form of gellan gum is not an alternative for capsule shell application.

Capsugel has made a long-term investment in the development of a capsule that could be certified organic using the current National List of Allowed Substances and has found that there is a lack of food-grade setting agents suitable to do what carrageenan does for capsules. Consumers purchasing dietary supplement products have a strong interest in the option of a vegetarian/vegan capsule that is organic and NOSB action is needed to meet the demands of U.S. consumers.

Capsugel thanks CP Kelco in advance to consider our demand of applying at the USDA –NOSB for having the low acyl form of gellan gum added on the National List of Allowed Substances (205.605).

We thank you in advance to keep us informed about CP Kelco decision and we stay at your disposal for any additional information you may need.

Kind regards,

Erasmo Schutzer
Senior Vice President Consumer Health & Nutrition

412 Mt Kemble Ave, Suite 200C, Morristown, NJ 07960 ⋮ +1 862 242 1700

capsugel.com
lonza.com

Ferrara Candy Company

October 30, 2017

Ms. Shannon Helms
CP Kelco Global Regulatory Affairs Manager
3100 Cumberland Boulevard, Suite 600
Atlanta, Georgia 30339

Re: Low Acyl Gellan Gum

We appreciate CP Kelco's support in working towards using low acyl gellan gum in our various confectionery products. Consumers desire a range of taste and texture experiences when it comes to selecting organic treats. With the limited range of gelling agents allowed in USDA Organic products, this poses formulation challenges.

The texture and sour stability of gellan gum products is of great interest to us. There are currently conventional confections that utilize low acyl gellan gum and produce a unique and desirable texture. We have tried formulating with the currently approved high acyl gellan gum, however the resulting candy viscosity is too thick to deposit into gummy moulds. Even when used at low level, the finished product texture is inconsistent due to interactions with sugar and other gelling agents. Low acyl gellan gum provides unique properties in gummy candies. It is much more consistent in our processes and it offers texture and sour flavor delivery variety for the modern organic consumer. As consumer demands shift, we would like to continue to expand our offerings to more organic and vegan products, in keeping with our tagline "Certified Organic. Certifiably Delicious."

Ferrara Pan appreciates CP Kelco for taking the initiative to petition low acyl gellan gum for the National List of Allowed Substances. Please let us know of any additional support you may need to complete your petition.

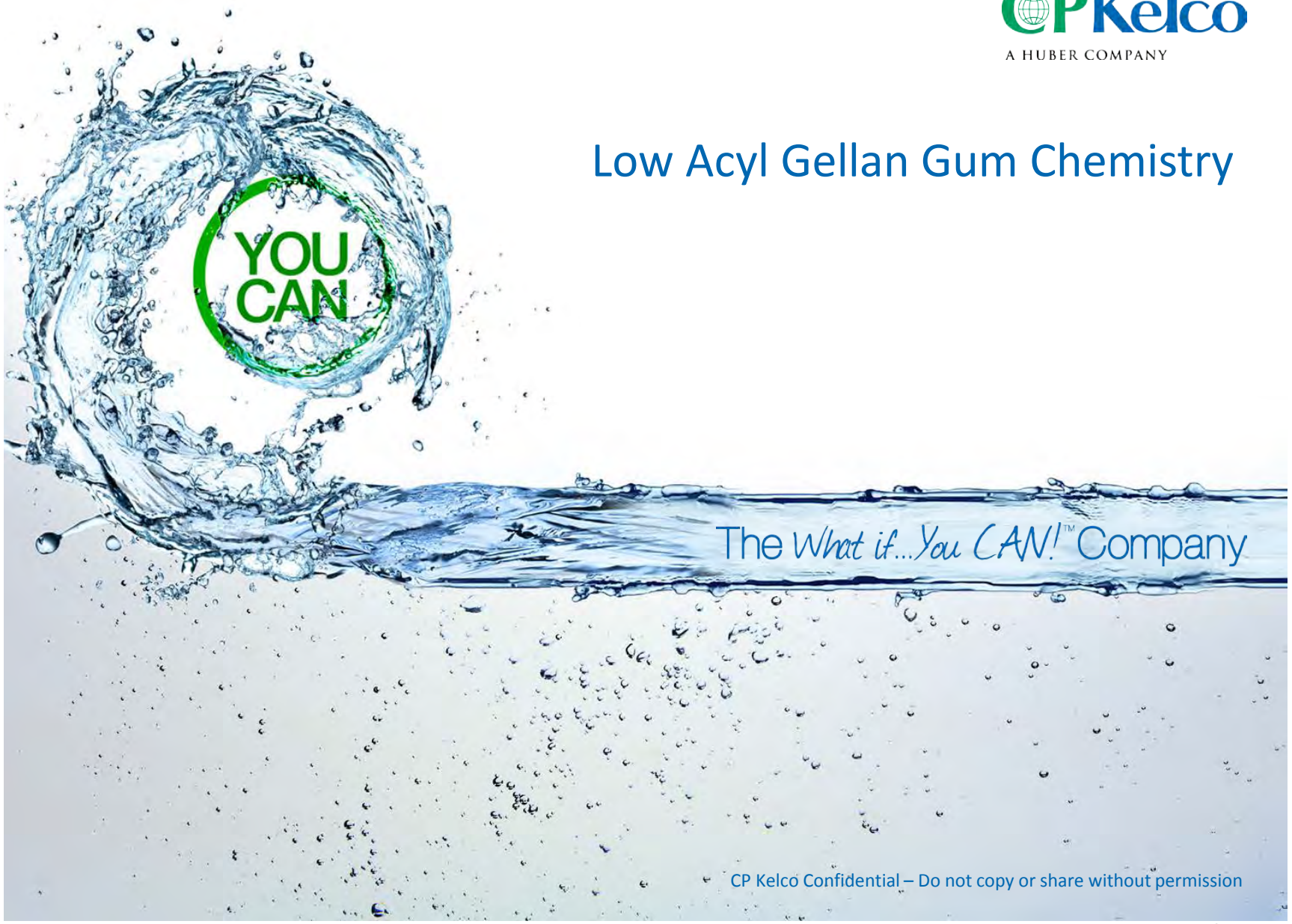
Regards,

Jeffrey Bogusz
Senior Director of Food Engineering and Innovation

Appendix 3a – Low Acyl Gum Chemistry

CPKelco
A HUBER COMPANY

Low Acyl Gellan Gum Chemistry



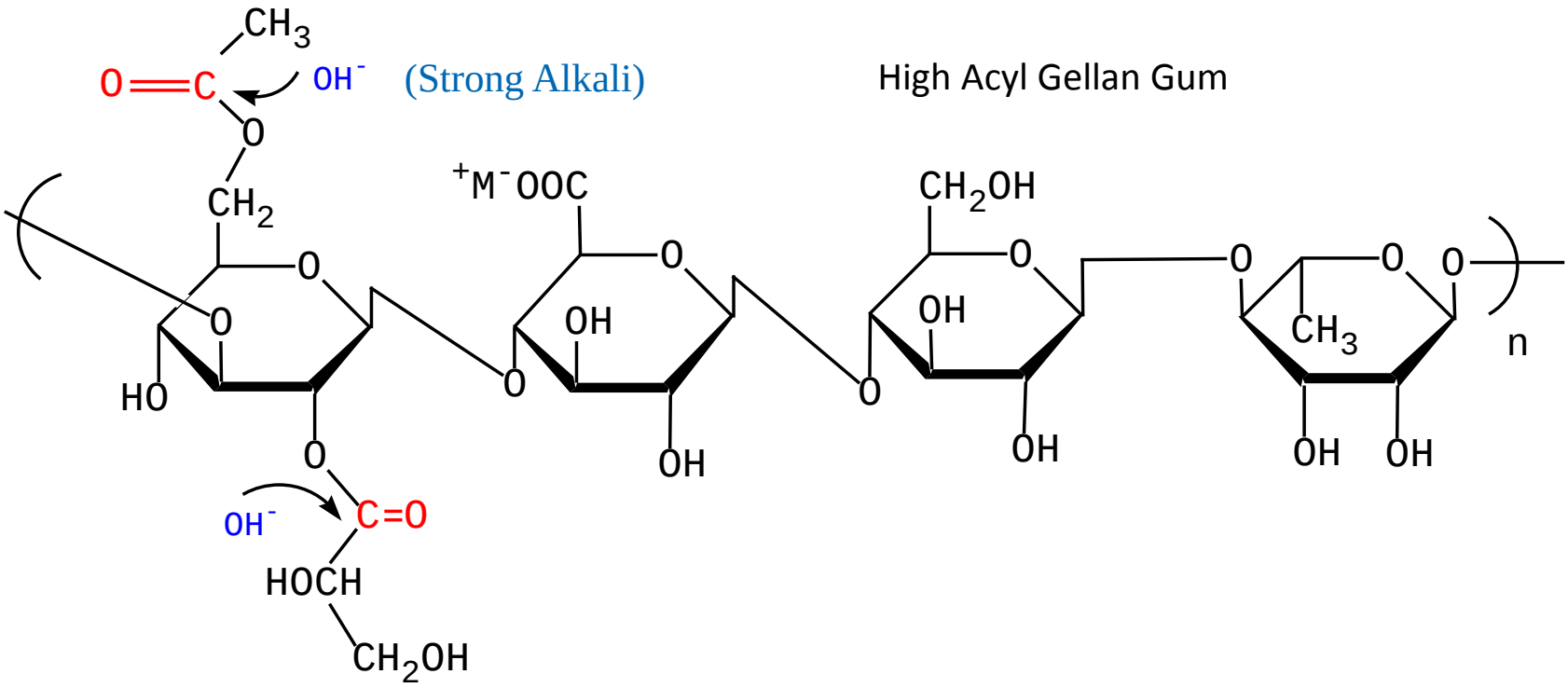
CP Kelco
A HUBER COMPANY

Deacylation Step

- High acyl gellan gum is converted to low acyl gellan gum with the addition of strong alkali at elevated temperature
- This is a well known chemical reaction commonly known as “saponification”
- During formation of the low acyl gellan gum, both the acetate and glycerate moeities are released and then removed from the product during recovery

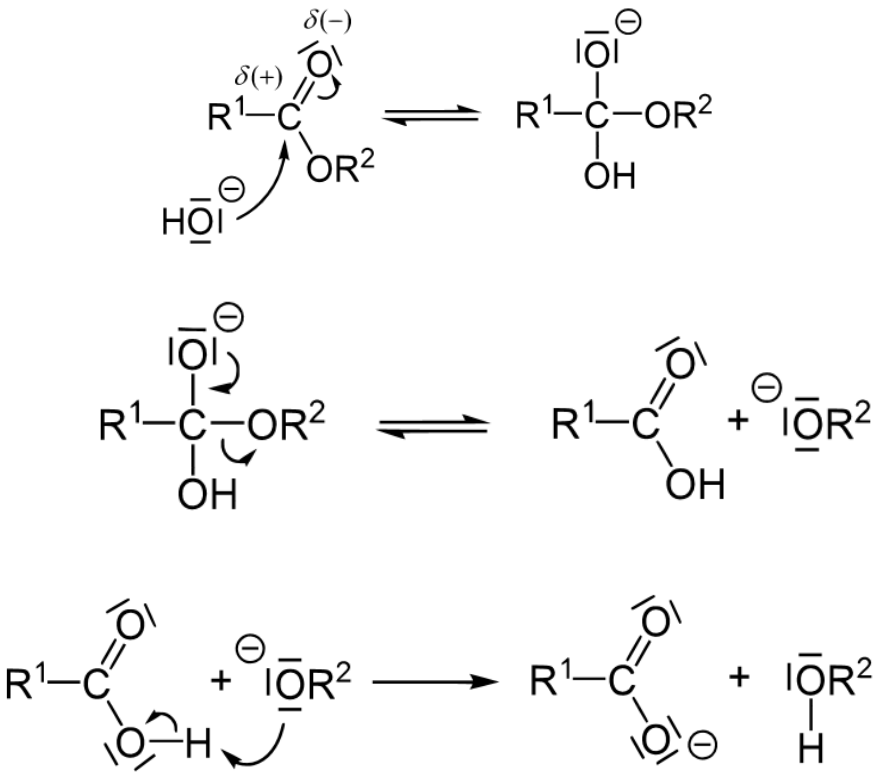
CP Kelco
A HUBER COMPANY

Gellan Chemistry - Saponification



CP Kelco
A HUBER COMPANY

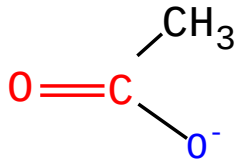
Gellan Chemistry – Saponification (2)



$R^1 = CH_3$ for acetate
$R^1 = C(OH)HCH_2OH$ for glycerate
R^2 = gellan molecule

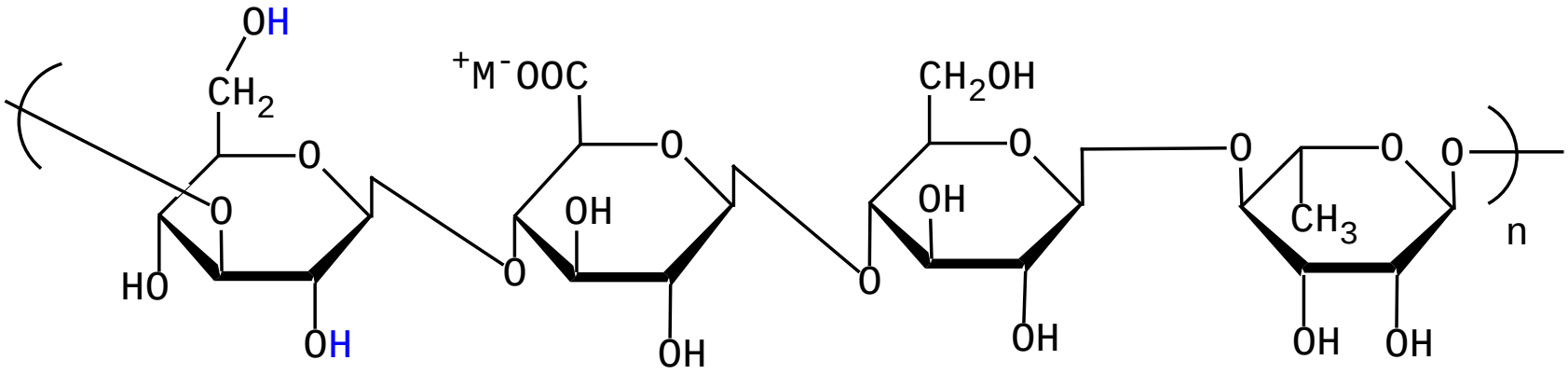
CP Kelco
A HUBER COMPANY

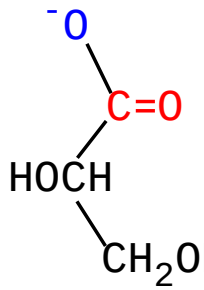
Gellan Chemistry – Saponification (3)



Acetate

Low Acyl Gellan Gum

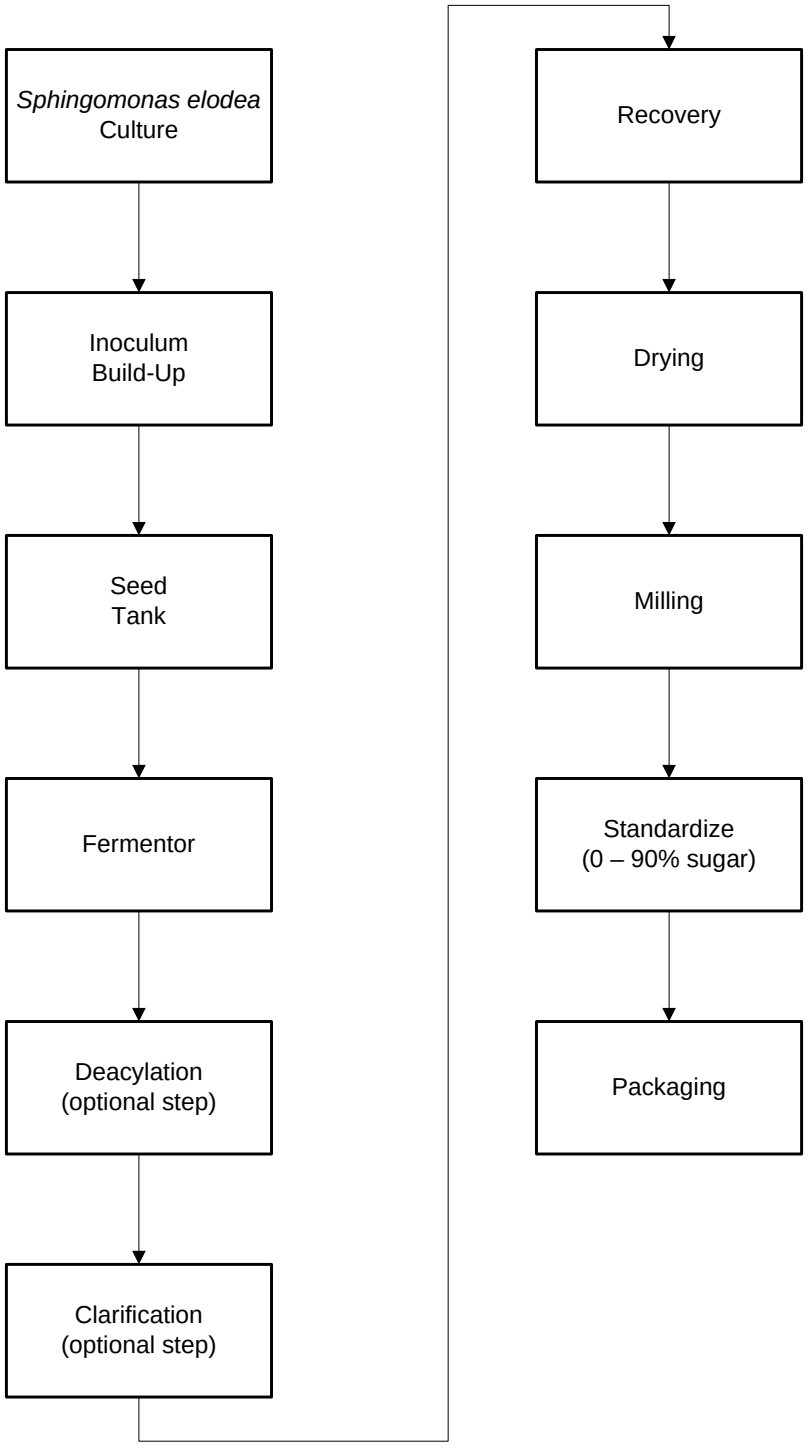




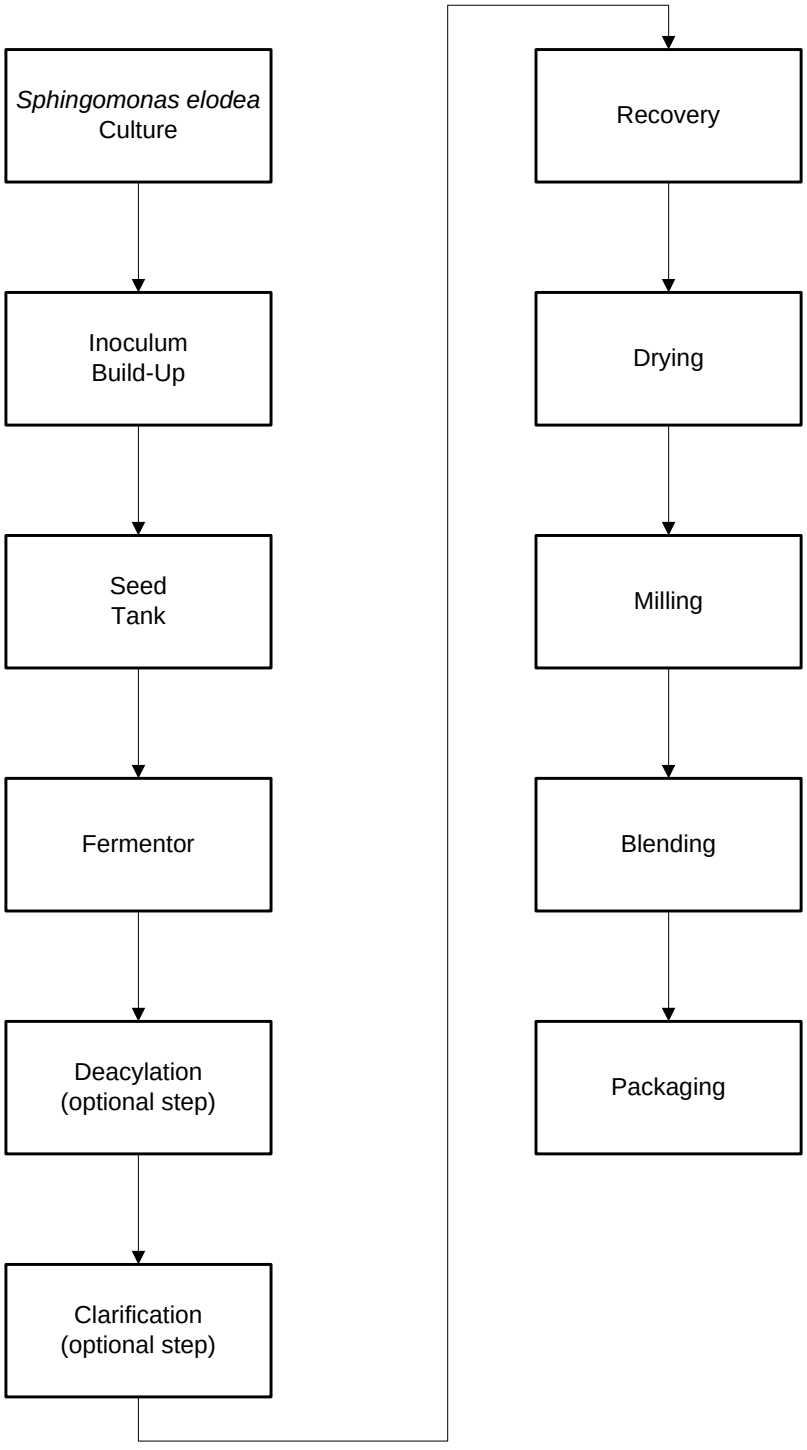
Glycerate

Appendix 3b – Manufacturing Flow Chart

Gellan Gum Manufacturing Process Flow Chart
(0 – 90% Standardized)



Gellan Gum Manufacturing Process Flow Chart



Appendix 4 – Food Chemicals Codex 10 (2016)

Gellan Gum

First Published: Prior to FCC 6
Last Revision: Third Supplement, FCC 9
INS: 418

CAS: [71010-52-1]

DESCRIPTION

Gellan Gum occurs as an off-white powder. It is a high-molecular-weight polysaccharide gum produced by fermentation of a carbohydrate with a pure culture of *Sphingomonas elodea* (previously identified as *Pseudomonas elodea*, but later reclassified), purified by recovery with isopropyl alcohol or ethanol, dried, and milled. It is a heteropolysaccharide comprising a tetrasaccharide-repeating unit of one rhamnose, one glucuronic acid, and two glucose units. The glucuronic acid is neutralized to mixed potassium, sodium, calcium, and magnesium salts. It may contain acyl (glyceryl and acetyl) groups as the *O*-glycosidically linked esters. It is soluble in hot or cold deionized water.

Function: Stabilizer; thickener
Packaging and Storage: Store in well-closed containers.

IDENTIFICATION

- **A. Procedure**

  Sample solution: Prepare a 1% solution by dissolving 1 g of sample in 99 mL of deionized water. Using a motorized stirrer and a propeller-type stirring blade, stir the mixture for about 2 h. [Note— Save part of this solution for *Identification* test *B*.]

  Analysis: Draw a small amount of the *Sample solution* into a wide-bore pipet, and transfer it into a solution of 10% calcium chloride.

  Acceptance criteria: A tough, worm-like gel forms instantly.

- **B. Procedure**

  Sample solution: Use the *Sample solution* from *Identification* test *A*.

  Analysis: Add 0.5 g of sodium chloride to the *Sample solution*, heat the solution to 80°, stirring constantly, and hold the temperature at 80° for 1 min. Stop heating and stirring the solution, and allow it to cool to room temperature.

  Acceptance criteria: A firm gel forms.

ASSAY

- **Alginates Assay,** Appendix IIIC

  Sample: 1.2 g, undried

  Acceptance criteria: A sample yields NLT 3.3% and NMT 6.8% of carbon dioxide (CO_2), calculated on the dried basis.

IMPURITIES

Inorganic Impurities

- **Lead,** *Lead Limit Test*, Appendix IIIB

  Sample solution: Prepare as directed for organic compounds using 2 g of sample.

  Control: 4 µg Pb (4 mL of *Diluted Standard Lead Solution*)

  Acceptance criteria: NMT 2 mg/kg

Organic Impurities

- **Isopropyl Alcohol**

  IPA standard solution: 1 mg/mL of isopropyl alcohol (chromatography-grade) in water

  TBA standard solution: 1 mg/mL of *tert*-butyl alcohol (chromatography-grade) in water

  Mixed standard solution: Pipet 4 mL each of the *IPA standard solution* and the *TBA standard solution* into a 125-mL graduated Erlenmeyer flask, dilute with water to about 100 mL, and mix. The solution contains about

40 µg/mL each of isopropyl alcohol and *tert*-butyl alcohol.

Sample: 5 g

Sample solution: Disperse 1 mL of a suitable antifoam emulsion, such as Dow-Corning G-10, or equivalent, in 200 mL of water contained in a 1000-mL 24/40 round-bottom distilling flask. Add the *Sample*, and shake for 1 h on a wrist-action mechanical shaker. Connect the flask to a fractionating column, and distill about 100 mL, adjusting the heat so that foam does not enter the column. Add 4.0 mL of *TBA standard solution* to the distillate to obtain the *Sample solution*.

Chromatographic system, Appendix IIA

Mode: Gas chromatography

Detector type: Flame-ionization

Column: 1.8-m × 3.2-mm (id) stainless steel, or equivalent, packed with 80- to 100-mesh Porapak QS, or equivalent

Temperatures

Column: 165°

Injection port: 200°

Detector: 200°

Carrier gas: Helium

Flow rate: 80 mL/min

Injection volume: About 5 µL

Analysis: Inject the *Mixed standard solution* and separately inject the *Sample solution*. From the chromatogram of the *Mixed standard solution*, determine the areas of the isopropyl alcohol and *tert*-butyl alcohol peaks and calculate the response factor, F, from the formula:

$$F = A_{IPA}/A_{TBA}$$

A_{IPA} = area of the isopropyl alcohol peak

A_{TBA} = area of the *tert*-butyl alcohol peak

[NOTE— The retention times of isopropyl alcohol and *tert*-butyl alcohol are about 2 min and 3 min, respectively.]

From the chromatogram of the *Sample solution*, calculate the isopropyl alcohol content, in mg/kg, in the portion of the sample taken:

$$\text{Result} = (S_{IPA} \times 4000)/(F \times S_{TBA} \times W)$$

S_{IPA} = area of the isopropyl alcohol peak in the *Sample solution* chromatogram

S_{TBA} = area of the *tert*-butyl alcohol peak in the *Sample solution* chromatogram

W = weight of the sample taken (g)

Acceptance criteria: NMT 0.075%

SPECIFIC TESTS

- **LOSS ON DRYING,** Appendix IIC**:**

105° for 2.5 h

Acceptance criteria: NMT 15.0%

ADDITIONAL INFORMATION

Materials of commerce are often comprised of FCC Gellan Gum standardized with significant amounts of FCC Sucrose or other suitable sugars to create a material suitable for applications requiring specific functionality at low levels of gellan gum, the ratio of which will be determined based on the natural variation of the gellan gum. Such standardized materials should be identified as the standardized form (gellan gum standardized with sugar) to indicate the presence and type of any added FCC-grade or other suitable sugars, and cannot be identified as pure FCC Gellan Gum unless the material meets the monograph requirements.

Auxiliary Information— Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
Monograph	Jeffrey Moore, Ph.D. Senior Scientific Liaison 1-301-816-8288	(FI2015) Food Ingredients 2015

FCC 10 Page 552

FCC 9 Supplement : No.3 Page 2017

Appendix 5 – Agriculture Marketing Service – National List

Organic Regulations

- Overview
- Organic Labeling
- The Organic Seal
- Program Handbook
- The National List
- National Organic Standards Board (NOSB)
- Trade & Equivalency Arrangements

Petitioned Substances: G

A | B | Ca-Cn | Co-Cz | D | E | F | G | H | I | J | K | L | M | N | O | P | R | S | T | U | V | W | X | Y | Z

Galangal, Frozen (PDF)

- Date Petition Received: 11/20/06
- Petition Area and Use: Handling: Add to 205.606, ingredient
- Technical Advisory Panel Report: No report requested
- NOSB Meeting Petition Review: March-07
- NOSB Committee Recommendation (PDF)
- Status of NOP Activity on NOSB Recommendation, FR Notice, Sunset: Interim Final Rule, 72 FR 35137
- Petition Supplemental Information: Docket #AMS-TM-07-0062

Gelatin (Fish) (2007) (PDF)

Gelatin (Fish) (2001) (PDF)

- Date Petition Received: 07/03/01; 01/16/07
- Petition Area and Use: Handling: Add to 205.606, ingredient, aid, 2 petitions
- Technical Advisory Panel Review (2002) (PDF)
- NOSB Meeting Petition Review: May-02; March-07
- NOSB Committee Recommendation, (2007) (PDF)
- NOSB Committee Recommendation (2002) (PDF)
- Status: Gelatin (CAS # 9000-70-8) added to 205.606; Interim Final Rule, 72 FR 35137
- Petition Supplemental Information: Docket #AMS-TM-07-0062

Gelatin Capsules

- Date Petition Received: 02/07/02
- Petition Area and Use: Handling: Add to 205.605, ingredient
- Status of NOP Activity on NOSB Recommendation, FR Notice, Sunset: Gelatin is considered to be an agricultural product.

Gellan Gum (PDF)

- Date Petition Received: 01/30/04
- Petition Area and Use: Handling: Add to 205.605(a), food additive
- Technical Advisory Panel Report (PDF)
- NOSB Meeting Petition Review: March-07
- NOSB Committee Recommendation (PDF)
- Status: Added to the National List, section 205.605(a), with annotation; 75 FR 77521

Gibberellic Acid (2012) (PDF)

- Petition Addendum (2013) (PDF)
- Date Petition Received: 07/23/2012; 4/11/13
- Petition Area and Use: Handling: Add to 205.605

News & Announcements

- 01/31 USDA Launches MARS, Delivering Market Data to Agricultural Producers Around the Globe Faster and Easier
- 06/06 USDA Seeks Nominations for the National Organic Standards Board
- 04/19 2016 Count of Certified Organic Operations Shows Continued Growth in U.S. Market

View all news & announcements >

Events

- 02/01 USDA Market News data is moving to the new platform: Market Analysis & Reporting Services or MARS

Recent Blogs

- 11/10 Growth and Opportunity in the Organic Sector
- 10/19 U.S. and Mexico Collaborate on Organic Monitoring and Enforcement
- 07/22 Understanding the USDA Organic Label

View all blogs >

- Technical Evaluation Report (2011) (PDF)
- NOSB Meeting Petition Review: N/A
- NOSB Formal Recommendation: N/A
- NOSB Subcommittee Proposal: N/A
- Status: Post-harvest use addressed under NOP 5023

Gibberellic Acid (PDF)

- Petition Amendment #1 (PDF)
- Date Petition Received: 09/27/10; Amended 08/12/11
- Petition Area and Use: Handling: Add to 205.605
- Technical Evaluation Report (2011) (PDF)
- NOSB Meeting Petition Review: May-12
- NOSB Committee Proposal (PDF)
- NOSB Formal Recommendation (PDF)
- Status: Not listed

Gibberellic Acid

- Petition Area and Use: 205.601
- NOSB Meeting Petition Review: September 1996
- Technical Advisory Panel Review (PDF)
- Status: Nonsynthetic, Not Prohibited

Ginger Root Extract (PDF)

- Date Petition Received: 08/03/07
- Petition Area and Use: Handling: Add to 205.606, ingredient
- Technical Advisory Panel Report: No report requested
- NOSB Meeting Petition Review: May-08
- NOSB Committee Recommendation (PDF)
- Status: Not listed

Glucono Delta Lactone (PDF)

- Date Petition Received: 03/15/02
- Petition Area and Use: Handling: Add to 205.605, processing aid

- Technical Evaluation Report (2016) (pdf)
- Technical Advisory Panel Report (PDF)
- Status of NOP Activity on NOSB Recommendation, FR Notice, Sunset: Added to the National List

Glucosamine Hydrochloride (PDF)

- Date Petition Received: 01/24/07
- Technical Evaluation Report (PDF)
- Petition Area and Use: Handling: Add to 205.605
- NOSB Committee Recommendation (PDF)
- Status: Petition withdrawn at request of petitioner

Glucose

- Petition Area and Use: Livestock – Add to 205.603
- Technical Advisory Panel Report (PDF)
- NOSB Meeting Review: November-95
- Status: Added to 205.603

Glycerides (mono and di)

- Petition Area and Use: Handling: Add to 205.605, processing aid
- Technical Evaluation Report (2015) (PDF)
- Technical Advisory Panel Report (1995) (PDF)
- NOSB Meeting Petition Review: April-95
- Status: Added to the National List, section 205.605(b), with annotation

Glycerin

- Petition Area and Use: Handling: Add to 205.605
- Technical Advisory Panel Report (PDF)
- NOSB Meeting Petition Review: November-95
- Status: Added to the National List, section 205.605(b), with annotation

Glycerin (Petition to remove) (PDF)

- Date Petition Received: 1/4/13
- Petition Area and Use: Handling: Remove from 205.605
- Technical Evaluation Report (2013) (PDF)
- Technical Advisory Panel Report (1995) (PDF)
- NOSB Meeting Petition Review: Apr-14; Oct-14; Apr-15
- NOSB Final Recommendation (2015) (PDF)
- NOSB Subcommittee Proposal (2015) (PDF)
- NOSB Subcommittee Proposal (Aug 2014) (PDF)
- NOSB Subcommittee Proposal (Jan 2014) (PDF)
- NOSB Subcommittee Proposal (2013) (PDF)
- Status: Recommendation under NOP review

Glycerin Oleate (PDF)

- Date Petition Received: 04/18/03
- Petition Area and Use: Crop: Add to 205.601, production aid
- Technical Advisory Panel Report (PDF)
- Status: Added to National List, section 205.601 until 12/31/06, prohibited after 12/31/06; Proposed Rule – 74 FR 26591

Glycerine

- Petition Area and Use: Livestock: Add to 205.603
- NOSB Meeting Petition Review: October 1999
- Technical Advisory Panel Report (PDF)
- Status: Added to the National List, section 205.603(a), with annotation

Glycine betaine (PDF)

- Date Petition Received: 03/13/08
- Petition Area and Use: Section 205.601, crop input
- Technical Advisory Panel Report: N/A
- NOSB Meeting Review: N/A
- Status: Withdrawn by petitioner on 03/11/09

Glycolic Acid (PDF)

- Date Petition Received: 5/31/16
- Petition Area and Use: Livestock: Add to 205.603, teat dip
- Technical Report (PDF)
- NOSB Meeting Petition Review: TBD
- NOSB Recommendation: TBD
- Status: Under NOSB Review

Glyphosate

- NOSB Meeting Review: Oct-95
- NOSB Meeting Minutes, 1995 (PDF)
- Status: Prohibited for organic production

Grape Seed Extract (PDF)

- Date Petition Received: 01/17/07
- Petition Area and Use: Handling: Add to 205.606, ingredient
- NOSB Committee Recommendation (PDF)
- Status of NOP Activity on NOSB Recommendation, FR Notice, Sunset: Reviewed at November 2007 NOSB meeting

Gums

- Petition Area and Use: Handling: Add to 205.606
- Technical Advisory Panel Report (PDF)
- NOSB Meeting Petition Review: November-95
- Status: Added to the National List, section 205.606, with annotation

Gypsum

- See “Calcium Sulfate”

Appendix 6 – 40 CFR 180

tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and foodretailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of theFFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policiesthat have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 18, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 is revised to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1246 is added to subpart D to read as follows:

§ 180.1246 Yeast Extract Hydrolysate from Saccharomyces cerevisiae: exemption from the requirement of a tolerance.

This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* on all food commodities when applied/used for the management of plant diseases.

[FR Doc. 04–4706 Filed 3–2–04; 8:45am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0003; FRL–7344–1]

Gellan Gum; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of gellan gum when used as an inert ingredient in a pesticide product. CP Kelco submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of gellan gum.

DATES: This regulation is effective March 3, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0003, must be received on or before May 3, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0371; e-mail address: *parker.james@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of

entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0003. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid =baa35b6058a65d5fafe66e7269d4d215&c=ecfr&tpl= =/ecfrbrowse/Title40/40cfrv21_02.tpl*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of July 16, 2003 (68 FR 42026) (FRL–7317–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 3E6567) by CP Kelco, 8355 Aero Dr., San Diego, CA 92123–1718. This notice included a summary of the petition prepared by CP Kelco. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of gellan gum (CAS No. 71010–52–1).

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Human Health Assessment

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by gellan gum are discussed in this unit. The information submitted in support of this petition included the review and evaluation of 14 toxicity studies performed using gellan gum by the Joint Expert Committee on Food Additives (JECFA) which is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Gellan gum is also approved as a food additive in 21 CFR 172.665.

Gellan gum is produced through the fermentation of Pseudomonas elodea (a non-pathogenic bacteria). Gellan gum is a water-soluble polysaccharide that is composed of repeating units, which are called monosaccharides. These four units are 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). Gellan gum has a molecular weight greater than 70,000 with 95% above 500,000.

According to the CP Kelco website (*http://www.cpkelco.com*) gellan gum would typically be used in icings and frostings, jams and jellies, jellied candies such as gummy bears, and various fruit and bakery fillings. As the name indicates, when dissolved in water, 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.

A. WHO/JECFA Evaluation

In 1990, gellan gum was evaluated by the JECFA. As part of their evaluation, they reviewed studies related to the absorption, distribution, and excretion of gellan gum (in rats). They also reviewed the following types of toxicological studies: Acute toxicity (in rats), short-term studies (in rats and monkeys), long-term/carcinogenicity (in mice, rats, and dogs), reproductive (in rats), and teratology (developmental) studies (in pregnant rats). The results of these reviews were discussed in the petitioner's July 16, 2003, Notice of Filing. The petitioner accurately and adequately stated the reviews performed by JECFA; therefore, the Agency has not reprinted them in their entirety in this final rule.

Selected summary information includes the following:

- Gellan gum was shown to be poorly absorbed and did not cause any deaths in rats which received a single large

dose (5 gram (g) per kilogram (kg) of body weight) in the diet or by gavage.

- Short-term (90-day) exposure of rats to gellan gum at levels up to 60 g/kg in the diet did not cause any adverse effects.
- In a 28-day study in prepubertal monkeys, no overt signs of toxicity were observed at the highest-dose level of 3 g/kg of body weight per day.
- In reproduction and teratogenicity studies in rats in which gellan gum was given at dose levels up to 50 g/kg in the diet, there was no evidence of interference with the reproductive process, and no embryotoxic or developmental effects were observed.
- Gellan gum was also shown to be non-genotoxic in a battery of standard short-term tests.
- In a study in dogs, which were treated for 1 year at dose levels up to 60 g/kg in the diet, there were no adverse effects that could be attributed to chronic exposure to gellan gum.
- In long-term carcinogenicity studies, gellan gum did not induce any adverse effects in mice or rats at the highest-dose levels of 30 g/kg and 50 g/kg in the diet, respectively.

The Agency notes that the dose levels used in these animal studies were in g/kg body weight not milligrams (mg)/kg as in most of the studies reviewed and evaluated by the Agency.

There was also a limited study on tolerance to gellan gum in humans. Results indicated that oral doses of up to 200 mg/kg of body weight administered over a 23-day period did not elicit any adverse reactions, although faecal bulking effects were observed in most humans.

In its conclusions, the JECFA Committee indicated that the potential laxative effect (at high intakes of gellan gum) should be taken into account when used as a food additive. The JECFA Committee also allocated an ADI (average daily intake) of ''not specified'' to gellan gum, which means that a specific limit on the average daily intake of gellan gum was not needed.

B. FDA Evaluation

Gellan gum is approved by the Food and Drug Administration (FDA) as a direct food additive when added to foods as a stabilizer or thickener according to good manufacturing practices when used according to the following conditions (21 CFR 172.665):

- The additive is a high molecular weight polysaccharide gum produced from Pseudomonas elodea by a pure culture fermentation process and purified by recovery with isopropyl alcohol.
- The strain of Pseudomonas elodea is non-pathogenic and non-toxic in man and animals.
- The additive is produced by a process that renders it free of viable cells of Pseudomonas elodea.

C. Conclusions

The evaluations performed by WHO and FDA indicate a substance of lower toxicity. The only concern that has been indicated for gellan gum as indicated by the JECFA Committee was a possible laxative effect which occurs only at high intakes of gellan gum. This laxative effect likely occurs as a result the body's limited ability to absorb gellan gum.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

A. Dietary Exposure

1. *Food*. Gellan gum has been safely used as a food additive for over 10 years in various food formulations. Foods which can commonly contain gellan gum include frostings, gelatins, puddings, fillings, jams, milk products, fruit juices, and soft candy. CP Kelco supplied to the Agency, the direct use levels (expressed as percent) of gellan gum in a variety of food formulations. The typical amount of gellan gum used as a food additive does not exceed 0.5% of the processed food.

Given the use of gellan gum as a thickening or jelling agent, there is a ''built in'' limitation as to the amount needed. Too much gellan gum would over-thicken, making the pudding or jam too stiff for the intended use. According to information provided by CP Kelco, the maximum percent of gellan gum in a food formulation to achieve the desired thickening or jelling effect would be less than 2%.

Gellan gum has a molecular weight which is greater than 70,000 with 95% above 500,000. Such large substances are not easily absorbed, as demonstrated by the rat metabolism study which indicated poor absorption. The constituents of gellan gum are naturally occurring materials (sugar monosaccharides) that, in fact, are found in living organisms.

Gellan gum is approved for use as a direct food additive by FDA. To the best of the Agency's knowledge gellan gum has been used for over 10 years as a stabilizer and thickener—as a gelling agent in foods without any reported incidence. The Agency estimated an annual U.S. population exposure for gellan gum using the annual production information provided by CP Kelco (100,000 kg) and a U.S. population estimate of approximately 290,809,777 as of July 1, 2003, from the U.S. census website (*http://eire.census.gov/popest/data/national/popbriefing.php*). The Agency estimated annual exposure of gellan gum to the U.S. population is approximately 0.94 mg/person/day.

Equation used to calculate exposure provided below:
100,000 (kg/year) / (290,809,777 (people) x 365 (days/year)) = 0.94
100,000,000,000 (mg/year) / 106,145,568,605 (people/day/year) = 0.94 mg/person/day

The amount of gellan gum that could occur in food as a result of its use as an inert ingredient in a pesticide product should not significantly increase the amount of gellan gum in the food supply above those amounts currently permitted by FDA. Furthermore, it is unlikely that the manner which gellan gum is used in pesticide formulations will differ significantly from it's use as a direct food additive due to ''built in'' limitations based on the desired thickening or gelling effect.

2. *Drinking water exposure*. Gellan gum is composed of repeating monosaccharides. When mixed with water, gellan gum acts as a thickener, thus producing a viscous solution. Eventually, the material will degrade to the constituent monosaccharides: Two glucose molecules, one glucuronic molecule, and one rhamnose molecule. The rate at which this occurs will

depend on the size of the ''bead'' that forms when dissolved in water. While physical/chemical degradation processes (such as hydrolysis) would occur, it is more likely that gellan gum would be degraded via microbial degradation. Due to the lower toxicity of the degradates, the naturally occurring sugars, there are no concerns for exposure to gellan gum in drinking water.

B. Other Non-occupational Exposure

The Agency believes that the potential for the use of gellan gum in and around the home exists.

1. *Dermal exposure*. Based on the high molecular weight of gellan gum, it is not likely to be absorbed through the skin.

2. *Inhalation exposure*. Based on the fact that gellan gum is a polysaccharide which would degrade into naturally occurring sugars, it is not likely to cause any adverse effects when inhaled. The resulting molecules are normally found in living organisms (including humans) and would be metabolized normally.

V. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to gellan gum and any other substances, and gellan gum does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that gellan gum has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. The JEFCA committee has evaluated reproductive and teratogenicity (developmental) toxicity studies in rats in which gellan gum was given at dose levels up to 50 g/kg in the diet and found no indication of increased susceptibility. Based on the WHO/JECFA evaluation of gellan gum, EPA has not used a safety factor analysis to assess the risk of gellan gum. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety for U.S. Population, Infants and Children

The JECFA Committee reviewed and evaluated 14 toxicity studies and as a result of their review and evaluation, JECFA determined an ADI (Acceptable Daily Intake) of ''not specified.'' The only concern was for the potential laxative effect at high intakes. FDA has also approved the use of gellan gum as a direct food additive when used as a stabilizer and thickening agent (21 CFR 172.665).

Based on the available information which includes an Agency estimated-daily exposure of 0.94 mg/kg/day, toxicity studies conducted in g/kg body weight rather than mg/kg body weight (with few to no effects), evaluations by both FDA and WHO/JEFCA, and the high molecular weight of gellan gum, the EPA finds that exempting gellan gum (CAS No. 71010–52–1) from the requirement of a tolerance will be safe.

VIII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . .'' EPA has been working with interested stakeholders to develop a screening and testing program, as well as a priority-setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing gellan gum for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for gellan gum.

D. International Tolerances

Gellan gum is used as a food additive in many countries. The Agency is not aware of any country requiring a tolerance for gellan gum nor have any CODEX Maximum Residue Levels (MRL's) been established for any food crops at this time.

E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL–6807–8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification. The results of the review and evaluation performed by WHO/JECFA as well as FDA's approval of gellan gum as a direct food additive, indicate a substance of lower toxicity. Therefore, gellan gum (CAS No. 71010–52–1) is to be classified as a List 4A inert ingredient.

IX. Conclusion

Based on the information in the official public docket, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of gellan gum (CAS No. 71010–52–1). Accordingly, EPA finds that exempting gellan gum from the requirement of a tolerance will be safe.

X. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was

provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0003 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 4, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2.*Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–-5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit X.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0003, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the

development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications '' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.''''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. In § 180.950, the table in paragraph (e) is amended by adding alphabetically the following entry to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical	CAS No.
* * *	* *
Gellan gum	71010–52–1
* * *	* *

[FR Doc. 04–4707 Filed 3–2–04; 8:45 am]

BILLING CODE 6560–50–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 1817

RIN 2700–AC94

Performance Period Limitations

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This final rule amends the NASA FAR Supplement (NFS) by clarifying that the five-year limitation on contracts applies to all procurement award instruments including agreements, orders under a Federal Supply Schedule, or other indefinite delivery/indefinite quantity contracts awarded by other agencies. The current NFS language has been interpreted to exclude certain types of award instruments, such as basic ordering agreements or blanket purchase agreements, from the five-year limitation. This change will ensure consistent application of the five-year performance period limitation and the waiver process for all award instruments.

EFFECTIVE DATE: March 3, 2004.

FOR FURTHER INFORMATION CONTACT: Eugene Johnson, NASA, Office of Procurement, Program Operations Division (Code HS), Washington, DC 20546; (202) 358–4703; e-mail: *eugene.johnson-1@nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The NFS at 1817.204(e)(i) currently states that the five-year limitation (basic plus option periods) applies to all NASA contracts regardless of type. This has been interpreted to mean that the limitation does not apply to agreements such as basic ordering agreements and blanket purchase agreements. This interpretation is not consistent with the intent of the limitation and does not support NASA's efforts to maximize opportunities for competition. This final rule clarifies that the limitation is applicable to all award instruments. This change to the NFS is being issued as a final rule since it does not have a significant effect beyond the internal operating procedures of NASA. Comments may be submitted to the above address.

B. Regulatory Flexibility Act

This final rule does not constitute a significant revision within the meaning of FAR 1.501 and Public Law 98–577, and publication for public comment is not required. However, NASA will consider comments from small entities concerning the affected NFS Part 1817 in accordance with 5 U.S.C. 610.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes do not impose recordkeeping or information collection requirements which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 1817

Government procurement.

Tom Luedtke,

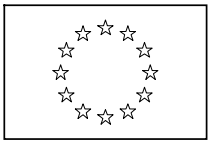
Assistant Administrator for Procurement.

■ Accordingly, 48 CFR Part 1817 is amended as follows:

■ 1. The authority citation for 48 CFR Part 1817 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

Appendix 7 – Dietary Food Additive Intake EU



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 01.10.2001
COM(2001) 542 final

REPORT FROM THE COMMISSION

on Dietary Food Additive Intake in the European Union

REPORT FROM THE COMMISSION

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EXECUTIVE SUMMARY

European Parliament and Council Directives 94/35/EC, 94/36/EC and 95/2/EC require each Member State to monitor the consumption and usage of food additives. The Commission is required to submit a report on this monitoring exercise to the European Parliament and Council.

Ten Member States and Norway, acting under EU Scientific Co-operation, have been working together to develop a tiered approach to evaluate dietary intake of food additives. The 'tiers' described are essentially additive intake estimation methods that progress in complexity and data requirements, intended to produce gradually a more accurate estimate of the additive intake. Where results of the estimates in a tier indicate that an ADI is unlikely ever to be exceeded, the additives in question are eliminated from further consideration. Resources can then be focused on the remaining additives for a more refined intake estimate. It must be emphasised that these tiers are essentially tools for establishing priorities for further monitoring.

This report represents a first attempt to obtain an overview of the dietary food additive intake in the European Union. Even if the results must be regarded as a very preliminary indication on the dietary intake of food additives, they indicate that the intake of the majority of food additives permitted today in the European Union is below the acceptable daily intake (ADI) set by the Scientific Committee on Food.

This report has many limitations. Food consumption data used was insufficient to estimate accurately food additive intake leading to worst case assumptions and consequent over-estimations of intake. Also several Member States did not use the agreed methodology for estimation of additive intake, leading to lack of comparability of the collected data. This highlights the need for Member States to apply the agreed, harmonised methodology to ensure consistency of approach and to allocate adequate resources for all future intake estimations. The current study should then be repeated and a new report should be drawn up within three years from now.

Introduction

The authorisation and use of food additives in the European Union are based on the framework Directive 89/107/EEC[1] on food additives. On the basis of the framework Directive, three specific directives were adopted by the Council and European Parliament: on sweeteners (Directive 94/35/EC[2]), colours (Directive 94/36/EC[3]) and on additives other than colours and sweeteners (Directive 95/2/EC[4]). Since the adoption of the last directive in 1995, legislation on food additives has been fully harmonised in the European Union.

According to European Parliament and Council Directives 94/35/EC (Article 8), 94/36/EC (Article 6) and 95/2/EC (Article 7) on food additives, the Member States shall establish a monitoring system for the consumption of food additives. The objective is to monitor food additive consumption and to ensure that their use does not exceed the acceptable daily intake (ADI) set for additives by the Scientific Committee on Food (SCF).

For this purpose, the Member States discussed, through scientific co-operation (SCOOP), a method to gather data that would be comparable among the Member States. The SCOOP task was finalised in January 1998.

In August 1999 the Commission sent to the Member States guidelines on how to report their findings to the Commission. Information was received from the following Member States: Austria, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Spain, Sweden and the United Kingdom. The other Member States had not been able to carry out the exercise due to lack of resources. From the EFTA countries, Norway submitted information to the Commission.

The report describes the monitoring task, how the results were reported and what kind of information was received. The food consumption data used for the intake calculations are described. Intake results are listed in tables for adults and children separately. The report also draws conclusions with regard to future work.

The report represents a first attempt to obtain an overview of the food additive intake in the European Union. It must be regarded as a very preliminary indication of the dietary intake of food additives.

The Commission would like to thank Dr Wendy Matthews from the United Kingdom Food Standards Agency, Dr Inge Meyland from the Danish Veterinary and Food Administration, Dr Pirjo-Liisa Penttilä from the Finnish National Food Administration and Dr Philippe Verger from the Institut National de la Recherche Agronomique (INRA), for assisting the Commission in drafting this report.

1 O.J. n° L 40, 11.2.1989, p. 27
2 O.J. n° L 237, 10.09.1994, p.1
3 O.J. n° L 237, 10.09.1994, p. 13
4 O.J. n° L 61, 18.03.1995, p. 1

2. BACKGROUND

In 1996, under Council Directive 93/5/EEC on assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food[5], a task was set up on "Methodologies for monitoring of food additive intakes" (SCOOP Task 4.2). The objectives of the task were:

- to identify data that can be used to assess likely additive intakes,
- to review methodologies currently used for monitoring additive usage and estimating intakes,
- to consider the need for different approaches to different types of additives,
- to establish systematic procedures for the identification of additives for which potential dietary intake gives most cause for concern
- and to develop a strategy that matches the complexity and cost of intake estimation to the level of concern posed by the potential intake of an additive.

The following Member States participated in the scientific co-operation task: Austria, Denmark, Greece, Finland, France, Ireland, the Netherlands, Spain, Sweden and the United Kingdom. In addition, Norway participated in the task. The report was produced in January 1998[6].

The participants of the SCOOP task reviewed the relevant methods for estimating the intake of food additives and proposed a tiered approach, which could be used by the Member States to meet the monitoring requirements set out in EC directives. According to the report, "*monitoring of additive intake should concentrate on discovering whether the exposure of consumers to any food additives regularly exceeds the acceptable daily intake (ADI)"*. This information can then be used by the Community regulator to determine what action (if any) is required to ensure that safety advice is being followed.

The definition of a number of key terms used throughout the report is given in box 1.

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5 O.J. n° L 052, 04.03.1993, p. 18

6 The scientific co-operation report on development of methodologies for the monitoring of food additive intake across the European Union (SCOOP/INT/REPORT/2)

Box 1:

Scientific Committee on Food (SCF) = A scientific advisory body to the European Commission on any problem relating to the protection of the health and safety of persons arising or likely to arise from the consumption of food.

Scientific co-operation (SCOOP) = Assistance to the European Commission and co-operation by the Member States in the scientific examination of questions relating to food.

Intake = The amount of food additive ingested in the diet (calculated as food consumption x food additive concentration).

Acceptable daily intake (ADI) = The amount of a food additive, expressed as mg/kg body weight, that can be ingested daily over a lifetime without incurring any appreciable health risk. The ADI is based on an evaluation of available toxicological data and established by identifying the No-Observed-Adverse-Effect-Level (NOAEL) in the most sensitive experiment among a battery of studies in test animals performed with the test compound and extrapolating to man by dividing the NOAEL with a safety factor of usually 100.

ADI "not specified" = A term used when, on the basis of the available toxicological, biochemical and clinical data, the total intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for the substance.

Maximum usage level = Highest level of a food additive permitted in foodstuff to achieve an intended technological effect. The levels are set in the specific directives: for sweeteners in Directive 94/35/EC, for colours in Directive 94/36/EC and for additives other than colours and sweeteners in Directive 95/2/EC.

Quantum satis = no maximum level is specified for the additive in question. However, the additive shall be used in accordance with good manufacturing practice, at a level not higher than necessary to achieve the intended purpose and provided that it does not mislead the consumer (Article 2(8) of Directive 95/2/EC).

In the tiered approach (see box 2), tier 1 is based on theoretical food consumption data[7] and maximum usage levels for additives as permitted by relevant Community legislation. The second and third tiers refer to assessment at the level of individual Member States, combining national data on food consumption with the maximum permitted usage levels for the additive (tier 2) and with its actual usage patterns (tier 3).

[7] Hansen, S. (1979). Conditions for Use of Food Additives Based on a Budget for an Acceptable Daily Intake. Journal of Food Protection 42 5, 429-434.

The SCF has recommended that special attention should be given to intake by children, since there is evidence suggesting that their dietary behaviour means that their intake of some additives, expressed on a bodyweight basis, may be markedly higher than that of adults. Therefore, in the SCOOP task, it was concluded that adults and children should be covered by a separate assessment.

Box 2:

TIER 1 = **theoretical food consumption data** combined with the **maximum permitted usage levels** for the additive

TIER 2 = **actual national food consumption data** combined with the **maximum permitted usage levels** for the additive

TIER 3 = **actual national food consumption data** combined with **the actual usage levels** of the additive

3. THE MONITORING TASK

The monitoring task was carried out in a stepwise manner. An overview of the method used is given in Annex I.

3.1. Additives excluded from the monitoring task:

Because priorities had to be set, it was decided to exclude from the monitoring exercise a series of additives on the basis of the following criteria:

- Additives with an ADI "not specified" allocated by the SCF; since an additive is only allocated an ADI "not specified" when, on the basis of the available scientific data, the total intake of the substance will not represent a hazard to health (see box 1).

- Additives that, based on the safety-in-use evaluation by the SCF, are only authorised in one or few specific food categories since their intake is limited to these food categories.

- New additives that have only been permitted for a short period of time since they were not in full use at the time information was collected.

These additives are listed in Annex II.

3.2. Additives subject to tier-1 screening

In tier 1, all additives with a numerical ADI were examined, with the exception of:

- those falling under 3.1, second and third bullet point and

- those authorised at *quantum satis*; they could not be examined in tier 1 or 2 since no maximum-permitted-use levels exist and were therefore moved to tier 3. These additives are listed in Annex IV.

The additives of tier 1 were screened using **theoretical food consumption data** combined with **maximum permitted use levels** of the additive. Food additives, for which the calculated intake exceeded the ADI, were moved to tier 2.

Up to this stage the exercise was carried out as part of the SCOOP task.

3.3. Additives subject to tier-2 screening

In tier 2 the additives from tier 1 that exceeded the calculated intake were examined. Their theoretical intake was calculated by combining the **mean national food consumption data** of the whole population with the **maximum permitted use levels** of the additive. This information was requested for both adults and young children, where available. The basis of the national consumption data was requested. Food additives, for which the calculated intake exceeded the ADI, were moved to tier 3.

3.4. Additives subject to tier-3 screening

At tier 3, two groups of additives were to be examined:

- additives moved to tier 3 from tier 2
- additives with numerical ADIs that are permitted for use at *quantum satis*

Member States were requested to examine these additives by calculating the **actual intake** from the **national food consumption data** combined with **actual use levels** of the additive.

4. THE MONITORING DATA

4.1. Instructions for reporting the monitoring data

A table containing information on additives and the permitted use levels was provided to the Member States. By adding the information from the national consumption data, the theoretical intake could be calculated (tier 2). The actual intake could be evaluated (tier 3) if both the national consumption data and the additive usage levels were available. It could be calculated by adding the usage level to the table.

For the purpose of the intake report:

- Young children means children under 3 years[8], referring to a bodyweight of 15 kg
- Adult refers to a bodyweight of 60 kg

Values were requested in:

- mg of additive/day

[8] Information submitted from the United Kingdom was for children of age range 1½ - 4½ years old referring to bodyweight of 15 kg.

- % of ADI based on 60 kg bodyweight for an adult or 15 kg for a young child, or on actual bodyweight, which had to be specified.

4.2. The type of monitoring data obtained

The following 6 Member States submitted information to the Commission as requested: Denmark, France, Italy, The Netherlands, Spain[9], the United Kingdom and in addition Norway. Austria, Finland, Germany[10], Ireland, Spain and Sweden submitted information obtained on a basis other than the intake estimation methods defined under the SCOOP task.

The data were submitted in the form of additive intake tables from the 7 countries in the requested format and 12 reports or notes on national studies.

Intake estimate was reported on average consumption of the population as a whole and in some cases also for high level consumers or special groups of the population.

Box 3:

Mean population intake = total food additive intake divided by the whole population

Mean intake for consumers only = total food additive intake divided by the number of actual consumers of the additive

High level consumer = a consumer with a high intake of the additive based on the distribution of individual intake values for actual consumers

The data present the following characteristics:

4.2.1. Age of data

- Collected between 1995 and 1999 for France, Spain (other additives than cyclamate), Austria (adults), Italy, Finland, Sweden, Denmark (nitrates and nitrites in meat and meat products), Ireland (second study) and the Netherlands.

- Collected between 1990 and 1994 for Ireland (first study), Spain (cyclamate), Austria (children over 6 years old, pregnant women, lactating women, elderly, diabetics), Norway and the United Kingdom (children).

- Collected between 1987 and 1989 for Denmark and the United Kingdom (adults).

For the purpose of monitoring the food additive intake in the European Union after the full harmonisation in 1995, the information gathered should have described the situation

[9] Information submitted from Spain was for the whole population. The division between adults and children was made on the basis of the assumption that children represent a percentage of the whole population. As data for children did not come from an actual survey, it was considered appropriate to report only the information for the whole population.

[10] Information for Germany was local data from Bavaria and consisted only of food consumption figures. The information on food additive intake was not provided.

after the entry into force of the Community legislation. However, some Member States were collecting data between 1987 and 1999. Because collecting food consumption data is very costly, it was considered useful for the purposes of this report to include any data submitted by the Member States, even if it dated from before 1995.

4.2.2. Representativity

Two surveys were performed locally and are, therefore, not considered to be representative of the whole population: In Spain, the intake study of cyclamate in Catalonia, and in Finland, the STRIP (Children's Coronary Heart Disease Risk Factor Intervention) project conducted on children in Turku.

4.2.3. Type of survey

- Recall for Austria (adults), Finland (adults) and Spain (cyclamate).
- Record for Austria (children over 6 years old, pregnant women, lactating women, elderly, diabetics), Denmark, Finland (children), Ireland, Italy, The Netherlands, France, Spain (other additives), and the United Kingdom.
- Food Frequency Questionnaire for Norway and Sweden (diabetics).

Box 4:

Recall = based on memory of food consumption prior to the interview

Record = food consumption recorded systematically by the consumer over a set period of time

Food frequency questionnaire (quantitative) = the consumer reports the frequency and amount of food consumed

4.2.4. Types of population

- Individuals for Austria, Italy, Finland, Spain (cyclamate), Denmark (nitrates and nitrites in meat and meat products), Ireland, Italy, The Netherlands, France (11 additives - tier 2), Sweden, Norway and the United Kingdom.
- Household for Denmark, France (17 additives - tier 2) and Spain (additives other than cyclamate).

4.2.5. Duration of the survey

- One-day survey in Austria, Finland (adults) and Spain.
- Two-day survey in the Netherlands.
- 4-day survey in Finland (children) and the United Kingdom (children).

- 7-day survey in Austria, Denmark (nitrates and nitrites in meat and meat products), Italy, France (11 additives - tier 2), Spain and the United Kingdom (adults).

- One month collection of typical consumption in Denmark

- One-year record in France (17 additives - tier 2).

5. INTAKE RESULTS

For the purposes of this report, only the data obtained on the basis of the estimation methods defined under the SCOOP task could be used. Data submitted that were obtained on a different basis could not be used because of their incomparability. Nevertheless, it was considered interesting to summarise the information received in Annex VI.

5.1. Tier 1

On the basis of tier 1, it is already possible to exclude a number of food additives from further examination, since the theoretical intake based on conservative assumptions on food consumption and additive usage did not exceed the ADI. For adults, there were 21 additives or additive groups* that were excluded from further examination. For children, 9 additives or additive groups were excluded. These additives are listed in Annex III.

5.2. Tier 2

The outcome of the tier 2 of this first monitoring of dietary food additive intake in the European Union shows relatively consistent results. Using the mean exposure of the population in six Member States and Norway, it is possible to exclude most additives from the list for tier-3 evaluation since the theoretical intake based on actual food consumption data combined with the maximum permitted usage levels for the additive did not exceed the ADI.

For adults and the whole population, the following food additives and food additive groups were excluded from further examination:

- E 210-213 benzoates, E 297 fumaric acid, E 310-312 gallates, E 315-316 erythorbates, E 320 BHA, E 321 BHT, E 355- 357 adipates, E 416 karaya gum, E 442 ammonium phosphatides, E 475 polyglycerol esters, E 476 polyglycerol polyricinoleate, E 479b TOSOM, E 483 stearyl tartrate, E 491/492/495 sorbitan esters, E 535-538 ferrocyanides, E 950 acesulfame K, and E 952 cyclamates.

- All the colours

For children, the following food additives and food additive groups were excluded from further examination:

* Additive group = closely related substances that have been allocated a group ADI (e.g. phosphoric acid and phosphates, saccharin and its salts etc.)

- E 200-203 sorbates, E 297 fumaric acid, E 310-312 gallates, E 315-316 erythorbates, E 320 BHA, E 355- 357 adipates, E 416 karaya gum, E 442 ammonium phosphatides, E 444 sucrose acetate isobutyrate, E 476 polyglycerol polyricinoleate, E 479b TOSOM, E 951 aspartame, E 952 cyclamates, E 954 saccharin, E 959 neohesperedine DC and E 999 quillaia extract.

- All the colours (except E 160b annatto).

Additives were moved to tier 3 for further detailed intake estimation on the basis that the theoretical intake at tier-2 level approached or exceeded the ADI at least in one Member State or if there was further information suggesting that some groups of consumers may have unusually high intake levels.

For adults and the whole population, the following food additives and food additive groups were moved to tier 3:

- E 220-228 sulphites, E 249-250 nitrites, E 432-436 polysorbates, E 473-474 sucrose esters and sucroglycerides, E 481-482 stearoyl-2-lactylates, E 493-494 sorbitan monolaureate and sorbitan monooleate, E 520-523 aluminium sulphates, E 541 sodium aluminium phosphate and E 554-556/559 aluminium silicates.

For children, the following food additives and food additive groups were moved to tier 3:

- E 160b annatto, E 220-228 sulphites, E 210-213 benzoates, E 249-250 nitrites, E 321 BHT, E 338-341/343/450-452 phosphoric acid and phosphates, E 432-436 polysorbates, E 473-474 sucrose esters and sucroglycerides, E 475 polyglycerol esters, E 481-482 stearoyl-2-lactylates, E 483 stearyl tartrate, E 491-495 sorbitan esters, 535-538 ferrocyanides, E 520-523 aluminium sulphates, E 541 sodium aluminium phosphate, E 554-556/559 aluminium silicates and E 950 acesulfame-K.

In addition, E 558 bentonite (both for adults and children) was moved to tier 3 due to lack of information on the intake of this additive at tier-2 level.

Furthermore, nine additives with numerical ADIs that are permitted for use at *quantum satis* were moved directly to tier 3 (see Annex IV) because actual use levels are necessary for intake estimations.

Results obtained for the intake of food additives at tier 2 are listed in Annex V for adults and the whole population (Table 1) and for young children (Table 2). The following information is given in the tables: E-number, the specific name and the ADI of the additive, the Member State that provided the information, the range of the intake of the additive expressed as a percentage of the ADI, consequence for tier-estimation.

5.3. Tier 3

No Member State submitted complete information on tier 3 results according to the method agreed.

Discussion

This report is the first attempt to obtain an overview of the dietary food additive intake in the European Union. The results reported must be regarded as a very preliminary indication on the dietary intake of food additives due to the many limitations the current exercise had.

In its request for information on food additive intake, the objective of the Commission was to obtain information from as many Member States as possible. Therefore, a pragmatic approach to use information calculated on the food consumption of the population mean was chosen. However, the use of the population mean does not take into account intake by high-level consumers. On the other hand, the estimates reported here are extremely conservative, since they assume that each additive is used in the widest possible range of foods at the maximum permitted levels, which in many cases leads to over-estimation of the additive intake. Therefore, more precise studies are needed in the future. In several Member States, work is already in progress for gathering information to enable more refined intake estimations to be carried out.

Today, 171 additives and additive groups are permitted for use in the EU. On the basis of the limited data available, it can be concluded that for the majority of these additives, intake is below the ADI set by the Scientific Committee on Food. As a result of tier-2 intake estimations, eight additives or additive groups were prioritised for tier-3 estimations for adults and seventeen additives or additive groups were prioritised for tier-3 estimations for children. The tier-2 values for these additives theoretically exceeded the ADI at least in one Member State or no information was provided on the substance. It should be noted that the range of intake of the same additive could vary considerably between different countries. In addition, nine additives allocated a numerical ADI, but permitted for use in certain foods according to *quantum satis*, were prioritised for tier-3 examination.

To carry out the tier-3 estimation for these additives, more detailed information should be collected on the real use of additives and on the real food consumption (actual intake, special groups of consumers, high-level consumers). This work should be carried out without delay.

In addition to action being taken on additives prioritised for tier 3, examination should also continue on additives that passed tier 2 and were not prioritised for tier 3. Firstly not all the Member States have studied these additives and, as stated above, the results can vary considerably depending on the country. Secondly, estimation of the intake of these additives should be done also on high-level consumers, not only on the population mean.

7. CONCLUSIONS

- The Member States should follow up the SCOOP task on methodologies for the monitoring of food additives in order to achieve harmonisation of intake studies of additives in the European Union. In addition, better food consumption data should be gathered in order to estimate dietary food additive intake more accurately.

- The preliminary results with limited data available indicate that for the majority of food additives the dietary intake is below the acceptable daily intake.

- For the additives that were moved to tier 3 (see Annex V) and certain additives that are permitted at *quantum satis* (see Annex IV), intake estimations should be carried out using actual food consumption data combined with the actual usage levels of the additive. The examination should be carried out by all the Member States without delay and the results should be reported to the Commission with a view to initiating necessary action, if any.

- Intake of additives that did not exceed the ADI in tier 2 should, nevertheless, be re-examined in the light of the more detailed food consumption data (see Annex V).

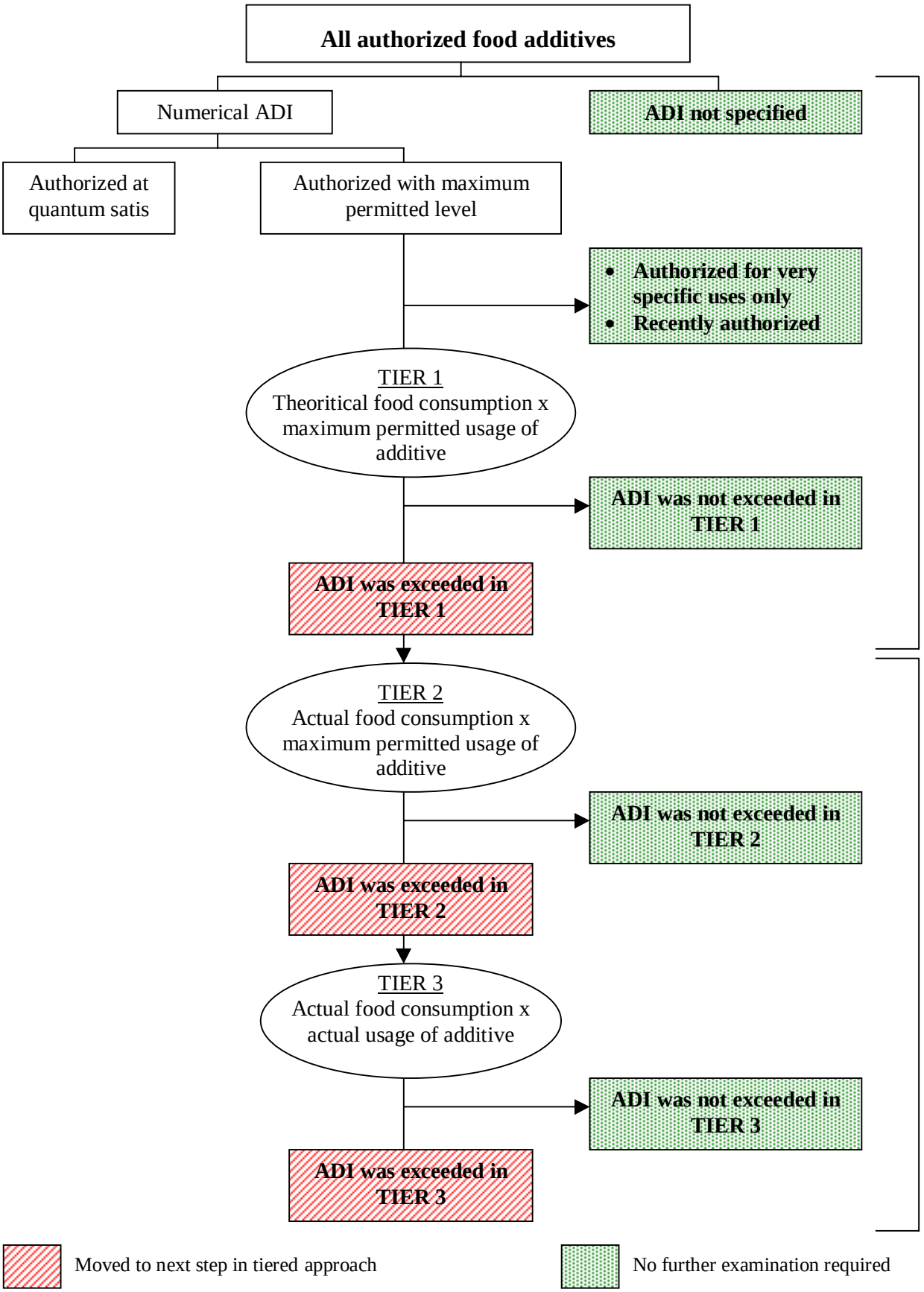
- Intake studies should be carried out in respect of the additives which, at the time of this exercise, had only recently been approved.

- Co-operation with the food industry should be developed with a view to obtaining better information on food additive usage.

- A new report on the overall situation on food additive intake in the European Union should be compiled in three years time. It is essential that efforts are made by all the Member States to participate fully in the next monitoring task on dietary intake of food additives.

Annex I

Outline of the tiered approach



Annex II

List of food additives with ADI "not specified", found acceptable for specified use as recommended by the SCF or new additives. These additives were excluded from the examination

E No	Name
	Polyethyleneglycol 6000
E 100	Curcumin
E 101	(i) Riboflavin (ii) Riboflavin-5'phosphate
E 140	Chlorophyls and Chlorophyllins
E 150a	Plain caramel
E 153	Vegetable carbon
E 160d	Lycopene
E 161b	Lutein
E 162	Beetroot Red, betanin
E 163	Anthocyanins
E 170	Calcium carbonates
E 171	Titanium dioxide
E 172	Iron oxides and hydroxides
E 173	Aluminium
E 174	Silver
E 175	Gold
E 230	Biphenyl, diphenyl
E 231 E 232	Orthophenyl phenol Sodium orthophenyl phenol
E 235	Natamycin
E 239	Hexamethylene tetramine
E 242	Dimethyl dicarbonate
E 260 E 261 E 262 E 263	Acetic acid Potassium acetate Sodium acetates Calcium acetate
E 270 E 325 E 326 E 327	Lactic acid Sodium lactate Potassium lactate Calcium lactate
E 280 E 281 E 282 E 283	Propionic acid Sodium propionate Calcium propionate Potassium propionate
E 284 E 285	Boric acid Sodium tetraborate (Borax)
E 290	Carbon dioxide
E 296 E 350 E 351 E 352	Malic acid Sodium malates Potassium malate Calcium malates
E 300 E 301 E 302 E 304	Ascorbic acid Sodium ascorbate Calcium ascorbate Fatty acid esters of ascorbic acid
E 306 E 307 E 308 E 309	Tocopherol-rich extract Alpha-tocopherol Gamma-tocopherol Delta-tocopherol
E 322	Lecithins
E 330 E 331 E 332 E 333	Citric acid Sodium citrates Potassium citrates Calcium citrates
E 353	Metatartaric acid
E 363	Succinic acid
E 380	Triammonium citrate
E 400 E 401 E 402 E 403 E 404	Alginic acid Sodium alginate Potassium alginate Ammonium alginate Calcium alginate
E 406	Agar
E 407a	Processed eucheuma seeweed
E 410	Locust bean gum
E 412	Guar gum
E 413	Tragacanth
E 414	Acacia gum (gum arabic)
E 415	Xanthan gum
E 417	Tara gum
E 418	Gellan gum
E 420	(i) Sorbitol (ii) Sorbitol syrup
E 421	Mannitol
E 422	Glycerol
E 425	(i) Konjac gum (ii) Konjac glucomannane
E 431	Polyoxyethylene (40) stearate
E 440	Pectins
E 459	Beta-cyclodextrine
E 460	Cellulose
E 461 E 463 E 464 E 465 E 466 E 469	Methyl cellulose Hydroxypropyl cellulose Hydroxypropyl methyl cellulose Ethyl methyl cellulose Carboxy methyl cellulose Enzymatically hydrolysed carboxy methyl cellulose
E 468	Crosslinked sodium carboxy methyl cellulose
E 470a E 470b	Sodium, potassium and calcium salts of fatty acids Magnesium salts of fatty acids

E No	Name
E 471	Mono and diglycerides of fatty acids
E 472a	Acetic acid esters of mono and diglycerides of fatty acids
E 472b	Lactic acid esters of mono and diglycerides of fatty acids
E 472c	Citric acid esters of mono and diglycerides of fatty acids
E 472d	Tartaric acid esters of mono and diglycerides of fatty acids
E 472f	Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids
E 500	Sodium carbonates
E 501	Potassium carbonates
E 503	Ammonium carbonates
E 504	Magnesium carbonates
E 507	Hydrochloric acid
E 508	Potassium chloride
E 509	Calcium chloride
E 511	Magnesium chloride
E 512	Stannous chloride
E 513	Sulphuric acid
E 514	Sodium sulphates
E 515	Potassium sulphates
E 516	Calcium sulphate
E 517	Ammonium sulphate
E 524	Sodium hydroxide
E 525	Potassium hydroxide
E 526	Calcium hydroxide
E 527	Ammonium hydroxide
E 528	Magnesium hydroxide
E 529	Calcium oxide
E 530	Magnesium oxide
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicates
E 553b	Talc
E 570	Fatty acids
E 574	Gluconic acid
E 575	Glucono-delta-lactone
E 576	Sodium gluconate
E 577	Potassium gluconate
E 578	Calcium gluconate
E 579	Ferrous gluconate
E 585	Ferrous lactate
E 620	Glutamic acid
E 621	Monosodium glutamate
E 622	Monopotassium glutamate
E 623	Calcium diglutamate
E 624	Monoammonium glutamate
E 625	Magnesium diglutamate

E No	Name
E 626	Guanylic acid
E 627	Disodium guanylate
E 628	Dipotassium guanylate
E 629	Calcium guanylate
E 630	Inosinic acid
E 631	Disodium inosinate
E 632	Dipotassium inosinate
E 633	Calcium inosinate
E 634	Calcium 5’-ribonucleotides
E 635	Disodium 5’-ribonucleotides
E 640	Glycine and its sodium salt
E 650	Zinc acetate
E 901	Beeswax, white and yellow
E 902	Candelilla wax
E 903	Carnauba wax
E 904	Shellac
E 905	Microcrystalline wax
E 912	Montan acid esters
E 914	Oxidised polyethylene wax
E 920	L-Cysteine
E 927b	Carbamide
E 938	Argon
E 939	Helium
E 941	Nitrogen
E 942	Nitrous oxide
E 943a	Butane
E 943b	Iso-butane
E 944	Propane
E 948	Oxygen
E 949	Hydrogen
E 953	Isomalt
E 957	Thaumatine
E 965	(i) Maltitol (ii) Maltitol syrup
E 966	Lactitol
E 967	Xylitol
E 1103	Invertase
E 1105	Lysozyme
E 1200	Polydextrose
E 1201	Polyvinylpyrrolidone
E 1202	Polyvinylpolypyrrolidone
E 1404	Oxidised starch
E 1410	Monostarch phosphate
E 1412	Distarch phosphate
E 1413	Phosphated distarch phosphate
E 1414	Acetylated distarch phosphate
E 1420	Acetylated starch
E 1422	Acetylated distarch adipate
E 1440	Hydroxy propyl starch
E 1442	Hydroxy propyl distarch phosphate
E 1450	Starch sodium octenyl succinate
E 1451	Acetylated oxidised starch
E 1518	Glyceryl triacetate (triacetine)
E 1520	Propan-1,2-diol

Annex III

Food additives for which the calculated intake in tier 1 did not exceed the ADI. These additives need no further examination at this stage

Table 1: Adults

E No	Name	ADI
E 102	Tartrazine	7.5 mg/kg
E 104	Quinoline Yellow	10 mg/kg
E 123	Amaranth	0.8 mg/kg
E 129	Allura Red AC	7 mg/kg
E 131	Patent Blue V	15 mg/kg
E 133	Brilliant Blue FCF	10 mg/kg
E 154	Brown FK	0.15 mg/kg
E 200 E 202 E 203	Sorbic acid Potassium sorbate Calcium sorbate	25 mg/kg
E 214 E 215 E 216 E 217 E 218 E 219	Ethyl p-hydroxybenzoate Sodium ethyl p-hydroxybenzoate Propyl p-hydroxybenzoate Sodium propyl p-hydroxybenzoate Methyl p-hydroxybenzoate Sodium methyl p-hydroxybenzoate	10 mg/kg
E 234	Nisin	0.13 mg/kg
E 251 E 252	Sodium nitrate Potassium nitrate	5 mg/kg
E 338 E 339 E 340 E 341 E 343 E 450 E 451 E 452	Phosphoric acid Sodium phosphates Potassium phosphates Calcium phosphates Magnesium phosphates Diphosphates Triphosphates Polyphosphates	70 mg/kg
E 385	Calcium disodium ethylene diamine tetra-acetate (EDTA)	2.5 mg/kg
E 405 E 477	Propane-1,2-diol alginate Propane-1,2-diol esters of fatty acids	25 mg/kg
E 444	Sucrose acetate isobutyrate	10 mg/kg
E 445	Glycerol esters of wood rosin	12.5 mg/kg
E 900	Dimethyl polysiloxane	1.5 mg/kg
E 951	Aspartame	40 mg/kg
E 954	Saccharin and its sodium, calcium and potassium salts	5 mg/kg
E 959	Neohesperidine dihydrochalcone (DC)	5 mg/kg
E 999	Quillaia extract	5 mg/kg

Table 2: Young children

E No	Name	ADI
E 123	Amaranth	0.8 mg/kg
E 154	Brown FK	0.15 mg/kg
E 214 E 215 E 216 E 217 E 218 E 219	Ethyl p-hydroxybenzoate Sodium ethyl p-hydroxybenzoate Propyl p-hydroxybenzoate Sodium propyl p-hydroxybenzoate Methyl p-hydroxybenzoate Sodium methyl p-hydroxybenzoate	10 mg/kg
E 234	Nisin	0.13 mg/kg
E 251 E 252	Sodium nitrate Potassium nitrate	5 mg/kg
E 385	Calcium disodium ethylene diamine tetra-acetate (EDTA)	2.5 mg/kg
E 405 E 477	Propane-1,2-diol alginate Propane-1,2-diol esters of fatty acids	25 mg/kg
E 445	Glycerol esters of wood rosin	12.5 mg/kg
E 900	Dimethyl polysiloxane	1.5 mg/kg

Annex IV

Food additives with numerical ADIs that are permitted for use at *quantum satis* (moved to tier 3)

E No	Name	ADI
E 141	Copper complexes of Chlorophyls and Chlorophyllins	15 mg/kg
E 150b E 150d	Caustic sulphite caramel Sulphite ammonia caramel	200 mg/kg
E 150c	Ammonia caramel	200 mg/kg
E 160a(ii) E 160e E 160f	Beta-carotene Beta-apo-8-carotenal Ethyl ester of beta-apo-8-carotenoic acid	5 mg/kg[11]
E 180	Litholrubine BK	1.5 mg/kg
E 334 E 335 E 336 E 337 E 354	Tartaric acid Sodium tartrates Potassium tartrates Sodium potassium tartrate Calcium tartrate	30 mg/kg
E 407	Carrageenan	75 mg/kg
E 472e	Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty esters	25 mg/kg
E 1505	Triethyl citrate	20 mg/kg

[11] The Scientific Committee on Food withdrew the ADI for betacarotene (opinion adopted on 7 September 2000) and stated that its use is temporarily acceptable as a food colour with currently estimated intake.

Annex V

Results obtained for the intake of food additives at tier 2

Table 1: Adults and the whole population

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 110	Sunset Yellow FCF Orange Yellow 5	2.5 mg/kg	DK, ES, IT, UK, NO	2 – 26	Tier 2
E 120	Cochineal, Carminic acid, Carmines	5 mg/kg	DK, ES, IT, UK, NO	3 – 22	Tier 2
E 122	Azorubine, Carmoisine	4 mg/kg	DK, ES, IT, UK, NO	3 – 16	Tier 2
E 124	Ponceau 4R, Cochineal Red A	4 mg/kg	DK, ES, IT, UK, NO	3 –16	Tier 2
E 127	Erythrosine	0,1 mg/kg	DK, ES, IT, UK	0	Tier 2
E 128	Red 2G	0,1 mg/kg	DK, ES, IT, UK, NO	2 – 20	Tier 2
E 132	Indigotine, Indigo carmine	5 mg/kg	DK, ES, IT, UK. NO	2 – 13	Tier 2
E 142	Green S	5 mg/kg	DK, ES, IT, UK, NO	3 – 20	Tier 2
E 151	Brilliant Black BN, Black PN	5 mg/kg	DK, ES, IT, UK, NO	3 – 20	Tier 2
E 155	Brown HT	3 mg/kg	DK, ES, IT, UK, NO	3 – 22	Tier 2
E 160b	Annatto, bixin, norbixin	0.065 mg/kg	ES, FR, IT, UK, NO	0 - 62	Tier 2
E 161g	Canthaxanthin	0.03 mg/kg	ES, FR, IT, UK	0	Tier 2
E 210 E 211 E 212 E 213	Benzoic acid Sodium benzoate Potassium benzoate Calcium benzoate	5 mg/kg	DK, ES, FR, IT, NL, UK, NO	6 - 84	Tier 2
E 220 E 221 E 222 E 223 E 224 E 226 E 227 E 228	Sulphur dioxide Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite Calcium hydrogen sulphite Potassium hydrogen sulphite	0.7 mg/kg	DK, ES, FR, IT, NL, UK, NO	20 - 266[12]	Tier 3
E 249 E 250	Potassium nitrite Sodium nitrite	0.1 mg/kg	DK, ES, FR, IT, NL, UK, NO	40 - 230[12]	Tier 3
E 297	Fumaric acid	6 mg/kg	DK, ES, FR, NL, UK	1- 17	Tier 2
E 310 E 311 E 312	Propyl gallate Octyl gallate Dodecyl gallate	0.5 mg/kg	DK, ES, NL, UK	12 - 34	Tier 2
E 315 E 316	Erythorbic acid Sodium erythorbate	6 mg/kg	DK, ES, FR, IT, NL, UK	1- 24	Tier 2
E 320	Butylated hydroxyanisole (BHA)	0.5 mg/kg	DK, ES, FR, IT, NL, UK	12 - 37	Tier 2
E 321	Butylated hydroxytoluene (BHT)	0.05 mg/kg	DK, ES, FR, IT, NL, UK	23 - 80	Tier 2
E 355 E 356 E 357	Adipic acid Sodium adipate Potassium adipate	5 mg/kg	DK, FR, UK	2 – 20	Tier 2
E 416	Karaya gum	12.5 mg/kg	DK, ES, IT, NL, UK	0 – 65	Tier 2
E 442	Ammonium phosphatides	30 mg/kg	DK, ES, FR, IT, NL, UK	1 – 11	Tier 2

[12] Conservative intake estimate based on the assumption that the additive is used in the widest possible range of foods and at maximum permitted levels. Work is in progress to refine intake estimates using actual usage data, which will considerably reduce the degree of overestimation in the current figure

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 432 E 433 E 434 E 435 E 436	Polyoxyethylene sorbitan monolaurate (polysorbate 20) Polyoxyethylene sorbitan monooleate (polysorbate 80) Polyoxyethylene sorbitan monopalmitate (polysorbate 40) Polyoxyethylene sorbitan monostearate (polysorbate 60) Polyoxyethylene sorbitan tristearate (polysorbate 65)	10 mg/kg	DK, ES, FR, IT, NL, UK	2 – 78 (QS uses)	Tier 3[13]
E 475	Polyglycerol esters of fatty acids	25 mg/kg	DK, ES, FR, IT, NL, UK, NO	3 – 53	Tier 2
E 476	Polyglycerol polyricinoleate	7.5 mg/kg	DK, ES, FR, NL, UK, NO	4 – 33	Tier 2
E 479b	Thermally oxidised soya bean oil (TOSOM)	25 mg/kg	DK, NL, UK, NO	1 – 10	Tier 2
E 481 E 482	Sodium stearoyl-2-lactylate Calcium stearoyl-2-lactylate	20 mg/kg	DK, ES, FR, IT, NL, UK, NO	2 – 114[12]	Tier 3
E 483	Stearyl tartrate	20 mg/kg	DK, ES, FR, IT, NL, UK, NO	1 – 98	Tier 2
E 491 E 492 E 495	Sorbitan monostearate Sorbitan tristearate Sorbitan monopalmitate	25 mg/kg	DK, ES, FR, IT, NL, UK, NO	3 – 75	Tier 2
E 493 E 494	Sorbitan monolaurate Sorbitan monooleate	5 mg/kg	DK, ES, IT, NL, UK, NO	16 – 354[12]	Tier 3
E 520 E 521 E 522 E 523 E 541 . E 554 E 555 E 556 E 559	Aluminium sulphate Aluminium sodium sulphate Aluminium potassium sulphate Aluminium ammonium sulphate Sodium aluminium phosphate, acidic Sodium aluminium silicate Potassium aluminium silicate Calcium aluminium silicate Aluminium silicate	7 mg/kg[14]	DK, FR, IT, NL, UK, NO	6 – 624[12]	Tier 3
E 535 E 536 E 538	Sodium ferrocyanide Potassium ferrocyanide Calcium ferrocyanide	0.03 mg/kg	DK, IT, NL, NO	0	Tier 2
E 558	Bentonite	7 mg/kg[14]		No info	Tier 3
E 950	Acesulfame-K	9 mg/kg	DK, FR, IT, NL, UK, NO	2 –37	Tier 2
E 952	Cyclamic acid and its sodium and calcium salts	11 mg/kg[15]	DK, FR, IT, NL, UK, NO	0 – 10	Tier 2
E 1505	Triethyl citrate	20 mg/kg	DK	0 (QS uses)	Tier 3[13]

[13] Even if the intake of this additive did not exceed the ADI at tier-2 estimation, it has been prioritised for tier 3 as it has some uses that are permitted at *quantum satis*.

[14] Provisional tolerable weekly intake (PTWI)

[15] The SCF allocated a new ADI for cyclamic acid (7 mg/kg) on 13 March 2000.

Table 2: Young children

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 102	Tartrazine	7.5 mg/kg	UK	52	Tier 2
E 104	Quinoline yellow	10 mg/kg	UK	20	Tier 2
E 110	Sunset Yellow FCF Orange Yellow 5	2.5 mg/kg	UK	80	Tier 2
E 120	Cochineal, Carminic acid, Carmines	5 mg/kg	UK	80	Tier 2
E 122	Azorubine, Carmoisine	4 mg/kg	UK	50	Tier 2
E 124	Ponceau 4R, Cochineal Red A	4 mg/kg	UK	50	Tier 2
E 127	Erythrosine	0.1 mg/kg	UK	0	Tier 2
E 128	Red 2G	0.1 mg/kg	UK	40	Tier 2
E 129	Allura Red AC	7 mg/kg	UK	55	Tier 2
E 131	Patent Blue V	15 mg/kg	UK	13	Tier 2
E 132	Indigotine, Indigo carmine	5 mg/kg	UK	40	Tier 2
E 133	Brilliant Blue FCF	10 mg/kg	UK	38	Tier 2
E 142	Green S	5 mg/kg	UK	76	Tier 2
E 151	Brilliant Black BN, Black PN	5 mg/kg	UK	76	Tier 2
E 155	Brown HT	3 mg/kg	UK	67	Tier 2
E 160b	Annatto, bixin, norbixin	0.065 mg/kg	FR, UK	108 - 170[12]	Tier 3
E 161g	Canthaxanthin	0.03 mg/kg	UK	0	Tier 2
E 200 E 202 E 203	Sorbic acid Potassium sorbate Calcium sorbate	25 mg/kg	UK	76	Tier 2
E 210 E 211 E 212 E 213	Benzoic acid Sodium benzoate Potassium benzoate Calcium benzoate	5 mg/kg	FR, UK	17 – 96	Tier 3
E 220 E 221 E 222 E 223 E 224 E 226 E 227 E 228	Sulphur dioxide Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite Calcium hydrogen sulphite Potassium hydrogen sulphite	0.7 mg/kg	FR, UK	83 - 1227[12]	Tier 3
E 249 E 250	Potassium nitrite Sodium nitrite	0.1 mg/kg	FR, UK	50 – 360[12]	Tier 3
E 297	Fumaric acid	6 mg/kg	FR, NL, UK	6 – 66	Tier 2
E 310 E 311 E 312	Propyl gallate Octyl gallate Dodecyl gallate	0.5 mg/kg	NL, UK	17 – 70	Tier 2
E 315 E 316	Erythorbic acid Sodium erythorbate	6 mg/kg	NL, UK	1 – 80	Tier 2

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 338 E 339 E 340 E 341 E 343 E 450 E 451 E 452	Phosphoric acid Sodium phosphates Potassium phosphates Calcium phosphates Magnesium phosphates Diphosphates Triphosphates Polyphosphates	70 mg/kg	NL, UK	53 - 172[12]	Tier 3
E 355 E 356 E 357	Adipic acid Sodium adipate Potassium adipate	5 mg/kg	NL, UK	3 – 7	Tier 2
E 416	Karaya gum	12.5 mg/kg	NL, UK	17 – 48	Tier 2
E 432 E 433 E 434 E 435 E 436	Polyoxyethylene sorbitan monolaurate (polysorbate 20) Polyoxyethylene sorbitan monooleate (polysorbate 80) Polyoxyethylene sorbitan monopalmitate (polysorbate 40) Polyoxyethylene sorbitan monostearate (polysorbate 60) Polyoxyethylene sorbitan tristearate (polysorbate 65)	10 mg/kg	NL, UK	47 – 107[12] (QS uses)	Tier 3
E 442	Ammonium phosphatides	30 mg/kg	NL, UK	8 – 33	Tier 2
E 444	Sucrose acetate isobutyrate	10 mg/kg	UK	13	Tier 2
E 473 E 474	Sucrose ester of fatty acids Sucroglycerides	20 mg/kg	FR, NL, UK	226 – 375[12]	Tier 3
E 475	Polyglycerol esters of fatty acids	25 mg/kg	FR, NL, UK	114 – 160[12]	Tier 3
E 476	Polyglycerol polyricinoleate	7.5 mg/kg	FR, NL, UK	49 – 53	Tier 2
E 479b	Thermally oxidised soya bean oil (TOSOM)	25 mg/kg	NL, UK	5	Tier 2
E 481 E 482	Sodium stearoyl-2-lactylate Calcium stearoyl-2-lactylate	20 mg/kg	FR, NL, UK	136 – 268[12]	Tier 3
E 483	Stearyl tartrate	20 mg/kg	FR, NL, UK	49 – 112[12]	Tier 3
E 491 E 492 E 495	Sorbitan monostearate Sorbitan tristearate Sorbitan monopalmitate	25 mg/kg	FR, NL, UK	150 – 190[12]	Tier 3
E 493 E 494	Sorbitan monolaurate Sorbitan monooleate	5 mg/kg	NL, UK	657 – 802[12]	Tier 3

E No	Name of the additive	ADI	Member States producing intake information	Range of estimated intake (% ADI)	Stays at tier 2 or moved to tier 3
E 520 E 521 E 522 E 523 E 541 E 554 E 555 E 556 E 559	Aluminium sulphate Aluminium sodium sulphate Aluminium potassium sulphate Aluminium ammonium sulphate Sodium aluminium phosphate, acidic Sodium aluminium silicate Potassium aluminium silicate Calcium aluminium silicate Aluminium silicate	7 mg/kg[14]	FR, NL, UK	40 – 750[12]	Tier 3
E 535 E 536 E 538	Sodium ferrocyanide Potassium ferrocyanide Calcium ferrocyanide	0.03 mg/kg		No info	Tier 3
E 558	Bentonite	7 mg/kg[14]		No info	Tier 3
E 950	Acesulfame-K	9 mg/kg	FR, NL, UK	3 – 107[12]	Tier 3
E 951	Aspartame	40 mg/kg	NL, UK	1 – 40	Tier 2
E 952	Cyclamic acid and its sodium and calcium salts	11 mg/kg	FR, NL, UK	1 – 74	Tier 2
E 954	Saccharin and its sodium, calcium and potassium salts	5 mg/kg	FR, NL, UK	2 – 51	Tier 2
E 959	Neohesperidine dihydrochalcone (DC)	5 mg/kg	NL, UK	1 – 18	Tier 2
E 999	Quillaia extract	5 mg/kg	FR, NL, UK	1 – 71	Tier 2

Annex VI

Other information

All the Member States did not use the intake estimation methods defined under the SCOOP task. The reasons for selecting different methods was based on earlier intake work carried out in some Member States. Other information using non-SCOOP intake methodology was available mainly from Austria, Finland, Ireland, Spain and Sweden.

These countries have based their intake estimations on earlier selective studies, information from the food industry, marketing surveys or product databases. Quite often stepwise or hierarchical approaches have been used; moving from conservative, less refined to more refined exposure estimates.

Food additive occurrence data have been studied using preliminary surveys based on national food ingredient databases in Austria and Ireland. In Finland, similar data were collected using a market survey, based on labelling information. Information on the use of food additives was also provided from laboratories, the food industry or marketing associations. Only when additives were found in specific food categories, was that food category considered in the intake estimation or samples taken to the laboratory for analysis. Quite often these preliminary studies revealed that food additives were not widely used in the products even if they were permitted by legislation (Finland, Ireland).

Austria

Austria submitted a report on a detailed study based on the tiered approach described in the SCOOP report. However, as this study was not reported in accordance with the guidelines sent out by the Commission, it was not possible to include the results in chapter 5 of this report. The reported tier-2 calculation showed that, on the basis of intakes by high-level consumers, the ADI was likely to be exceeded for 15 additives or groups of additives. A tier-3 calculation has been carried out for several additives. Intake calculated for both 'whole population' and for 'consumers only' are reported. While intake by high-level consumers exceeding the ADI was only reported for a few additives based on 'whole population' estimates, intake by high-level consumers exceeding the ADI was reported for several additives based on 'consumers only' estimates.

Finland

Intake estimations (from 1999) submitted by Finland were done at tier-3 level and were targeted especially at children from 1-6 years. Estimations for children's intake were based on individual food consumption and analysed food additive levels in products consumed in Finland. The only food additives for which the ADI was exceeded were nitrites and benzoates.

For adults (consumers only, see box 3) nitrite intake was 93 % of the ADI; for children from 1-6 years (consumers only) 67% of ADI when the actual weight of each child was used. For high level consumers (95th percentile) the intake of children was 121-189 % of the ADI.

The average intake of benzoic acid for adults was 8.6 % of the ADI and with consumers only 113 % of the ADI. Average intake of children was 40 % of the ADI and with high-level consumers (95th percentile) 101-160 % of the ADI.

Ireland

The food additives in the Irish food supply were monitored using the Irish National Food Ingredient Database (INFID). This exercise showed the trend of individual additives' usage between two sampling periods 1995/97 and 1998/99. It also indicated which additives were most widely used in the foods chosen for the study. A number of additives were found not to be present in the foods included in the database.

Following the SCOOP tier-1 exercise, a variety of approaches such as portion size back calculations, food-intake data and nutrient-intake back calculations were used as a second stage screen. This identified 20 additives for further consideration.

Spain

Spain submitted information on cyclamate intake related to a published study conducted in 1992 in a region of Spain (Catalonia). For the cyclamate level in foodstuffs, the study was based on information from industry.

This study can be considered as a “tier 3” survey despite the fact that it is not designed to be representative of the whole population of Spain. The information provides clear indications of the major contribution made by soft drinks to cyclamate exposure and confirms that, even if it was unlikely to have caused any safety concerns at the time of the study, the margin of safety between the exposure and the ADI is small for high consumers of cyclamates.

Sweden

Information submitted by Sweden consists of a report of the Swedish Food Administration on intake of aspartame, acesulfame-K, saccharin and cyclamate among diabetics. This study was conducted in January 1999 on 1120 Swedish diabetic adults (16-90 years) and children (0-15 years).

Concerning sweetened foods, the maximum amount allowed was assumed to have been added. An estimated worst case calculation was performed assuming that all the foods consumed were sweetened by the same sweetener.

This study provides different scenarios for exposure assessment of diabetics, including children, who are a particularly exposed population for artificial sweeteners. The calculations are based on the measurement of intake of sweetened foods and on several assumptions concerning the type and the concentration of the substances in the food commodities. It shows that the intake of aspartame, acesulfame-K, saccharin and cyclamate, can be close to or exceed their respective ADI for the population of diabetics if they consume only one type of sweetener.

Appendix 8 – JECFA Evaluations

Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives

GELLAN GUM	
INS:	418
Functional class:	THICKENING AGENT; STABILIZER; GELLING AGENT
Latest evaluation:	1990
ADI:	NOT SPECIFIED
Comments:	The potential laxative effect at high intakes should be taken into account when used as a food additive
Report:	TRS 806-JECFA 37/25
Specifications:	COMPENDIUM ADDENDUM 5/FNP 52 Add.5/49 (1997)
Tox monograph:	FAS 28-JECFA 37/289
Previous status:	1996, COMPENDIUM ADDENDUM 4/FNP 52 Add.4/55. R 1990, COMPENDIUM/669. N

12 Nov 01

See Also:
Toxicological Abbreviations
Gellan gum (WHO Food Additives Series 28)

GELLAN GUM

First draft prepared by Dr F.S.D. Lin,
Division of Toxicological Review and Evaluation,
Center for Food Safety and Applied Nutrition,
US Food and Drug Administration.

1. EXPLANATION

Gellan gum has not been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives.

Gellan gum is a high molecular weight polysaccharide gum produced as a fermentation product by a pure culture of *Pseudomonas elodea*. The production organism is an aerobic, gram-negative bacterium, which has been very well characterized and demonstrated to be non-pathogenic. Chemical structure of the polysaccharide has been determined. It has a tetrasaccharide repeat unit consisting of two glucose (Glc) residues, one glucuronic acid (GlcA) residue, and one rhamnose (Rha) residue:

-> 3)-ßD-G1c-(1->4)-ß-D-G1cA-(1->4)-ß-D-G1c-(1->4)-L-Rha-(1->

The glucuronic acid is neutralized by the presence of potassium, calcium, and magnesium ions. The relative concentrations of these ions will control the physical properties of the gum material such as gel strength, melting point and setting point. The molecular weight of the polysaccaride is greater than 70 000 with 95% above 500 000. The gum has been proposed for use as a stabilizer and thickener in foods.

There are three basic forms of gellan gum product which have been characterized and are distinguished by their 1) polysaccharide content, 2) the percent of o-acetyl substitution on the polysaccharide and 3) the protein content (including nucleic residues and other organic nitrogen sources).

It is noted that a relatively pure (>95% polysaccharide) non-acetylated gum product was used in the acute toxicity studies, the 13-week oral rat study and the genotoxicity studies. For the remaining toxicological studies, a blend of 5 products with lower purities and varied degrees of acetylation was used. This blend, which contained 58.5% polysaccharide, was intended to represent the complete range of possible compositions of the gum product and was considered as the "worst case" in terms of purity.

2. BIOLOGICAL DATA

2.1 Biochemical aspects

2.1.1 Absorption, distribution and excretion

The absorption, distribution and excretion of gellan gum was studied using a dually radiolabelled (^{3}H and ^{14}C) preparation. The use of dual labelling allowed simultaneous quantitation of both polysaccharide and "protein" fractions of gellan gum.

The gellan gum was prepared in separate fermentations using ^{3}H-glucose and ^{14}C-glucose as carbon source. The ^{3}H product was subjected to multi-stage purification process to give a relatively pure ^{3}H-polysaccharide. This was added to the media of the ^{14}C fermentation, which was then precipitated in isopropanol to yield a product with the polysaccharide fraction labelled with both isotopes and the non-polysaccharide (or "protein") fraction labelled only

with $^{14}CO_2$.

One male and one female Sprague-Dawley rat were gavaged with single doses of the $^{3}H/^{14}C$-gellan gum (ca. 960 mg/kg; ca. 4 µCi). Expired air was collected for 24 hours after dosing. Less than 0.55% of the given radioactivity was detected as ^{14}C.

Four male and 3 female Sprague-Dawley rats were dosed with single gavage dose of $^{3}H/^{14}C$-gellan gum (ca. 870 mg/kg; 2.9 - 4.1 µCi ^{14}C; 0.7 - 0.9 µCi ^{3}H). Urine and faeces were collected for 7 days, at which time the animals were sacrificed and their tissues analyzed for residual radioactivity. Females excreted 86.8% and 1.9% of the given ^{14}C in their faeces and urine, respectively. Males excreted 86% of the dosed ^{14}C in the faeces and 3.3% in the urine. Females excreted 4.1% of the dosed ^{3}H in their urine and 100.1% in their faeces, while males excreted 3.6% of the total ^{3}H in their urine and 99.6% in their faeces. In all animals, the activities of ^{3}H in tissues (blood, brain, liver, kidney, lung, muscle, skin, heart and carcass) were too low to be quantitated accurately. Tissue and carcass radioactivity for ^{14}C averaged 3.8% of dose for male rats and 3.0% of dose for female rats.

A male and four female Sprague-Dawley rats were gavaged with about 1 g/kg of radiolabelled gellan gum and blood samples collected from the tail vein at different time intervals over a 7-day period. Data were reported as ^{14}C dmp/ml blood (^{3}H dmp/ml blood was not reported). The peak level of radioactivity, which amounted to about 0.4% of the administered radioactivity, occurred about 5 hours after dosing (Selim, 1984a).

2.2 Toxicological studies

2.2.1 Acute toxicity

Species	Sex	Route	LD_{50} (mg/kg b.w.)	Reference
Rat	M&F	oral	>5000	Wolfe & Bristol, 1980
	M&F	inhalation	>5.09 mg/l	Coate et al., 1980

Gellam gum is practically non-toxic to rats when administered as a single large dose (5 g/kg b.w.) in diet or via gavage.

2.2.2 Short-term studies

2.2.2.1 Rat

Male and female Sprague-Dawley rats (20/sex/group) were fed dietary levels of GG ranging from 0-6% for 13 weeks. Although the animals on this study experienced symptoms of a sialodacryoadenitis viral infection, all animals survived treatment and there were no adverse effects associated with the feeding of GG (Batham *et al.*, 1983).

2.2.2.2 Monkey

Prepubertal rhesus monkeys (2/sex/group) were dosed by oral gavage with GG at levels of 0, 1, 2 or 3 g/kg/day for 28 days. There were no overt signs of toxicity reported (Selim, 1984b).

2.2.3 Long-term/carcinogenicity studies

2.2.3.1 Mouse

Groups of 50 male and 50 female Swiss Crl mice were fed GG admixed in the diet at 0, 1,0, 2.0 and 3.0% for 96 and 98 weeks for males and females, respectively. All animals were examined twice daily for mortality and morbidity. Physical examination for the presence of palpable masses was initiated on a weekly basis starting in week 26. Bodyweights and food consumption were measured for 7-day periods on a weekly basis for the first 26 weeks of treatment and every 2 weeks thereafter. At necropsy, a complete gross pathological examination was performed on the following organs and tissues of the animals from the control and 3.0% groups: adrenals,

aorta (thoracic), bone (sternum), brain (fore-, mid- and hind-), caecum, colon, duodenum, epididymis, oesophagus, eyes, Harderian gland, heart, ileum, jejunum, kidneys, lacrimal gland, liver (sample of 2 lobes), lung (sample of 2 lobes), lymph nodes (mandibular and mesenteric), mammary gland (inguinal), nasal turbinates, optic nerves, ovaries, pancreas, pituitary, prostate, rectum, salivary gland, sciatic nerve, seminal vesicles, skeletal muscle, skin, spinal cord, spleen, stomach, testes, thymus, thyroid lobes (and parathyroids,), tongue, trachea, urinary bladder, uterus, vagina, Zymbal's gland and all gross lesions. Only the liver, kidneys, ovaries, testes, adrenals, pituitary, lungs and heart were examined for animals of the 1.0 and 2.0% groups. There were no effects attributable to the feeding of GG on either body weight gain or food consumption. There were no neoplastic or non-neoplastic changes which were associated with the feeding of GG (Batham *et al.,* 1987).

2.2.3.2 Rat

Groups of 50 F_1 generation Sprague-Dawley rats of each sex were exposed to GG *in utero* and continued on GG diets for approximately 104 weeks. The dietary levels of GG were 0, 2.5, 3.8 and 5.0%. The rats were observed daily for the first 4 weeks of treatment and weekly thereafter for clinical signs of toxicity. Individual bodyweights and food consumption were measured on a weekly basis for the first 26 weeks of treatment and every two weeks thereafter. Funduscopic and biomicroscopic examinations were conducted on the control and 5% groups during weeks 1, 13, 26, 52, 78 and 103. Clinical chemistry and haematological samples were collected at weeks 13, 25, 39 and 51. After 104 weeks, ophthalmoscopic examinations, haematology, clinical chemistries and organ weight data revealed no changes which could be attributed to the feeding of GG. Survival of male treated rats was poor when compared to controls whereas female treated rats exhibited better survival than their concurrent controls. Male rats, fed GG at the 3.8 and 5.0% dietary levels, exhibited lower bodyweights after 76 weeks. The initial bodyweights were 5.2 and 3.4% lower than the control values for the 3.8% and 5.0% dietary levels, respectively. The authors concluded that in spite of the initial bodyweight deficit, the growth pattern for these treated groups was identical to that of the control. In addition, this effect was not seen in either the females or any other species tested. There is no basis to suggest that the lower bodyweights, observed in the male rats, are indicative of toxicity.

Organs and tissues as those listed in the above mouse study were examined for histopathological changes at study termination. There were no neoplastic or non-neoplastic changes that could be associated with the feeding of GG. The authors concluded that under

the conditions of this bioassay, GG was non-carcinogenic to Sprague-Dawley rats (Batham *et al.,* 1985).

2.2.3.3 Dog

Diets containing 0, 3, 4.5 and 6% GG were fed to groups of 5 beagle dogs per sex for a period of 52 weeks. The dogs were observed daily for clinical signs of toxicity and were measured for bodyweights and food consumption. Ophthalmoscopic examinations were performed during pretreatment and after 12 , 24, 39 and 51 weeks.

Haematology and clinical chemistry were measured during pretreatment and after 6, 13, 25, 39 and 50 weeks. After 52 weeks all animals were killed and grossly examined. The following organs and tissues were removed, processed and examined for histopathological lesions: adrenals, aorta, bone and marrow, brain, caecum, colon, duodenum, epididymis, oesophagus, eyes, gall bladder, heart, ileum, jejunum, kidneys, liver, lungs, lymph nodes, mammary gland, optic nerves, ovaries and ovariducts, pancreas, pituitary, prostate, rectum, salivary gland, sciatic nerve, skeletal muscle, skin, spinal cord, spleen, stomach, testes, thymus, thyroid and parathyroid, tongue, trachea, urinary bladder and uterus.

All animals survived treatment. Food intake was higher in the treated groups compared to the controls. There were no adverse effects associated with the feeding of GG to beagle dogs for a period of one year (Batham *et al.,* 1986).

2.2.4 Reproduction studies

Groups of 26 male and 26 female CD (Sprague-Dawley) rats were administered GG in their diets at doses of 0, 2.5, 3.8 or 5.0%. Males were treated for 70 days prior to mating and for three weeks after mating. Females were treated for 14 days prior to mating and throughout mating, gestation and lactation. Selection was made for the pups (F_1) of this mating and they were allowed to mature and were mated to form the F_2 generation.

There was no treatment-related effect on mating or fertility index, conception rate, length of gestation, length of parturition, number of live pups, number of dead pups, post-implantation loss index, survival index on day 4, 7, 14 or 21 or lactation index for any of the generations (Robinson *et al.,* 1985a).

2.2.5 Teratology studies

GG was fed to groups of 25 pregnant female Sprague-Dawley rats at dietary levels of 0, 2.5, 3,8 or 5.0% during days 6-15 of gestation. GG had no fetotoxic or teratogenic effects on rats when ingested in the diet at levels up to 5.0% (*Robinson et al.,* 1985b).

2.2.6 Genotoxicity studies

Results of genotoxicity assays on gellan gum

Test system	Test object	Concentration of gellan gum	Results	Reference
Ames test (1)	S. typhimurium TA98, TA100 TA1535 TA1537 TA1538	10, 30, 100, 300 and 1000 œg/plate	Negative	Robertson et al., 1985a
DNA repair test	Rat hepatocyte	3, 5, 10 & 20 mg/ml	Negative	Robertson et al., 1985a,b
V-79/HGPRT	Chinese hamster lung fibroblasts	3, 5, 10 & 20 mg/ml	Negative	Robertson et al., 1985c

(1) Both with and without rat liver S-9 fraction.

2.3 Observations in humans

Five female volunteers and five male volunteers, all normal in health and free from gastrointestinal disease, participated in the

clinical study. Following a 7-day control period, each of the volunteers consumed the test substance at a daily dose level of 175 mg/kg for 7 days, then the dose was increased to 200 mg/kg/day for a further 16 days. Plasma biochemistry parameters, haematological indices, urinalysis parameters, blood glucose and plasma insulin concentrations and breath hydrogen concentrations were monitored on the first day of the control period and repeated on the last day of the treatment period.

The authors concluded that the ingestion of gellan gum at the given dose levels caused no adverse dietary nor physiological effects in any of the volunteers on the study. There were no allergenic nor other subjective untoward manifestations, reported by or observed in any of the human subjects. The ingestion of gellan gum, at the stated daily intake levels, did not cause any adverse toxicological effects. However, gellan gum does act as a faecal bulking agent, increases faecal bile acid, decreases faecal neutral sterols, and decreases serum cholesterol (Eastwood *et al.,* 1987).

3. COMMENTS

Gellan gum was shown to be poorly absorbed and did not cause any deaths in rats which received a single large dose (5 g per kg of body weight) in the diet or by gavage. Short-term (90-day) exposure of rats to gellan gum at levels up to 60 g/kg in the diet did not cause any adverse effects. In a 28-day study in prepubertal monkeys, no overt signs of toxicity were observed at the highest dose level of 3 g per kg of body weight per day. In reproduction and teratogenicity studies in rats in which gellan gum was given at dose levels up to 50 g/kg in the diet, there was no evidence of interference with the reproductive process, and no embryotoxic or developmental effects were observed. Gellan gum was also shown to be non-genotoxic in a battery of standard short-term tests.

In a study in dogs, which were treated for 1 year at dose levels up to 60 g/kg in the diet, there were no adverse effects that could be attributed to chronic exposure to gellan gum. In long-term carcinogenicity studies, gellan gum did not induce any adverse effects in mice or rats at the highest dose levels of 30 g/kg and 50 g/kg in the diet, respectively.

Results from a limited study on tolerance to gellan gum in humans indicated that oral doses of up to 200 mg per kg of body weight administered over a 23-day period did not elicit any adverse reactions, although faecal bulking effects were observed in most subjects.

4. EVALUATION

The Committee allocated an ADI "not specified" to gellan gum, and pointed out that its potential laxative effect at high intakes should be taken into account when it is used as a food additive (Annex I, ref. 88, Section 2.2.3).

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See Also:
Toxicological Abbreviations
GELLAN GUM (JECFA Evaluation)

Appendix 9 – Standards for Fermented Milk

FAO/CODEX Standards for Fermented Milk

FAO/WHO Additives listing for Fermented Milk

CODEX STANDARD FOR FERMENTED MILKS

CODEX STAN 243-2003

1. SCOPE

This standard applies to fermented milks, that is Fermented Milk including, Heat Treated Fermented Milks, Concentrated Fermented Milks and composite milk products based on these products, for direct consumption or further processing in conformity with the definitions in Section 2 of this Standard.

2. DESCRIPTION

2.1 ***Fermented Milk*** is a milk product obtained by fermentation of milk, which milk may have been manufactured from products obtained from milk with or without compositional modification as limited by the provision in Section 3.3, by the action of suitable microorganisms and resulting in reduction of pH with or without coagulation (iso-electric precipitation). These starter microorganisms shall be viable, active and abundant in the product to the date of minimum durability. If the product is heat-treated after fermentation the requirement for viable microorganisms does not apply.

Certain Fermented Milks are characterized by specific starter culture(s) used for fermentation as follows:

Yoghurt:	Symbiotic cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*.
Alternate Culture Yoghurt:	Cultures of *Streptococcus thermophilus* and any *Lactobacillus species*.
Acidophilus Milk:	*Lactobacillus acidophilus*.
Kefir:	Starter culture prepared from kefir grains, *Lactobacillus kefiri*, species of the genera *Leuconostoc*, *Lactococcus* and *Acetobacter* growing in a strong specific relationship. Kefir grains constitute both lactose fermenting yeasts (*Kluyveromyces marxianus*) and non-lactose-fermenting yeasts (*Saccharomyces unisporus*, *Saccharomyces cerevisiae* and *Saccharomyces exiguus*).
Kumys:	*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Kluyveromyces marxianus*.

Other microorganisms than those constituting the specific starter culture(s) specified above may be added.

2.2 ***Concentrated Fermented Milk*** is a Fermented Milk the protein of which has been increased prior to or after fermentation to minimum 5.6%. Concentrated Fermented Milks includes traditional products such as Stragisto (strained yoghurt), Labneh, Ymer and Ylette.

2.3 ***Flavoured Fermented Milks*** are composite milk products, as defined in Section 2.3 of the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) which contain a maximum of 50% (m/m) of non-dairy ingredients (such as nutritive and non nutritive sweeteners, fruits and vegetables as well as juices, purees, pulps, preparations and

Adopted in 2003. Revision 2008, 2010.

preserves derived therefrom, cereals, honey, chocolate, nuts, coffee, spices and other harmless natural flavouring foods) and/or flavours. The non-dairy ingredients can be mixed in prior to/or after fermentation.

2.4 ***Drinks based on Fermented Milk*** are composite milk products, as defined in Section 2.3 of the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), obtained by mixing Fermented Milk as described in Section 2.1 with potable water with or without the addition of other ingredients such as whey, other non-dairy ingredients, and flavourings. Drinks Based on Fermented Milk contain a minimum of 40% (m/m) fermented milk.

Other microorganisms than those constituting the specific starter cultures may be added.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Raw materials

- Milk and/or products obtained from milk.
- Potable water for the use in reconstitution or recombination.

3.2 Permitted ingredients

- Starter cultures of harmless microorganisms including those specified in Section 2;
- Other suitable and harmless microorganisms (*in products covered by Section 2.4*);
- Sodium chloride;
- Non-dairy ingredients as listed in Section 2.3 (Flavoured Fermented Milks);
- Potable water (*in products covered by Section 2.4*);
- Milk and milk products (*in products covered by Section 2.4*);
- Gelatine and starch in:
  - fermented milks heat-treated after fermentation;
  - flavoured fermented milk;
  - drinks based on fermented milk; and
  - plain fermented milks if permitted by national legislation in the country of sale to the final consumer;

  provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers/ thickeners listed in section 4. These substances may be added either before or after adding the non-dairy ingredients.

3.3 Composition

	Fermented Milk	Yoghurt, Alternate Culture Yoghurt and Acidophilus milk	Kefir	Kumys
Milk protein[(a)] (% m/m)	min. 2.7%	min. 2.7%	min. 2.7%	
Milk fat (% m/m)	less than 10%	less than 15%	less than 10%	less than 10%
Titrable acidity, expressed as % lactic acid (% m/m)	min. 0.3%	min. 0.6%	min. 0.6%	min. 0.7%
Ethanol (% vol./w)				min. 0.5%

	Fermented Milk	Yoghurt, Alternate Culture Yoghurt and Acidophilus milk	Kefir	Kumys
Sum of microorganisms constituting the starter culture defined in section 2.1 (cfu/g, in total)	min. 10^7	min. 10^7	min. 10^7	min. 10^7
Labelled microorganisms[(b)] (cfu/g, total)	min. 10^6	min. 10^6		
Yeasts (cfu/g)			min. 10^4	min. 10^4

(a) Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined.
(b) Applies where a content claim is made in the labelling that refers to the presence of a specific microorganism (other than those specified in section 2.1 for the product concerned) that has been added as a supplement to the specific starter culture.

In Flavoured Fermented Milks and Drinks based on Fermented Milk the above criteria apply to the fermented milk part. The microbiological criteria (based on the proportion of fermented milk product) are valid up to the date of minimum durability. This requirement does not apply to products heat-treated after fermentation.

Compliance with the microbiological criteria specified above is to be verified through analytical testing of the product through to "the date of minimum durability" after the product has been stored under the storage conditions specified in the labeling.

3.4 Essential manufacturing characteristics

Whey removal after fermentation is not permitted in the manufacture of fermented milks, except for Concentrated Fermented Milk (Section 2.2).

4. FOOD ADDITIVES

Only those additives classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those individual additives listed may be used and only within the limits specified.

In accordance with Section 4.1 of the Preamble to the *General Standard for Food Additives* (CODEX STAN 192-1995), additional additives may be present in the flavoured fermented milks and drinks based on fermented milk as a result of carry-over from non-dairy ingredients.

	Fermented Milks and Drinks based on Fermented Milk		Fermented Milks Heat Treated After Fermentation and Drinks based on Fermented Milk Heat Treated After Fermentation	
Additive class	Plain	Flavoured	Plain	Flavoured
Acidity regulators	–	X	X	X
Carbonating agents	X[(b)]	X[(b)]	X[(b)]	X[(b)]
Colours	–	X	–	X

Additive class	Fermented Milks and Drinks based on Fermented Milk		Fermented Milks Heat Treated After Fermentation and Drinks based on Fermented Milk Heat Treated After Fermentation	
	Plain	Flavoured	Plain	Flavoured
Emulsifiers	–	X	–	X
Flavour enhancers	–	X	–	X
Packaging gases	–	X	X	X
Preservatives	–	–	–	X
Stabilizers	X[(a)]	X	X	X
Sweeteners	–	X	–	X
Thickeners	X[(a)]	X	X	X

(a) Use is restricted to reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer.
(b) Use of carbonating agents is technologically justified in Drinks based on Fermented Milk only.
X The use of additives belonging to the class is technologically justified. In the case of flavoured products the additives are technologically justified in the dairy portion.
– The use of additives belonging to the class is not technologically justified

Acidity regulators, colours, emulsifiers, packaging gases and preservatives listed in Table 3 of the *General Standard for Food Additives* (CODEX STAN 192-1995) are acceptable for use in fermented milk products categories as specified in the table above.

INS No.	Name of additive	Maximum level
Acidity regulators		
334	Tartaric acid L(+)-	2 000 mg/kg as tartaric acid
335(i)	Monosodium tartrate	
335(ii)	Sodium L(+)-tartrate	
336(i)	Monopotassium tartrate	
336(ii)	Dipotassium tartrate	
337	Potassium sodium L(+)-tartrate	
355	Adipic acid	1 500 mg/kg as adipic acid
356	Sodium adipate	
357	Potassium adipate	
359	Ammonium adipate	
Carbonating agents		
290	Carbon dioxide	GMP
Colours		
100(i)	Curcumin	100 mg/kg
101(i)	Riboflavin, synthetic	300 mg/kg
101(ii)	Riboflavin 5'-phosphate, sodium	
102	Tartrazine	300 mg/kg
104	Quinoline yellow	150 mg/kg
110	Sunset yellow FCF	300 mg/kg
120	Carmines	150 mg/kg

INS No.	Name of additive	Maximum level
122	Azorubine (Carmoisine)	150 mg/kg
124	Ponceau 4R (Cochineal red A)	150 mg/kg
129	Allura red AC	300 mg/kg
132	Indigotine	100 mg/kg
133	Brilliant blue FCF	150 mg/kg
141(i)	Chlorophylls, copper complexes	500 mg/kg
141(ii)	Chlorophyllins, copper complexes, sodium and potassium salts	
143	Fast green FCF	100 mg/kg
150b	Caramel II – sulfite caramel	150 mg/kg
150c	Caramel III – ammonia caramel	2 000 mg/kg
150d	Caramel IV – sulfite ammonia caramel	2 000 mg/kg
151	Brilliant black (Black PN)	150 mg/kg
155	Brown HT	150 mg/kg
160a(i)	Carotene, *beta*-, synthetic	100 mg/kg
160e	Carotenal, *beta*-apo-8'-	
160f	Carotenoic acid, methyl or ethyl ester, *beta*-apo-8'-	
160a(iii)	Carotenes, *beta*-, *Blakeslea trispora*	
160a(ii)	Carotenes, *beta*-, vegetable	600 mg/kg
160b(i)	Annatto extracts, bixin-based	20 mg/kg as bixin
160b(ii)	Annatto extracts, norbixin-based	20 mg/kg as norbixin
160d	Lycopenes	30 mg/kg as pure lycopene
161b(i)	Lutein from *Tagetes erecta*	150 mg/kg
161h(i)	Zeaxanthin, synthetic	150 mg/kg
163(ii)	Grape skin extract	100 mg/kg
172(i)	Iron oxide, black	100 mg/kg
172(ii)	Iron oxide, red	
172(iii)	Iron oxide, yellow	
Emulsifiers		
432	Polyoxyethylene (20) sorbitan monolaurate	3 000 mg/kg
433	Polyoxyethylene (20) sorbitan monooleate	
434	Polyoxyethylene (20) sorbitan monopalmitate	
435	Polyoxyethylene (20) sorbitan monostearate	
436	Polyoxyethylene (20) sorbitan tristearate	
472e	Diacetyltartaric and fatty acid esters of glycerol	10 000 mg/kg
473	Sucrose esters of fatty acids	5 000 mg/kg
474	Sucroglycerides	5 000 mg/kg
475	Polyglycerol esters of fatty acids	2 000 mg/kg
477	Propylene glycol esters of fatty acids	5 000 mg/kg
481(i)	Sodium stearoyl lactylate	10 000 mg/kg
482(i)	Calcium stearoyl lactylate	10 000 mg/kg

INS No.	Name of additive	Maximum level
491	Sorbitan monostearate	5 000 mg/kg
492	Sorbitan tristearate	
493	Sorbitan monolaurate	
494	Sorbitan monooleate	
495	Sorbitan monopalmitate	
900a	Polydimethylsiloxane	50 mg/kg
Flavour enhancers		
580	Magnesium gluconate	GMP
620	Glutamic acid, (L+)-	GMP
621	Monosodium L-glutamate	GMP
622	Monopotassium L-glutamate	GMP
623	Calcium di-L-glutamate	GMP
624	Monoammonium L-glutamate	GMP
625	Magnesium di-L-glutamate	GMP
626	Guanylic acid, 5′-	GMP
627	Disodium 5′-guanylate-	GMP
628	Dipotassium 5′-guanylate-	GMP
629	Calcium 5′-guanylate	GMP
630	Inosinic acid, 5′-	GMP
631	Disodium 5′-inosinate	GMP
632	Dipotassium 5′-inosinate	GMP
633	Calcium 5′-inosinate	GMP
634	Calcium 5′-ribonucleotides-	GMP
635	Disodium 5′-ribonucleotides-	GMP
636	Maltol	GMP
637	Ethyl maltol	GMP
Preservatives		
200	Sorbic acid	1 000 mg/kg as sorbic acid
201	Sodium sorbate	
202	Potassium sorbate	
203	Calcium sorbate	
210	Benzoic acid	300 mg/kg as benzoic acid
211	Sodium benzoate	
212	Potassium benzoate	
213	Calcium benzoate	
234	Nisin	500 mg/kg
Stabilizers and Thickeners		
170(i)	Calcium carbonate	GMP
331(iii)	Trisodium citrate	GMP

INS No.	Name of additive	Maximum level
338	Phosphoric acid	1 000 mg/kg, singly or in combination, as phosphorus
339(i)	Sodium dihydrogen phosphate	
339(ii)	Disodium hydrogen phosphate	
339(iii)	Trisodium phosphate	
340(i)	Potassium dihydrogen phosphate	
340(ii)	Dipotassium hydrogen phosphate	
340(iii)	Tripotassium phosphate	
341(i)	Monocalcium dihydrogen phosphate	
341(ii)	Calcium hydrogen phosphate	
341(iii)	Tricalcium orthophosphate	
342(i)	Ammonium dihydrogen phosphate	
342(ii)	Diammonium hydrogen phosphate	
343(i)	Monomagnesium phosphate	
343(ii)	Magnesium hydrogen phosphate	
343(iii)	Trimagnesium phosphate	
450(i)	Disodium diphosphate	
450(ii)	Trisodium diphosphate	
450(iii)	Tetrasodium diphosphate	
450(v)	Tetrapotassium diphosphate	
450(vi)	Dicalcium diphosphate	
450(vii)	Calcium dihydrogen diphosphate	
451(i)	Pentasodium triphosphate	
451(ii)	Pentapotassium triphosphate	
452(i)	Sodium polyphosphate	
452(ii)	Potassium polyphosphate	
452(iii)	Sodium calcium polyphosphate	
452(iv)	Calcium polyphosphate	
452(v)	Ammonium polyphosphate	
542	Bone phosphate	
400	Alginic acid	GMP
401	Sodium alginate	GMP
402	Potassium alginate	GMP
403	Ammonium alginate	GMP
404	Calcium alginate	GMP
405	Propylene glycol alginate	GMP
406	Agar	GMP
407	Carrageenan	GMP
407a	Processed euchema seaweed (PES)	GMP
410	Carob bean gum	GMP
412	Guar gum	GMP
413	Tragacanth gum	GMP
414	Gum Arabic (Acacia gum)	GMP
415	Xanthan gum	GMP
416	Karaya gum	GMP
417	Tara gum	GMP
418	Gellan gum	GMP

INS No.	Name of additive	Maximum level
425	Konjac flour	GMP
440	Pectins	GMP
459	Cyclodextrin, *-beta*	5 mg/kg
460(i)	Microcrystalline cellulose (Cellulose gel)	GMP
460(ii)	Powdered cellulose	GMP
461	Methyl cellulose	GMP
463	Hydroxypropyl cellulose	GMP
464	Hydroxypropyl methyl cellulose	GMP
465	Methyl ethyl cellulose	GMP
466	Sodium carboxymethyl cellulose (Cellulose gum)	GMP
467	Ethyl hydroxyethyl cellulose	GMP
468	Cross-linked sodium carboxymethyl cellulose (Cross-linked cellulose gum)	GMP
469	Sodium carboxymethyl cellulose, enzymatically hydrolyzed (Cellulose gum, enzymatically hydrolyzed)	GMP
470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	GMP
470(ii)	Salts of oleic acid with calcium, potassium and sodium	GMP
471	Mono- and di- glycerides of fatty acids	GMP
472a	Acetic and fatty acid esters of glycerol	GMP
472b	Lactic and fatty acid esters of glycerol	GMP
472c	Citric and fatty acid esters of glycerol	GMP
508	Potassium chloride	GMP
509	Calcium chloride	GMP
511	Magnesium chloride	GMP
1200	Polydextrose	GMP
1400	Dextrins, roasted starch	GMP
1401	Acid treated starch	GMP
1402	Alkaline treated starch	GMP
1403	Bleached starch	GMP
1404	Oxidized starch	GMP
1405	Starches, enzyme treated	GMP
1410	Mono starch phosphate	GMP
1412	Distarch phosphate	GMP
1413	Phosphated distarch phosphate	GMP
1414	Acetylated distarch phosphate	GMP
1420	Starch acetate	GMP
1422	Acetylated distarch adipate	GMP
1440	Hydroxypropyl starch	GMP
1442	Hydroxypropyl distarch phosphate	GMP
1450	Starch sodium octenyl succinate	GMP
1451	Acetylated oxidized starch	GMP
Sweeteners[a]		
420	Sorbitol	GMP
421	Mannitol	GMP

INS No.	Name of additive	Maximum level
950	Acesulfame potassium	350 mg/kg
951	Aspartame	1 000 mg/kg
952	Cyclamates	250 mg/kg
953	Isomalt (Hydrogenated isomaltulose)	GMP
954	Saccharin	100 mg/kg
955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
956	Alitame	100 mg/kg
961	Neotame	100 mg/kg
962	Aspartame-acesulfame salt	350 mg/kg on an acesulfame potassium equivalent basis
964	Polyglycitol syrup	GMP
965	Maltitols	GMP
966	Lactitol	GMP
967	Xylitol	GMP
968	Erythritol	GMP

(a) The use of sweeteners is limited to milk-and milk derivative-based products energy reduced or with no added sugar.

5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels for contaminants that are specified for the product in the *General Standard for Contaminants and Toxins in Foods and Feeds* (CODEX STAN 193-1995).

The milk used in the manufacture of the products covered by this Standard shall comply with the Maximum Levels for contaminants and toxins specified for milk by the *General Standard for Contaminants and Toxins in Foods and Feeds* (CODEX STAN 193-1995) and with the maximum residue limits for veterinary drug residues and pesticides established for milk by the CAC.

6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice. The products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the following specific provisions apply:

7.1 Name of the food

7.1.1 The name of the products covered by sections 2.1, 2.2 and 2.3, shall be fermented milk or concentrated fermented milk as appropriate.

However, these names may be replaced by the designations Yoghurt, Acidophilus Milk, Kefir, Kumys, Stragisto, Labneh, Ymer and Ylette, provided that the product complies with the specific provisions of this Standard. Yoghurt may be spelled as appropriate in the country of retail sale.

"Alternate culture yoghurt", as defined in Section 2, shall be named through the use of an appropriate qualifier in conjunction with the word "yoghurt". The chosen qualifier shall describe, in a way that is accurate and not misleading to the consumer, the nature of the change imparted to the yoghurt through the selection of the specific *Lactobacilli* in the culture for manufacturing the product. Such change may include a marked difference in the fermentation organisms, metabolites and/or sensory properties of the product when compared to the product designated solely as "yoghurt". Examples of qualifiers which describe differences in sensory properties include terms such as "mild" and "tangy". The term "alternate culture yoghurt" shall not apply as a designation.

The above specific terms may be used in connection with the term "frozen" provided (i) that the product submitted to freezing complies with the requirements in this Standard, (ii) that the specific starter cultures can be reactivated in reasonable numbers by thawing, and (iii) that the frozen product is named as such and is sold for direct consumption, only.

Other fermented milks and concentrated fermented milks may be designated with other variety names as specified in the national legislation of the country in which the product is sold, or names existing by common usage, provided that such designations do not create an erroneous impression in the country of retail sale regarding the character and identity of the food.

7.1.2 Products obtained from fermented milk(s) heat treated after fermentation shall be named "Heat Treated Fermented Milk". If the consumer would be misled by this name, the products shall be named as permitted by national legislation in the country of retail sale. In countries where no such legislation exists, or no other names are in common usage, the product shall be named "Heat Treated Fermented Milk".

7.1.3 The designation of Flavoured Fermented Milks shall include the name of the principal flavouring substance(s) or flavour(s) added.

7.1.4 The name of the products defined in Section 2.4 shall be drinks based on fermented milk or may be designated with other variety names as allowed in the national legislation of the country in which the product is sold. In particular, water added as an ingredient to fermented milk shall be declared in the list of ingredients[1] and the percentage of fermented milk used (m/m) shall clearly appear on the label. When flavoured, the designation shall include the name of the principal flavouring substance(s) or flavour(s) added.

[1] As prescribed in section 4.2.1.5 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985)

7.1.5 Fermented milks to which only nutritive carbohydrate sweeteners have been added, may be labeled as "sweetened _____", the blank being replaced by the term "Fermented Milk" or another designation as specified in Section 7.1.1 and 7.1.4. If non-nutritive sweeteners are added in partial or total substitution to sugar, the mention "sweetened with _____" or "sugared and sweetened with _____" should appear close to the name of the product, the blank being filled in with the name of the artificial sweeteners.

7.1.6 The names covered by this Standard may be used in the designation, on the label, in commercial documents and advertising of other foods, provided that it is used as an ingredient and that the characteristics of the ingredient are maintained to a relevant degree in order not to mislead the consumer.

7.2 Declaration of fat content

If the consumer would be mislead by the omission, the milk fat content shall be declared in a manner acceptable in the country of sale to the final consumer, either as (i) a percentage of mass or volume, or (ii) in grams per serving as qualified in the label, provided that the number of servings is stated.

7.3 Labelling of non-retail containers

Information required in Section 7 of this Standard and Sections 4.1 to 4.8 of the *General Standard for the Labelling of Pre-packaged Foods,* and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer, shall appear on the container. However, lot identification and the name and address of the manufacturer or packager may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents.

8. METHODS OF SAMPLING AND ANALYSIS

See CODEX STAN 234-1999.

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5

CX/MMP 04/6/10
January 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON MILK AND MILK PRODUCTS

Sixth Session

Auckland, New Zealand, 26 – 30 April 2004

SPECIFIC FOOD ADDITIVES LISTING FOR THE CODEX STANDARD FOR FERMENTED MILK PRODUCTS

Governments and international organizations wishing to submit comments on the "Specific Food Additives Listing for the Codex Standard for Fermented Milk Products" are invited to do so **no later than 15 March 2004** to: Codex Committee on Milk and Milk Products, New Zealand Food Safety Authority, 68 - 86 Jervois Quay, P.O. Box 2835, Wellington, New Zealand (Facsimile: +64 4 463 2583 or E-mail: daniel.herd@nzfsa.govt.nz), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

This paper contains the **introduction** that outlines the instructions for the CCMMP Drafting Group on fermented milk additives (page 1), the **background** that outlines relevant developments from CCMMP 5 to CCFAC 35 (p 1), the **summary of comments** from Drafting Group members (p 6), the Drafting Group **recommendations** to CCMMP 6 (p 7) and a **table of additives in fermented milks** at Attachment 1, page 8.

INTRODUCTION

The Report of the Fifth Session of the Codex Committee on Milk and Milk Products (CCMMP 5), 8-12 April 2002 in Wellington, New Zealand included the following under agenda item 3b:

The Committee decided that a drafting group under the direction of Australia, assisted by Argentina, Denmark, France, Germany, New Zealand, Spain, Switzerland, the United States, the European Community and the International Dairy Federation (IDF), would review and finalize the specific food additive listings and their respective corresponding maximum use levels for circulation, additional comment and further consideration at the next Session of the CCMMP. In taking this decision, the Committee agreed that the drafting group should take account of the Committee's discussions under agenda item 2, the above discussions under the current agenda item and written comments submitted.

At CCMMP 5, the Committee's discussions under agenda item 2, relevant to food additives were reported in Alinorm 03/11 as follows:

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In regard to the Codex General Standard for Food Additives (GSFA), the Committee noted that decisions taken by the 34th meeting of the Codex Committee on Food Additives and Contaminants (CCFAC) related to the relationship between Codex commodity standards and the GSFA should be considered in the continued elaboration of standards for milk and milk products. These included general principles of the GSFA as well as the respective roles of the Codex Secretariat, Codex Commodity Committees and CCFAC. The Committee noted that the CCFAC discussion might lead to the revision of the Preamble to the GSFA and that in any case, the Committee should continue to follow the Codex Alimentarius Procedural Manual section concerning Relations Between Commodity Committees and General Committees.

BACKGROUND

There is debate within the CCFAC on the draft GSFA and the roles of the Commodity committees with respect to the regulation of food additives. Some delegations did not attend the 35th meeting of CCFAC in Tanzania in 2003, at which changes to the GSFA were discussed. Some delegations suggested that the Codex Alimentarius Procedural Manual is out of date and that CCFAC had decided in the past to update the section on food additives.

The 35th CCFAC "expressed general support for the generic table approach taken in the revised Codex Standard for Fermented Milks and the Draft Revised Codex Standard for Creams and Prepared Creams in addition to the specific listing of food additives and their respective use levels in the Standards."

"However, for the proper assessment of specific maximum levels, it was reaffirmed that information on the specific listing of food additives and their respective use levels was still required from Codex Commodity Committees in the endorsement process and in the context of the General Standard for Food additives and that a co-ordination process was necessary." (ALINORM 03/12A, paras. 32-33)

In summary the general table of food additives in the Codex Standard for Fermented Milk Products provides:

- Plain fermented milk products are not permitted to contain any food additives except for the functional classes of stabilizers and thickeners in reconstituted and recombined products.
- Plain fermented milks heat-treated after fermentation are permitted to contain stabilizers, thickeners, acids, acidity regulators and packaging gases.
- Only flavoured products are permitted to contain colours, sweeteners (as additives), emulsifiers and flavour enhancers.

The draft GSFA does not include flavourings or processing aids. It is not clear to the Drafting Group whether additives permitted by carry-over from non-dairy ingredients need to be included in the specific additive lists under the relevant categories. It is a much simpler task if they are not included. Furthermore, the current categories within the draft GSFA are very broad. The relevant categories for some of these products include dairy based drinks and dairy-based desserts (including non-fermented products), which can include non-dairy ingredients such as fruit and nuts.

The IDF has prepared a list of additives (Attachment 1), consistent with the draft GSFA as requested in terms of the instructions from CCFAC. This list however contains more additives, including some colours that were not considered at CCMMP 5. The Drafting Group regards the new IDF list as providing *prima facie* evidence of technological need. It is not clear to the Drafting Group considering the developments outlined above how the technological justification of the IDF list should be carried out, or whether this task will be undertaken by the CCFAC.

CCFAC & CAC ENDORSEMENT

CCFAC 35 in Tanzania in 2003 supported the table for general additive permissions in the CCMMP Standard for Fermented Milk Products at step 8, but noted the specific additives list with maximum limits was not included.

There was debate at CCFAC about some aspects of the draft GSFA, in particular on the maximum levels proposed within the draft GSFA. Some countries did not agree with the current position where any two countries providing a level is regarded as *prima facie* evidence of technological need. An alternative proposal for maximum levels that are widely permitted was discussed, but no agreement was reached. It should be noted that CCFAC had previously highlighted that the procedural manual needed an update on this matter.

At CCMMP 5, the following section for food additive permissions was included in the draft revised Standard for Fermented Milks. The Committee forwarded the draft revised Standard to the 25th session of Codex Alimentarius Commission for final adoption at step 8.

4 FOOD ADDITIVES

Only those additives classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those individual additives listed may be used and only within the limits specified.

In accordance with Section 4.1 of the Preamble to the General Standard for Food Additives (CODEX STAN 192 (Rev. 2-1999), additional additives may be present in the flavoured fermented milks as a result of carry-over from non-dairy ingredients.

	Fermented Milks		**Fermented Milks Heat-Treated After Fermentation**	
Additive class	**Plain**	**Flavoured**	**Plain**	**Flavoured**
Colours	-	X	-	X
Sweeteners	-	X	-	X
Emulsifiers	-	X	-	X
Flavour enhancers	-	X	-	X
Acids	-	X	X	X
Acidity regulators	-	X	X	X
Stabilizers	X[1]	X	X	X
Thickeners	X[1]	X	X	X
Preservatives	-	-	-	X
Packaging gases		X	X	X

X = The use of additives belonging to the class is technologically justified. In the case of flavoured products the additives are technologically justified in the dairy portion.

- = The use of additives belonging to the class is not technologically justified

[1] = Use is restricted to reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer.

COMMENTS FROM THE DRAFTING GROUP MEMBERS

Most delegations supported the suggestion to allow the IDF to elaborate the specific additives in fermented milks. Some members of the Drafting group suggested to concentrate on the contentious matter of colourings permitted in flavoured products and let IDF deal with other additives.

Switzerland

The scope of this drafting group is to review and finalize the specific food additive listings and their respective corresponding maximum use levels for circulation, additional comment and further consideration at the next CCMMP. It is important to remember, that the additives section of the standard on fermented milk is excluded from adoption at Step 8 at the next CAC.

CCMMP is, according to the Codex Procedural Manual (p 84), the relevant Commodity Committee that should prepare a section on food additives in the draft commodity standard. The section should include the names of those additives which are considered to be technologically necessary or which are widely permitted for use in the food within maximum levels where appropriate. CCFAC endorses the additives proposed by CCMMP on the basis of technological justification. Therefore Switzerland is of the opinion that the drafting group should have a close look at the technological necessity of the additives foreseen within the additive classes we agreed on at the last CCMMP.

IDF

The attached Excel spreadsheet is based on Section 4 "Table of additive classes" (as approved by the 5th CCMMP) in the Fermented Milk standard and all applicable sections (covering any kind of fermented milk or fermented milk product) found in the GSFA. The additive provisions of the "old" Fermented Milks standards (A-11(a) and A-11 (b)) have also been included, as appropriate. [It should be noted that the asterisk found in the spreadsheet on "YES" for Stabilizers and Thickeners used in Plain Fermented Milks is meant to recognize the footnote in the Standard which restricts their use to "reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer".]

Although the list is rather extensive, we elected to start from as broad a perspective as possible in order to provide for consistency with the GSFA (in its current form) and the desire to avoid potential problems for the standard as additive technology evolves in the future. We do recognize, however, that this approach is not foolproof since many of the additive listings in the GSFA are at various stages in the Codex step process. The current status in the step process is noted for each additive in the spreadsheet. We also recognize that the CCMMP may wish to sanction a more restrictive list, but we did not feel we were in a position to limit additives for use in fermented milks which had already been recognized by government delegations via their input into the GSFA. IDF will, however, as part of the Drafting Group continue to scrutinize the list to make certain that the additives included in this list are actually in use by the world's fermented milk manufacturers and that the usage levels are appropriate. For example, we are currently looking at the appropriateness of sulfites for these products.

Australia (comments to IDF)

There is considerable debate within the CCFAC working party looking at additive levels within the draft GSFA. The division in views about levels in flavoured fermented milks is basically the same division of views about levels in the GSFA. CCMMP cannot resolve this debate but it may help if the IDF levels are presented clearly as evidence of technological need.

The IDF approach to levels, which were largely consistent with the GSFA proposed levels is correct. The context of the draft GSFA levels was on *prima facie* evidence of "technological need". These levels may be reduced based on "technological justification" but there is no clear method for doing this for products in international trade. Most countries seem to want to impose their own national "technologically justified" levels into the Codex standards, which is not very practical. Some delegations are also using a "no additives" or "limited number" of additives approach, but again this is not practical as many countries (including Australia) do not even agree with the Codex definition of an additive and have nationally "justified" levels.

CCFAC, with advice from JECFA have to endorse the levels for additives proposed by CCMMP considering intakes from all sources. What CCFAC requires is evidence of technological need as IDF is supplying, but CCMMP is charged with providing "justified" levels, without clear instructions on how to do this.

The drafting group discussion should be limited to the colours, which were the most contentious issue. CCFAC endorsed the table of additives, which basically limits this discussion to flavoured fermented milks. A complication is that the draft GSFA does not yet include flavourings.

In summary the IDF proposed levels are what CCFAC asked for but some moderation may occur both at CCMMP 6 and at CCFAC 36.

Spain

GENERAL COMMENTS - Having several additives with a variety of functions may lead to error, as the user may think that each function has a MAXIMUM LEVEL assigned to it. They should be gathered in a comprehensive list with the different functions they may have in common. This should be labelled with its technological function on the food (in the context of those established by JECFA), which should be assigned by the manufacturer.

Colours:

123	Amaranth	ADI	0-0.50 mg/kg
127	Erythrosine	ADI	0-0.10 mg/kg
128	Red 2 G	ADI	0-0.10 mg/kg
151	Brilliant Black BN	ADI	0-1 mg/kg
155	Brown HT	ADI	0-1.50 mg/kg
160 b	Annatto	ADI	0-0.065 mg/kg
161 g	Canthaxanthin	ADI	0-0.05 mg/kg

They all have very low ADIs and should not be added to those food products that are consumed by the majority of the population, primarily children, as they may exceed the intake established for these additives.

Sweeteners:

The use of polyols as sweeteners in fermented milks and flavoured milks heat-treated after fermentation, may produce a laxative effect, especially when the products are fluid or semi-fluid. Therefore, the use of 420, 421, 953 and 967 should not be proposed for those products. If the proposed use involves another function, and this must be as a humectant, the levels used when the additive is a sweetener are not justified, which means that polyols could be kept as humectants, but in smaller levels.

Phosphates:

This group of additives should not appear on the list with different technological functions, as the manufacturer of the food product will label the product with the technological action of the additive. Also, the proposed levels are very high, and ADI for phosphates is in the order of 0-70 mg/kg (*Note from Australia: should be mg/kg of body weight*), but that is from all sources and this level is not technologically justified.

Intense sweeteners (950, 951, 952, 954 & 957):

Having these additives twice, as Sweeteners and Flavour enhancers, is not justified with the same levels, as it may mislead the consumer. Also, an additive with a specified ADI, as 950 and 957, cannot appear on the proposal with a GMP level.

Acids:

This group of additives appears twice, under this function and as acidity regulators, which may mislead the user.

Acidity regulators

SO_2 Generators:

The use of this group of additives is not justified in this case, as they do not act as acidity regulators or as stabilisers. They are preservatives, and other additives are proposed for that purpose. Their use cannot be considered for flavoured fermented milks, or for milks heat-treated after fermentation, natural or flavoured.

Stabilisers:

Additives 200 – 203, Sorbic acid and Sorbates, which have a clear and defined preservative action, cannot be used in all products, natural or flavoured, in levels that may inhibit microbial development and with a "stabilising" function. In the case of INS 475, Polyglycerol esters of fatty acids, in natural milk, heat treated or not, total intake of the additive would be contained in 200 g of food, therefore, the proposed level of 30,000 mg should be lowered. It appears that the proposed use of 541i and 541ii; acid and basic Aluminium sodium phosphate, respectively, in this type of product, is not technologically justified. Also, the weekly admissible intake of Aluminium should be taken into account, because the ADI for this product is conditioned by the (PTWI = permitted tolerable weekly intake) 7 mg/kg of body weight per week established for Aluminium. The proposed levels for Polyols in stabilising function are extremely high. Also, taking into account that one intake of 20 g of a polyol has a laxative effect, the amounts of 50,000 mg/kg and 30,000 mg/kg should be reduced.

Preservatives:

The use of preservatives in products that have undergone heat treatment is not technologically justified and should be reconsidered.

Regarding the Recommendations, we would like to suggest the reconsideration of the last recommendation – low ADIs do not necessarily lead to the exclusion of the use of additives, being made by the Group in charge of drafting the proposal.

The type of product such as fermented milk and its high consumption by all kind of population (children, elderly, sick people, etc.) should carefully consider certain additives –such as colourings with low ADIs, that could be replaced by other additives with similar function and with a higher safety margin in relation to intake levels.

On the other hand, the technological need for the use of these additives in these food products should be presented by the Food Products Committees directly to the CCFAC for approval. In the GSFA, proposals should be underwritten by a technological justification on the use of these proposed additives, which in this case should be reviewed by the CCMMP.

New Zealand

You have summarised the issues very well, and the recommendations are appropriate. In particular we support the simplification of the listing that will follow from listing by primary function, and omitting those that are covered by the carry-over principle. The list could be simplified further by combining (where possible) the listings that have roman numerals, e.g. 339, sodium phosphates. However this is only a formatting matter, to improve presentation and ease of use.

USA

General Comments

- The U.S. believes that the concept of "prima facie evidence of technological need" based on the approach taken by the CCFAC in developing the GSFA is being inappropriately applied and does not believe that the CCMMP should adopt the position that by virtue of its appearance on the list that "prima facie evidence of technological need" has been established for any given additive. The approach taken by CCFAC has been to assume that if a country reports the use of an additive in a particular food category, this is prima facie evidence of technological need. If a country does not agree that the use of the additive in that particular food category is technologically needed, then there is a process for resolving whether the use is actually necessary. The approach taken by CCFAC does not mean that any proposed use of an additive is automatically accepted.
- The U.S. does not agree that the drafting group discussion relative to the list should be confined to colors. The U.S. feels that the drafting group should look at the technological necessity of the additives.
- The U.S. feels that the CCMMP should focus on food additives that perform the technological effects agreed to by the 5th Session of the CCMMP and if necessary their maximum use levels.

- The U.S. feels that it is important for the functional use of the additives listed to be consistent with the functional uses assigned in the INS standard.
- The U.S. suggests that food additives with multifunctions be listed once, along with their functional uses and permissible level(s).

Specific Comments

Acidity Regulators

The U.S. does not feel that sulfites are justified for use as acidity regulators. The functional uses assigned to these additives in the INS standard are preservatives, antibrowning and antioxidants.

Stabilizers

The U.S. does not feel that sorbic acid and sorbates are justified for their use as stabilizers. There functional uses according to the INS standard are primarily as preservatives.

Colors

The U.S. would like to provide the following information for consideration by the Committee.

The U.S. notes that the following food colors require certification by the U.S. Food and Drug Administration. The use of non-certified colors in foods is a violation under U.S. law.

INS No.	Color	FD&C Certification No.
102	Tartrazine	FD& C Yellow No. 5
110	Sunset Yellow FCF	FD&C Yellow No. 6
127	Erythrosine	FD&C Red No. 3
129	Allura Red	FD&C Red No. 40
132	Indigotine	FD& C Blue No.2
133	Brilliant Blue FCF	FD&C Blue No. 1
143	Fast Green FCF	FD&C Green No. 3

The U.S. also notes that the following colors are unapproved for use in foods sold in the U.S. Foods containing these colors are deemed adulterated when sold in the U.S.

INS No.	Color
104	Quinoline Yellow
122	Azorubine
123	Amaranth
124	Ponceau 4R
128	Red 2G
151	Brilliant Black PN
172i	Iron Oxide
172ii	Iron Oxide
172iii	Iron Oxide
181	Tannic Acid

In the U.S. the above colors are considered to have public health safety concerns. We note that the 35th Session of Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1989) assigned an acceptable daily intake (ADI) "Not Specified" for the use of tannic acid as a "filtering aid where the application of good manufacturing practice ensures that it is removed from food after use."

Sweeteners

The U.S. feels that the use of cyclamates is not technologically justified based on unresolved safety concerns. The U.S. notes that the sweetener list may be incomplete.

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Emulsifiers

The U.S, notes that the additive class entitled "emulsifiers" contains emulsifying salts which are not the same as emulsifiers. The U.S. also notes that this category contains several compounds whose functional uses as listed in the INS standard are not considered emulsifiers.

Preservatives

The U.S. feels that the use of preservatives in products which have undergone a bactericidal heat treatment is not technologically justified. The U.S. notes that the preservative list appears to be incomplete as it does not contain some of the preservatives listed as either acidity regulators or stabilizers.

Flavor Enhancers

The U.S. notes that the flavor enhancer list appears to be incomplete. There does not appear to be any ketones listed.

SUMMARY OF COMMENTS

The major issues raised in comments on IDF table (of proposed levels of additives in fermented milks) from the Drafting Group members can be summarised as follows:

1. Technological need/justification

The IDF proposed levels appear to be be based on the concept of technological need as requested by CCFAC, although clear instructions from CCFAC are required as to who does the technological justification, both for permission of additives and for specific levels. It should be noted that the levels in the draft GSFA are based on *prima facie* evidence of technological need from national regulations of at least two countries. Some countries want to revise the levels on the basis of " widely permitted" as required by the Codex Alimentarius Procedural Manual.

2. Primary function

The IDF table lists some additives under the number of functions which may cause confusion (the user may think that each function has a maximum level assigned to it). One listing under a primary function determined by the manufacturer would simplify the table and prevent possible misunderstanding.

3. Carry over principle

There is confusion about the need to list additives present as carry over from ingredients in fermented milk products. If the carry-over principle applies to additives and processing aids, then there is no need to list the sulphites (from fruit) or parabens (from flavours). This is complicated as this issue has not been resolved at CCFAC. The table will be much simpler if additives from carry-over do not have to be specifically listed in each category. Conversely, the table may be much longer when other additives carried over from ingredients are considered.

4. Acceptable daily intakes

There is general concern about the use of additives with low ADIs. JECFA has determined acceptable daily intakes which are safe. The levels of additives in the GSFA are not safety levels but must be assessed against the ADIs considering levels of intake from all sources (eg levels of colours from fermented milks could be insignificant compared to levels of colours from eg confectionery and soft drinks).

5. Specific comments

Specific comments for consideration by CCMMP 6 were submitted by the USA and Spain (on individual additives) and by New Zealand (on formatting).

RECOMMENDATIONS

The Drafting Group recommends that:

- the revised IDF table of additives in fermented milks (attached here) be forwarded to CCFAC clearly identified as being based on prima facie evidence of technological need;

- CCMMP request clarification from CCFAC on the principles to be used in the process of technological justification of the use specific additives and their levels of use;
- CCMMP approve the principle of primary function of additives with more that one permission level, allowing for flexibility in the performance of other functions as required by manufacturers;
- CCMMP request clarification from CCFAC that where additives are carried over from permissions in ingredients, these additives do not need to be listed again in the standard for fermented milk; and
- CCMMP confirm that low ADIs do not necessarily lead to the exclusion of the use of additives.

ATTACHMENT 1: Standard for Fermented Milks: Food Additives

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
	INS Number	Additive Name	Plain			Flavoured			Plain			Flavoured		
Additive Class			Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted ?	Max Level	Source	Permitted?	Max Level	Source
Colours			NO	N/A	N/A	YES	ADI	GSFA	NO	N/A	N/A	YES	ADI	GSFA
	100i	Curcumin					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	101i	Riboflavin From Bacillus Subtilis					GMP	01.7, step 6					GMP	01.7, step 6
	101ii	Riboflavin 5'-Phosphate Sodium					GMP	01.7, step 6					GMP	01.7, step 6
	102	Tartrazine					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	104	Quinoline Yellow					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	110	Sunset Yellow FCF					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	120	Carmines					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	122	Azorubine					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	123	Amaranth					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	124	Ponceau 4R					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	127	Erythrosine					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	128	Red 2G					30 mg/kg	01.7, step 6					30 mg/kg	01.7, step 6
	129	Allura Red AC					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	132	Indigotine					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	133	Brilliant Blue; FCFC					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	141i	Chlorophylls, Copper Complexes					300 mg/kg	01.7, step 6					300 mg/kg	01.7, step 6
	141i	Chlorophylls, Copper Complexes					500 mg/kg	01.7, step 3					500 mg/kg	01.7, step 3
	141ii	Chlorophylls, Copper Complexes, Sodium And Potassium Salts					200 mg/kg	01.7, step 6					200 mg/kg	01.7, step 6
	141ii	Chlorophylls, Copper Complexes, Sodium And Potassium Salts					500 mg/kg	01.7, step 3					500 mg/kg	01.7, step 3
	143	Fast Green FCF					100 mg/kg	01.7, step 8					100 mg/kg	01.7, step 8
	150a	Caramel Colour, Class I; Plain					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	150b	Caramel Colour, Class Ii;					160 mg/kg	01.7, step 3					160 mg/kg	01.7, step 3
	150c	Caramel Colour, Class Iii;					2000 mg/kg	01.7, step 8					2000 mg/kg	01.7, step 8
	150d	Caramel Colour, Class Iv;					2000 mg/kg	01.7, step 8					2000 mg/kg	01.7 step 8
	151	Brilliant Black PN;					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	155	Brown HT;					150 mg/kg	01.7, step 6					150 mg/kg	01.7, step 6
	160a	Carotenes					200 mg/kg	01.7, step 6					200 mg/kg	01.7, step 6
	160a (ii)	Carotenes (Vegetable); Natural Extacts					GMP	01.7, step 6					GMP	01.7, step 6
	160b	Annatto Extracts;					100 mg/kg	01.7, step 6					100 mg/kg	01.7, step 6
	160e	Beta-Apo-8'-Carotenal					200mg/kg	01.7, step 6					200mg/kg	01.7, step 6
	160f	Beta-Apo-8'-Carotenoic Acid, Methyl And Ethyl Esters					200mg/kg	01.7, step 6					200mg/kg	01.7, step 6
	161g	Canthaxanthin					GMP	01.7, step 6					GMP	01.7, step 6
	163ii	Grape Skin Extract					100 mg/kg	01.7, step 6					100 mg/kg	01.7, step 6
	172i	Iron Oxide Black					GMP	01.7, step 6					GMP	01.7, step 6
	172ii	Iron Oxide Red					GMP	01.7, step 6					GMP	01.7, step 6
	172iii	Iron Oxide Yellow					GMP	01.7, step 6					GMP	01.7, step 6
	181	Tannic Acid; Tannins (Food Grade)					400 mg/kg	01.7, step 6					400 mg/kg	01.7, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Sweeteners			**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**	**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**
	420	Sorbitol (Including Sorbitol Syrup)					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	421	Mannitol					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	636	Maltol					200 mg/kg	01.7, step 6					200 mg/kg	01.7, step 6
	637	Ethyl Maltol					200 mg/kg	01.7, step 6					200 mg/kg	01.7, step 6
	950	Acesulfame Potassium					GMP	01.2, step 6					GMP	01.2, step 6
	951	Aspartame					3,000 mg/kg	01.7.1, step 6					3,000 mg/kg	01.7, step 6
	952	Cyclamates					250 mg/kg	01.7, step 6					250 mg/kg	01.7, step 6
	953	Isomalt					GMP	01.2.1.1, step 6					GMP	01.2.1.2, step 6
	954	Saccharin					200 mg/kg	01.7.1, step 6					200 mg/kg	01.7.1, step 6
	955	Sucralose					400 mg/kg	01.7, step 6					400 mg/kg	01.7, step 6
	956	Alitame					100 mg/kg	01.27 step 6					100 mg/kg	01.27 step 6
	957	Thaumatin					GMP	01.2, step 3					GMP	01.2, step 3
	967	Xylitol					30,000 mg/kg	01.2, step 3					GMP	01.2.1.2, step 6
	968	Erythritol					40,000 mg/kg	01.2, step 3					40,000 mg/kg	01.2, step 3
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Emulsifiers			**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**	**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**
	325	Sodium Lactate					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	331i	Sodium Dihydrogen Citrate					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	331iii	Trisodium Citrate					1500 mg/kg	01.2.1, step 6					1500 mg/kg	01.2.1, step 6
	332i	Potassium Dihydrogen Citrate					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	332iii	Tripotassium Citrate					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	334	L(+)-Tartaric Acid					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	335i	Monosodium L(+)-Tartrate					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	335ii	Sodium L(+)-Tartrate					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	336i	Tartrate					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	336ii	Tartrate					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	337	Potassium Sodium L(+)-Tartrate					2000 mg/kg	01.7, step 6					2000 mg/kg	01.7, step 6
	338	Phosphoric Acid					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	339i	Sodium Dihydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6

	INS Number	Additive Name	Fermented Milks					Fermented Milks Heat Treated After Fermentation				
			Plain			Flavoured		Plain			Flavoured	
	339iii	Trisodium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	340ii	Dipotassium Hydrogen Phosphate				8,800 mg/kg *	01.7, ste 6				8,800 mg/kg *	01.7, step 6
	340iii	Tripotassium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	342i	Ammonium Dihydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	343iii	Trimagnesium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	400	Alginic Acid				5,000 mg/kg	01.2.1.2, step 6				5,000 mg/kg	01.2.1.2, step 6
	401	Sodium Alginate				GMP	01.2, step 3				5,000 mg/kg	01.2.1.2, step 6
	402	Potassium Alginate				5,000 mg/kg	01.2.1.2, step 6				5,000 mg/kg	01.2.1.2, step 6
	403	Ammonium Alginate				5,000 mg/kg	01.2.1.2, step 6				5,000 mg/kg	01.2.1.2, step 6
	404	Calcium Alginate				5,000 mg/kg	01.2.1.2, step 6				5,000 mg/kg	01.2.1.2, step 6
	405	Propylene Glycol Alginate				10,000 mg/kg	01.7, step 6				10,000 mg/kg	01.7, step 6
	406	Agar				5,000 mg/kg	01.1.2.1.2, step 6				5,000 mg/kg	01.1.2.1.2, step 6
	407	Carrageenan				5,000 mg/kg	01.7, step 6				5,000 mg/kg	01.7, step 6
	410	Carob Bean Gum				5,000 mg/kg	01.2.1.2, step 6				5,000 mg/kg	01.2.1.2, step 6
	412	Guar Gum				5,000mg/kg	01.2.1.2, step 6				5,000mg/kg	01.2.1.2, step 6
	413	Tragacanth Gum				GMP	01.2.1.2, step 6				GMP	01.2.1.2, step 6
	414	Gum Arabic				GMP	01.2.1.2, step 6				GMP	01.2.1.2, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	416	Karaya Gum				200 mg/kg	01.2.1.1, step 6					5000 mg/kg	01.2.1.2, step 6	
	418	Gellan Gum				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	420	Sorbitol (Including Sorbitol Syrup)				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	421	Mannitol				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	422	Glycerol				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	425	Konjac Flour				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	440	Pectins (Amidated and Non-Amidated)				GMP	01.2.1.1, step 6					10,000 mg/kg	01.2.1.2, step 6	
	450i	Disodium Pyrophosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	450iii	Tetrasodium Pyrophosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	450v	Tetrapotassium Pyrophosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	450vi	Dicalcium Pyrophosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	451i	Pentasodium Triphosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	451ii	Pentapotassium Triphosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	452i	Sodium Polyphosphates, Glassy				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	452ii	Potassium Polyphosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	452iv	Calcium Polyphosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	452v	Ammonium Polyphosphate				8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6	
	460i	Microcrystalline Cellulose				GMP	01.2.1.1, step 6					20,000 mg/kg	01.2.1.2, step 6	
	460ii	Powdered Cellulose				GMP	01.2.1.1, step 6					GMP	01.2.1.2, step6	
	461	Methyl Cellulose				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	463	Hydroxypropyl Cellulose				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	464	Hydroxypropyl Methyl Cellulose				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	
	465	Methyl Ethyl Cellulose				GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6	

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	466	Sodium Carboxymethyl Cellulose					GMP	01.2, step 3					5,000 mg/kg	01.2.1.2, step 6
	470	Salts Of Myristic, Palmitic And Stearic Acids (Calcium, Potassium, Sodium)					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	470	Salts of Oleic Acid (Calcium, Potassium, Sodium)					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
Additive Class			Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted?	Max Level	Source
Emulsifiers			NO	N/A	N/A	YES	ADI	GSFA	NO	N/A	N/A	YES	ADI	GSFA
	471	Mono and diglycerides					5000mg/kg	01.2, step 6					5000mg/kg	01.2, step 6
	472b	Lactic and Fatty Acid Esters of Glycerol					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	472c	Citric And Fatty Acid Esters Of Glycerol					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	472e	Diacetyltartaric and Fatty Acid Esters of Glycerol					10,000 mg/kg	01.7, step 6					10,000 mg/kg	01.7, step 6
	472f	Tartaric Acetic & Fatty Acid Esters of Glycerol (Mixed)					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	473	Sucrose Esters of Fatty Acids					10,000 mg/kg	01.7, step 6					10,000 mg/kg	01.7, step 6
	474	Sucroglycerides					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	475	Polyglycerol Esters of Fatty Acids					10,000 mg/kg	07.1, step 6					10,000 mg/kg	01.2.1, step 6
	476	Polyglycerol Esters Of Interesterified Ricinoleic Acid					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	477	Propylene Glycol Esters Of Fatty Acids					5,000 mg/kg	01.7, step 8					5,000 mg/kg	01.7, step 8
	480	Dioctyl Sodium Sulfosuccinate					25 mg/kg	01.1.2, step 6					25 mg/kg	01.1.2, step 6
	481i	Sodium Stearoyl-2-Lactylate					10,000 mg/kg	01.7, step 6					10,000 mg/kg	01.7, step 6
	482i	Calcium Stearoyl-2-Lactylate					10,000 mg/kg	01.7, step 6					10,000 mg/kg	01.7, step 6
	483	Stearoyl Tartrate					5,000 mg/kg	07.1, step 6					5,000 mg/kg	07.1, step 6
	491	Sorbitan Monostearate					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	492	Sorbitan Tristearate					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	493	Sorbitan Monolaurate					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	494	Sorbitan Monooleate					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	495	Sorbitan Monopalmitate					5,000 mg/kg	01.7, step 6					5,000 mg/kg	01.7, step 6
	541i	Sodium Aluminium Phosphate, Acidic					2,000 mg/kg	01.7, step 6					2,000 mg/kg	01.7, step 6
	541ii	Sodium Aluminium Phosphate, Basic					2,000 mg/kg	01.7, step 6					2,000 mg/kg	01.7, step 6
	542	Bone Polyphosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	953	Isomalt					GMP	01.2.1.1, step 6					GMP	01.2.1.2, step 6
	954	Saccharin					200 mg/kg	01.7.1, step 6					200 mg/kg	01.7.1, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	965	Maltitol and Maltitol Syrup					50,000 mg/kg	01.2, step 3					50,000 mg/kg	01.2, step 3
	966	Lactitol					30,000 mg kg	01.2, step 3					30,000 mg kg	01.2, step 3
	967	Xylitol					30,000 mg/kg	01.2, step 3					GMP	01.2.1.2, step 6
	1400	Dextrins, White and Yellow, Roasted Starch					GMP	01.2, step 3					GMP	01.2, step 3
	1401	Acid Treated Starch					GMP	01.2, step 3					GMP	01.2, step 3
	1403	Bleached Starch					GMP	01.2, step 3					GMP	01.2, step 3
	1404	Oxidized Starch					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	1405	Enzyme Treated Starch					GMP	01.2, step 3					GMP	01.2, step 3
	1410	Monostarch Phosphate					GMP	01.2, step 3					GMP	01.2, step 3
	1412	Distarch Phosphate					GMP	01.2, step 3					GMP	01.2, step 3
	1414	Acetylated Distarch Phosphate					GMP	01.2.1.2, step 6					GMP	01.2.1.2, step 6
	1420	Starch Acetate					GMP	01.2, step 3					GMP	01.2, step 3
	1422	Acetylated Distarch Adipate					GMP	01.2, step 3					GMP	01.2, step 3
	1440	Hydroxypropyl Starch					5,000mg/kg	01.2.1.2, step 6					5,000mg/kg	01.2.1.2, step 6
	1442	Hydroxypropyl Distarch Phosphate					GMP	01.2, step 3					GMP	01.2, step 3
	1450	Starch Sodium Octenyl Succinate					GMP	01.2, step 3					GMP	01.2, step 3
	1520	Propylene Glycol					10,000 mg/kg	01.7, step 6					10,000 mg/kg	01.7, step 6

	INS Number	Additive Name	Plain			Flavoured			Plain			Flavoured		
Additive Class			Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted ?	Max Level	Source	Permitted?	Max Level	Source
FI Enhancers			NO	N/A	N/A	YES	ADI	GSFA	NO	N/A	N/A	YES	ADI	GSFA
	338	Phosphoric Acid					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	339i	Sodium Dihydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	339iii	Trisodium Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6
	340ii	Dipotassium Hydrogen Phosphate					8,800 mg/kg *	01.7, step 6					8,800 mg/kg *	01.7, step 6

			Fermented Milks					Fermented Milks Heat Treated After Fermentation				
			Plain			Flavoured		Plain			Flavoured	
	INS Number	Additive Name										
	340iii	Tripotassium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	450i	Disodium Pyrophosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	450iii	Tetrasodium Pyrophosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	450v	Tetrapotassium Pyrophosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	450vi	Dicalcium Pyrophosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	451i	Pentasodium Triphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	451ii	Pentapotassium Triphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	452i	Sodium Polyphosphates, Glassy				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	452ii	Potassium Polyphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	452iv	Calcium Polyphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	452v	Ammonium Polyphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	542	Bone Polyphosphate				8,800 mg/kg *	01.7, step 6				8,800 mg/kg *	01.7, step 6
	636	Maltol				200 mg/kg	01.7, step 6				200 mg/kg	01.7, step 6
	950	Acesulfame Potassium				GMP	01.2, step 6				GMP	01.2, step 6
	951	Aspartame				3,000 mg/kg	01.7, step 6				3,000 mg/kg	01.7.1, step 6
	952	Cyclamates				250 mg/kg	01.7, step 6				250 mg/kg	01.7, step 6
	954	Saccharin				200	01.7, step 6				200	01.7, step 6
	957	Thaumatin				GMP	01.2, step 3				GMP	01.2, step 3

	INS Number	Additive Name	Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Acids			**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**
	260	Acetic Acid, Glacial					GMP	01.2.1.2, step 6		GMP	01.2.1, step 6		GMP	01.2.1.2, step 6
	270	Lactic Acid					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	296	Malic Acid					GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
	297	Fumaric Acid					GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
	330	Citric Acid					1,500 mg/kg	01.2.1, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	334	L(+)-Tartaric Acid					2000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6
	338	Phosphoric Acid					8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	355	Adipic Acid					6,000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		6,000 mg/kg	01.7, step 6
	507	Hydrochloric Acid					GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Acidity Reg.			**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**
	220	Sulfur Dioxide					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	221	Sodium Sulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	222	Sodium Hydrogen Sulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	223	Sodium Metabisulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	224	Potassium Metabisulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	225	Potassium Sulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	227	Calcium Hydrogen Sulfite					100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	260	Acetic Acid, Glacial					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	270	Lactic Acid					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	296	Malic Acid					GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
	297	Fumaric Acid					GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
	322	Lecithin					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	325	Sodium Lactate					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	326	Potassium Lactate					GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	330	Citric Acid			1,500 mg/kg	01.2.1, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	331i	Sodium Dihydrogen Citrate			GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	332i	Potassium Dihydrogen Citrate			GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	332ii	Tripotassium Citrate			GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	332iii	Tripotassium Citrate			GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	334	L(+)-Tartaric Acid			2000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	2000 mg/kg	01.7, step 6
	335i	Monosodium L(+)-Tartrate			2000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	2000 mg/kg	01.7, step 6
	335ii	Sodium L(+)-Tartrate			2000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	2000 mg/kg	01.7, step 6
	336i	Tartrate			2000 mg/kg	01.7, step 6	2000 mg/kg	01.7, step 6	2000 mg/kg	01.7, step 6
	337	Potassium Sodium L(+)-Tartrate			2000 mg/kg	01.7, step 6	2000 mg/kg	01.7, step 6	2000 mg/kg	01.7, step 6
	339i	Sodium Dihydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	339iii	Trisodium Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	340ii	Dipotassium Hydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	340iii	Tripotassium Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	342i	Ammonium Dihydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	343iii	Trimagnesium Phosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	355	Adipic Acid			6,000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	6,000 mg/kg	01.7, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	356	Sodium Adipate			6,000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	6,000 mg/kg	01.7, step 6
	357	Potassium Adipate			6,000 mg/kg	01.7, step 6	GMP	01.2.1, step 6	6,000 mg/kg	01.7, step 6
	421	Mannitol			GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	450i	Disodium Pyrophosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450iii	Tetrasodium Pyrophosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450v	Tetrapotassium Pyrophosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450vi	Dicalcium Pyrophosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	451i	Pentasodium Triphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	451ii	Pentapotassium Triphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452i	Sodium Polyphosphates, Glassy			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452ii	Potassium Polyphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452iv	Calcium Polyphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452v	Ammonium Polyphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	460i	Microcrystalline Cellulose			GMP	01.2.1.1, step 6	20,000 mg/kg	01.2.1.2, step 6	20,000 mg/kg	01.2.1.2, step 6
	460ii	Powdered Cellulose			GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	GMP	01.2.1.2, step 6
	504i	Magnesium Carbonate			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	504ii	Magnesium Hydrogen Carbonate			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	507	Hydrochloric Acid			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	528	Magnesium Hydroxide			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	542	Bone Polyphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6		
	575	Glucono delta-Pentapotassium			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	542	Bone Polyphosphate			8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6		
	575	Glucono delta-Pentapotassium			GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
	INS Number	Additive Name	Plain			Flavoured			Plain			Flavoured		
	541i	Sodium Aluminium Phosphate, Acidic				2,000 mg/kg	01.7, step 6		2,000 mg/kg	01.7, step 6		2,000 mg/kg	01.7, step 6	
	541ii	Sodium Aluminium Phosphate, Basic				2,000 mg/kg	01.7, step 6		2,000 mg/kg	01.7, step 6		2,000 mg/kg	01.7, step 6	
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Stabilizers			**YES***	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**
	200	Sorbic Acid		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6
	201	Sodium Sorbate		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6
	202	Potassium Sorbate		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6
	203	Calcium Sorbate		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6		1000 mg/kg	01.7, step 6
	220	Sulfur Dioxide		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	221	Sodium Sulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	222	Sodium Hydrogen Sulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	223	Sodium Metabisulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	224	Potassium Metabisulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	225	Potassium Sulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	227	Calcium Hydrogen Sulfite		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6		100 mg/kg	01.7, step 6
	290	Carbon Dioxide		GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6
	297	Fumaric Acid		GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6		GMP	01.2.1, step 6
	325	Sodium Lactate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	331i	Sodium Dihydrogen Citrate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	331iii	Trisodium Citrate		1500 mg/kg	01.2.1, step 6		1500 mg/kg	01.2.1, step 6		1500 mg/kg	01.2.1, step 6		1500 mg/kg	01.2.1, step 6
	332i	Potassium Dihydrogen Citrate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	332iii	Tripotassium Citrate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	334	L(+)-Tartaric Acid		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6
	335ii	Sodium L(+)-Tartrate		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6
	336i	Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	336ii	Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	337	Potassium Sodium L(+)-Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	338	Phosphoric Acid		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339i	Sodium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339iii	Trisodium Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	340ii	Dipotassium Hydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	340iii	Tripotassium Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	342i	Ammonium Dihydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	343iii	Trimagnesium Phosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	400	Alginic Acid	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	401	Sodium Alginate	GMP	01.2, step 3	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	402	Potassium Alginate	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	403	Ammonium Alginate	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	404	Calcium Alginate	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	405	Propylene Glycol Alginate	GMP	01.2, step 3	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	406	Agar	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6
	407	Carrageenan	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6
	407a	Processed Eucheuma Seaweed	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6
	410	Carob Bean Gum	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6
	412	Guar Gum	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6
	413	Tragacanth Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	414	Gum Arabic	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	415	Xanthan Gum	GMP	01.2.1.1, step6	GMP	01.2.1.1, step 6	5000 mg/kg	01.2.1.2, step 6	5000 mg/kg	01.2.1.2, step 6
	416	Karaya Gum	200 mg/kg	01.2.1.1, step 6	200 mg/kg	01.2.1.1, step 6	2000 mg/kg	01.2.1.2, step 6	2000 mg/kg	01.2.1.2, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	417	Tara Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	418	Gellan Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	420	Sorbitol (Including Sorbitol Syrup)	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	421	Mannitol	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	422	Glycerol	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	425	Konjac Flour	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	432	Polyoxyethylene (20) Sorbitan Monolaurate	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6
	433	Polyoxyethylene (20) Sorbitan Monooleate	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6
	434	Polyoxyethylene (20) Sorbitan Monopalmitate	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6
	435	Polyoxyethylene (20) Sorbitan Monostearate	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6
	436	Polyoxyethylene (20) Sorbitan Tristearate	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	6,000 mg/kg	01.7, step 6
	440	Pectins (Amidated and Non-Amidated)	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	10,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.2.1.2, step 6
	442	Phosphatidic Acid, Ammonium Salt	GMP	01.1.2, step 6	5,000 mg/kg	01.7, step 6	GMP	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	450i	Disodium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450iii	Tetrasodium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450v	Tetrapotassium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450vi	Dicalcium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	451i	Pentasodium Triphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	451ii	Pentapotassium Triphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452i	Sodium Polyphosphates, Glassy	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452ii	Potassium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452iv	Calcium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452v	Ammonium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	460i	Microcrystalline Cellulose	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	20,000 mg/kg	01.2.1.2, step 6	20,000 mg/kg	01.2.1.2, step 6
	460ii	Powdered Cellulose	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	GMP	01.2.1.2, step 6
	461	Methyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	463	Hydroxypropyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	465	Methyl Ethyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	466	Sodium Carboxymethyl Cellulose	GMP	01.2, step 3	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	470	Salts Of Myristic, Palmitic And Stearic Acids (Calcium, Potassium, Sodium)	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	470	Salts of Oleic Acid (Calcium, Potassium, Sodium)	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	471	Mono and Diglycerides	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6
	472a	Acetic And Fatty Acid Esters Of Glycerol	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	472b	Lactic and Fatty Acid Esters of Glycerol	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	472c	Citric And Fatty Acid Esters Of Glycerol	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	472e	Diacetyltartaric and Fatty Acid Esters of Glycerol	GMP	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6	GMP	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	472f	Tartaric Acetic & Fatty Acid Esters of Glycerol (Mixed)	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	473	Sucrose Esters of Fatty Acids	5,000 mg/kg	01.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	10,000 mg/kg	01.7, step 6
	474	Sucroglycerides	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	475	Polyglycerol Esters of Fatty Acids	30,000 mg/kg	01.2.1, step 6	10,000 mg/kg	01.2.1	30,000 mg/kg	07.1, step 6	10,000 mg/kg	01.2.1, step 6
	476	Polyglycerol Esters Of Interesterified Ricinoleic Acid	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.7, step 6
	477	Propylene Glycol Esters Of Fatty Acids	5,000 mg/kg	01.1.2, step 8	5,000 mg/kg	01.7, step 8	5,000 mg/kg	01.1.2, step 8	5,000 mg/kg	01.7, step 8
	480	Dioctyl Sodium Sulfosuccinate	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6
	481i	Sodium Stearoyl-2-Lactylate	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	482i	Calcium Stearoyl-2-Lactylate	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	491	Sorbitan Monostearate	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6

			Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	INS Number	Additive Name								
	492	Sorbitan Tristearate	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	493	Sorbitan Monolaurate	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	494	Sorbitan Monooleate	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	495	Sorbitan Monopalmitate	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	528	Magnesium Hydroxide	GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6	GMP	01.2.1, step 6
	541i	Sodium Aluminium Phosphate, Acidic	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6
	541ii	Sodium Aluminium Phosphate, Basic	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6	2,000 mg/kg	01.7, step 6
	542	Bone Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	636	Maltol	200 mg/kg	01.1.2, step 6	200 mg/kg	01.7, step 6	200 mg/kg	01.1.2, step 6	200 mg/kg	01.7, step 6
	637	Ethyl Maltol	200 mg/kg	01.7, step 6	200 mg/kg	01.7, step 6	200 mg/kg	01.7, step 6	200 mg/kg	01.7, step 6
	965	Maltitol and Maltitol Syrup	50,000 mg/kg	01.2, step 3	50,000 mg/kg	01.2, step 3	50,000 mg/kg	01.2, step 3	50,000 mg/kg	01.2, step 3
	966	Lactitol	30,000 mg kg	01.2, step 3	30,000 mg kg	01.2, step 3	30,000 mg kg	01.2, step 3	30,000 mg kg	01.2, step 3
	967	Xylitol	30,000 mg/kg	01.2, step 3	30,000 mg/kg	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	1200	Polydextrose	GMP	01.2, step 6	GMP	01.2, step 6	GMP	01.2, step 6	GMP	01.2, step 6
	1400	Dextrins, White and Yellow, Roasted Starch	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1401	Acid Treated Starch	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1402	Alkaline Treated Starch	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1403	Bleached Starch	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1404	Oxidized Starch	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	1405	Enzyme Treated Starch	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1410	Monostarch Phosphate	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1412	Distarch Phosphate	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1414	Acetylated Distarch Phosphate	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	1420	Starch Acetate	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1422	Acetylated Distarch Adipate	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1440	Hydroxypropyl Starch	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6
	1442	Hydroxypropyl Distarch Phosphate	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3	GMP	01.2, step 3
	1520	Propylene Glycol	10,000 mg/kg	01.7, step 6	10,000 mg/kg	01.7, step 6	10,000 mg/kg	01.7, step 6	10,000 mg/kg	01.7, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
	INS Number	Additive Name	Plain			Flavoured			Plain			Flavoured		
Additive Class			Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted?	Max Level	Source	Permitted?	Max Level	Source
Thickeners			YES*	ADI	GSFA	YES	ADI	GSFA	YES	ADI	GSFA	YES	ADI	GSFA
	325	Sodium Lactate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	334	L(+)-Tartaric Acid		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6
	335ii	Sodium L(+)-Tartrate		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6		GMP	01.2.1, step 6		2000 mg/kg	01.7, step 6
	336i	Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	336ii	Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	337	Potassium Sodium L(+)-Tartrate		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6		2000 mg/kg	01.7, step 6
	338	Phosphoric Acid		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339i	Sodium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	339iii	Trisodium Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	340ii	Dipotassium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	340iii	Tripotassium Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	342i	Ammonium Dihydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	343iii	Trimagnesium Phosphate		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6		880 mg/kg *	01.2, step 6		8,800 mg/kg *	01.7, step 6
	400	Alginic Acid		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6
	401	Sodium Alginate		GMP	01.2, step 3		GMP	01.2, step 3		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6
	402	Potassium Alginate		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6		5,000 mg/kg	01.2.1.2, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	403	Ammonium Alginate	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	404	Calcium Alginate	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	405	Propylene Glycol Alginate	GMP	01.2, step 3	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	406	Agar	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6	5,000 mg/kg	01.1.2.1.2, step 6
	407	Carrageenan	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6
	407a	Processed Eucheuma Seaweed	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.7, step 6
	410	Carob Bean Gum	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6
	412	Guar Gum	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6	GMP	01.2, step 3	5,000mg/kg	01.2.1.2, step 6
	413	Tragacanth Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	414	Gum Arabic	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	415	Xanthan Gum	GMP	01.2.1.1, step6	GMP	01.2.1.1, step 6	5000 mg/kg	01.2.1.2, step 6	5000 mg/kg	01.2.1.2, step 6
	416	Karaya Gum	200 mg/kg	01.2.1.1, step 6	200 mg/kg	01.2.1.1, step 6	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	417	Tara Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	418	Gellan Gum	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	420	Sobitol (Including Sorbitol Syrup)	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	421	Mannitol	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	422	Glycerol	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	425	Konjac Flour	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	440	Pectins (Amiadated and Non-Amidated)	GMP	01.2.1.1, step6	GMP	01.2.1.1, step 6	10,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.2.1.2, step 6
	442	Phosphatidic Acid, Ammonium Salt	GMP	01.1.2, step 6	5,000 mg/kg	01.7, step 6	GMP	01.1.2, step 6	5,000 mg/kg	o1.7, step 6
	450i	Disodium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450iii	Tetrasodium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450v	Tetrapotassium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	450vi	Dicalcium Pyrophosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6

	INS Number	Additive Name	Fermented Milks				Fermented Milks Heat Treated After Fermentation			
			Plain		Flavoured		Plain		Flavoured	
	451i	Pentasodium Triphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	451ii	Pentapotassium Triphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452i	Sodium Polyphosphates, Glassy	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452ii	Potassium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452iv	Calcium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	452v	Ammonium Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6
	460i	Microcrystalline Cellulose	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	20,000 mg/kg	01.2.1.2, step 6	20,000 mg/kg	01.2.1.2, step 6
	460ii	Powdered Cellulose	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	GMP	01.2.1.1, step 6	GMP	01.2.1.2, step 6
	461	Methyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	463	Hydroxypropyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	464	Hydroxypropyl Methyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	465	Methyl Ethyl Cellulose	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	466	Sodium Carboxymethyl Cellulose	GMP	01.2, step 3	GMP	01.2, step 3	5,000 mg/kg	01.2.1.2, step 6	5,000 mg/kg	01.2.1.2, step 6
	471	Mono and Diglycerides	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6	5,000 mg/kg	01.2, step 6
	472b	Lactic and Fatty Acid Esters of Glycerol	GMP	01.2, step 3	GMP	01.2.1.2, step 6	GMP	01.2, step 3	GMP	01.2.1.2, step 6
	472c	Citric And Fatty Acid Esters Of Glycerol	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6	GMP	01.2.1.2, step 6
	473	Sucrose Esters of Fatty Acids	5,000 mg/kg	01.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	10,000 mg/kg	01.7, step 6
	474	Sucroglycerides	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6	5,000 mg/kg	01.1.2, step 6	5,000 mg/kg	01.7, step 6
	475	Polyglycerol Esters of Fatty Acids	30,000 mg/kg	01.2.1	10,000 mg/kg	01.2.1, step 6	30,000 mg/kg	07.1, step 6	10,000 mg/kg	01.7, step 6
	480	Dioctyl Sodium Sulfosuccinate	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6	25 mg/kg	01.1.2, step 6
	481i	Sodium Stearoyl-2-Lactylate	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	482i	Calcium Stearoyl-2-Lactylate	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6	5,000 mg/kg	01.2.1.2, step 6	10,000 mg/kg	01.7, step 6
	542	Bone Polyphosphate	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6	880 mg/kg *	01.2, step 6	8,800 mg/kg *	01.7, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	965	Maltitol and Maltitol Syrup		50,000 mg/kg	01.2, step 3		50,000 mg/kg	01.2, step 3		50,000 mg/kg	01.2, step 3		50,000 mg/kg	01.2, step 3
	966	Lactitol		30,000 mg kg	01.2, step 3		30,000 mg kg	01.2, step 3		30,000 mg kg	01.2, step 3		30,000 mg kg	01.2, step 3
	967	Xylitol		30,000 mg/kg	01.2, step 3		30,000 mg/kg	01.2, step 3		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	1200	Polydextrose		GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6
	1400	Dextrins, White and Yellow, Roasted Starch		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1401	Acid Treated Starch		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1402	Alkaline Treated Starch		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1403	Bleached Starch		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1404	Oxidized Starch		GMP	01.2, step 3		GMP	01.2.1.2, step 6		GMP	01.2, step 3		GMP	01.2.1.2, step 6
	1405	Enzyme Treated Starch		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1410	Monostarch Phosphate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1412	Distarch Phosphate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1414	Acetylated Distarch Phosphate		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6		GMP	01.2.1.2, step 6
	1420	Starch Acetate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1422	Acetylated Distarch Adipate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1440	Hydroxypropyl Starch		GMP	01.2, step 3		5,000mg/kg	01.2.1.2, step 6		GMP	01.2, step 3		5,000mg/kg	01.2.1.2, step 6
	1442	Hydroxypropyl Distarch Phosphate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1450	Starch Sodium Octenyl Succinate		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3		GMP	01.2, step 3
	1520	Propylene Glycol		10,000 mg/kg	01.7, step 6		10,000 mg/kg	01.7, step 6		10,000 mg/kg	01.7, step 6		10,000 mg/kg	01.7, step 6
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Preservatives			**NO**	**N/A**	**N/A**	**NO**	**N/A**	**N/A**	**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**
	200	Sorbic Acid											1000 mg/kg	01.7, step 6
	201	Sodium Sorbate											1000 mg/kg	01.7, step 6
	202	Potassium Sorbate											1000 mg/kg	01.7, step 6
	203	Calcium Sorbate											1000 mg/kg	01.7, step 6
	210	Benzoic Acid											300 mg/kg	01.7, step 8
	211	Sodium Benzoate											300 mg/kg	01.7, step 8
	212	Potassium Benzoate											300 mg/kg	01.7, step 8
	213	Calcium Benzoate											300 mg/kg	01.7, step 8
	214	Ethyl p-Hydroxybenzoate											120 mg/kg	01.7, step 6
	216	Propyl p-Hydroxybenzoate											120 mg/kg	01.7, step 6
	218	methyl p-hydroxybenzoate											120 mg/kg	01.7, step 6
	260	Acetic Acid, Glacial											GMP	01.2.1.2
	334	L(+)-Tartaric Acid											2000 mg/kg	01.7, step 6
	335i	Monosodium L(+)-Tartrate											2000 mg/kg	01.7, step 6
	335ii	Sodium L(+)-Tartrate											2000 mg/kg	01.7, step 6

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	336i	Tartrate											2000 mg/kg	01.7, step 6
	336ii	Tartrate											2000 mg/kg	01.7, step 6
	337	Potassium Sodium L(+)-Tartrate											2000 mg/kg	01.7, step 6
	338	Phosphoric Acid											8,800 mg/kg *	01.7, step 6
	339i	Sodium Dihydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	339ii	Disodium Hydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	339iii	Trisodium Phosphate											8,800 mg/kg *	01.7, step 6
	340i	Potassium Dihydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	340ii	Dipotassium Hydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	340iii	Tripotassium Phosphate											8,800 mg/kg *	01.7, step 6
	341i	Calcium Dihydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	341ii	Calcium Hydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	341iii	Tricalcium Phosphate											8,800 mg/kg *	01.7, step 6
	342i	Ammonium Dihydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	342ii	Diammonium Hydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	343ii	Magnesium Hydrogen Phosphate											8,800 mg/kg *	01.7, step 6
	343iii	Trimagnesium Phosphate											8,800 mg/kg *	01.7, step 6
	450i	Disodium Pyrophosphate											8,800 mg/kg *	01.7, step 6
	450iii	Tetrasodium Pyrophosphate											8,800 mg/kg *	01.7, step 6
	450v	Tetrapotassium Pyrophosphate											8,800 mg/kg *	01.7, step 6
	450vi	Dicalcium Pyrophosphate											8,800 mg/kg *	01.7, step 6
	451i	Pentasodium Triphosphate											8,800 mg/kg *	01.7, step 6
	451ii	Pentapotassium Triphosphate											8,800 mg/kg *	01.7, step 6
	452i	Sodium Polyphosphates, Glassy											8,800 mg/kg *	01.7, step 6
	452ii	Potassium Polyphosphate											8,800 mg/kg *	01.7, step 6
	452iv	Calcium Polyphosphate											8,800 mg/kg *	01.7, step 6
	452v	Ammonium Polyphosphate											8,800 mg/kg *	01.7, step 6
	542	Bone Polyphosphate											8,800 mg/kg *	01.7, step 6
Additive Class			**Permitted?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**	**Permitted ?**	**Max Level**	**Source**	**Permitted?**	**Max Level**	**Source**
Pack.Gases			**NO**	**N/A**	**N/A**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**	**YES**	**ADI**	**GSFA**
	290	Carbon Dioxide					GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6
	941	Nitrogen					GMP	01.2, step 6		GMP	01.2, step 6		GMP	01.2, step 6
	942	Nitrous Oxide					GMP	01.2.1.1, step 6		GMP	01.2.1.1, step 6		GMP	01.2.1.1, step 6
		* Measured as Phosphates	note-	at step 3 for 01.2, at	2,200 mg/kg and 01.7	at 10,500 mg/kg								

Appendix 10 – Standards for Dairy Spread

Codex Standard for Dairy Spread

FAO/WHO Dairy Spread

STANDARD FOR DAIRY FAT SPREADS

CODEX STAN 253-2006

1. SCOPE

This Standard applies to dairy fat spreads intended for use as spreads for direct consumption, or for further processing, in conformity with section 2 of this Standard.

2. DESCRIPTION

Dairy fat spreads are milk products relatively rich in fat in the form of a spreadable emulsion principally of the type of water-in-milk fat that remains in solid phase at a temperature of 20°C.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Raw materials

– Milk and/or products obtained from milk.

Raw materials, including milk fat, may have been subjected to any appropriate processing (e.g. physical modifications including fractionation) prior to its use.

3.2 Permitted ingredients

The following substances may be added:

– Flavours and flavourings;
– Safe and suitable processing aids;
– Where allowed in accordance with the *General Principles for the Addition of Essential Nutrients for Food* (CAC/GL 9-1987), maximum and minimum levels for vitamins A, D and other nutrients, where appropriate, should be laid down by national legislation in accordance with the needs of individual countries including, where appropriate, the prohibition of the use of particular nutrients;
– Sodium chloride and potassium chloride as a salt substitute;
– Sugars (any carbohydrate sweetening matter);
– Inulin and malto-dextrins (limited by GMP);
– Starter cultures of harmless lactic acid and/or flavour producing bacteria;
– Water;
– Gelatine and Starches (limited by GMP). These substances can be used in the same function as thickeners, provided they are added only in amounts functionally necessary as governed by GMP taking into account any use of the thickeners listed in section 4.

3.3 Composition

The milk fat content shall be no less than 10% and less than 80% (m/m) and shall represent at least 2/3 of the dry matter.

Compositional modifications of Dairy Fat Spreads are restricted by the requirements of section 4.3.3 of the *General Standard for the Use of Dairy Terms*.

4. FOOD ADDITIVES

Only those additive functional classes indicated as technologically justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below the table may be used and only within the functions and limits specified.

Adopted in 2006. Amendment 2008, 2010.

Additive functional class	Justified use in dairy fat spreads:	
	< 70% milk fat content[(a)]	≥ 70% milk fat content
Acidity regulators	X	X
Anticaking agents	–	–
Antifoaming agents	X	X
Antioxidants	X	X
Bleaching agents	–	–
Bulking agents	–	–
Carbonating agents	–	–
Colours	X	X
Colour retention agents	–	–
Emulsifiers	X	–
Firming agents	–	–
Flavour enhancers	X	–
Foaming agents	–	–
Gelling agents	–	–
Humectants	–	–
Preservatives	X	X
Propellants	X	X
Raising agents	–	–
Sequestrants	–	–
Stabilizers	X	–
Thickeners	X	–

[(a)] The application of GMP in the use of emulsifiers, stabilizers, thickeners and flavour enhancers includes consideration of the fact that the amount required to obtain the technological function in the product decreases with increasing fat content, fading out at fat content about 70%.

INS no.	Name of additive	Maximum level
Colours		
100(i)	Curcumin	5 mg/kg
160a(i)	Carotene, *beta*-, synthetic	35 mg/kg, singly or in combination
160a(ii)	Carotene, *beta*-, *Blakeslea trispora*	
160e	Carotenal, *beta*-apo-8'-	
160f	Carotenoic acid, ethyl ester *beta*-apo-8'-	
160b(i)	Annatto extracts – bixin based	20 mg/kg
Emulsifiers		
432	Polyoxyethylene (20) sorbitan monolaurate	10 000 mg/kg, singly or in combination (Dairy fat spreads for baking purposes only)
433	Polyoxyethylene (20) sorbitan monooleate	

INS no.	Name of additive	Maximum level
434	Polyoxyethylene (20) sorbitan monopalmitate	
435	Polyoxyethylene (20) sorbitan monostearate	
436	Polyoxyethylene (20) sorbitan tristearate	
471	Mono and diglycerides of fatty acids	Limited by GMP
472a	Acetic and fatty acid esters of glycerol	Limited by GMP
472b	Lactic and fatty acid esters of glycerol	Limited by GMP
472c	Citric and fatty acid esters of glycerol	Limited by GMP
472e	Diacetyltartaric and fatty acid esters of glycerol	10 000 mg/kg
473	Sucrose esters of fatty acids	10 000 mg/kg, dairy fat spreads for baking purposes only
474	Sucroglycerides	10 000 mg/kg, dairy fat spreads for baking purposes only
475	Polyglycerol esters of fatty acids	5 000 mg/kg
476	Polyglycerol esters of interesterified ricinoleic acid	4 000 mg/kg
481(i)	Sodium stearoyl lactylate	10 000 mg/kg, singly or in combination
482(i)	Calcium stearoy lactylate	
491	Sorbitan monostearate	10 000 mg/kg, singly or in combination
492	Sorbitan tristearate	
493	Sorbitan monolaurate	
494	Sorbitan monooleate	
495	Sorbitan monopalmitate	
Preservatives		
200	Sorbic acid	2 000 mg/kg, singly or in combination (as sorbic acid) for fat contents < 59% and 1 000 mg/kg singly or in combination (as sorbic acid) for fat contents ≥ 59%
201	Sodium sorbate	
202	Potassium sorbate	
203	Calcium sorbate	
Stabilizers/thickeners		
340(i)	Potassium dihydrogen phosphate	880 mg/kg, singly or in combination, as phosphorous
340(ii)	Dipotassium hydrogen phosphate	
340(iii)	Tripotassium phosphate	
341(i)	Calcium dihydrogen sphosphate	
341(ii)	Calcium hydrogen phosphate	
341(iii)	Tricalcium phosphate	
450(i)	Disodium diposphate	
400	Alginic acid	Limited by GMP
401	Sodium alginate	Limited by GMP
402	Potassium alginate	Limited by GMP
403	Ammonium alginate	Limited by GMP
404	Calcium alginate	Limited by GMP
406	Agar	Limited by GMP
405	Propylene glycol alginate	3 000 mg/kg
407	Carrageenan	Limited by GMP
407a	Processed euchema seaweed (PES)	Limited by GMP
410	Carob bean gum	Limited by GMP
412	Guar gum	Limited by GMP
413	Tragacanth gum	Limited by GMP
414	Gum arabic (acacia gum)	Limited by GMP

INS no.	Name of additive	Maximum level
415	Xanthan gum	Limited by GMP
418	Gellan gum	Limited by GMP
422	Glycerol	Limited by GMP
440	Pectins	Limited by GMP
460(i)	Microcrystalline cellulose (Cellulose gel)	Limited by GMP
460(ii)	Powdered cellulose	Limited by GMP
461	Methyl cellulose	Limited by GMP
463	Hydroxypropyl cellulose	Limited by GMP
464	Hydroxypropyl methyl cellulose	Limited by GMP
465	Methyl ethyl cellulose	Limited by GMP
466	Sodium carboxymethyl cellulose (Cellulose gum)	Limited by GMP
500(i)	Sodium carbonate	Limited by GMP
500(ii)	Sodium hydrogen carbonate	Limited by GMP
500(iii)	Sodium sesquicarbonate	Limited by GMP
1400	Dextrin, roasted starch	Limited by GMP
1401	Acid-treated starch	Limited by GMP
1402	Alkaline-treated starch	Limited by GMP
1403	Bleached starch	Limited by GMP
1404	Oxidized starch	Limited by GMP
1405	Starches, enzyme treated	Limited by GMP
1410	Monostarch phosphate	Limited by GMP
1412	Distarch phosphate	Limited by GMP
1413	Phosphated distarch phosphate	Limited by GMP
1414	Acetylated distarch phosphate	Limited by GMP
1420	Starch acetate esterified with acetic anhydride	Limited by GMP
1422	Acetylated distarch adipate	Limited by GMP
1440	Hydroxypropyl starch	Limited by GMP
1442	Hydroxypropyl distarch phosphate	Limited by GMP
Acidity regulators		
325	Sodium lactate	Limited by GMP
326	Potassium lactate	Limited by GMP
327	Calcium lactate	Limited by GMP
329	Magnesium lactate, DL-	Limited by GMP
331(i)	Sodium dihydrogen citrate	Limited by GMP
331(ii)	Disodium monohydrogen citrate	Limited by GMP
334	Tartaric acid, L(+)-	5 000 mg/kg, singly or in combination as tartaric acid
335 (i)	Sodium (L+)-tartrate	
335 (ii)	Disodium tartrate	
336 (i)	Monopotassium tartrate	
336 (ii)	Dipotassium tartrate	
337	Potassium sodium (L+)-tartrate	
339 (i)	Sodium dihydrogen phosphate	880 mg/kg, singly or in combination as phosphorous
339 (ii)	Sodium hydrogen phosphate	
339 (iii)	Trisodium phosphate	
338	Phosphoric acid	
524	Sodium hydroxide	Limited by GMP
526	Calcium hydroxide	Limited by GMP

INS no.	Name of additive	Maximum level
Antioxidants		
304	Ascorbyl palmitate	500 mg/kg, as ascorbyl stearate
305	Ascorbyl stearate	
307	Tocopherols	500 mg/kg
310	Propyl gallate	200 mg/kg, singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), and propyl gallate (INS 310) as a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.
320	Butylated hydroxyanisole	200 mg/kg, singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), and propyl gallate (INS 310) as a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.
321	Butylated hydroxytoluene	75 mg/kg, singly or in combination: butylated hydroxyanisole (INS 320), butylated hydroxytoluene (INS 321), and propyl gallate (INS 310) as a combined maximum level of 200 mg/kg on a fat or oil basis. May be used only in dairy fat spreads intended for cooking purposes.
Anti-foaming agents		
900a	Polydimethylsiloxane	10 mg/kg in dairy fat spreads for frying purposes, only
Flavour enhancers		
627	Disodium 5'-guanylate	Limited by GMP
628	Dipotassium 5'-guanylate	Limited by GMP

5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels for contaminants that are specified for the product in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

The milk used in the manufacture of the products covered by this Standard shall comply with the Maximum Levels for contaminants and toxins specified for milk by the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) and with the maximum residue limits for veterinary drug residues and pesticides established for milk by the CAC.

6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice. The products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the following specific provisions apply:

7.1 Name of the food

7.1.1 The name of the food shall be ”Dairy Fat Spread” Other names may be used if allowed by national legislation in the country of retail sale.

7.1.2 Dairy fat spreads with reduced fat content may be labelled as “reduced fat” in line with the *Guidelines for the Use of Nutrition and Health Claims* (CAC/GL 23-1997).

7.1.3 The designations and any qualifying terms should be translated into other languages in a non-misleading way and not necessarily word for word and should be acceptable in the country of retail sale.

7.1.4 Dairy fat spread may be labelled to indicate whether it is salted or unsalted according to national legislation.

7.1.5 Dairy fat spreads that have been sweetened shall be labelled to indicate that they have been sweetened.

7.2 Declaration of fat content

The milk fat content shall be declared in a manner found acceptable in the country of retail sale, either (i) as a percentage by mass, or (ii) in grams per serving as quantified in the label provided that the number of servings is stated.

7.3 Labelling of non-retail containers

Information required in Section 7 of this Standard and Sections 4.1 to 4.8 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer or packer shall appear on the container. However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable on the accompanying documents.

8. METHODS OF SAMPLING AND ANALYSIS

See CODEX STAN 234-1999.

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4(c)

CX/MMP 04/6/6
January 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON MILK AND MILK PRODUCTS

Sixth Session

Auckland, New Zealand, 26 – 30 April 2004

PROPOSED DRAFT REVISED STANDARD FOR DAIRY SPREADS

(Prepared by the European Commission with the assistance of France, Ireland, Germany, New Zealand, Switzerland, United Kingdom)

Governments and international organizations wishing to submit comments at Step 3 on the "Proposed draft Standard for Dairy Spreads" (see Annexe) are invited to do so **no later than 19 March 2004** to: Codex Committee on Milk and Milk Products, New Zealand Food Safety Authority, 68 - 86 Jervois Quay, P.O. Box 2835, Wellington, New Zealand (Facsimile: +64 4 463 2583 or E-mail: daniel.herd@nzfsa.govt.nz), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

At the 5th Session of the Codex Committee on Milk and Milk Products (Wellington, 8-12 April 2002) the Committee agreed to return the Proposed Draft Revised Standard for Diary Spreads back to Step 2 for revision by a drafting Group. Furthermore, it was agreed that the Group is led by the European Commission with the assistance of Argentina, France, Germany, Ireland, Italy, New Zealand, Switzerland and the United Kingdom (paragraph 99 in Alinorm 03/11).

A "revised" text of the Proposed Draft Standard for Dairy Spreads, which has been redrafted by the European Commission, was sent to the Drafting Group Members with a request for their observations. The European Commission received comments from France, Ireland, Germany, New Zealand, Switzerland and the United Kingdom. Ireland was in agreement with the proposed text.

Many comments received are now incorporated in the Proposed Draft Standard for Dairy Spreads. As there were diverging and/or opposite comments from different Drafting Group members, not all of them could be accommodated.

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PROPOSED DRAFT REVISED STANDARD FOR DAIRY SPREADS

(at Step 3)

1. SCOPE

This Standard applies to dairy spreads with a milk-fat content of less than 80% and not less than 10% intended for human consumption. This Standard shall apply to products which remain solid at a temperature of 20 °C, and which are suitable for use as spreads.

2. DESCRIPTION

Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived exclusively from milk and/or certain milk products, for which the milk-fat is the essential constituent of value. However, other substances necessary for their manufacture may be added, provided those substances are not used for the purpose of replacing, either in whole or in part, any milk constituents.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1. Raw materials

Milk and/or products obtained from milk

3.2 Permitted Ingredients

- Sodium chloride and food grade salt
- Starter cultures of harmless lactic acid and/or flavour producing bacteria
- Potable water
- [Vitamins, in accordance with the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987]*
- Gelatine and starches

  These substances can be used in the same function as stabilizers and thickeners, provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice taking into account any use of the stabilizers/thickeners listed in section 4
- Sugar
- Mono-, di-, oligo- and polysaccharides (including inulin) and malto-dextrins.

[*Where allowed in accordance with the General Principles, maximum and minimum levels for vitamins A, D and other vitamins, where appropriate, should be laid down by national legislation in accordance with the needs of each individual country including, where appropriate, the prohibition of the use of particular vitamins.]

3.3 Composition - The final draft shall include only one of these two options:

<u>First option</u>: (the option preferred by European Commission)

3.3.1 Three-quarter-fat butter

The product with a milk-fat content of not less than 60 % but not more than 62 %

Dairy Spreads

3.3.2 Half-fat butter

The product with a milk-fat content of not less than 39 % but not more than 41 %

3.3.3 Dairy spread X % milk-fat

The product with the following milk-fat contents:

- more than 10 % but less than 39 %,
- more than 41 % but less than 60 %,
- more than 62 % but less than 80 %

Second option: (a compromise option)

Dairy spreads X% milk-fat [1] **< 80%**

The milk-fat content must be at least two-thirds of the dry matter excluding salt.

4. FOOD ADDITIVES

Only those additive classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those individual additives listed may be used and only within the limits specified.

	Fat content		
Additive class:	**60% to less than 80%**	**39% to less than 60%**	**10% to less than 39%**
Colours	X	X	X
Acidity regulators	X	X	X
Emulsifiers	-	X	X
Preservatives	-	X	X
Thickeners and stabilizers	-	X	X
Antioxidants	-	X	X
Antioxidant synergists	-	X	X
Antifoaming agents	-	-	X
Flavour enhancers	-	-	X
Natural flavours	-	-	X
Miscellaneous	-	-	X

X = technologically justified function.

- = no technologically justified function

[1] The terms "three-quarter-fat butter" and "half-fat butter" may, in some cases, be used in the name of the food as provided for in section 7.1.

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Dairy Spreads

INS No.	Name of Food Additive	Maximum level
	Colours	
	For all products:	
160a(i)	160a(i) β-Carotene (synthetic)	25mg/kg
160a(ii)	Carotenes (natural extracts)	600 mg/kg
160b	Annatto extracts	10 mg/kg, expressed on bixin/norbixin basis
	Acidity Regulators	
	For all products	
339	Sodium orthophosphates	2 g/kg
500(i)	Sodium carbonate	Limited by GMP
500(ii)	Sodium hydrogen carbonate	
524	Sodium hydroxide	
526	Calcium hydroxide	
	Additionally, for products with less than 39% fat	
260	Acetic acid	Limited by GMP
261	Potassium acetate	
262 (i)	Sodium acetate	
263	Calcium acetate	
270	Lactic acid (L-, D- and DL-)	
325	Sodium lactate	
326	Potassium lactate	
327	Calcium lactate	
330	Citric acid	
331	Sodium citrates	
331 (i)	Sodium dihydrogen citrate	
331 (iii)	Trisodium citrate	
332	Potassium citrate	
333	Calcium citrate	
334	Tartaric acid	
335	Sodium tartrates	
335 (i)	Monosodium tartrate	
335 (ii)	Disodium tartrate	
336	Potassium tartrate	
337	Sodium potassium tartrate	
338	Orthophosphoric acid	5 g/kg
339	Sodium orthophosphates	
340	Potassium phosphates	
341	Calcium orthophosphate	
	Emulsifiers	
	For products with less than 60% fat	
322	Lecithins	Limited by GMP
	Polyoxyethylene (20) sorbitan:	10 g/kg singly or in combination for baking purposes only
432	Monolaurate	
433	Mono-oleate	
434	Monopalmitate	
435	Monostearate	
436	Tristearate	
452(i)	Sodium polyphosphate	5 g/kg
452(ii)	Potassium polyphosphate	
471	Mono- and di-glycerides of fatty acids	Limited by GMP
472(a)	Acetic and fatty acid esters of glycerol	

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Dairy Spreads

INS No.	Name of Food Additive	Maximum level
	Colours	
	For all products:	
160a(i)	160a(i) β-Carotene (synthetic)	25mg/kg
160a(ii)	Carotenes (natural extracts)	600 mg/kg
160b	Annatto extracts	10 mg/kg, expressed on bixin/norbixin basis
	Acidity Regulators	
	For all products	
339	Sodium orthophosphates	2 g/kg
500(i) 500(ii) 524 526	Sodium carbonate Sodium hydrogen carbonate Sodium hydroxide Calcium hydroxide	Limited by GMP
472(b) 472(c) 472(d) 472(e) 472(f)	Lactic and fatty acid esters of glycerol Citric and fatty acid esters of glycerol Tartaric acid esters of mono- and di-glycerides of fatty acids Diacetyltartaric and fatty acid esters of glycerol Mixed tartaric, acetic and fatty acid esters of glycerol	
473 474	Sucrose esters of fatty acids Sucroglycerides	10 g/kg for baking purposes only
475	Polyglycerol esters of fatty acids	5 g/kg
477	Propylene glycol esters of fatty acids	10 g/kg for baking purposes only
481 481 (i) 482 482 (i)	Sodium lactylates Sodium stearoyl lactylate Calcium lactylates Calcium stearoyl lactylate	10 g/kg singly or in combination
491 492 493 494 495	Sorbitan monostearate Sorbitan tristearate Sorbitan monolaurate Sorbitan monooleate Sorbitan monopalmitate	10 g/kg singly or in combination
	Additionally, for products with less than 39% fat	
476	Polyglycerol esters of interesterified riconoleic acid	4 g/kg
	Preservatives	
	For products with less than 60% fat	
200 202 203	Sorbic acid Potassium sorbate Calcium sorbate	2,000 mg/kg singly or in combination (as sorbic acid) for products with a fat content of less than 60%
	Thickeners and stabilizers	
	For products with less than 60% fat	
339	Sodium orthophosphates	5 g/kg
400 401 402 403 404 405	Alginic acid Sodium alginate Potassium alginate Ammonium alginate Calcium alginate Propylene glycol alginate	Limited by GMP

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Dairy Spreads

INS No.	Name of Food Additive	Maximum level
	Colours	
	For all products:	
160a(i)	160a(i) β-Carotene (synthetic)	25mg/kg
160a(ii)	Carotenes (natural extracts)	600 mg/kg
160b	Annatto extracts	10 mg/kg, expressed on bixin/norbixin basis
	Acidity Regulators	
	For all products	
339	Sodium orthophosphates	2 g/kg
500(i)	Sodium carbonate	Limited by GMP
500(ii)	Sodium hydrogen carbonate	
524	Sodium hydroxide	
526	Calcium hydroxide	
406	Agar	
407 (i)	Carrageenan and its Na, K, NH 4 salts (including furcellaran)	
410	Carob bean gum	
412	Guar Gum	
413	Tragacanth gum	
414	Gum arabic	
415	Xanthan gum	
418	Gellan gum	
422	Glycerol	
440	Pectins	
450 (i)	Disodium diphosphate	
460 (i)	Mycrocrystalline cellulose	
460 (ii)	Cellulose	
461	Methyl cellulose	
463	Hydroxypropyl cellulose	
464	Hydroxypropyl methyl cellulose	
465	Methyl ethyl cellulose	
466	Sodium carboxymethyl cellulose	
500 (i)	Sodium carbonates	
500(iii)	Sodium sesquicarbonate	
	Modified starches, as follows	
1400	Dextrine roasted starch	Limited by GMP
1401	Acid treated starch	
1402	Alkaline treated starch	
1403	Bleached starch	
1404	Oxidised starch	
1405	Enzyme treated starch	
1410	Monostarch phosphate	
1412	Distarch phosphate	
1413	Phosphated distarch phosphate	
1414	Acetylated distarch phosphate	
1420	Starch acetate ester. Acetic anhydride	
1422	Acetylated distarch adipate	
1440	Hydroxypropyl starch	
1442	Hydroxypropyl distarch phosphate Starch acetate Cellulose and microcrystalline cellulose	

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Dairy Spreads

INS No.	Name of Food Additive	Maximum level
	Colours	
	For all products:	
160a(i)	160a(i) β-Carotene (synthetic)	25mg/kg
160a(ii)	Carotenes (natural extracts)	600 mg/kg
160b	Annatto extracts	10 mg/kg, expressed on bixin/norbixin basis
	Acidity Regulators	
	For all products	
339	Sodium orthophosphates	2 g/kg
500(i) 500(ii) 524 526	Sodium carbonate Sodium hydrogen carbonate Sodium hydroxide Calcium hydroxide	Limited by GMP
	Antioxidants	
	For products with less than 60% fat	
300 301 302 304	Ascorbic acid (L-) Sodium ascorbate Calcium ascorbate Ascorbyl palmitate	Limited by GMP
305	Ascorbyl stearate	500 mg/kg
306 307	Mixed tocopherols concentrate Alpha-tocopherol	Limited by GMP
	Flavour enhancers	
	For products with less than 39% fat	
508 509 510 511	Potassium chloride Calcium chloride Ammonium chloride Magnesium chloride	Limited by GMP
620 621 622 623 624 625	Glutamic acid Monosodium glutamate Monopotassium glutamate Calcium diglutamate Monoammonium glutamate Magnesium diglutamate	10 g/kg singly or in combination (as glutamic acid)
626 627 628 629 630	Guanylic acid Sodium guanylate Potassium guanylate Calcium guanylate Inosinic acid	500 mg/kg singly or in combination (expressed as guanylic acid)
	Natural flavours	
	For products with less than 39% fat	
	Natural flavours and their identical synthetic equivalents and other synthetic flavours, except those which are known to present a toxic hazard	Limited by GMP
	Miscellaneous	
	For products with less than 39% fat	
420 421 953 965	Sorbitol and sorbitol syrup Mannitol Isomalt Maltitol	Limited by GMP

INS No.	Name of Food Additive	Maximum level
	Colours	
	For all products:	
160a(i)	160a(i) β-Carotene (synthetic)	25mg/kg
160a(ii)	Carotenes (natural extracts)	600 mg/kg
160b	Annatto extracts	10 mg/kg, expressed on bixin/norbixin basis
	Acidity Regulators	
	For all products	
339	Sodium orthophosphates	2 g/kg
500(i)	Sodium carbonate	Limited by GMP
500(ii)	Sodium hydrogen carbonate	
524	Sodium hydroxide	
526	Calcium hydroxide	
966	Lactitol	
967	Xylitol	
290	Carbon dioxide	Limited by GMP
941	Nitrogen	
942	Nitrous oxide	

5. CONTAMINANTS

5.1 Heavy Metals

The products covered by this Standard shall comply with the maximum limits established by the Codex Alimentarius Commission.

5.2 Pesticide Residues

The products covered by this Standard shall comply with the maximum residue limits established by the Codex Alimentarius Commission.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 - 1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

6.2 It is important that control measures or a combination of control measures are applied at both primary production and processing level to minimise or prevent the microbiological, chemical or physical contamination of milk. These should be selected and applied to achieve the appropriate level of public health protection.

6.3 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

7. LABELLING

In addition to provisions of the Codex General Standard for the Labelling of Pre-packaged Foods and the General Standard for the Use of Dairy Terms, the following information must be indicated in the labelling and presentation:

(a) the sales description as defined in section 3.3;

(b) the total percentage fat content by weight at the time of production;

7.1 Name of the food

7.1.1 The name of the food to be declared on the label shall be as specified in section 3.3

7.1.2 If in section 3.3 the option 2 is retained the draft should include the following paragraph:

Provided that the terms "three-quarter-fat butter" and "half-fat butter" are acceptable in the country of retail sale, these names may be used for the products with the following milk-fat contents:

- Three-quarter-fat butter for products with a milk-fat content of not less than 60 % but not more than 62 %

- Half-fat butter for products with a milk-fat content of not less than 39 % but not more than 41 %

7.1.3 In addition:

(a) the term 'reduced-fat' may be used for products referred to in section 3.3 with a milk-fat content of more than 41 % but not more than 62 %;

(b) the terms 'low-fat' or 'light' may be used for products referred to in section 3.3 with a milk-fat content of 41 % or less.

The term 'reduced-fat' and the terms 'low-fat' or 'light' may, however, replace respectively the terms 'three-quarter-fat' or 'half-fat'.

7.2 Declaration of milk fat content

7.2.1 The product shall be labelled to indicate average milk-fat content by mass in a manner found acceptable in the country of sale.

7.3 Labelling of Non-Retail Containers

Information on the above labelling requirements shall be given either on the container or in accompanying documents, except that the name of the food, lot identification and the name and address of the manufacturer or packer shall appear on the container.

However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly linked with the accompanying documents.

8. METHODS OF SAMPLING AND ANALYSIS

See Codex Alimentarius, Volume 13.

8.1 The measured fat content shall not deviate by more than two percentage points from the declared fat content.

Appendix 11 – Standards for Milk Products

Codex Standards for Milk Products

Codex Standard for Cream Cheese

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 (b) **CX/MMP 04/6/5**
January 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON MILK AND MILK PRODUCTS

Sixth Session

Auckland, New Zealand, 26 – 30 April 2004

PROPOSED DRAFT REVISED STANDARDS FOR INDIVIDUAL CHEESES

(at Step 3)

(Prepared by International Dairy Federation)

Governments and international organizations wishing to submit comments at Step 3on the Revised Proposed Draft Standards for Individual Cheeses are invited to do so **no later than 15 March 2004** to: Codex Committee on Milk and Milk Products, New Zealand Food Safety Authority, 68 - 86 Jervois Quay, P.O. Box 2835, Wellington, New Zealand (Facsimile: +64 4 463 2583 or E-mail: daniel.herd@nzfsa.govt.nz), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

INTRODUCTION

At the 5th Session of the CCMMP (April 2002) the Committee agreed that the IDF would revise the proposed standards for individual cheese varieties on the basis of the discussions that took place during the Session, written comments submitted and the "Guidance for Inclusion of Details in Codex Standards for Individual Cheese Varieties" for circulation at Step 3 and further consideration at the 6th Session of the CCMMP (ALINORM 03/11, para. 96). The "Guidance" was attached the ALINORM report as Appendix VII.

IDF's analysis of the discussions that took place during the 5th Session and the written comments submitted to the Session has been included as an attachment to this paper. The following principles have been applied:

1. The primary basis for the redrafting is the Proposed Draft Standards as tabled at the 5th Session of the Committee (CX/MMP 02/7 part 2)

2. All written comments submitted[1] and the outcome of the discussions that took place at the 5th Session[2], have been reviewed and discussed. Each written comment submitted has been examined individually. However:

[1] CX/MMP 02/7 add 1 and CRDs 3, 4, 5, 6, 7, 8, 9, 10, 14, 17 tabled at the 4th Session of the CCMMP.
[2] ALINORM 03/11, para's 85-96.

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- With regard to absolute minimum fat contents, only comments related to cream cheese have been reviewed, as the CCMMP has agreed on the values for the other varieties.

- Comments in support of the current draft wordings have not been repeated unless opposite views have been expressed in comments of others.

The conclusions have been incorporated into the revised drafts standards together with any consequential amendments necessary due to the conclusions drawn by the CCMMP on other matters. The recommendations from IDF that led to the amendments are included in attached report.

3. The general approach used has been that a Government comment has been accepted unless proper technological, scientific, editorial or similar arguments make it advisable not to follow it or to amend it, using the Guidance for Inclusion of Details in Codex Standards for Individual Cheese Varieties as attached to the ALINORM report as Appendix VII. However, if the CCMMP or another Codex body has already decided on the matter, these decisions have been followed. Also, where Governments have expressed different views, possible solutions are provided with the aim of facilitating a decision. They take into account technical justification and/or existing commercial trading practices.

Abbreviations used in this document:

GSUDT: General Standard for the Use of Dairy Terms (CODEX STAN 206-1999).

GSLPF: General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1-1991).

GSFA: Draft General Standard for Food Additives (currently being developed by the CCFAC)

GSUC: Group General Standard for Unripened Cheese Including Fresh Cheese (CODEX STAN 221-2001)

PROPOSED DRAFT REVISED STANDARDS FOR INDIVIDUAL CHEESES

CONTENTS:

PROPOSED DRAFT REVISED STANDARD FOR CREAM CHEESE (C-31)

(at Step 3)

1. SCOPE

This Standard applies to Cream Cheese intended for direct consumption or for further processing in conformity with the description in Section 2 of this Standard.

In some countries, the term "cream cheese" is used to designate cheeses, such as high fat ripened hard cheese, that do not conform to the description I Section 2. This Standard does not apply to such cheeses.

2. DESCRIPTION

Cream Cheese is a soft, spreadable, unripened and rindless 1 cheese in conformity with the Standard for Unripened Cheeses Including Fresh Cheeses (CODEX STAN XXX-2001) and the General Standard for Cheese (CODEX STAN A-6 – 1978, Rev. 2-2001). The cheese has a near white through to light yellow colour. The texture is spreadable and smooth to slightly flaky and without holes, and the cheese spreads and mixes readily with other foods.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 RAW MATERIALS

Milk and/or products obtained from milk.

3.2 PERMITTED INGREDIENTS

- Starter cultures of harmless lactic acid and/ or flavour producing bacteria and cultures of other harmless micro-organisms;
- Rennet or other safe and suitable coagulating enzymes;
- Sodium chloride;
- Potable water;
- Gelatine and starches: These substances can be used in the same function as stabilizers, provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice taking into account any use of the stabilizers/thickeners listed in section 4;
- Vinegar.

3.3 COMPOSITION

Milk constituent:	Minimum content (m/m):	Maximum content (m/m):	Reference level (m/m):
Milk fat in dry matter:	25 %	Not restricted	60-70 %
Moisture on fat free basis:	67 %	-	Not specified
Dry matter:	22%	Restricted by the MMFB	Not specified

1 The cheese has been kept in such a way that no rind is developed (a "rindless" cheese)

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Cream Cheese

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Compositional modifications of Cream Cheese beyond the minima and maxima specified above for milkfat, moisture and dry matter are not considered to be in compliance with section 4.3.3 of the General Standard for the Use of Dairy Terms (CODEX STAN 206-1999).

4. FOOD ADDITIVES

Only those additives classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

	Justified use:	
Additive functional class:	**Cheese mass**	**Surface/rind treatment**
Colours:	X[1]	-
Bleaching agents:	-	-
Acids:	X	-
Acidity regulators:	X	-
Stabilizers:	X[2]	-
Thickeners:	X[2]	-
Emulsifiers:	X	-
Antioxidants:	X	-
Preservatives:	X	-
Salt substitutes:	X	-
Foaming agents:	X[3]	-
Anti-caking agents:	-	-

[1]) Only to obtain the colour characteristics, as described in Section 2
[2]) Stabilizers and thickeners including modified starches may be used in compliance with the definition of milk products and only to heat treated products to the extent they are functionally necessary, taking into account any use of gelatine and starches as provided for in section 3.2.
[3]) For whipped products, only
X = The use of additives belonging to the class is technologically justified
- = The use of additives belonging to the class is not technologically justified

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Cream Cheese

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No.	*Name of food additive*	*Maximum level*
	Colours	
160a(i)	Carotenes (synthetic)	25 mg/kg
160a(ii)	Carotenes (vegetable)	600 mg/kg
160b	Annatto extracts	10 mg/kg of cheese on bixin/norbixin basis
160e	β-apo-8`-carotenal	35 mg/kg
160f	β-apo-8`-carotenic acid, methyl and ethyl ester	35 mg/kg
171	Titanium dioxide	Limited by GMP
	Acids	
260	Acetic acid glacial	)
270	Lactic acid (L-, D- and DL-)	)
296	Malic acid (DL-)	) Limited by GMP
330	Citric acid	)
507	Hydrochloric acid	)
574	Gluconic acid	)
	Acidity regulators	
170	Calcium carbonates	)
261	Potassium acetates	)
262	Sodium acetates	)
263	Calcium acetates	)
325	Sodium lactate	)
326	Potassium lactate	)
327	Calcium lactate	) Limited by GMP
350	Sodium malates	)
351	Potassium malates	)
352	Calcium malates	)
500	Sodium carbonates	)
501	Potassium carbonates	)
575	Glucono-delta-lactone (GDL)	)
577	Potassium gluconate	)
578	Calcium gluconate	)
	Stabilizers/thickeners	
331	Sodium citrates	)
332	Potassium citrates	) Limited by GMP
333	Calcium citrates	)
339	Sodium phosphates	)
340	Potassium phosphates	) 10000 mg/kg, singly or in
		) combination
341	Calcium phosphates	)
450i	Disodium diphosphate	)
452	Polyphosphates	)
400	Alginic acid	)
401	Sodium alginate	)
402	Potassium alginate	) Limited by GMP
403	Ammonium alginate	)
404	Calcium alginate	)
405	Propylene glycol alginate	5 g/kg, singly or in combination

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CX/MMP 04/6/5
Cream Cheese

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No.	*Name of food additive*		*Maximum level*
406	Agar	)	
407	Carrageenan or its Na, K, NH_4 salts (includes furcelleran)	)	
410	Carob bean gum	)	
412	Guar gum	)	
413	Tragacanth gum	)	Limited by GMP
415	Xanthan gum	)	
416	Karaya gum	)	
417	Tara gum	)	
418	Gellan gum	)	
466	Sodium carboxymethyl cellulose	)	
576	Sodium gluconate	)	
	Modified starches as follows:		
1400	Dextrins, roasted starch white and yellow	)	
1401	Acid-treated starch	)	
1402	Alkaline treated starch	)	
1403	Bleached starched	)	
1404	Oxidized starch	)	
1405	Starches, enzyme-treated	)	
1410	Monostarch phosphate	)	
1412	Distarch phosphate esterified with sodium trimetasphosphate; esterified with phosphorus-oxychloride	)	Limited by GMP
1413	Phosphated distarch phosphate	)	
1414	Acetylated distarch phosphate	)	
1420	Starch acetate esterified with acetic anhydride	)	
1421	Starch acetate esterified with vinyl acetate	)	
1422	Acetylated distarch adipate	)	
1440	Hydroxypropyl starch	)	
1442	Hydroxypropyl distarch phosphate	)	
	Emulsifiers:		
322	Lecithins	)	
470	Salts of fatty acids (with base AL, Ca, Na, Mg, K and NH_4)	)	
471	Mono- and di-glycerides of fatty acids	)	
472a	Acetic and fatty acid esters of glycerol	)	Limited by GMP
472b	Lactic and fatty acid esters of glycerol	)	
472c	Citric and fatty acid esters of glycerol	)	
472f	Mixed tartaric, acetic and fatty acid esters of glycerol	)	
	Antioxidants:		
300	Ascorbic acid (L-)	)	
301	Sodium ascorbate	)	Limited by GMP
302	Calcium ascorbate	)	
304	Ascorbyl palmitate	)	0.5 g/kg
305	Ascorbyl stearate	)	
306	Mixed tocopherols concentrate		Limited by GMP
307	Alpha-tocopherol		0.2 g/kg

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CODEX STANDARD FOR CREAM CHEESE

CODEX STAN 275-1973

1. SCOPE

This Standard applies to Cream Cheese intended for direct consumption or for further processing in conformity with the description in Section 2 of this Standard.

In some countries, the term "cream cheese" is used to designate cheeses, such as high fat ripened hard cheese, that do not conform to the description in Section 2. This Standard does not apply to such cheeses.

2. DESCRIPTION

Cream Cheese is a soft, spreadable, unripened and rindless[1] cheese in conformity with the *Standard for Unripened Cheeses Including Fresh Cheeses* (CODEX STAN 221-2001) and the *General Standard for Cheese* (CODEX STAN 283-1978). The cheese has a near white through to light yellow colour. The texture is spreadable and smooth to slightly flaky and without holes, and the cheese spreads and mixes readily with other foods.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Raw materials

Milk and/or products obtained from milk.

3.2 Permitted ingredients

- Starter cultures of harmless lactic acid and/ or flavour producing bacteria and cultures of other harmless micro-organisms
- Rennet or other safe and suitable coagulating enzymes
- Sodium chloride and potassium chloride as a salt substitute
- Potable water
- Safe and suitable processing aids
- Gelatine and starches: These substances can be used in the same function as stabilizers, provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice taking into account any use of the stabilizers/thickeners listed in section 4
- Vinegar.

[1] The cheese has been kept in such a way that no rind is developed (a "rindless" cheese).

Formerly CODEX STAN C-31-1973. Adopted in 1973. Revision 2007. Amendment 2008, 2010.

3.3 Composition

Milk constituent	Minimum content *(m/m)*	Maximum content *(m/m)*	Reference level *(m/m)*
Milk fat in dry matter:	25%	Not restricted	60–70%
Moisture on fat free basis:	67%	–	Not specified
Dry matter:	22%	Restricted by the MFFB	Not specified

Compositional modifications of Cream Cheese beyond the minima and maxima specified *above for milkfat, moisture and dry matter are not considered to be in compliance with section 4.3.3 of the General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999).

4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

Additive functional class	Justified use	
	Cheese mass	Surface/rind treatment
Colours:	X[(a)]	–
Bleaching agents:	–	–
Acidity regulators:	X	–
Stabilizers:	X[(b)]	–
Thickeners:	X[(b)]	–
Emulsifiers:	X	–
Antioxidants:	X	–
Preservatives:	X[(b)]	–
Foaming agents:	X[(c)]	–
Anticaking agents:	–	–

(a) Only to obtain the colour characteristics, as described in Section 2.
(b) Stabilizers and thickeners including modified starches may be used in compliance with the definition of milk products and only to heat treated products to the extent they are functionally necessary, taking into account any use of gelatine and starches as provided for in section 3.2.
(c) For whipped products, only.
X The use of additives belonging to the class is technologically justified.
– The use of additives belonging to the class is not technologically justified.

INS no.	Name of additive	Maximum level
Preservatives		
200	Sorbic acid	1 000 mg/kg singly or in combination as sorbic acid
201	Sodium sorbate	
202	Potassium sorbate	
203	Calcium sorbate	
234	Nisin	12.5 mg/kg
280	Propionic acid	Limited by GMP
281	Sodium propionate	
282	Calcium propionate	
283	Potassium propionate	
Acidity regulators		
170(i)	Calcium carbonate	Limited by GMP
260	Acetic acid, glacial	Limited by GMP
261(i)	Potassium acetate	Limited by GMP
261(ii)	Potassium diacetate	Limited by GMP
262(i)	Sodium acetate	Limited by GMP
263	Calcium acetate	Limited by GMP
270	Lactic acid, L-, D- and DL-	Limited by GMP
296	Malic acid, DL-	Limited by GMP
325	Sodium lactate	Limited by GMP
326	Potassium lactate	Limited by GMP
327	Calcium lactate	Limited by GMP
330	Citric acid	Limited by GMP
331(i)	Sodium dihydrogen citrate	Limited by GMP
332(i)	Potassium dihydrogen citrate	Limited by GMP
333	Calcium citrates	Limited by GMP
334	Tartaric acid L(+)-	1 500 mg/kg singly or in combination as tartaric acid
335(i)	Monosodium tartrate	
335(ii)	Sodium L(+)-tartrate	
336(i)	Monopotassium tartrate	
336(ii)	Dipotassium tartrate	
337	Potassium sodium L(+)-tartrate	
338	Phosphoric acid	880 mg/kg as phosporous
350(i)	Sodium hydrogen DL-malate	Limited by GMP
350(ii)	Sodium DL-malate	Limited by GMP
351(i)	Potassium hydrogen malate	Limited by GMP
351(ii)	Potassium malate	Limited by GMP
352(ii)	Calcium malate, D, L-	Limited by GMP
500(i)	Sodium carbonate	Limited by GMP
500(ii)	Sodium hydrogen carbonate	Limited by GMP
500(iii)	Sodium sesquicarbonate	Limited by GMP
501(i)	Potassium carbonate	Limited by GMP
501(ii)	Potassium hydrogen carbonate	Limited by GMP
504(i)	Magnesium carbonate	Limited by GMP
504(ii)	Magnesium hydrogen carbonate	Limited by GMP

INS no.	Name of additive	Maximum level
507	Hidrochloric acid	Limited by GMP
575	Glucono-delta-lactone	Limited by GMP
577	Potassium gluconate	Limited by GMP
578	Calcium gluconate	Limited by GMP
Stabilizers		
339(i)	Sodium dihydrogen phosphate	4 400 mg/kg singly or in combination, expressed as phosphorus
339(ii)	Disodium hydrogen phosphate	
339(iii)	Trisodium phosphate	
340(i)	Potassium dihydrogen phosphate	
340(ii)	Dipotassium hydrogen phosphate	
340(iii)	Tripotassium phosphate	
341(i)	Calcium dihydrogen phosphate	
341(ii)	Calcium hydrogen phosphate	
341(iii)	Tricalcium phosphate	
342(i)	Ammonium dihydrogen phosphate	
342(ii)	Diammonium hydrogen phosphate	
343(ii)	Magnesium hydrogen phosphate	
343(iii)	Trimagnesium phosphate	
450(i)	Disodium diphosphate	
450(iii)	Tetrasodium diphosphate	
450(v)	Tetrapotassium diphosphate	
450(vi)	Dicalcium diphosphate	
451(i)	Pentasodium triphosphate	
451(ii)	Pentapotassium triphosphate	
452(i)	Sodium polyphosphate	
452(ii)	Potassium polyphosphate	
452(iv)	Calcium polyphosphate	
452(v)	Ammonium polyphosphate	
400	Alginic acid	Limited by GMP
401	Sodium alginate	Limited by GMP
402	Potassium alginate	Limited by GMP
403	Ammonium alginate	Limited by GMP
404	Calcium alginate	Limited by GMP
405	Propylene glycol alginate	5 000 mg/kg
406	Agar	Limited by GMP
407	Carrageenan	Limited by GMP
407a	Processed euchema seaweed (PES)	Limited by GMP
410	Carob bean gum	Limited by GMP
412	Guar gum	Limited by GMP
413	Tragacanth gum	Limited by GMP
415	Xanthan gum	Limited by GMP
416	Karaya gum	Limited by GMP
417	Tara gum	Limited by GMP
418	Gellan gum	Limited by GMP
466	Sodium carboxymethyl cellulose (Cellulose gum)	Limited by GMP

INS no.	Name of additive	Maximum level
1400	Dextrins, roasted starch	Limited by GMP
1401	Acid-treated starch	Limited by GMP
1402	Alkaline treated starch	Limited by GMP
1403	Bleached starch	Limited by GMP
1404	Oxidized starch	Limited by GMP
1405	Starches, enzyme-treated	Limited by GMP
1410	Monostarch phosphate	Limited by GMP
1412	Distarch phosphate	Limited by GMP
1413	Phosphated distarch phosphate	Limited by GMP
1414	Acetylated distarch phosphate	Limited by GMP
1420	Starch Acetate	Limited by GMP
1422	Acetylated distarch adipate	Limited by GMP
1440	Hydroxypropyl starch	Limited by GMP
1442	Hydroxypropyl distarch phosphate	Limited by GMP
Emulsifiers		
322	Lecithins	Limited by GMP
470(i)	Salt of myristic, palmitic and stearic acids wit ammonia, calcium, potassium and sodium	Limited by GMP
470(ii)	Salt of oleic acid with calcium, potassium and sodium	Limited by GMP
471	Mono- and di-glycerides of fatty acids	Limited by GMP
472a	Acetic and fatty acid esters of glycerol	Limited by GMP
472b	Lactic and fatty acid esters of glycerol	Limited by GMP
472c	Citric and fatty acid esters of glycerol	Limited by GMP
472e	Diacetyltartaric and fatty acid esters of glycerol	10 000 mg/kg
Antioxidants		
300	Ascorbic acid, L-	Limited by GMP
301	Sodium ascorbate	Limited by GMP
302	Calcium ascorbate	Limited by GMP
304	Ascorbyl palmitate	500 mg/kg singly or in combination as ascorbyl stearate
305	Ascorbyl stearate	
307b	Tocopherol concentrate, mixed	200 mg/kg singly or in combination
307c	Tocopherol, dl-*alpha*-	
Colours		
160a(i)	Carotene, *beta*-, synthetic	35 mg/kg singly or in combination
160a(iii)	Carotene, *beta*-, *Blakeslea trispora*	
160e	Carotenal, *beta*-apo-8'-	
160f	Carotenoic acid, ethyl ester, *beta*-apo-8'-	
160a(ii)	Carotenes, *beta*-, vegetable	600 mg/kg
160b(ii)	Annatto extracts – norbixin-based	25 mg/kg
171	Titanium dioxide	Limited by GMP
Foaming agent		
290	Carbon dioxide	Limited by GMP
941	Nitrogen	Limited by GMP

5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels for contaminants that are specified for the product in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995).

The milk used in the manufacture of the products covered by this Standard shall comply with the Maximum Levels for contaminants and toxins specified for milk by the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) and with the maximum residue limits for veterinary drug residues and pesticides established for milk by the CAC.

6. HYGIENE

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice. The products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the following specific provisions apply:

7.1 Name of the food

The name Cream Cheese may be applied in accordance with section 4.1 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), provided that the product is in conformity with this Standard. Where customary in the country of retail sale, alternative spelling may be used. The name may be translated into other languages so that the consumer in the country of retail sale will not be mislead.

The use of the name is an option that may be chosen only if the cheese complies with this standard. Where the name is not used for a cheese that complies with this standard, the naming provisions of the *General Standard for Cheese* (CODEX STAN 283-1978) apply.

The designation of products in which the fat content is below or above the reference range but equal to or above 40% fat in dry matter as specified in section 3.3 of this Standard shall be accompanied by an appropriate qualification describing the modification made or the fat content (expressed as fat in dry matter or as percentage by mass whichever is acceptable in the country of retail sale), either as part of the name or in a prominent position in the same field of vision. The designation of products in which the fat content is below 40% fat in dry matter but above the absolute minimum specified in section 3.3 of this Standard shall *either* be accompanied by an appropriate

qualifier describing the modification made or the fat content (expressed as fat in dry matter or as percentage by mass), either as part of the name or in a prominent position in the same field of vision, *or alternatively* the name specified in the national legislation of the country in which the product is manufactured and/or sold or with a name existing by common usage, in either case provided that the designation used does not create an erroneous impression the retail sale regarding the character and identity of the cheese.

Suitable qualifiers are the appropriate characterizing terms specified in Section 7.3 of the *General Standard for Cheese* (CODEX STAN 283-1978) or a nutritional claim in accordance with the *Guidelines for the Use of Nutritional Claims* (CAC/GL 23-1997)[2].

7.2 Country of origin

The country of origin (which means the country of manufacture, not the country in which the name originated) shall be declared. When the product undergoes substantial transformation[3] in a second country, the country in which the transformation is performed shall be considered to be the country of origin for the purpose of labelling.

7.3 Declaration of milkfat content

The milk fat content shall be declared in a manner found acceptable in the country of retail sale , either (i) as a percentage by mass, (ii) as a percentage of fat in dry matter, or (iii) in grams per serving as quantified in the label, provided that the number of servings is stated.

7.4 Labelling of non-retail containers

Information specified in Section 7 of this Standard and Sections 4.1 to 4.8 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name of the manufacturer or packer shall appear on the container, and in the absence of such a container, on the product itself. However, lot identification and the name and address may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents.

8. METHODS OF SAMPLING AND ANALYSIS

See CODEX STAN 234-1999.

[2] For the purpose of comparative nutritional claims, the minimum fat content of 60 % fat in dry matter constitutes the reference.
[3] For instance, repackaging, cutting, slicing, shredding and grating is not regarded as substantial transformation.

Appendix 12 – Product Labeling Information

PRODUCT DATA SHEET

CPKelco
A HUBER COMPANY

KELCOGEL® GELLAN GUM

Document No.: 300-X
Effective Date: 19 Apr 2017

Description

KELCOGEL® gellan gum is a multifunctional gelling agent for use in foods and personal care applications. **KELCOGEL** gellan gum is ideal for a variety of gelling, texturizing, stabilizing and film forming applications.

Features

- excellent stability
- high gel strength
- heat stable
- sparkling clarity
- outstanding flavor release
- easily combined with other hydrocolloids
- fluid gel suspension
- high compatibility with protein

Typical Applications

- aspics
- bakery fillings
- beverages / fluid gels
- confections
- dairy products
- dessert gels
- non-standard jams and jellies
- personal care
- fruit preparations

Typical Use Level

KELCOGEL gellan gum forms gels at extremely low gum use levels - as low as 0.05%. Gel strength can be increased by manipulating both gum and ion concentration.

Dispersion/Hydration

Model gels are produced by adding **KELCOGEL** gellan gum to tap water under shear, heating to 90°C, adding ions and cooling to set. Both monovalent and divalent ions can be used: K+, Na+, Ca++ and Mg++. Sequestrants such as sodium citrate or phosphates may be required for hydration in hard water.

Standard Packaging

Packed in 25-kg Leverpak drums (or their equivalent) with polyethylene liners (21 CFR §177.1520). All packaging materials comply with relevant UK, EU, and United States food contact legislation.

Ingredient/Labeling

KELCOGEL gellan gum
Food grade gellan gum, CAS: 71010-52-1; E418
For use as a stabilizer and thickener
Kosher approved; Halal approved

Regulatory Information

Gellan gum complies with requirements contained in the following regulations and standards: *Food Chemicals Codex,* 21 CFR § 172.665 (USA), *Canadian Food and Drug Law* (Item G.2, Table IV), JECFA, the purity criteria in the current EC Directive, 1829/2003/EC, and *Japan's Specifications and Standards for Food Additives*

Storage Conditions/ Shelf Life

Store in a roofed and well-ventilated area in the unopened original package. Functional properties of the product are guaranteed to conform with the stated sales specifications for **730 days** from the date of manufacture when stored under these conditions. Product quality should be re-evaluated prior to use if this "Best Before" date has been exceeded.

Quality System

Manufactured according to a Quality System registered to ISO 9001.

KELCOGEL® GELLAN GUM

Document No.: 300-X
Effective Date: 19 Apr 2017

Specifications

Testing to the following specifications is conducted on every product lot.

Property	Requirement	Test Method
Particle Size	Tyler Standard Screen Scale, Ro-Tap	KTM146
- 28 mesh (600 µm)	Not less than 99% through	
- 42 mesh (355 µm)	Not less than 98% through	
Loss on Drying	Not more than 14%	KTM003
Powder Color	Not less than 72	KTM006
Appearance	White to tan, uniform in appearance	
Solution pH		KTM005
- 1% gum in DI water	4.5 – 6.5	
Transmittance		KTM087
- 0.5% gum in 6 mM $CaCl_2$	Not less than 74%	
Isopropyl Alcohol	Not more than 750 mg/kg (ppm)	KTM520
Bacteria*	Not more than 10,000 cfu/g	KTM800
Fungal (Yeast & Mold) Count	Not more than 400 cfu/g	KTM803
Coliform	Negative by Most Probable Number (MPN)	KTM801
Escherichia coli	Absent in 25 g	KTM802
Salmonella spp.	Absent in 25 g	KTM804

* Total viable mesophilic aerobic count, 48 hr incubation

Specifications – Guaranteed to Comply

Testing to the following specifications is conducted on a skip-lot basis and may not be reported on the Certificate of Analysis. Product is guaranteed by CP Kelco to comply with compendial requirements applicable for each property.

Property	Requirement	Test Method
Identification	Pass	KTM519
Total Nitrogen	Not more than 3.0%	KTM516
Assay	3.3 – 6.8% CO_2	KTM503
Ash	4.0 – 14.0%	KTM255
Heavy Metals	Not more than 20.0 mg/kg (ppm)	KTM514
Lead	Not more than 2.0 mg/kg (ppm)	KTM514
Arsenic	Not more than 2.0 mg/kg (ppm)	KTM514
Mercury	Not more than 1.0 mg/kg (ppm)	KTM514
Cadmium	Not more than 1.0 mg/kg (ppm)	KTM514
Staphylococcus aureus	Absent in 1.0 g	KTM806
Pseudomonas aeruginosa	Absent in 1.0 g	KTM807

KELCOGEL® GELLAN GUM

Document No.: 300-X
Effective Date: 19 Apr 2017

METHODS OF TESTING (For test methods not listed, follow the applicable compendium. Full details of test methods are available upon request)

Particle Size (KTM146)
Shake 50 g product on 28 and 42 mesh (600 and 355 μm) Tyler Standard Screens for 20 minutes using a Ro-Tap sieve shaker.

Loss on Drying (KTM003)
Spread 3-5 g product evenly on a tared weighing pan and weigh accurately. Dry in an oven at 105°C for 2½ hours. Cool in a desiccator and reweigh.

Powder Color (KTM006)
Test method is available upon request.

Solution pH (KTM005)
Slowly add 3 g product to 297 mL deionized water in a 400-mL beaker while stirring at 800 rpm using a low-pitched, propeller-type stirrer. After stirring for 30 min, measure the pH of this solution using a pH meter.

Transmittance (KTM087)
Slowly add 1.50 g product to 250 g deionized water in a tared hot cup while stirring at 800 ± 20 rpm. Add 48 ± 1 mL deionized water and mix for at least 1 minute. Heat to 90°C and hold at this temperature for 1 minute with continued stirring. Pipet 3.0 mL of a 0.6 M calcium chloride solution (prepared by dissolving 88.21 g $CaCl_2 \cdot 2H_2O$ to a total of 1 L in deionized water) into the heated solution and continue mixing for 1 minute. Using deionized water at 80°C, adjust the weight of the solution to 301 g and mix for 30 seconds. Measure the transmittance of this solution using a Bausch and Lomb Spectronic 215, or other suitable spectrometer, at 490 nm. Use deionized water as the 100% transmittance standard. **Note:** After adding the solution to the cuvette, allow to cool to room temperature (approximately 1 hour) before measuring the transmittance.

NOTE: CP Kelco reserves the right to use company test methodology.

www.cpkelco.com

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CPKelco
A HUBER COMPANY

10040280
AH 7/13/17

ATLANTA, GA 30339

KELCOGEL®

Food Grade Gellan Gum, CAS: 71010-52-1; E418

example only

For use as a stabilizer and thickener

D.O.T Hazard Classification: Non-hazardous material
OSHA Hazard: Warning: Combustible dust. Ensure appropriate electrical classification and avoidance of ignition sources in dusty environments. Handle in a manner consistent with good industrial hygiene practices. avoid creating or inhaling aerosols of this or any other material. Refer to the Safety Data Sheets for this product.

Keep in a cool, dry place. Made in USA

Lot No. 7G0000K

Manufacturing Date: 10 Jul 2017
Shelf Life/Best Before Date: 09 Jul 2019

Net Wt. 25 kg
(55.1 lb)

07/10/2017

7G0000K

Registered trademark of CP Kelco US, Inc.

Appendix 13 – Safety Studies

Abstract of Summaries of
Safety Studies on Gellan Gum

1. Acute Studies

Ten rats (five/sex) were dosed at 5,000 mg/kg with gellan gum in a corn oil suspension. Two females died at day 2 and day 4, respectively. The oral LD_{50} was greater than 5000 mg/kg. Another 10 rats were exposed to a nominal dust concentration of 6.09 mg/L of air for four hours (mean gravimetric concentration was 0.033 mg/L). No deaths occurred, so the LC_{50} is greater than the exposure values. The product was tested in rabbits' eyes by the method of Draize. The mean score at 24 hours was 2.0, by day 4 it was 0.0, meaning that gellan gum is not an eye irritant. Similarly, it was found to be non-irritating to the skin of rabbits.

2. A 13-week (90 day) Dietary Study in the Rat.

Groups of 20 male and 20 female rats were treated at 0, 3.0, 4.5, and 6.0% of the diet for 13 weeks. Achieved intake ranged from 1.44 g/kg/day (final week, low dose males) to 7.26 g/kg/day (first week, high dose females). There were no deaths or treatment related clinical signs, changes in body weight or food consumption. There were no adverse changes in hematological, blood biochemical or urinalysis parameters. No group differences were seen at necropsy or after histopathological examination.

3. A Two-Generation Reproduction Study in the Rat

Groups of 26 male and 26 female rats, forming the F_0 generation were treated with dietary concentrations of 0, 2.5, 3.8, and 5.0% gellan gum. Males were treated for at least 70 days prior to mating; females for at least 14 days prior to mating. Treatment continued throughout the mating, gestation, and lactation periods. The F_1 generation animals (26/sex/group) were treated for 80 days at the same dose levels as their parents, and mated as above. The F_2 generation pups were killed following weaning. No animals died during the study. There were no adverse findings in relation to clinical signs, body weights, food consumption, gross pathology, estrous cycles of females, mating and fertility indices, conception rate, maternal performance, and viability, survival, and lactation indices of pups in all generations.

4. A Teratology Study (dietary) in the Rat

Groups of 25 mated rats were treated with dietary concentrations of 0, 2.5, 3.8, and 5.0% gellan gum from day 6 to day 15 of gestation. They were sacrificed on day 20. There were no deaths or effects on clinical signs, necropsy findings, body weights, or food consumption. There were also no effects on uterine

parameters, major fetal malformations, and minor external and visceral anomalies. While there was an increased incidence of reduced ossification in the ribs in the 2.5% group, and increased numbers of fetuses with reduced ossification of the parietal bones in the 3.8% group, these parameters were not effected in the 5% group. The 3.8% group also had a significant increase in the percentage of fetuses with common skeletal variants effecting sternebrae 1 to 4.

5. Developmental Toxicity (Embryo-Fetal Toxicity and Teratogenic Potential) Study of Gellan Gum Administered Orally to New Zealand White Rabbits

Gellan gum was provided orally to artificially-inseminated rabbits (18 per dose group) on days 6-18 of gestation at concentrations of 0, 2.5%, 3.8%, and 5.0% of the diet. Middle and high dosed animals had statistically significant decreases in average body weight gains and feed consumption; however, none of the dosed groups exhibited a significant effect on the average numbers of corpora lutea, implantations, or resorptions, as compared to the control group values. Similarly, the average of fetal body weights and sex ratios were not significantly different among the four groups. Gross external, soft tissue, and skeletal examinations of the fetuses did not reveal any malformations or variations that were considered effects of the test article.

The maternal non-observable effect level (NOEL) for gellan gum administered via the diet was greater than 2.5% based on inhibitory effects on food consumption and weight gain. The developmental NOEL was greater than 5.0%; consequently, this article is not considered to be a developmental toxicant in pregnant rabbits because it did not produce adverse effects on embryo-fetal viability, growth, or morphology when administered at the highest concentration that could be tested.

6. A 52-Week Dietary Study in the Beagle Dog

Groups of 5 male and 5 female dogs were treated with dietary concentrations of 3, 4.5, and 6% gellan gum for 52 weeks. Achieved intakes were approximately 1.0, 1.5, and 2.0 g/kg/day. There were no deaths, and no treatment-related effects on clinical signs, body weights, ophthalmoscopy, hematology, and clinical biochemistry, or gross pathological or histopathological findings. The food intake of all groups receiving gellan gum was frequently higher than the controls.

Safety Studies, Gellan Gum
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7. A 28-Day Study in Rhesus Monkeys

Groups of 2 male and 2 female monkeys were treated by gavage with 0, 1, 2, and 3 g/kg/day, for 28 days. One animal died due to perforation of the esophagus with the gavage tube. No other deaths occurred, and there was no treatment-related effect on clinical signs, body weight, ophthalmoscopy, hematology, or biochemistry. The surviving animals were not sacrificed.

8. In Vitro Genotoxicity Evaluation

i) Microbial Mutagenicity (Ames) Test

Gellan gum was tested at 10, 30, 100, 300, and 1000 micrograms/plate, with and without S-9 activation, using mutant strains of S. typhimurium. It was not detectably mutagenic.

ii) Unscheduled DNA Synthesis in Rat Hepatocytes

Hepatocytes were isolated from a male rat by collagenase perfusion. Cultures in Leibovitz L-15 medium containing 5×10^5 viable hepatocytes were exposed to gellan gum concentrations of 5, 10, and 20 mg/ml for 20 hours. The cultures also contained 10 microcuries/ml of ^3H thymidine. The amount of unscheduled DNA synthesis was quantitated by autoradiography. Gellan gum was considered to be negative in this system because it did not induce statistically significant increases in the grain counts of cells exposed to gellan gum over the negative control.

iii) V-79 Mammalian Cell Mutagenesis

Cultures of V-79 Chinese hamster lung fibroplasts were exposed to gellan gum concentrations of 3, 5, 10, and 20 mg/ml, with and without S-9 activation, for 3 hours. Mutation at the HGPRT locus was measured as resistance to 6-thioguanine after an expression period of 5 days. Gellan gum did not induce 3-fold or greater increases in mutation frequency relative to the controls, and thus, was not detectably mutagenic.

iv) Assay for Chromosomal Aberrations in Chinese Hamster Ovary Cells

Cultures of Chinese hamster ovary cells were exposed to gellan gum concentrations of 2, 5, 10, 15, and 20 mg/ml, with and without microsomal enzyme activation. Gellan gum did not induce any increases in chromosomal aberration frequency relative to the concurrent negative and solvent

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controls at any of the concentrations tested, with or without S-9 metabolic activation and is considered negative in this study under the conditions of the test.

v) Mouse Micronucleus Assay

Adult male and female Harlan mice, Sprague-Dawley strain ICR, were dosed by oral gavage with 45, 225, and 450 mg/kg of gellan gum suspended in deionized water for two consecutive days. They were sacrificed 24 and 48 hours after the second dosing for extraction of the bone marrow. Each dose group consisted of five male and five female animals, as did positive and negative control groups. Gellan gum did not induce a significant increase in bone marrow polychromatic erythrocytes under the conditions of this assay and is considered negative in the mouse bone marrow micronucleus test.

9. Disposition Study with Radiolabeled Gellan Gum

Gellan gum was prepared in separate fermentations using ^{3}H glucose and ^{14}C glucose. The ^{3}H product was subjected to a multi-stage purification process to yield "pure" ^{3}H polysaccharide. This was added to the media of the ^{14}C fermentation, which was precipitated in isopropanol to yield a product with the polysaccharide fraction labeled with both radio-isotopes and the non-polysaccharide fraction labeled only with ^{14}C. Rats were dosed with this material at 1 g/kg. Four to six percent of the ^{3}H was excreted in the urine, with the remainder excreted in the feces, indicating that the polysaccharide fraction was hydrolyzed only slightly. For the ^{14}C activity, 0.5% was found in various tissues, 3% in the carcass, 2-3% excreted in the urine, and 86% in the feces. No more than 7% was unaccounted for. This indicated that a maximum of 15% of the non-polysaccharide fraction is absorbed.

10. Toxicity Screen with 50 Microorganisms

Fifty bacterial species that have been implicated in human infections were grown on media gelled with gellan gum. Colony characteristics, biochemical reactions, hemolytic patterns, and plating efficiency were compared with that of cultures of the same organisms grown on standard agar media. The comparisons were favorable.

11. An <u>In Utero</u>/Chronic Toxicity/Carcinogenicity Study of Gellan Gum in the Rat

Groups of 75 male and 75 female rats were treated with dietary concentrations of gellan gum of 0, 2.5, 3.8, and 5.0% for 63 days. The animals were mated, and the treatment of the females continued

throughout gestation and lactation. After weaning, 60 male and 60 female pups per dose group were selected for the chronic and carcinogenicity phases of the test.

After 51 weeks, 10 male and 10 female animals per group were sacrificed. The gross and histopathological examinations revealed findings normally expected for the Sprague-Dawley rat of this age group. There was no indication of any treatment-related findings. The organ weights were also within the normal range for rats of this age and strain. No findings attributable to treatment were observed.

After 104 weeks, all surviving animals were killed.

Histopathological examination revealed no change in the profile of spontaneous neoplastic or non-neoplastic findings that were considered to indicate any adverse effect of gellan gum when administered in the diet. Average daily intakes were approximately 1.2, 2.0 or 2.6 g/kg/day for males, and 1.6, 2.5 or 3.2 g/kg/day for females.

12. A Dietary Carcinogenicity Study of Gellan Gum in the Mouse

Gellan gum was administered to mice for 98 weeks for males and 96 weeks for females via the diet at concentrations of 1, 2, or 3%, which represented average daily intakes of approximately 1.6, 3.2, or 4.9 g/kg/day for males and approximately 2.2, 4.2, and 6.2 g/kg/day for females; treatment at these dosages produced no overt signs of toxicity and no effect on the spontaneous tumor profile of mice of this age and strain.

13. The Dietary Effects of Gellan Gum in Humans

Following a 7-day control period, five female and five male volunteers consumed a weight of gellan gum corresponding to 175 mg/kg body weight for 7 days, followed by 200 mg gellan gum per kg body weight for a further 16 days. Measurements before and at the end of the 23-day test period showed that the gellan gum acted as a fecal bulking agent for all of the male volunteers and for four of the females. Dietary transit time increased for 2 females and 2 males and decreased for 3 females and 3 males. There were no incidences of loss of normal bowel habit. Fecal bile acid concentrations increased for 4 females and for 4 males; the average increases were from 0.69 to 0.83 m.mol/24 hours (females) and from 1.22 to 1.44 m.mol/24 hours (males). Fecal fat concentrations and fecal neutral sterols decreased, on average, for females but increased, on average, for males. Fecal volatile short-chain fatty acids increased slightly, on average, for both females and males.

Gellan gum ingestion had no significant effect on any of (a) the plasma biochemistry parameters; (b) the hematological indices (with the exception of two male volunteers who exhibited elevated eosinophils); (c) the urinalysis parameters; (d) the blood glucose and plasma insulin concentrations; and (e) the breath hydrogen concentrations. There were no significant changes in HDL cholesterol, triglyceride or phospholipid concentrations. Serum cholesterol concentrations decreased significantly (p. <0.1) by 13% on average for females, and by 12%, on average, for males.

Subjectively, none of the volunteers reported any allergenic responses. Only one female reported feelings of abdominal distension for a few days at the outset of the trial; two females experienced an increased tendency to flatulence. The data available indicate that the ingestion of gellan gum at a high level for 23 days caused no adverse dietary or physiological effects in any of the volunteers. In particular, all of the enzymatic and other parameters that act as sensitive indicators of adverse toxicological effects remained unchanged. The fecal bulking effects and decreases in serum cholesterol may be regarded as desirable from a dietary point of view.

A second 21-day dietary study was conducted using ten male and ten female volunteers to resolve questions raised by the elevated eosinophil levels in two male volunteers. Those two subjects were included in the second study. There was no such response by them or any of the other 18 volunteers on this occasion.

14. Clinical Laboratory Study of Gellan Gum Utilizing PRIST and RAST by Enzyme Immuno-Assay Method.

This study was conducted as a companion study to the second dietary study examining gellan gum's potential to induce an allergic response. Serum samples taken from volunteers from both dietary studies, including the male subjects who exhibited elevated eosinophils in the first study, were assayed for total IgE using PRIST (Paper Radio Immuno-Sorbent Test, Pharmacia Diagnostics, U.S.A.) and for allergen-specific IgE using RAST (Radio-Allergic-Sorbent Test, Pharmacia Diagnostics, U.S.A.). There was no evidence from these studies of any sensitization to gellan gum, even in individuals with extremely high IgE levels. An extremely high serum IgE level indicates a marked genetic predisposition to react to any allergenic substance. The investigators concluded that the gellan gum preparation used in these studies is non-sensitizing, even in highly susceptible individuals.

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Appendix 14 – Safety Data Sheet

Safety Data Sheet

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03
Canadian Workplace Hazardous Material Information System (WHMIS) 2015
Mexico NOM-018-STPS-2000; NOM-018-STPS-2015
Globally Harmonized System (GHS)

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: KELCOGEL®

Pure substance/mixture Substance

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Food additive. Stabilizer. Thickening agent.

1.3. Details of the supplier of the safety data sheet

Company:
CP Kelco U.S., Inc.
a Huber Company
3100 Cumberland Boulevard, Suite 600
Atlanta, GA 30339 USA
Tel: +1 800 535 2687

E-mail customer.request@cpkelco.com

Internet www.cpkelco.com

1.4. Emergency telephone number CHEMTREC: +1 800 424 9300 or International +1 703 527 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Physical Hazards Not classified

Health Hazards Not classified

Environmental Hazard Not classified

OSHA Regulatory Status This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200). Combustible dusts.

GHS Classification Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

2.2. Label elements

Symbols/Pictograms None

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Signal Word Warning

Hazard Statements May form combustible dust concentrations in air

Precautionary Statements

Prevention
Employ good industrial hygiene practice
Do not handle until all safety precautions have been read and understood.
Do not breathe dust
Wear protective gloves/protective clothing/eye protection/face protection
Combustible dust may form combustible (explosive) dust-air mixtures
Take precautionary measures against static discharges

Response
IF exposed or concerned: Get medical advice/attention
Wash with plenty of soap and water

Storage
Store away from incompatible materials
Keep in a dry place

Disposal Dispose of contents/containers in accordance with local regulations

Hazards not otherwise classified (HNOC) COMBUSTIBLE DUST MAY FORM COMBUSTIBLE (EXPLOSIVE) DUSTAIR MIXTURES. Slippery, can cause falls if walked on.

SECTION 3: Composition/information on ingredients

Pure substance/mixture Substance

Chemical Name	CAS Number	TSCA: United States	Canada (DSL)	Mexico	REACH registration number	OSHA Regulatory Status	WHMIS	% by Wt
Gellan gum - Low Acyl	71010-52-1	Y	Y	Y	Exempt	Regulated Combustible dusts	--	--

Legend
X / Y: Complies - / N: Not Listed , Exempt

SECTION 4: First aid measures

4.1. Description of first aid measures

General Advice Employ good industrial hygiene practice. Wear suitable protective clothing, gloves and eye/face protection. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. When in doubt or if symptoms are observed, get medical advice.

Eye Contact In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin Contact Wash with plenty of soap and water.

Ingestion Rinse mouth thoroughly with water.

Inhalation Do not breathe dust. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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Aspiration hazard	Not an expected route of exposure.
4.2. Most important symptoms and effects, both acute and delayed	Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.
4.3. Indication of any immediate medical attention and special treatment needed	Treatment should be symptomatic and supportive. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

SECTION 5: Firefighting measures

General Advice	Treat as "Class A" fire. Product will burn when in contact with a flame Self extinguishes when ignition source is removed. Tends to smoulder.
5.1. Extinguishing media	
Suitable Extinguishing Media	Water spray (fog). Foam. Dry chemical. Carbon dioxide (CO2).
Unsuitable Extinguishing Media	None known.
5.2. Special hazards arising from the substance or mixture	Avoid dust formation.
Dust Explosion Hazard	Can contain sufficient fines to cause a combustible dust explosion. Do not breathe smoke, gases or vapors generated
Hazardous Combustion Products	Carbon dioxide Carbon monoxide
5.3. Advice for firefighters	
Special protective equipment for firefighters	Wear a self-contained breathing apparatus and chemical protective clothing.
Fire-fighting measures	Water mist may be used to cool closed containers. Combustible dust may form combustible (explosive) dust-air mixtures.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	Keep unauthorized personnel away. Ensure adequate ventilation. Avoid dust formation. Use only non-sparking tools. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Use personal protection recommended in Section 8.
For non-emergency personnel	Keep unauthorized personnel away.
For emergency responders	Keep unauthorized personnel away. Use personal protection recommended in Section 8.
6.2. Environmental precautions	Avoid runoff to waterways and sewers.
6.3. Methods and material for	Large Spill:. Do not dry sweep dust. Wet dust with water before sweeping or use

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containment and cleaning up a vacuum to collect dust. Small Spill:. Vacuum or sweep material and place in a disposal container. The use of water wash down is not recommended unless the spilled material is already wet.

6.4. Reference to other sections Section 8: Exposure controls and personal protection. See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid exposure - obtain special instructions before use
Do not handle until all safety precautions have been read and understood.
Minimize dust generation and accumulation
Do not breathe dust
Ensure adequate ventilation
Wear appropriate personal protective clothing to prevent skin contact
Handle in accordance with good industrial hygiene and safety practice
Keep away from heat/sparks/open flames/hot surfaces. - No smoking
Use only non-sparking tools

7.2. Conditions for safe storage, including any incompatibilities Keep container tightly closed and dry. Store away from incompatible materials.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

OSHA *Dust: OSHA has not established specific exposure limits for this material. However, OSHA has established limits for particulates not otherwise regulated (PNOR) which are the least stringent exposure limits applicable to dusts.

Gellan gum - Low Acyl - 71010-52-1

OSHA	TWA: Not established
ACGIH	TWA: Not established
ACGIH	STEL: Not evaluated

Predicted No Effect Concentration (PNEC) No information available

Derived No Effect Level (DNEL) No information available

Biological Limit Values: No information available

8.2. Exposure controls

Engineering Measures Provide a good standard of controlled ventilation (5 to 10 air changes per hour). Use exhaust ventilation to keep airborne concentrations below exposure limits. In case of insufficient ventilation, wear suitable respiratory equipment.

Personal protective equipment

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Eye/Face Protection	Wear safety glasses with side shields (or goggles).
Skin and Body Protection	Wear suitable protective clothing.
Hand Protection	For operations where prolonged or repeated skin contact may occur, impervious gloves should be worn.
Respiratory Protection	In case of inadequate ventilation wear respiratory protection.
Thermal hazards	None known. Wear suitable protective clothing.
Hygiene Measures	Follow general hygiene considerations recognized as common good workplace practices. The worker should wash daily at the end of each work shift, and prior to eating, drinking, smoking, etc.
Environmental Exposure Controls	Dispose of in accordance with local regulations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Powder. Solid.
Color	White to light tan
Odor	Odorless
Odor Threshold	No information available
pH:	Neutral solution (1 %)
Melting Point / Melting Range	Not applicable
Boiling Point	Not applicable
Freezing Point	Not applicable
Flash Point:	No information available
Evaporation Rate	Not applicable
Flammability (solid, gas)	No information available
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Water Solubility	Soluble
Partition coefficient	No information available
Autoignition Temperature	No information available
Oxidizing Properties	Not oxidizing
Decomposition Temperature	No information available

SECTION 10: Stability and reactivity

10.1. Reactivity	None
10.2. Chemical stability	Stable under normal conditions
10.3. Possibility of hazardous reactions	No specific hazard known
10.4. Conditions to avoid	Dust formation Keep away from heat, sparks and flame Strong oxidizing agents
10.6. Hazardous decomposition products	None known

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SECTION 11: Toxicological information

General Information Users are advised to consider national Occupational Exposure Limits or other equivalent values.

Information on Likely Routes of Exposure

Inhalation Do not breathe dust.

Skin Not a skin sensitizer. Prolonged or repeated contact may dry skin and cause irritation.

Eyes Dust contact with the eyes can lead to mechanical irritation.

Ingestion Ingestion is not a likely route of exposure.

Aspiration hazard Not an expected route of exposure.

11.1. Information on toxicological effects

Gellan gum - Low Acyl - 71010-52-1

Oral LD50	> 5000 mg/kg Rat
Inhalation LC50	> 5.09 mg/l Rat

Acute Toxicity Based on available data, the classification criteria are not met.

Chronic Effects Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory Sensitization Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation Based on available data, the classification criteria are not met.

Skin Sensitization Based on available data, the classification criteria are not met.

Mutagenicity Based on available data, the classification criteria are not met.

Reproductive Toxicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Specific target organ toxicity - Single exposure No data available.

Specific target organ toxicity - Repeated exposure No data available.

SECTION 12: Ecological information

12.1. Ecotoxicity Not considered to be harmful to aquatic life.

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Gellan gum - Low Acyl - 71010-52-1
WGK Classification (VwVwS) 8235 WGK: 2

12.2. Persistence and degradability Readily biodegradable.

12.3. Bioaccumulative potential This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).

Partition coefficient No information available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment This substance does not meet the criteria for classification as PBT or vPvB.

12.6. Other adverse effects None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contaminated Packaging Product residue may remain in empty containers. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Waste codes Waste codes should be assigned by the user based on the application for which the product was used

Disposal Methods Dispose of waste product or used containers according to local regulations

Gellan gum - Low Acyl - 71010-52-1
European Waste Catalog 160306

SECTION 14: Transport information

Mode of Transportation (Road, Water, Air, Rail)

TDG -Canada	Not regulated
US DOT	Not regulated
ADR	Not regulated
RID	Not regulated
ADN	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated
ICAO	Not regulated

14.1. UN number None

14.2. UN proper shipping name None

14.3. Transport hazard class(es) None

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14.4. Packing group None

14.5. Environmental hazards No

14.6. Special precautions for user Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Global Inventories

Pure substance/mixture Substance

Chemical Name	CAS Number	EC No	REACH registration number	Australia (AICS)	Canada (DSL)	China (IECSC)	Japan	S. Korea (KECL)	Mexico	New Zealand	Philippines (PICCS)	Taiwan	TSCA: United States
Gellan gum - Low Acyl	71010-52-1	275-117-5	Exempt	Y	Y	Y	- (ENCS) 11-(4)-871 (ISHL)	KE-17592	Y	Y	Y	Y	Y

Legend
X / Y: Complies - / N: Not Listed Exempt

US Federal Regulations

EPA

CERCLA
Not listed

CAA (Clean Air Act)
Not listed

CWA (Clean Water Act)
Not listed

U.S. State Right-to-Know Regulations

Chemical Name	California Proposition 65	Massachusetts	Minnesota	New Jersey	Pennsylvania
Gellan gum - Low Acyl	N	N	N	N	N

CANADA

WHMIS:
This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all the information required by the HPR

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SECTION 16: Other information

Prepared by

CP Kelco Global Regulatory Affairs
Email: Regulatory.Affairs@cpkelco.com

Reason for Version

OSHA (Occupational Safety and Health Administration of the US Department of Labor).

Training Advice

Do not handle until all safety precautions have been read and understood.

Abbreviations and acronyms

International Agency for Research on Cancer (IARC)
International Air Transport Association (IATA)
International Maritime Dangerous Goods (IMDG)
International Uniform Chemical Information Database (IUCLID)
Workplace Hazardous Materials Information System (WHMIS) status and classification
EPA SARA Title III Section 312 (40 CFR 370) Hazard Classification
DOT (Department of Transportation)
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
TWA - Time-Weighted Average
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA)
The Classification, Labeling and Packaging of Substances and Mixtures (CLP) Regulation (EC 1272/2008)
PPE - Personal Protection Equipment
NIOSH - National Institute for Occupational Safety and Health
TDG (Transport of Dangerous Goods) Canada
CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act)
Reportable Quantity (RQ) (RQ/% in mixture)
STEL - Short Term Exposure Limit
TLV® - Threshold Limit Value
Derived No Effect Level (DNEL)
SVHC: Substances of Very High Concern for Authorization:
Land transport (ADR/RID)
Biochemical oxygen demand (BOD)
Chemical oxygen demand (COD)
ICAO (air)
(IMDG) International Maritime Dangerous Goods
Positive Pressure Self-Contained Breathing Apparatus (SCBA)
Predicted No Effect Concentration (PNEC)
Globally Harmonized System (GHS)

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet

Appendix 15 – Literature Search

GELLAN GUM: A BIBILOGRAPHY OF SCIENTIFIC LITERATURE

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