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

Submitted by:

CP Kelco U.S., Inc.
8355 Aero Drive
San Diego, California 92123

Date:

September 30, 2004

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Regulatory Affairs
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September 30, 2004 **Via: Federal Express**

National Organic Standards Board
c/o Robert Pooler
Agricultural Marketing Specialist
USDA/AMS/TM/NOP
Room 4008, Ag Stop 0268
1400 Independence Avenue, SW
Washington, D.C. 20090-6456

RE: Petition for Evaluation of Gellan Gum for Inclusion on the National List of Substances Allowed in Organic Production Handling

Dear Mr. Pooler:

CP Kelco U.S., Inc. (Kelco) respectfully submits this Petition for the inclusion of Gellan Gum into the National Organic List as a Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)" to the USDA National Organic Standards Board for consideration.

The petition is prepared in accordance to the guidelines given in the National List Petition Process section of the National Organic Program internet website and well as the requirements listed in the *Federal Register* document of July 13, 2000 [65 FR 43259-43261].

We believe that it will be a great benefit to a wide variety of food manufacturers whose formulations require a gum to have gellan gum on the National List. Gellan gum imparts little mouth feel while holding particles, such as bits of fruit, in suspension. Gellan gum can be used at a significant lower concentration (≤ 20%) than the other gums that are listed on the National List and it provides the most firm and brittle texture of any gelling agent.

We appreciate the considerable time and effort your organization and the National Organic Board members spend on this important matter of assuring the US consumer that those products listed as organic meet the requirements of The Organic Food Production Act of 1990 as amended.

National Organic Standards Board
c/o Robert Pooler, Ag Stop 0268
Re: Petition for Gellan Gum
September 30, 2004
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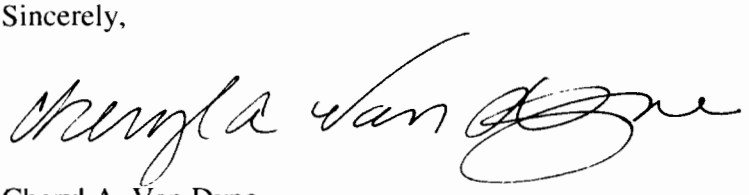
If you have any questions about this petition or need additional copies, please contact me at the phone number or email listed below.

Sincerely,



Cheryl A. Van Dyne
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Enclosure: Two (2) Copies of National Organic List Petition – Gellan Gum

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National Organic List Petition: Gellan Gum

1. *Category for Inclusion on National List*

Non organic (non-agricultural) synthetic substance allowed as an ingredient in processed products labeled as organic or made with organic (specified ingredients or food group(s) as defined in 7 CFR 205.605(b).

2. *Common Name*

Gellan gum

3. *Manufacturer Name and Address*

A. Corporate Headquarters

CP Kelco U.S., Inc.
1313 North Market Street
Wilmington, DE 19894

B. Manufacturing/Processing Facility

CP Kelco U.S., Inc.
2025 E. Harbor Drive
San Diego, California 92113

C. Contact for USDA Correspondence

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4. *List of Uses and Mode of Action for Handling Uses*

Gellan gum, 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 (fruit drinks, drinking jellies, novelty drinks); yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; pourable and spoonable dressings; dairy desserts; and canned pet food. The mode of action is as a thickening or gelling agent with film-forming and texturizing attributes [Appendix 1]. 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 undesirable texture in the finished product. A report is appended to provide typical gellan gum use levels in various food products [Appendix 2: **CBI**].

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 the gum are found in consumer products, such as liquid detergents, cleaners, suspensions and films.

5. *Sources and Detailed Description of Manufacturing Procedures* - **CBI**

REDACTED INFORMATION

1 Page Redacted

5. *Sources and Detailed Description of Manufacturing Procedures(continued)*

- Packaging

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

6. *Summary of Previous Certification Reviews of Gellan Gum*

This section is not applicable.

7. *Regulatory Information*

Since 1990, Gellan gum has been approved by the US Food and Drug Administration 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 [Appendix 1]. FDA also approved an exemption for gellan gum under 21 CFR 170.39 threshold of regulation, for its use as a coating or sizing agent on food-contact articles.

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 Publication* of the American Association of Feed Control Officials.

Food grade gellan gum meets the requirements of the *Food Chemicals Codex.*

Gellan gum may be used in pesticide formulations as an inert, meeting requirements of 40 CFR 180.950 [Appendix 5].

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 [Appendices 6 and 7].

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 [Appendices 8 through 10].

7. Regulatory Information(continued)

Gellan gum carries approval for use in Kosher and Halal food products.

Gellan gum is used as a thickener and emulsifier in other non-food formulations, such as prescription pharmaceuticals, personal care products, over-the-counter drugs, and many industrial applications like air fresheners, toilet bowl cleaners, etc.

8. *The Chemical Abstract Service (CAS) Registry Number or Other Product Numbers*

The CAS Registry number for gellan gum is 71010-52-1.
The EU Registry Number for gellan gum is 2751175
The EINECS Inventory Number for gellan gum is 2751175
The Korean Gazette Number for gellan gum is KE-17592

Appendix 11 contains examples of labels of products currently being marketed in the US and elsewhere that contain gellan gum.

9. *Physical Properties and Chemical Mode of Action*

Gellan gum is a water soluble high molecular weight polysaccharide that is composed of repeating monosaccharide units. The four monosaccharides are rhamnose (a sugar found in a variety of plants), glucuronic acid (an oxidized glucose molecule), and two glucose units (a component of sucrose, which is common sugar). The glucuronic acid is neutralized by a mixture of potassium sodium, calcium and magnesium salt ions. The polysaccharide is substituted with 0-5% acyl groups (calculated as acetyl but also has glyceryl) on the first glucose moiety as the O-glycosidically linked ester.

The molecular weight of the gum is greater than 70,000 Daltons with 95% above 500,000 Daltons when analyzed using a molecular sieve chromatography, a low angle laser light scattering, or a low shear intrinsic viscosity procedure.

9. Physical Properties and Chemical Mode of Action (continued)

a. physical, chemical, and microbial properties; chemical interaction with other substances:

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 Point	Decomposes without Melting >150° C
Structural Form	See Below

Gellan gum, low acyl gellan gum Molecular Formula

$$[\rightarrow 3)-\beta-\mathrm{D}-\mathrm{Glc}p-(1\rightarrow 4)-\beta-\mathrm{D}-\mathrm{Glc}pA-(1\rightarrow 4)-\beta-\mathrm{D}-\mathrm{Glc}p-(1\rightarrow 4)-\alpha-\mathrm{L}-\mathrm{Rha}p-(1\rightarrow]$$

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	≤ 3 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 validated by CP Kelco.

Gellan gum forms gels in the presence of mono- and polyvalent ions when heated and cooled. The gum is stable under normal storage conditions.

9. Physical Properties and Chemical Mode of Action (continued)

b. toxicity and environmental persistence

There is no toxic effect of this gum. The safety information is discussed in item 10 below. 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.

c. environmental impacts from its use of manufacture

In its manufacturing process, 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 land fills or treated in waste water treatment plants. These actions will not result in an adverse effect on the environment.

d. effects on human health

As noted in item 10 below, 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.

e. effects on soil organisms, crops, or livestock

Gellan gum is a direct food additive and is also used in the production of pet food. According to the American Society for Testing and Materials (ASTM), polymers are biodegradable if degradation results from the action of naturally occurring micro-organisms such as bacteria, fungi, and algae. Therefore, the likelihood of gellan gum (a biopolymer/polysaccharide) to have an adverse effect on livestock is nil. [http://www.hnd.usace.army.mil/techinfo/CPW/PWTB/4204920.pdf]

10. *Safety Information for Gellan Gum*

Gellan gum 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 12]. 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 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 fecal bulking aid.

The Material Safety Data sheet is appended [Appendix 13]. A substance report from the National Institute of Environmental Health Studies was not found.

11. *Research Information and Bibliographies*

Literature searches have been conducted on gellan gum though August 2004. Appended is a bibliography list of relevant literature associated with this gum's safety and technical effect [Appendix 14]. 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.

11. Research Information and Bibliographies(continued)

No published articles were found that presented contrasting positions to the one stated in this petition; i.e., gellan gum should be included on the National Organic List.

12. Petition Justification Statement

Gellan gum 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. Other gums, like carageenan, which is a non-synthetic gum on the National Organic List, presents an undesirable mouthfeel in these types of products.

Another unique quality of 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 pie fillings, retorted gels, or beverages.

Gellan gum is also heat stable in low solids, low pH heated systems, such as in bakery fillings, whereas carrageenan is not and degrades and loses gel strength, and pectin will not provide enough structure.

Gellan gum can be substituted for gelatin (animal based gelling agent) as a non-animal source gelling system. This would support dietary requirements of vegetarians or others with dietary restrictions.

Finally, 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, gellan gum can be used without process modification whereas pectin requires special handling such as preparation of concentrated gum solutions.

Gellan gum provides many characteristics, some of which are better than and some that are similar to the currently listed gums (either non-synthetic or synthetic). For example, gellan gum presents high viscosity at low polymer concentrations; is used to thicken, suspend and gel water based systems; provides unique particle suspension properties (e.g., beads); provides high clarity; ranges of textures are from firm and brittle to soft and elastic with different gellan gum types; provides process flexibility (for example will hydrate in cold systems with appropriate

12. Petition Justification Statement (continued)

processing); can stabilize oil in water emulsions; is an excellent suspension agent but is shear thinning and can be applied by spraying; can form films and act as a rheology modifier.

In summary, the unique qualities of gellan gum are that it can be use at a significantly lower level (≤20%) than other gums; the strength of water dessert gels is increased; it provides the most firm and brittle texture of any gelling agent; and, it allows the suspension of particles without resulting in mouthfeel of the suspension.

The benefits of this gum are similar to those gums already approved and listed on the National Organic List. Since several of the gums on the National Organic List are used as an ingredient in formulated food products, the benefits for farm ecosystem are not relevant. Certainly with gellan gum being approved by EPA as an inert ingredient to be used in various pesticides, that agency found that it would not cause adverse effects and provides a benefit for certain pesticide formulations that require a gelling agent.

The beneficial effects of gellan gum on human health has been well documented by its approval as a food additive for use in a wide variety of food products. This 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), not specified (NS).

Gellan gum's unique attributes listed above will allow many more products containing this gum to be produced and labeled as organic. CP Kelco concludes that it would be in the best interest of the organic program to add this gum to the National Organic List.

13. A Commercial Confidential Information Statement

The written justification for each section of this petition and certain Appendices that are marked CBI is found at Appendix 15.

Appendices Table of Contents

Appendices Table of Contents (continued)

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 Xanthan Gum monograph, the "Food Chemicals Codex," 4th ed. (1996), pp. 437–438, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address http://www.nap.edu), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(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]

§ 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:

PYRUVIC ACID TEST

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1*N* hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2*N* hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note "positive" for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and "negative" for xanthan gum if the sample

GELLAN GUM – USE IN PRODUCTS TO BE LABELED ORGANIC - **CBI**

UNIQUE GELLAN GUM FUNCTIONALITIES – GENERAL

2 PAGES REDACTED

GELLAN GUM – USE IN PRODUCTS TO BE LABELED ORGANIC - **CBI**

UNIQUE GELLAN GUM FUNCTIONALITIES – GENERAL

2 PAGES REDACTED

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

1 Page Redacted

FIFTH EDITION

FOOD CHEMICALS CODEX

Effective January 1, 2004

COMMITTEE ON FOOD CHEMICALS CODEX

Food and Nutrition Board

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

For sample analyses, maintain the temperatures of the column oven, injector port, and detector at 180°, 250°, and 350°, respectively. Adjust the electrometer to provide about half of the full-scale deflection when 0.1 ng of PCP is injected.

Procedure (**Note**: Inject each *PCP Standard Solution* and *Sample Preparation* twice to ensure that consistent responses are obtained. Following each injection of *PCP Standard Solutions* or *Sample Preparation*, rinse the syringe 10 times with hexane. After each injection of *PCP Standard Solutions* or *Sample Preparation*, inject 5 µL of hexane onto the gas chromatograph, or equivalent, and record the chromatogram. If peaks are observed at the retention time for PCP, repeat the hexane injection until such peaks are no longer encountered.) Inject 5-µL portions of each of the *PCP Standard Solutions* (0.0, 0.02, 0.10, 0.20, 0.50, 1.0, and 2.0 ng, respectively) and the *Reagent Blank* into the gas chromatograph sequentially, and record the chromatograms. Measure the areas under the PCP peaks and the peak heights for each of the *PCP Standard Solutions* (retention time for PCP should be about 10 min), corrected for the *Reagent Blank*. The maximum acceptable *Reagent Blank* for satisfactory performance of the method is 0.01 µg/g. Similarly, inject 5 µL of the *Sample Preparation* into the gas chromatograph, and record the chromatogram. Measure the area under the PCP peak and the peak height, corrected for the *Reagent Blank*. Determine the amount of PCP in the *Sample Preparation* by comparing the peak area and height to the peak area and height obtained from injection of known amounts of *PCP Standard Solutions*; to ensure valid measurement of PCP in the *Sample Preparation*, the size of the PCP peak from the *Sample Preparation* and the standards should be within ±10%. The *Sample Preparation* may require further dilution. Designate as A_S the amount of PCP, expressed in nanograms, in the aliquot of the *Sample Preparation*. Calculate the concentration of PCP, in micrograms per gram, in the sample by the formula

$$5A_S.$$

Protein Determine as directed under *Nitrogen Determination*, Appendix IIIC, transferring 1 g of sample, accurately weighed, into a 500-mL Kjeldahl flask. Percent protein equals percent N × 5.55.

Sulfur Dioxide Determine as directed under *Sulfur Dioxide Determination*, Appendix X. However, instead of using a 50-g sample, dissolve a 20.0-g sample in 100 mL of a 5% alcohol in water mixture, and proceed as directed under *Sample Introduction and Distillation*.

Packaging and Storage Store in tight containers.

Gellan Gum

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 *Pseudomonas elodea*, purified by recovery with isopropyl alcohol, 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.

REQUIREMENTS

Identification

A. 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. (Save part of this solution for *Identification Test B*). Draw a small amount of the solution into a wide-bore pipet, and transfer it into a solution of 10% calcium chloride. A tough, wormlike gel forms instantly.

B. Add 0.5 g of sodium chloride to the 1% deionized water solution prepared for *Identification Test A*, 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. A firm gel forms.

Assay A sample yields not less than 3.3% and not more than 6.8% of carbon dioxide (CO_2), calculated on the dried basis.

Isopropyl Alcohol Not more than 0.075%.

Lead Not more than 2 mg/kg.

Loss on Drying Not more than 15.0%.

TESTS

Assay Determine as directed under *Alginates Assay*, Appendix IIIC, but use about 1.2 g of undried sample, accurately weighed.

Isopropyl Alcohol

IPA Standard Solution Transfer 500.0 mg of chromatographic-quality isopropyl alcohol into a 50-mL volumetric flask, dilute to volume with water, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute to volume with water, and mix.

TBA Standard Solution Transfer 500.0 mg of chromatographic-quality *tert*-butyl alcohol into a 50-mL volumetric flask, dilute to volume with water, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute to volume with water, and mix.

Mixed Standard Solution Pipet 4 mL each of the *IPA Standard Solution* and of the *TBA Standard Solution* into a 125-mL, graduated Erlenmeyer flask, dilute to about 100 mL with water, and mix. This solution contains approximately 40 µg each of isopropyl alcohol and of *tert*-butyl alcohol per milliliter.

Sample Preparation 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 about 5 g of sample, accurately weighed,

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 Preparation*.

Procedure (See *Chromatoghaphy*, Appendix IIA.) Inject about 5 µL of the *Mixed Standard Solution* into a suitable gas chromatograph equipped with a flame-ionization detector and a 1.8-m × 3.2-mm stainless steel column, or equivalent, packed with 80- to 100-mesh Porapak QS, or equivalent. Maintain the column at 165°. Set the temperature of both the injection port and the detector to 200°. Use helium as the carrier gas, flowing at 80 mL/min. The retention time of isopropyl alcohol is about 2 min, and that of *tert*-butyl alcohol is about 3 min.

Determine the areas of the *IPA* and *TBA* peaks, and calculate the response factor, *f*, by the formula

$$A_{IPA}/A_{TBA},$$

in which A_{IPA} is the area of the isopropyl alcohol peak, and A_{TBA} is the area of the *tert*-butyl alcohol peak.

Similarly, inject about 5 µL of the *Sample Preparation*, and determine the peak areas, recording the area of the isopropyl alcohol peak as S_{IPA}, and that of the *tert*-butyl alcohol peak as S_{TBA}. Calculate the isopropyl alcohol content, in milligrams per kilogram, in the sample taken by the formula

$$(S_{IPA} \times 4000)/(f \times S_{TBA} \times W),$$

in which W is the weight, in grams, of the sample taken.

Lead Determine as directed under *Lead Limit Test*, Appendix IIIB, using a *Sample Solution* prepared as directed for organic compounds, using 2 g of sample, and 4 µg of lead (Pb) ion in the control.

Loss on Drying Determine as directed under *Loss on Drying*, Appendix IIC, drying a sample at 105° for 2.5 h.

Packaging and Storage Store in well-closed containers.

Geranium Oil, Algerian Type

Rose Geranium Oil, Algerian Type

CAS: [8000-46-2]

DESCRIPTION

Geranium Oil, Algerian Type, occurs as a light to deep yellow liquid with a characteristic odor resembling rose and geraniol. It is the oil obtained by steam distillation from the leaves of *Pelargonium graveolens* L'Her. (Fam. Geraniaceae). It is soluble in most fixed oils, and it is soluble, usually with opalescence, in mineral oil and in propylene glycol. It is practically insoluble in glycerin.

Function Flavoring agent.

REQUIREMENTS

Identification The infrared absorption spectrum of the sample exhibits relative maxima at the same wavelengths as those of a typical spectrum as shown in the section on *Infrared Spectra*, using the same test conditions as specified therein.
Assay Not less than 13.0% and not more than 29.5% of esters, calculated as geranyl tiglate ($C_{15}H_{24}O_2$).
Acid Value Between 1.5 and 9.5.
Angular Rotation Between −7° and −13°.
Ester Value after Acetylation Between 203 and 234.
Refractive Index Between 1.464 and 1.472 at 20°.
Solubility in Alcohol Passes test.
Specific Gravity Between 0.886 and 0.898.

TESTS

Assay Determine as directed in *Ester Value* under *Esters*, Appendix VI, using about 6 g of sample, accurately weighed. The ester value multiplied by 0.422 equals the percentage of geranyl tiglate ($C_{15}H_{24}O_2$).
Acid Value Determine as directed under *Acid Value*, Appendix VI, using about 5 g of sample, accurately weighed. Modify the procedure by using 15 mL of water, instead of alcohol, as diluent and by agitating the mixture thoroughly during the titration to keep the oil in suspension.
Angular Rotation Determine as directed under *Optical (Specific) Rotation*, Appendix IIB, using a 100-mm tube.
Ester Value after Acetylation Determine as directed under *Total Alcohols*, Appendix VI, using about 1.9 g of the acetylated sample oil, accurately weighed, for saponification. Calculate the ester value after acetylation by the formula

$$A \times 28.05/B,$$

in which A is the number of milliliters of 0.5 N alcoholic potassium hydroxide consumed in the saponification, and B is the weight, in grams, of acetylated sample oil.
Refractive Index Determine as directed under *Refractive Index*, Appendix IIB, using an Abbé or other refractometer of equal or greater accuracy.
Solubility in Alcohol Determine as directed under *Solubility in Alcohol*, Appendix VI. One milliliter of sample dissolves in 3 mL of 70% alcohol, but on further dilution with the alcohol, opalescence may occur, sometimes followed by separation of paraffin particles.
Specific Gravity Determine by any reliable method (see *General Provisions*).

Packaging and Storage Store in a cool place protected from light in full, tight containers that are made from steel or aluminum and that are suitably lined.

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).

REPORT FROM THE COMMISSION

on Dietary Food Additive Intake in the European Union

TABLE OF CONTENTS

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.

1. 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.

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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).

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[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

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[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

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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:

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* 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.

6. 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).

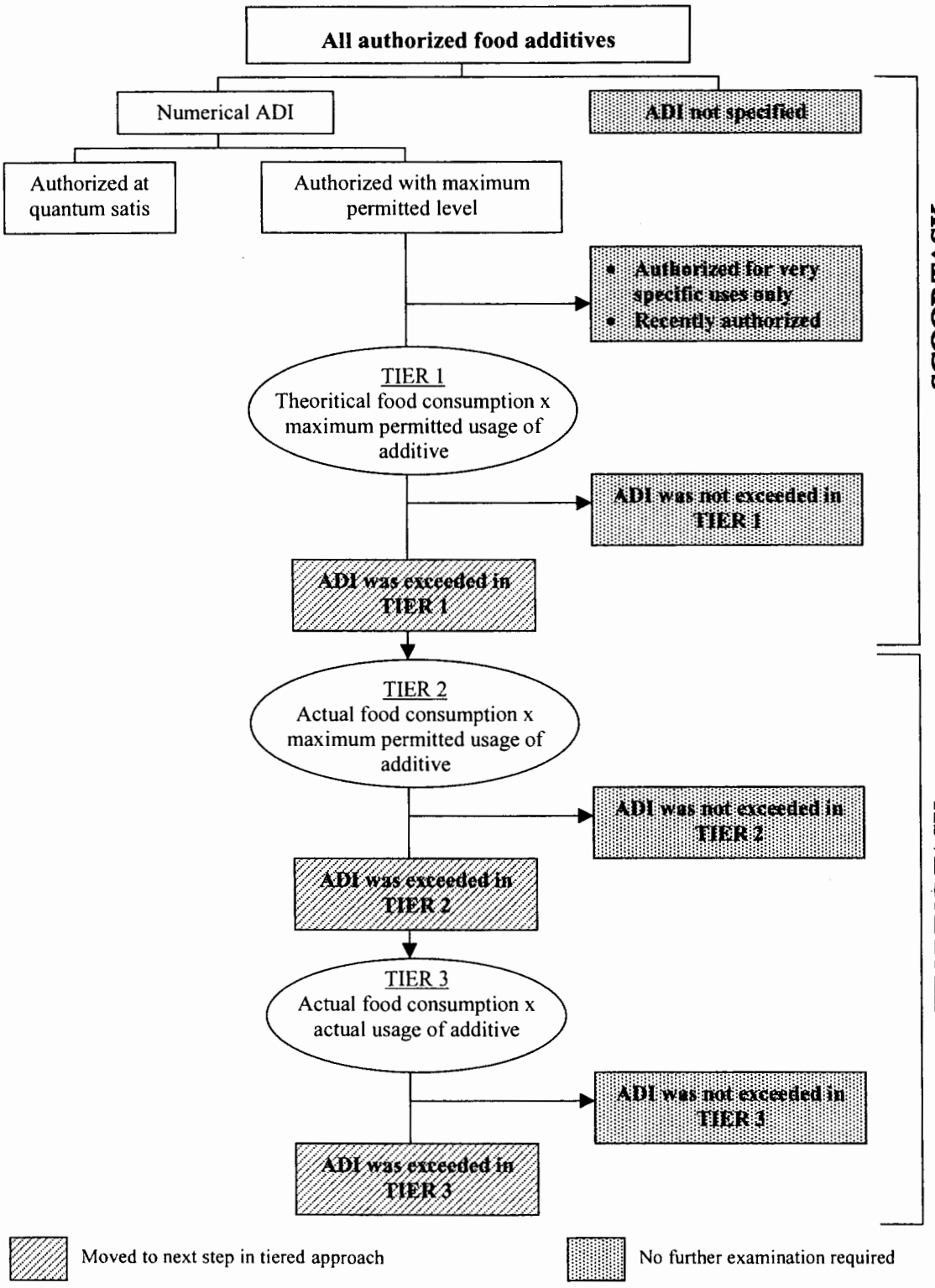
- Intake studies should be carried out in respect of the additives which, at the time of this exercise, had only recently been approved.

- 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 No	Name
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.

IPCS INCHEM Home

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-Glc-(1->4)-ß-D-GlcA-(1->4)-ß-D-Glc-(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	R
Ames test (1)	S. typhimurium TA98, TA100 TA1535 TA1537 TA1538	10, 30, 100, 300 and 1000 œg/plate	Negative	R 1
DNA repair test	Rat hepatocyte	3, 5, 10 & 20 mg/ml	Negative	R 1
V-79/HGPRT	Chinese hamster lung fibroblasts	3, 5, 10 & 20 mg/ml	Negative	R 1

(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)

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:

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.

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		
Additive Class	INS Number	Additive Name	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

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	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				
	INS Number	Additive Name	Plain		Flavoured			Plain		Flavoured		
	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
Fl 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

			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**
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

			Fermented Milks				Fermented Milks Heat Treated After Fermentation			
	INS Number	Additive Name	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

			Fermented Milks						Fermented Milks Heat Treated After Fermentation					
			Plain			Flavoured			Plain			Flavoured		
	INS Number	Additive Name												
	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					
			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	**INS Number**	**Additive Name**	**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

			Fermented Milks				Fermented Milks Heat Treated After Fermentation			
	INS Number	Additive Name	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

			Fermented Milks				Fermented Milks Heat Treated After Fermentation			
	INS Number	Additive Name	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	o1.7, 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
	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			
	INS Number	Additive Name	Plain		Flavoured		Plain		Flavoured	
	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

			Fermented Milks				Fermented Milks Heat Treated After Fermentation			
	INS Number	Additive Name	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			
	INS Number	Additive Name	Plain		Flavoured		Plain		Flavoured	
	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		
	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								

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.

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 %

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.

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
	Additionally, for products with less than 39% fat	
260 261 262 (i) 263 270 325 326 327 330 331 331 (i) 331 (iii) 332 333 334 335 335 (i) 335 (ii) 336 337	Acetic acid Potassium acetate Sodium acetate Calcium acetate Lactic acid (L-, D- and DL-) Sodium lactate Potassium lactate Calcium lactate Citric acid Sodium citrates Sodium dihydrogen citrate Trisodium citrate Potassium citrate Calcium citrate Tartaric acid Sodium tartrates Monosodium tartrate Disodium tartrate Potassium tartrate Sodium potassium tartrate	Limited by GMP
338 339 340 341	Orthophosphoric acid Sodium orthophosphates Potassium phosphates Calcium orthophosphate	5 g/kg
	Emulsifiers	
	For products with less than 60% fat	
322	Lecithins	Limited by GMP
432 433 434 435 436	Polyoxyethylene (20) sorbitan: Monolaurate Mono-oleate Monopalmitate Monostearate Tristearate	10 g/kg singly or in combination for baking purposes only
452(i) 452(ii)	Sodium polyphosphate Potassium polyphosphate	5 g/kg
471 472(a)	Mono- and di-glycerides of fatty acids Acetic and fatty acid esters of glycerol	Limited by GMP

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

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	

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

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
966 967	Lactitol Xylitol	
290 941 942	Carbon dioxide Nitrogen Nitrous oxide	Limited by GMP

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.

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 (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.

- 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)

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

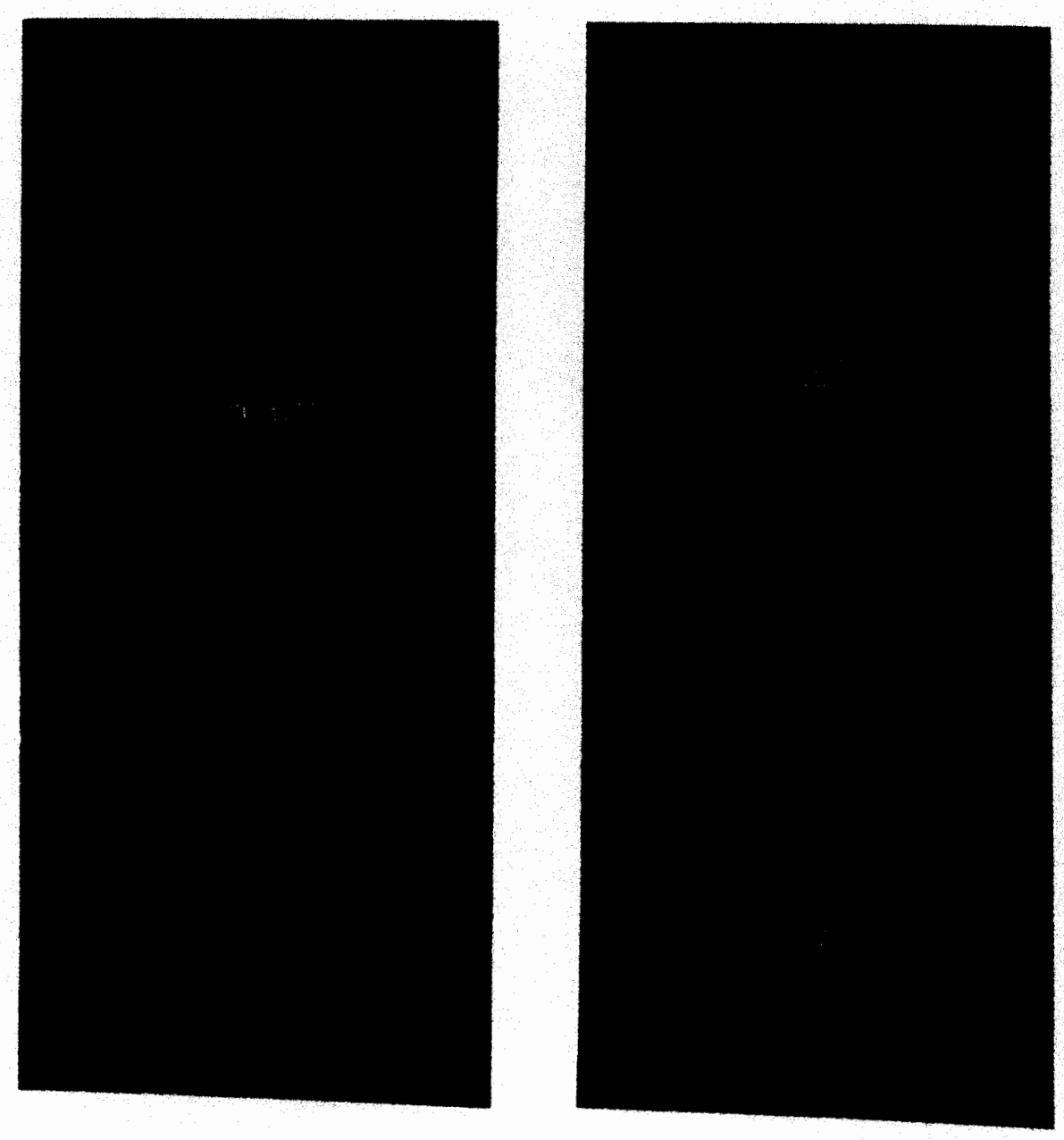
Only those additives classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

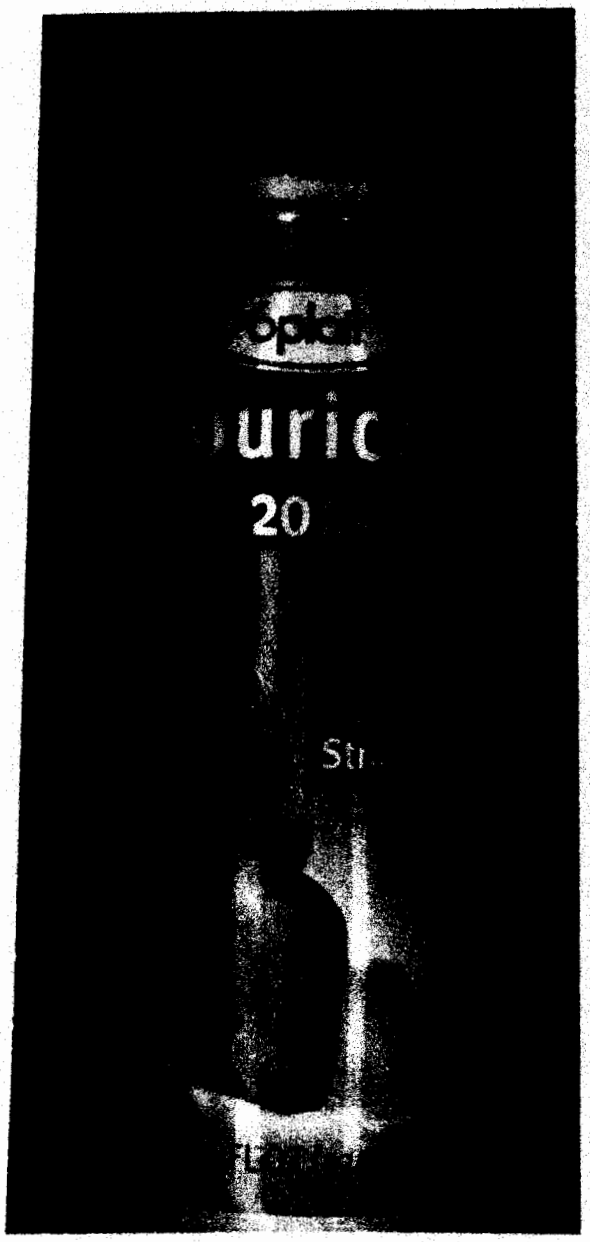
	Justified use:	
Additive functional class:	**Cheese mass**	**Surface/rind treatment**
Colours:	X[1]	-
Bleaching agents:	-	-
Acids:	X	-
Acidity regulators:	X	-
Stabilizers:	X[2]	-
Thickeners:	X[2]	-
Emulsifiers:	X	-
Antioxidants:	X	-
Preservatives:	X	-
Salt substitutes:	X	-
Foaming agents:	X[3]	-
Anti-caking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

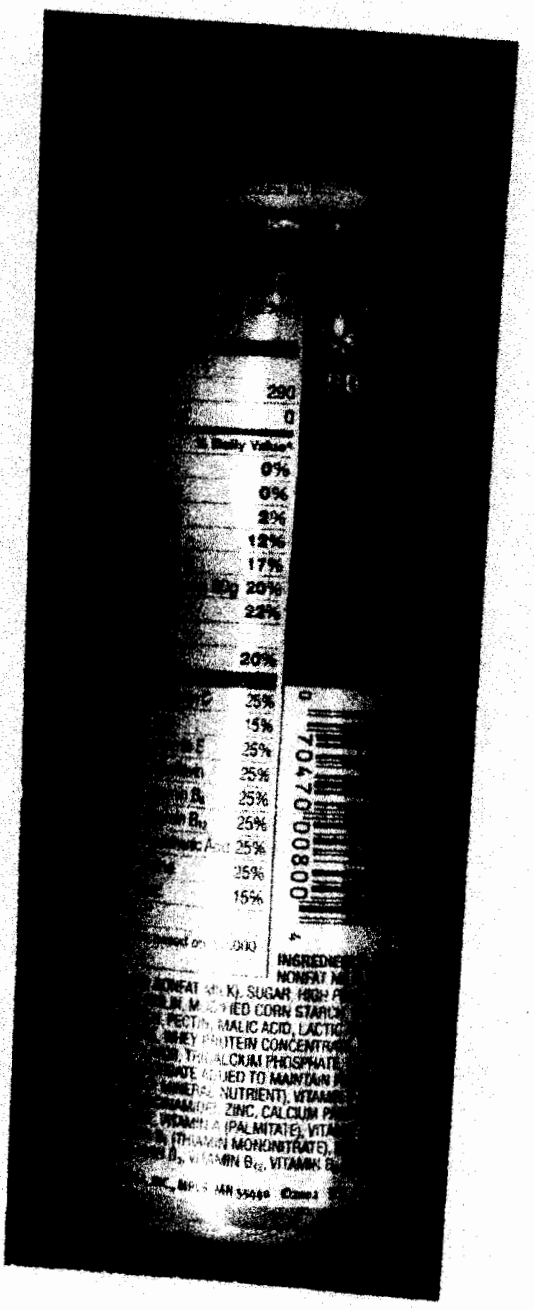
[1]) Only to obtain the colour characteristics, as described in Section 2
[2]) Stabilizers and thickeners including modified starches may be used in compliance with the definition of milk products and only to heat treated products to the extent they are functionally necessary, taking into account any 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

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

No.	*Name of food additive*	*Maximum level*
406	Agar	Limited by GMP
407	Carrageenan or its Na, K, NH_4 salts (includes furcelleran)	
410	Carob bean gum	
412	Guar gum	
413	Tragacanth gum	
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	
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	
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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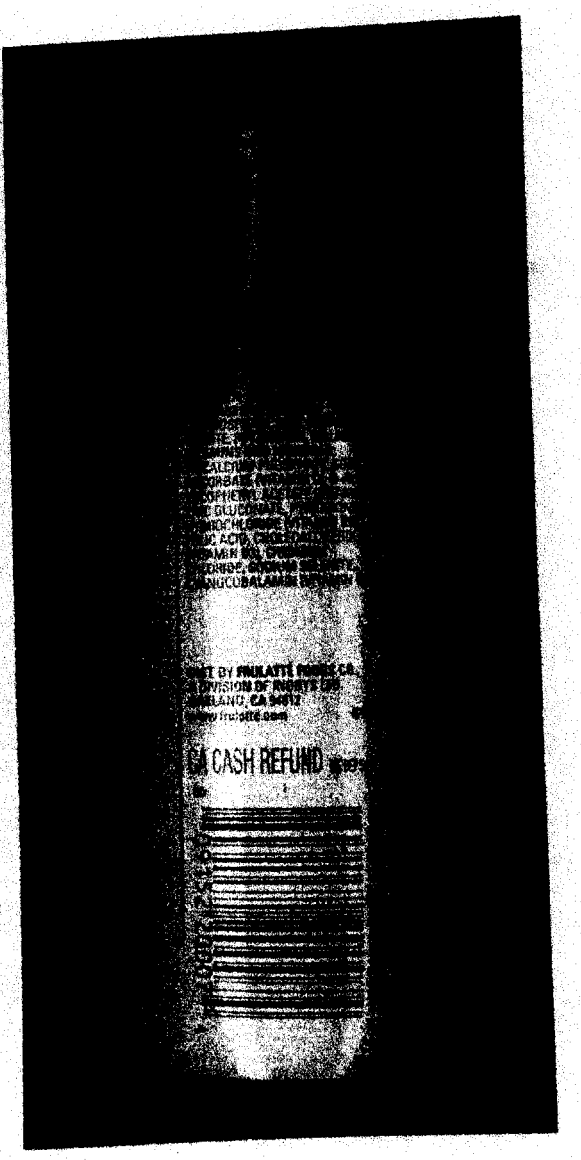
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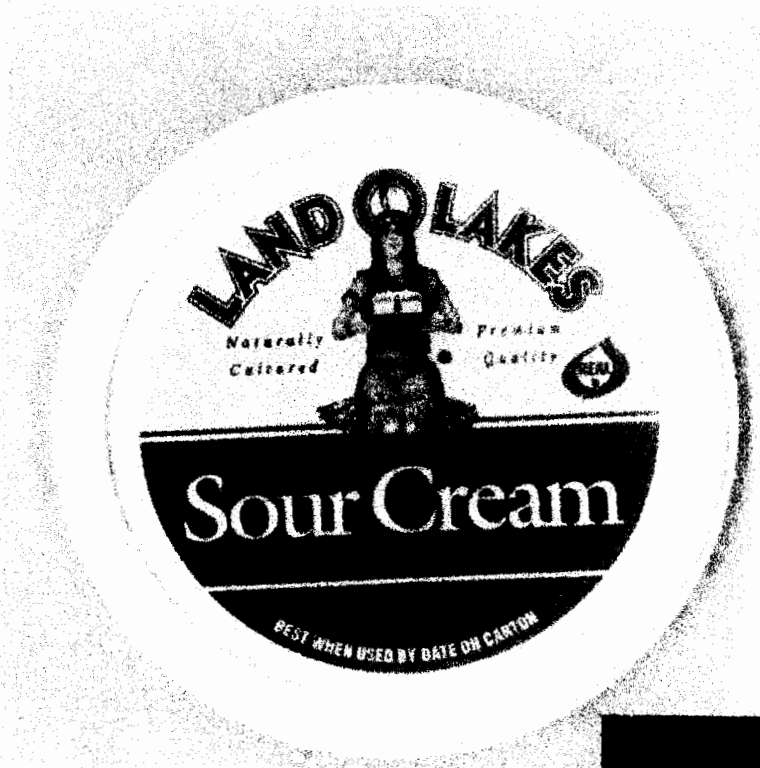
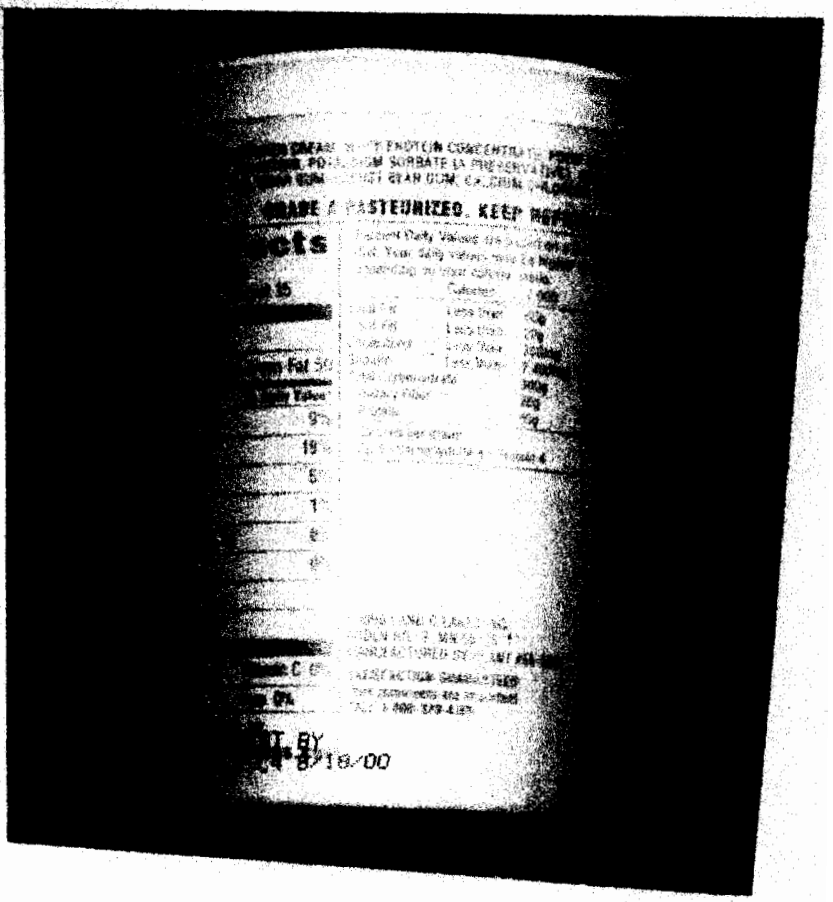

LAND O LAKES
Naturally Cultured
Premium Quality
Sour Cream
BEST WHEN USED BY DATE ON CARTON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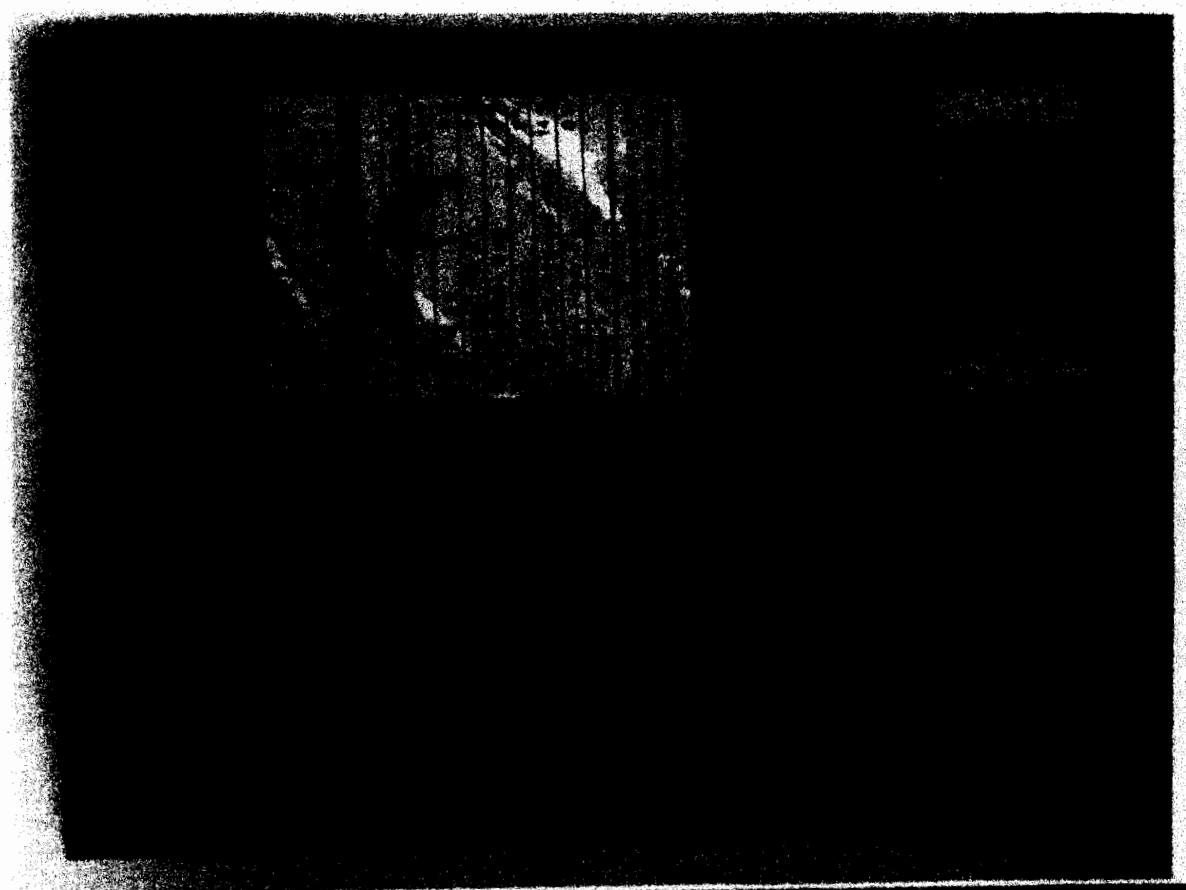

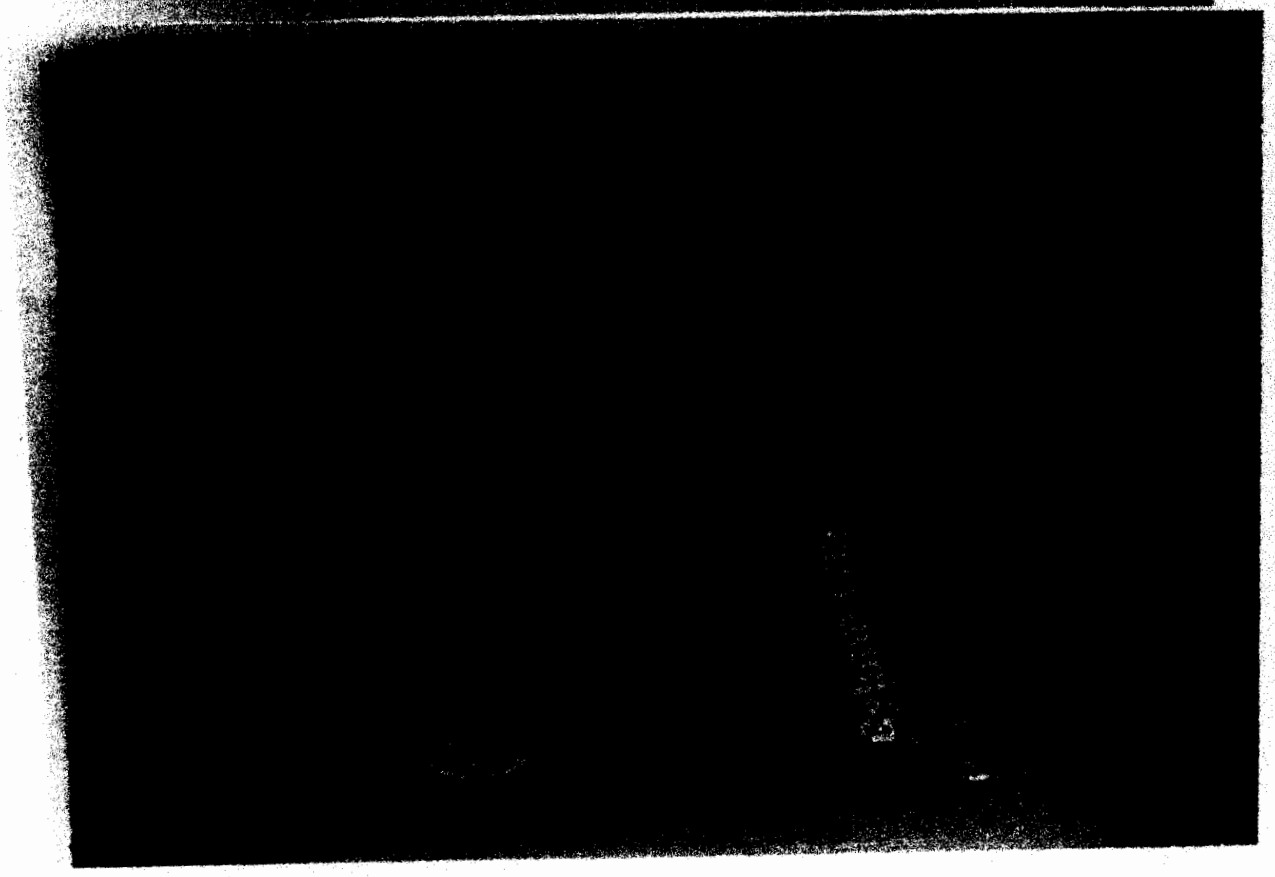

New Improved Recipe

Nestlé®

TOLL HOUSE®

8" x 8" Pan Size

12 Rich Brownies

Topped with Semi-Sweet Morsels

NET WT 18 OZ
(1 LB 2 OZ) 510 g

Keep Brownie Dough Refrigerated

Nestlé

12 TOLL HOUSE Rich Brownies

USE OR FREEZE BY:

Nutrition Facts

Serving Size 1/12 Package (43 g)
Servings Per Container 12

Amount Per Serving		% Daily Value*
Calories 180	Calories from Fat 60	
Total Fat 7 g		11%
Saturated Fat 2.5 g		13%
Cholesterol 15 mg		5%
Sodium 160 mg		6%
Total Carbohydrate 26 g		9%
Dietary Fiber 2 g		8%
Sugars 18 g		
Protein 2 g		

Vitamin A 0% • Vitamin C 0%
Calcium 0% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs

	Calories:	2,000	2,500
Total Fat	Less than	65 g	80 g
Sat Fat	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total Carbohydrate		300 g	375 g
Dietary Fiber		25 g	30 g

INGREDIENTS: SUGAR, PARTIALLY HYDROGENATED SOYBEAN AND COTTONSEED OILS, WATER, BLEACHED ENRICHED FLOUR (FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), CORNSTARCH, NESTLÉ TOLL HOUSE MORSELS (SEMI SWEET CHOCOLATE (SUGAR, CHOCOLATE LIQUOR, COCOA BUTTER, MILKFAT, SOY LECITHIN, VANILLIN – AN ARTIFICIAL FLAVOR, NATURAL FLAVOR)), COCOA PROCESSED WITH ALKALI, EGGS, MOLASSES, SALT, ARTIFICIAL FLAVORS, BAKING SODA, SODIUM ALUMINUM PHOSPHATE, GELLAN GUM, MONO- AND DIGLYCERIDES AND POLYSORBATE 60. SPICE. MAY CONTAIN PEANUT/NUT TRACES.

502210 4

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NESTLÉ USA, INC.
SOLON, OH 44139 USA
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PAT. 6,024,997

UNBAKED BROWNIE DOUGH MAY BE FROZEN FOR UP TO 2 MONTHS IF PLACED IN FREEZER BEFORE THE "USE BY" DATE INDICATED ON THE PACKAGE.

Questions or Comments?

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Visit us at www.nestleusa.com
Nestlé makes the very best!

Nestlé

Glass

33-36 mins.

Cookies


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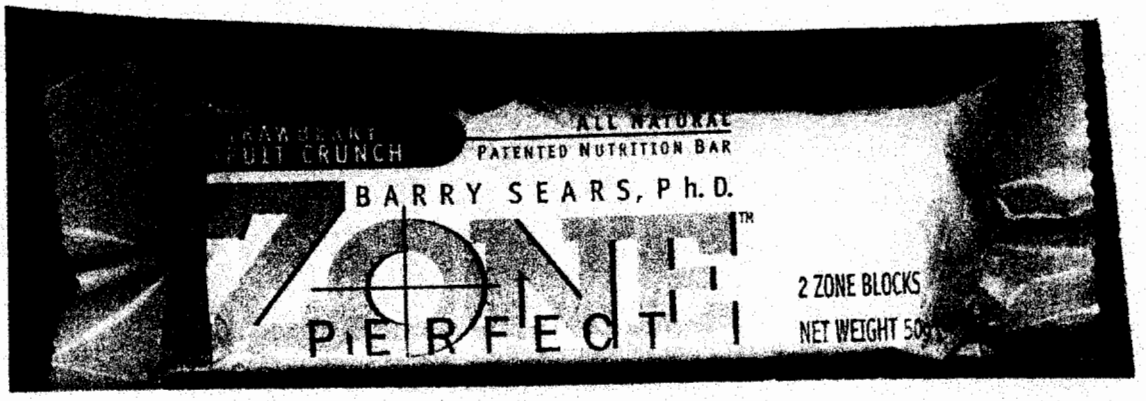
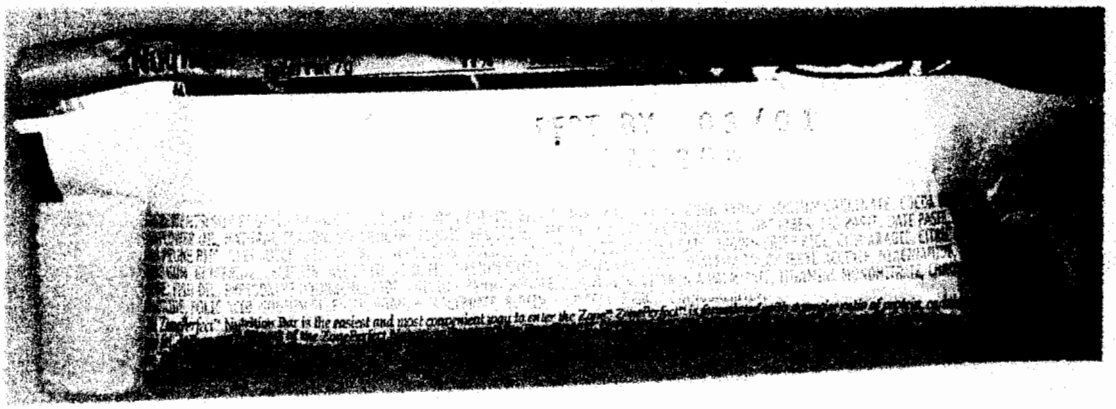

ALL NATURAL
PATENTED NUTRITION BAR
BARRY SEARS, Ph.D.
ZONE
PERFECT
2 ZONE BLOCKS



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.

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

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.

CPKelco

Material Safety Data

ISSUE DATE: 16-Apr-04
IAW: ANSI Z400.1-1998
SUPERSEDES: 16-Apr-03
VER: 03

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	**KELCOGEL®**
END USE:	Food
CHEMICAL NAME:	Gellan gum
CHEMICAL FAMILY:	Polysaccharide
COMPANY:	**CP Kelco, 8355 Aero Dr., San Diego, CA 92123, USA**
PHONE:	1+800-535-2687 (Main number - Americas) 1+858-292-4900 - 8 a.m. - 5 p.m. (Pacific Time) weekdays

FOR CHEMICAL EMERGENCY, SPILL LEAK, FIRE, EXPOSURE, OR ACCIDENT:

1+800-424-9300 CHEMTREC - Day or Night -.
Toll free in the continental U.S., Hawaii, Puerto Rico, Canada, Alaska, or Virgin Islands.
For calls originating elsewhere: 1+703-527-3887 (collect calls accepted).

2. COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT(S)	CAS RN NO.
gellan gum	71010-52-1

This product is considered hazardous according to the OSHA Hazard Communication Standard 29 CFR 1910.1200 due to flammable dust potential.
If this product is used in a manner that could generate particulates (dust), refer to MSDS Section 7, Handling and Storage, and Section 8, Recommended Exposure Limits and Personal Protective Equipment.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance and Odor: white to tan powder with slight odor

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.

POTENTIAL HEALTH EFFECTS

LIKELY ROUTES OF EXPOSURE: skin contact and inhalation

EYE CONTACT: No more than slightly irritating based on toxicity studies. The dry powder may cause foreign body irritation in some individuals.

SKIN CONTACT: No more than slightly toxic or slightly irritating based on toxicity studies. Prolonged contact with the dry powder may cause drying or chapping of the skin.

INHALATION: Inhalation of the dust may cause coughing and sneezing.

INGESTION: Is not toxic if swallowed based on toxicity studies. No significant adverse health effects are expected to develop if only small amounts (less than a mouthful) are swallowed.

Refer to Section 11 for toxicological information.

4. FIRST AID MEASURES

IF IN EYES OR ON SKIN, immediate first aid is not likely to be required. However, this material can be removed with water. Wash heavily contaminated clothing before reuse.

IF INHALED, immediate first aid is not likely to be required. However, if symptoms occur, remove to fresh air. Remove material from eyes, skin and clothing. Get medical attention if nasal, throat or lung irritation develops

IF SWALLOWED, immediate first aid is not likely to be required. A physician or Poison Control Center can be contacted for advice.

5. FIRE FIGHTING MEASURES

FLASH POINT: not applicable

CONDITIONS TO AVOID: see Section 7

HAZARDOUS PRODUCTS OF COMBUSTION: carbon dioxide, carbon monoxide

EXTINGUISHING MEDIA: In case of fire, use water, dry chemical, CO_2, or alcohol foam.

UNUSUAL FIRE AND EXPLOSION HAZARDS: This material as normally packaged and handled can contain sufficient fines to form an explosive mixture if dispersed in a sufficient quantity of air. Surfaces that may be covered with this product will become extremely slippery upon application of water.

FIRE FIGHTING EQUIPMENT: Fire fighters and others exposed to products of combustion should wear self-contained breathing apparatus. Equipment should be thoroughly decontaminated after use.

6. ACCIDENTAL RELEASE MEASURES

In case of spill, do not blow material. Use vacuum equipment designed specifically for handling combustible dusts.

NOTE - The use of water wash down is not recommended unless the spilled material is already wet. Wet material on a walking surface will be extremely slippery. Wet spills should be thoroughly flushed with water until non-slippery.

Refer to Section 13 for disposal information and Section 15 for reportable quantity information.

7. HANDLING AND STORAGE

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICES. THESE PRACTICES INCLUDE AVOIDING UNNECESSARY EXPOSURE AND REMOVAL OF MATERIAL FROM EYES, SKIN, AND CLOTHING.

Keep away from heat, sparks and flame. Avoid creating dust cloud in handling transfer and clean up.

Store in a cool (50-80°F), dry (<65% relative humidity) place in a sealed container.

MATERIALS OR CONDITIONS TO AVOID

Avoid conditions that generate dust; product may form flammable dust-air mixtures.

Avoid emptying package in or near flammable vapors; static charges may cause flash fire.

Keep away from heat, flame, sparks and other ignition sources.

Avoid storing near incompatible materials. See MSDS Section 10

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EYE PROTECTION: This product does not cause significant eye irritation or eye toxicity requiring special protection. Where there is significant potential for eye contact, wear chemical goggles and have eye flushing equipment available.

SKIN PROTECTION: Although this product does not present a significant skin concern, minimize skin contamination by following good industrial practice. Wearing protective gloves is recommended. Wash hands and contaminated skin thoroughly after handling.

RESPIRATORY PROTECTION: Avoid breathing dust. Use NIOSH approved respiratory protection equipment when airborne exposure is excessive. Consult the respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. Respiratory protection programs must comply with 29 C.F.R. 1910.134.

VENTILATION: Provide natural or mechanical ventilation to control exposure levels below airborne exposure limits (see below). The use of local mechanical exhaust ventilation is preferred at sources of air contamination such as open process equipment.

AIRBORNE EXPOSURE LIMITS:

OSHA PEL	ACGIH TLV
15 mg/m3 (total dust) 8-hr TWA	not established
5 mg/m3 (respirable) 8-hr TWA	not established

* 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: white to tan powder

pH: approximately neutral (as a 1% solution)

Solubility in Water: soluble, forming viscous solutions, becoming a paste at concentrations greater than about 5%

NOTE: These physical data are typical values based on material tested but may vary from sample to sample. Typical values should not be construed as a guaranteed analysis of any specific lot or as specifications for the product.

10. STABILITY AND REACTIVITY

STABILITY: Product is stable under normal conditions of storage and handling. Store in a cool, dry place to maintain product performance.

MATERIALS TO AVOID: strong oxidizers

HAZARDOUS DECOMPOSITION PRODUCTS: Thermal decomposition products may include carbon dioxide and carbon monoxide.

HAZARDOUS POLYMERIZATION: will not occur

11. TOXICOLOGICAL INFORMATION

The dry powder may cause foreign body irritation in some individuals. Prolonged contact with the dry powder may cause drying or chapping of the skin. Excessive inhalation of dust may be annoying and can mechanically impede respiration. Due to the hygroscopic properties, they can form a paste or gel in the airway.

Data from laboratory studies and from the scientific literature on material(s) analogous to this product are summarized.

- Oral - rat LD50: > 5,000 mg/kg

- Inhalation - rat LC50 (4-hr): > 6 mg/l (nominal)
- Eye Irritation - rabbit: nonirritating
- Skin Irritation - rabbit: nonirritating
- No adverse effects were observed in long-term feeding studies with rats (up to 3,000 mg/kg/day), mice (up to 6,000 mg/kg/day) and dogs (up to 2,000 mg/kg/day).
- No adverse effects were observed in a 2-generation reproduction study with rats (up to 3,000 mg/kg/day).
- No birth defects were noted when this material was given orally to rabbits (up to 1,500 mg/kg/day) and rats (up to 4,000 mg/kg/day) during pregnancy.

12. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
CP Kelco has not conducted environmental toxicity studies with this product.

BIODEGRADABILITY
This product is biodegradable.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with local, state, and federal regulations. Dry or wet solid material can be landfilled in accordance with local, state, and federal regulations. Liquids may be sewered in accordance with local, state, and federal regulations if care is taken to avoid pluggage or blockage of sewer systems recognizing that these materials are intended to increase viscosity and form gels. As a carbohydrate, this material is readily biodegradable, when at low concentrations, in a biological wastewater treatment plant.

14. TRANSPORT INFORMATION

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

This product is not hazardous under the applicable DOT, ICAO/IATA, or IMDG regulations.

15. REGULATORY INFORMATION

CHEMICAL INVENTORIES:

Gellan gum is listed on the following chemical inventories: TSCA Inventory, European Inventory of Existing Chemical Substances (EINECS), Canadian Non Domestic Substances List (NDSL), Australian Inventory of Chemical Substances (AICS), and Korean Existing Chemicals List (ECL).

SARA HAZARD NOTIFICATION

- Hazard Categories Under Title III Rules (40 CFR 370): not applicable
- Section 302 Extremely Hazardous Substances: not applicable
- Section 313 Toxic Chemical(s): not applicable

CERCLA REPORTABLE QUANTITY:

- Not applicable

Refer to **Section 11** for OSHA Hazardous Chemical(s) and **Section 13** for RCRA classification.

REGULATORY AND COMPENDIA INFORMATION

Gellan gum complies with 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*

16. OTHER INFORMATION

MSDS PRODUCED IN ACCORDANCE WITH ANSI MSDS STANDARDS (ANSI Z400.1).

REASON FOR VERSION: Updated Section 3

HMIS RATINGS:

Health	1	Slight Hazard
Flammability	1	Slight Hazard
Reactivity	0	Minimal Hazard

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Gellan Gum, A Bibliography of Scientific Literature

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Confidential Business Information

Commercial Confidential Information Statement

The justification to support each claim's confidentiality is provided below:

Appendix 2: CP Kelco Report, "Gellan Gum – Use in Products to be Labeled Organic," undated, is considered by CP Kelco U.S., Inc. as trade secret and, if released, would place the company at a competitive disadvantage.

Section 5 of the petition (Manufacturing Procedures): This entire section except the last part on packaging is confidential trade secret information and, if released, would cause considerable financial and commercial harm to the company.

Appendix 3: Manufacturing Diagram: This diagram is confidential trade secret information and, if released, would cause considerable financial and commercial harm to the company.