GR

Original Submission

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Xantham Gum

Purified by Recovery with Ethanol

GRAS Notification

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October 1, 2002

Letter

000003

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October 1, 2002

Dr. Laura Tarantino
Acting Director
Office of Food Additive Safety
Center for Food, Safety and Nutrition HFS 200
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Tarantino:

In accordance with the proposed rule for Substances Generally Recognized as Safe, which was published in the *Federal Register* at Vol. 62, No. 74 on April 17, 1997. Ingredients Solutions, Inc. of Searsport, Maine & Zibo Zhongxuan Biological Product Co., Ltd. of the People's Republic of China are submitting a Notice of a claim that the use of Xanthan gum purified and recovered with ethanol as a food ingredient is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act, because such use is GRAS.

Xanthan gum is a naturally occurring polysaccharide, secreted by the non-pathogenic organism *Xanthomonas campestris*. The product as currently regulated as a food additive at 21 CFR §172.695 is purified and recovered with isopropyl alcohol. Xanthan gum purified and recovered with isopropyl alcohol is approved for use under §170.3 (o) (8), (28), and (29) as a stabilizer and thickener, an emulsifier, and a surface-active agent.

A GRAS Report in support of the safe use in foods of Xanthan gum as purified and recovered with ethanol rather than isopropyl alcohol was prepared by Ingredients Solutions, Inc. and Zibo Zhongxuan Biological Product Co., Ltd., and was reviewed by a Panel of Experts qualified by training and experience to assess the safety of food ingredients. The Experts concurred with the companies' determination that Xanthan gum as purified and recovered with ethanol is safe for general use in foods. The Panel relied upon previously published reports of the human consumption of Xanthan gum as it is currently processed, reports on the purification and processing of other food ingredients with ethanol, and a large body of published literature covering the safety and technical effects in food of both Xanthan gum and ethanol. A copy of the Expert Opinion is attached to this notice.

This Notification of a claim for premarket exemption is based on a GRAS determination under proposed §170.30. Ingredients Solutions, Inc. and Zibo Zhongxuan Biological Product Co., Ltd. have prepared a Notification document in triplicate, which accompanies this letter. Ingredients Solutions, Inc., as the US based partner dealing with this product, would appreciate notice of the receipt of this document, and looks forward to any comments the agency would care to make on the Notification. The receipt may be sent to:

Ingredients Solutions, Inc.
33 Mt. Ephraim Road
Searsport, ME 04974-0407

If you have any questions regarding the content of the Notification, you may reach either myself at the number listed above or Dr. Harris J. Bixler at (207) 548-2636.

Sincerely,

Lee B. Dexter
Technical Consultant

CC: Dr. Harris J. Bixler, Ingredients Solutions, Inc.
Mr. Grant Cui, Zibo Zhongxuan Biological Product Co., Ltd.

Claim

Section I: GRAS Claim

Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. GRAS Notification

Introduction

Xanthan gum is a food-grade polysaccharide gum, derived from *Xanthomonas campestris* by a pure-culture fermentation. The polysaccharide contains a mixture of six-carbon sugars, including D-glucose, D-mannose, and D-glucuronic acid. The strain of *Xanthomonas campestris* used to produce the Xanthan gum is non-pathogenic and non-toxic to humans and animals. Further, the strain has not been genetically modified. The gum may be manufactured as the calcium, potassium, or sodium salt of the polysaccharide.

The Xanthan gum, which is the subject of this Notification, differs from that originally approved as a direct food additive at 21 CFR §172.695 in that it is purified and recovered with ethanol, rather than isopropyl alcohol. Purification with ethanol does not change the ability of Xanthan gum to meet the specifications set out in 21 CFR §172.695, accept that no isopropyl alcohol residue is present. In all other respects, Xanthan gum purified and recovered with ethanol meets the specifications for Xanthan gum set out in 21 CFR §172.695. It meets the viscosity requirements at 21 CFR §172.695 (d) (2), and is positive for both the Locust Bean Gum Gel Test and the Pyruvic Acid Test.

This Notification document contains the information required in proposed 170.36 to allow the FDA to evaluate whether the submitted notice provides a sufficient basis for a generally recognized as safe (GRAS) determination. Additionally, the Notification provides data and information which documents the ability of Xanthan gum to provide technical effects under 21 CFR §170.3 (o) beyond those listed in 21 CFR §172.695.

000007

Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. of Searsport, Maine, and The Peoples Republic of China, respectively, are submitting this Notification jointly. However, as Ingredients Solutions, Inc. is a company, located within the continental US, a copy of the GRAS Report, which supports this Notification, and supporting references will be available in the company's offices. Both companies will be referred to as "Ingredients Solutions" in this Notification, unless a specific distinction is necessary.

In compliance with 21 CFR § 170.30, Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. determined that Xanthan gum purified by recovery with ethanol could be considered GRAS when used in accordance with current Good Manufacturing Practice. Both companies wish to voluntarily notify the Center for Food Safety and Applied Nutrition (CFSAN) of that determination, and according to proposed § 170.36, the companies are submitting the following GRAS exemption claim.

Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. have prepared a GRAS Report, which forms the basis for the information found in this Notification. The companies also commissioned a panel of experts (Expert Panel), qualified by scientific training and experience, to assess the safety of Xanthan gum purified and recovered with ethanol as a food ingredient. The Expert Panel critically evaluated the Xanthan gum GRAS Report as well as other data and information relevant to the use and safety of this ingredient. In a telephone conference held on December XX, 2001, the Expert Panel concurred with the company's determination that Xanthan gum purified and recovered with ethanol can be considered generally recognized as safe for general use in food. Based on the data and information contained in the Report and the opinion of the Expert Panel (which is attached to this Notification), Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. explicitly accept responsibility for the GRAS determination of Xanthan gum purified and recovered with ethanol.

Section I. GRAS Exemption Claim

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Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. hereby notify the U.S. Food and Drug Administration that the use of Xanthan gum purified and recovered with ethanol as a food ingredient is exempt from the premarket approval requirements of the Federal Food, Drug, and

Cosmetic Act, because Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd. have determined that such use is GRAS.

1. Notifiers:

Ingredients Solutions, Inc.
Dr. Harris J. Bixler
33 Mt. Ephraim Road
Searsport, ME, USA 04974
Telephone: (207) 548-0074
Fax: (207) 548-2921

Zibo Zhongxuan Biological Product Co., Ltd.
33 Yongliu West Road Linzi
Zibo Shandong, P.R. China
Telephone: +86-533-722-0838
Fax: +86-533-721-6024

2. Common or Usual Name:

Xanthan Gum

3. Applicable Conditions of Use:

Applications for Xanthan gum purified and recovered with ethanol include general use in foods as a multiple-use direct additive. The ingredient should be used under the conditions of current Good Manufacturing Practice.

In order to classify the various effects ingredients may have in food, FDA has published a list of 32 physical or technical functional effects for which direct food ingredients may be added to food. These are codified at 21 CFR §170.3 (o) (1-32). Applications for Xanthan gum purified and recovered with ethanol are covered under the following term as listed in 21 CFR §170.3 (o).

000009

(6) "Dough strengtheners": Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of

Sciences/National Research Council under "dough conditioner."
(8) "Emulsifiers and emulsifier salts": Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.
(14) "Formulation aides": Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.
(16) "Humectants": Hygroscopic substances included in food to promote retention of moisture, including moisture-retention agents and antidusting agents.
(20) "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.
(24) "Processing aids": Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.
(28) "Stabilizers and thickeners": Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.
(29) "Surface-active agents": substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.
(31) "Synergists": Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.
(32)"Texturizers": Substances, which affect the appearance or feel of the food.

4. Basis of the GRAS Determination

The basis of the GRAS determination for Xanthan gum purified and recovered with ethanol was the use of scientific procedures.

5. Availability of Data and Information and Key to References

000010

The data and information that are the basis of the GRAS determination for Xanthan gum purified and recovered with ethanol will be available for FDA review and copying at the address of the notifier listed above. The notifier will also be pleased to provide the agency with a copy of the GRAS Report, or any references contained therein, upon written request. Throughout this Notification, citations to the published literature, which were included in the GRAS Report, are denoted as follows: [Author (*et al)*, Year, Tab (number) Volume (number)]. In order to facilitate review of this document a complete list of references from the Xanthan gum GRAS Report is included in Appendix II as a key.

6. Signature of an official for Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd.

Official for Ingredients Solutions, Inc. | Date

______________________________ October 1, 2002

Lee B. Dexter
Technical Consultant

Notification
Table of Contents

000012

October 1, 2002

Ingredients Solutions, Inc. & Zibo Zhongxuan Biological Product Co., Ltd.
GRAS Notification

Table of Contents

Page

GRAS Notification Table of Contents, Cont'd.

GRAS Notification Table of Contents, Cont'd.

Page

GRAS Notification Table of Contents, Cont'd.

Page

GRAS Notification Table of Contents, Cont'd.

Page

GRAS Notification Table of Contents, Cont'd.

Page

GRAS Notification Table of Contents, Cont'd.

Page

GRAS Notification Table of Contents, Cont'd.

Page

Section II: Chemical Identity

Introduction

Ingredients Solutions, Inc., Searsport, Maine (ISI), and Zibo Zhongxuan Biological Product Co., Ltd, People's Republic of China (ZZBP) are submitting the following GRAS Notification in support of the safety of Xanthan gum (purified by recovery with ethanol) as an ingredient in foods in general. In preparing the Notification, ISI and ZZBP have included relevant information and data that is publicly available, as well as the results of studies that have been commissioned by the companies. The report presents a balanced discussion of the safety and use of Xanthan gum, when recovered and purified with ethanol, and the companies certify that no adverse information has been knowingly omitted.

A Panel of Experts qualified to review the safety of food ingredients reviewed a four-volume GRAS Report in support of the safety of Xanthan gum (purified by recovery with ethanol) and concurred with the companies' finding that the ingredient can be considered generally recognized as safe. The opinion of the Experts is contained in an Appendix to this Notification.

Xanthan gum was the first of a new generation of polysaccharides produced by biotechnology. The polymer was discovered by the US Department of Agriculture (USDA) and named Xanthan gum [Whistler, *et al.*, 1993 Vol 4 Tab 73]. The gum, produced as an extracellular polysaccharide by *Xanthomonas campestris*, originally classified as NRRL B-1459, appeared to have valuable properties that would allow it to compete with natural gums [Glicksman, ed., 1982 Vol 2 Tab 22]. The commercial production of Xanthan gum began in the 1960s in the USA. Today, there are four major suppliers world-wide. [IMR Report, 1998 Vol 3 Tab 27].

[redacted]

The commercial Xanthan gum product currently being produced or sold in the U.S. [redacted]

The advantages of a hydrocolloid obtained by fermentation are numerous: production and availability are not dependent on external factors such as weather, and politics, and a more consistent quality and performance of the texturizing agent can be assured, especially in comparison to other natural gums that are essentially harvested from the wild [Morris, 2001 Vol 3 Tab 45].

In most countries, food legislative authorities recognize Xanthan gum as a safe and valuable food additive. Where regulated, permitted use levels are in accordance with 'Good Manufacturing Practice'. Xanthan gum has been approved in the USA since 1969 and is defined under §21 CFR 172.695. European regulations have been in place since 1974. Xanthan is registered under the number E415 in Annex I *(Food Additives Generally Permitted for Use in Foodstuffs not Referred to in Article 20)* of the European Parliament and Council Directive No. 95/2/EC of 20 February 1995. Recently, in its 53rd

Session, JECFA prepared revised specifications for Xanthan gum, which limits residual alcohols (either isopropanol or ethanol are permitted as recovery agents) to not more than 500 mg/kg [JECFA, FNP Addendum 7, 1999 Vol 2 Tab 21]. A chromatographic method is given for the determination of the residual recovery agents.

Xanthan gum has a long history of safe use, and continues to be widely sold into the food industry. Approximately 50 million pounds are used worldwide in food applications [IMR Report, 1998 Vol 3 Tab 27]. Of this amount 38% is used in sauces and dressings, 20% in prepared meals, 12% in dairy, 12% in bakery, and 18% in other food applications (including 1% in pet foods) [IMR Report, 1998 Vol 3 Tab 27].

The following section discusses the chemical identity of Xanthan gum products, which have been purified and recovered with ethanol.

A. *Common or Usual Name and Identity*

Xanthan gum

B. *Formal Names (IUPAC or Chemical Abstracts Names)*

Xanthan gum

C. *Synonyms, Other Common Names, Tradenames*

Trademark: [redacted]

D. *Chemical Formulae, Structures and Molecular Weights*

1. Empirical Formula

$(C_{67}H_{97}O_{56}M^{+}{}_{3})_n$ - (2 repeat units to allow for 50% pyruvate)

2. Structural Formula

Xanthan is an anionic bacterial polysaccharide composed of an β-(1→4)-D-Glc (cellulosic) backbone with a trisaccharide sidechain linked to the C3 of every second glucose residue. The sidechain is β-D-Man-(1→ 4)- β-D-GlcA-(1→2)- α-D-Man-(1→3) with approximately 50% of the terminal D-mannose units containing a pyruvic acid moiety as a 4,6-cyclic acetal. The non-terminal D-mannose unit is stoichiometrically substituted at *O-6* with an acetyl group [BeMiller, 1991 Vol 2 Tab 4 and Jansson *et al.*, 1975 Vol 3 Tab 29].

Primary Structure of Xanthan Gum

II. Chemical Identity, Continued

3. Molecular Weight

2-4 million daltons

E. *Chemical Abstracts Service Registry Number (CAS Registry No.)*

CAS Number 11138-66-2

F. *Quantitative Composition of Xanthan Gum Purified by Recovery with Ethanol*

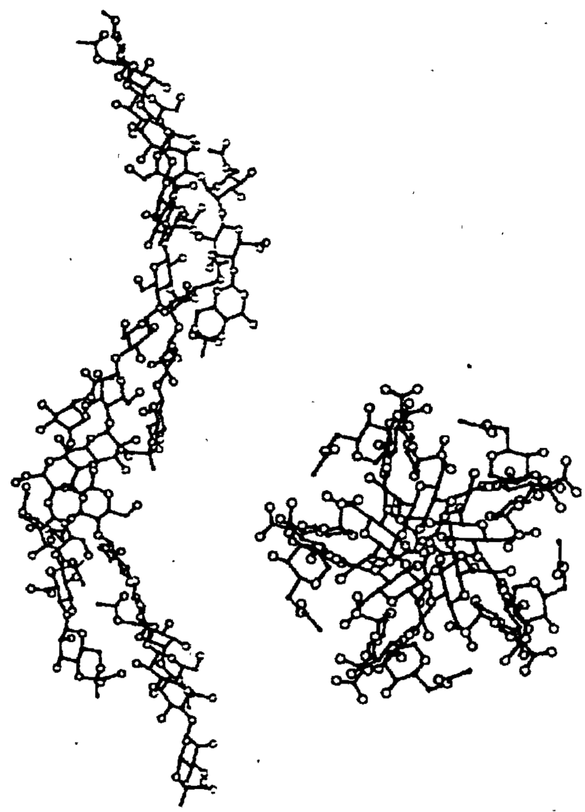
1. Product Identity

Xanthan gum purified by recovery with ethanol is identical in chemical structure to that recovered with isopropanol. The following description therefore applies to Xanthan gum purified with either ethanol or isopropanol. As shown in Figure 1, the primary structure of the Xanthan gum molecule is composed of a backbone of 1,4-linked β-D-glucose with side chains containing two mannose and one glucuronic acid unit [Jansson *et al.,* 1975 Vol 3 Tab 29]. According to Jansson *et al.*, 1975, half of the terminal mannose units carry a pyruvic acid residue and the non-terminal D-mannose unit is stoichiometrically substituted at *O-6* with an acetyl group. These side chains represent a very large proportion of the molecule (about 60%) and give Xanthan gum many of its unique properties. Xanthan gum has a high molecular weight of about 2-4 million with a low polydispersity. The polymer hydrates completely, even in cold water [Jansson *et al.*, 1975 Vol 3 Tab 29].

The secondary and tertiary structures of Xanthan gum have not been as well characterized as the primary structures. The molecular conformation was interpreted by Moorhouse *et al.,* 1977 using X-ray diffraction studies on Xanthan fibers. This study revealed that Xanthan gum occurred as a helix (Figure 1) with a pitch of 4.7nm (0.94nm per disaccharide backbone). In this conformation, it is possible that the molecule is stabilized through hydrogen bonds.

1977 also proposed that the macromolecules in solution should be considered a rigid helix. Additionally, these authors did not reject the existence of a double or triple helix [Moorhouse *et al.,* 1977 Vol 3 Tab 44]. Milas *et al.,* 1995, recently proposed a local double-helix structure, based on small-angle neutron-scattering experiments, however, microscopy studies by Wilkins *et al.,* 1993 and Kirby *et al.,* 1995 have yet to clearly define the structure [Milas *et al.,* 1995 Vol 3 Tab 41].

Figure 1 – Molecular Conformation of Xanthan



[From Moorhouse *et al.,* 1977 Vol 3 Tab 44]

000027

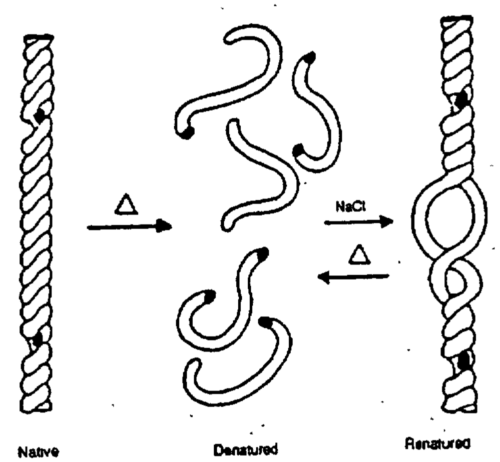
Xanthan in solution undergoes a conformational transition under the influence of temperature. This may indicate that Xanthan gum goes from a rigid ordered state to a more flexible, disordered state (see Figure 2a). Milas and Rinaudo published two studies indicating that Xanthan could have two ordered conformations: a native A conformation and a renatured B conformation. The B conformation has the same molecular weight as the native form but it exhibits a higher viscosity at the same concentration. The transition from native to denatured is irreversible whereas the transition from renatured to denatured is reversible. The transition temperature (T_m) depends on different factors, such as gum concentration and ionic strength. It also varies with the pyruvyl and acetyl contents of the Xanthan macromolecule [Milas *et al.*, 1984 Vol 3 Tab 42 and Milas *et al.*, 1986 Vol 3 Tab 43].

This conformational transition can be measured by different analytical techniques such as optical rotation, calorimetry, circular dichroism and viscosimetry. The most useful and practical technique is optical rotation, as illustrated in Figure 2b. The thermal transition temperature at low concentrations (0.1-0.3%) in distilled water is generally close to 40°C. In the presence of a small amount of salt and at concentrations generally used in food applications the thermal transition occurs at much higher temperatures, generally above 90°C (see Figure 2b) [Milas *et al.,* 1995 Vol 3 Tab 41].

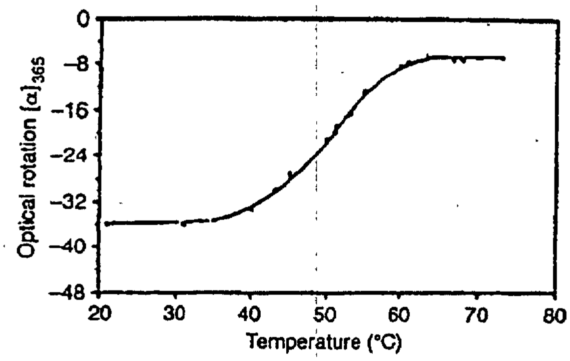
000028

Figure 2 a and b

a: Conformational Changes of Xanthan Gum in Solution



b: Thermal Transition of Xanthan Gum Measured By Optical Rotation (distilled water, concentration 0.25%)



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2. Xanthan Gum In Solution

a. Rheological properties

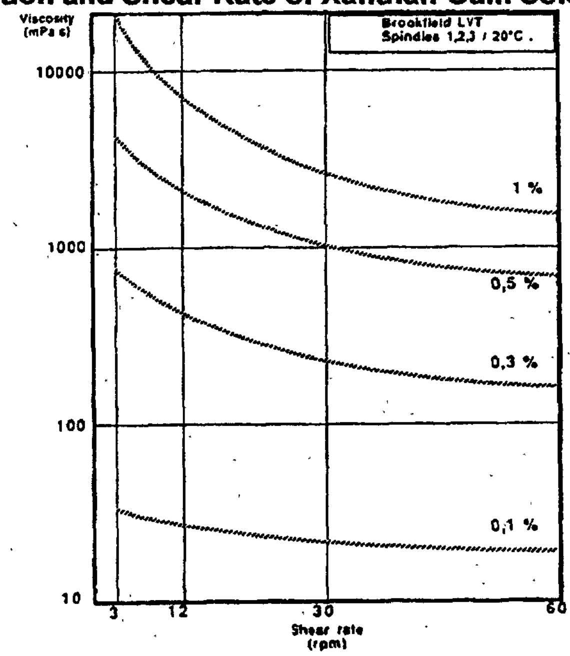
Aqueous solutions of Xanthan exhibit a very high viscosity, even at low concentrations, and very strong pseudoplasticity with no evidence of thixotropy [Whitcomb *et al.*, 1978 Vol 4 Tab 75]. These properties result from the unique rigid, rod-like conformation of Xanthan in solution and from its high molecular weight: Xanthan gum forms reversible entanglements at very low concentrations. In Figure 3, flow curves of Xanthan solutions at different concentrations are presented: all solutions show a very high viscosity at low shear rates and a very strong pseudoplastic character, which increases with concentration. This behavior can have various advantages: as the viscosity decreases with the increasing shear rate, the product becomes easy to pour, mix or pump, and the organoleptic properties of food products are affected (the shear rate in the mouth is about 50s-1) [Whitcomb *et al.*, 1978 Vol 4 Tab 75].

The thickening properties of Xanthan compared with other food hydrocolloids are illustrated in Figure 4. Low shear-rate viscosities show that values for Xanthan solutions are always greater, especially at low concentrations. The shear-thinning character of Xanthan solutions is more pronounced than that of other gums. This behavior results from the semi-rigid conformation of the Xanthan polymer, which is more sensitive to shear than a random-coil conformation. Another feature of a Xanthan gum solution is its high yield value even at low concentrations. The yield value is the minimum shear stress required for a solution to flow. As illustrated in Figure 5, the yield value results from the formation of a weak network in the solution. This is the result of interactions between Xanthan macromolecules, but the network is not a true gel because these interactions are not permanent and are shear-reversible [Whitcomb *et al.*, 1978 Vol 4 Tab 75 and Urlacher, *et al.*, 1997 Vol 5 Tab 82].

The yield value is difficult to measure because it is necessary to work at very low shear rates, and frequently this value is extrapolated with different rheological models, such as those of Bingham and Herschel-Buckley [Launay *et al.,* 1986 Vol 3 Tab 35]. In Table 1 it is clearly shown that Xanthan exhibits a significant yield value at low concentrations. This explains the ability of Xanthan solutions to stabilize dispersions such as emulsions or suspensions. A good illustration of this stabilizing property is given in Figure 6, in which setting rates of standardized particles of sand are compared for different hydrocolloids [Launay *et al.,* 1986 Vol 3 Tab 35].

Figure 3

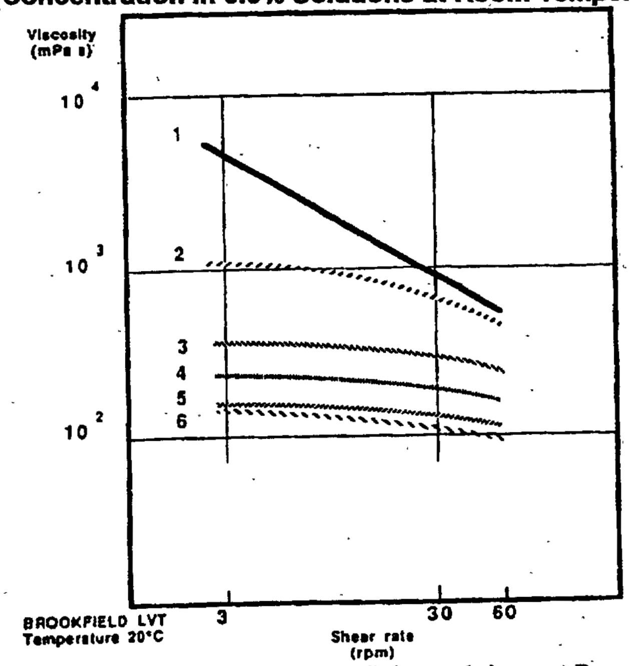
Effects of Concentration and Shear Rate of Xanthan Gum Solution in Distilled Water



000031

II. Chemical Identity, (continued)

Figure 4
Effect of Shear Rate on Different Thickeners in Distilled Water [1]
(Concentration in 0.5% Solutions at Room Temperature)



[1] 1. Xanthan Gum, 2. Guar Gum, 3. Hydroxyethylcellulose, 4. Locust Bean Gum, 5. Sodium Carboxymethlycellulose, 6. Alginate

II. Chemical Identity, (continued)

Figure 5 - Weak Network of Xanthan Macromolecules in Solution

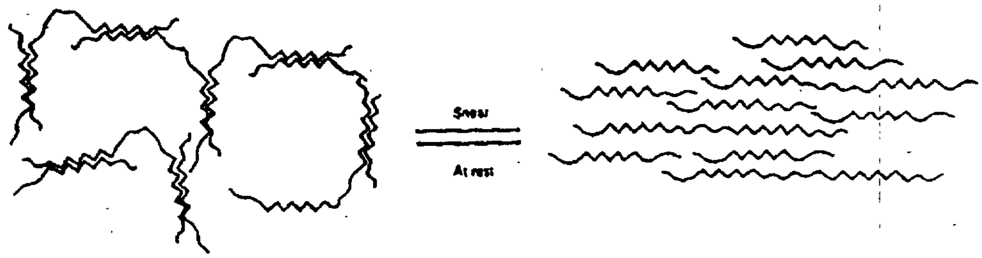


Table 1 - Yield Values (Mpa) of Hydrocolloid at Different Concentrations in 1% KCl Solution

(Bingham extrapolation with a Rheomat 30 rheometer)

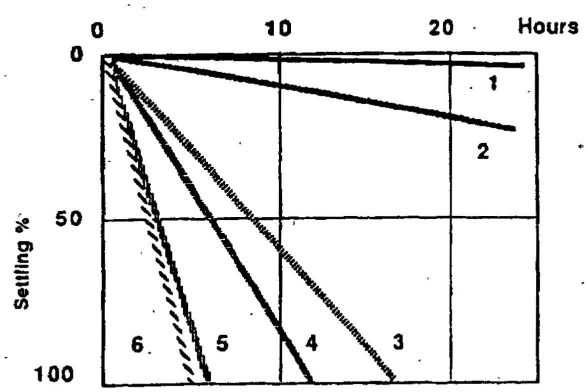
	Concentration (%)	
Hydrocolloid	**0.3**	**0.5**
Xanthan gum	500	2,200
Guar gum	210	4,000
Hydroxyethyl cellulose	60	830
Locust Bean gum	<50	360
Sodium carboxymethylcellulose	<50	410
Sodium alginate	<50	210

000033

Figure 6

Suspending Properties of Silica Sand (100-250 µm) in Hydrocolloid Solutions[1]

(0.5% Xanthan Gum or 1% Other Gums in Tap Water)



[1] 1. Xanthan Gum, 2. Guar Gum, 3. Hydroxyethylcellulose, 4. Locust Bean Gum, 5. Sodium Carboxymethlycellulose, 6. Sodium Alginate.

b. Stability

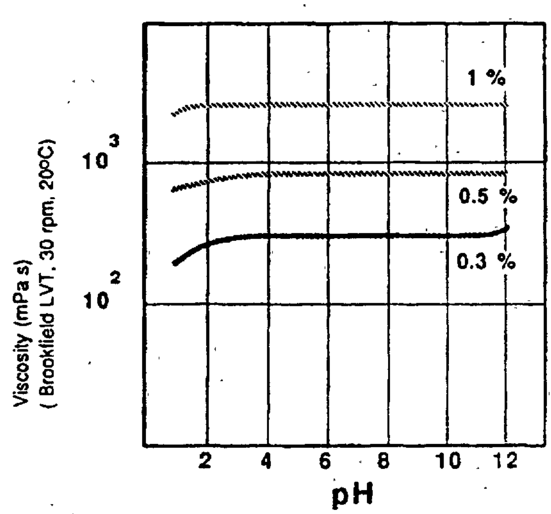
Most food products contain salts, sometimes at very high concentration (up to 15% in soya sauce), some foods are very acid, for example dressings, fruit preparations and drinks, and many of them are heat treated using high temperature short-time (HTST), ultra heat treatment (UHT) or sterilization processes. Thus food stabilizers must be stable in various conditions of ionic strength, pH and temperature.

The secondary structure of the Xanthan molecule in which the side chains are 'wrapped around' the cellulose backbone explains the unusual resistance of this hydrocolloid to degradation by acids or bases, high temperatures, freezing and thawing, enzymes and prolonged mixing [Launay *et al.*, 1986 Vol 3 Tab 35].

(1) Acids and Bases

Xanthan solutions are stable over a wide range of pH. As shown in Figure 7, only extreme pH conditions (below 2.5 and above 11) affect the solution properties. This stability is dependent on the gum concentration: the higher the concentration, the more stable the solution. Xanthan can be used in formulations containing acetic, citric or phosphoric acid [Harris, ed., 1990 Vol 2 Tab 23].

Figure 7 - Effects of pH on Solution Viscosity at different Xanthan Gum Concentrations

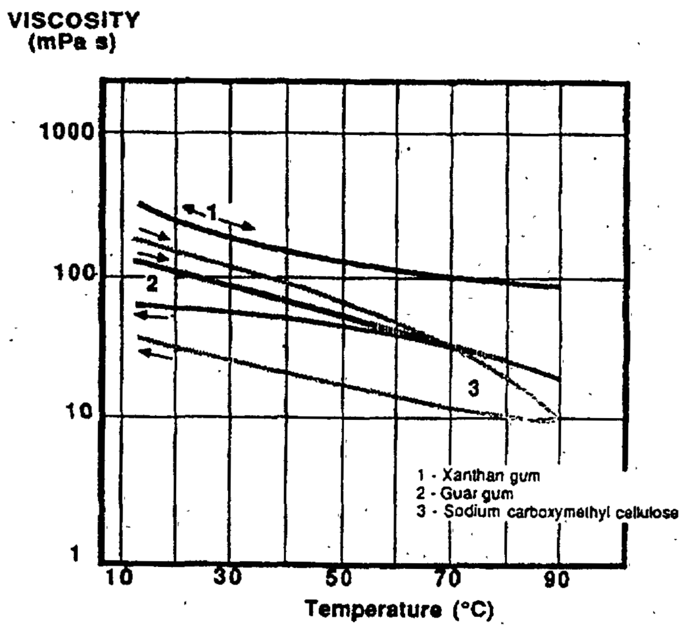


(2) *Temperature*

Xanthan solution viscosity is only slightly affected by increasing the temperature from 10 to 90°C in the presence of salts, which enhance heat stability by stabilizing the ordered conformation (Figure 8). This property is quite unusual amongst the hydrocolloids. In food products, sterilization treatments, such as 30 min at 120°C, are very common. In Figure 8 the stability of gum solutions is compared with Xanthan gum. Over 90% of the initial viscosity is retained, whereas guar, alginates and carboxymethylcellulose show greater viscosity loss [Williams, *et al.*, 1997 Vol 4 Tab 77].

Figure 8 - Temperature Stability of Xanthan Gum Compared with Guar Gum and Sodium Carboxymethylcellulose

(Concentration = 0.28% in tap water)



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(3) Enzymes

Xanthan has been found to be very resistant to enzyme degradation. It can be used in the presence of many common enzymes such as amylase, pectinase and cellulase, whether they originate from the raw materials or are specifically added during processing [Williams, *et al.*, 1997 Vol 4 Tab 77].

(4) Freeze-thaw cycles and microwave treatment

Microwave treatment is direct, fast and selective heating. In most cases, even for stabilized products, microwave treatment causes moisture separation in the finished product, especially when a freeze-thaw cycle takes place. Consequently, microwaveable foods need to be over stabilized, especially with a microwave-stable hydrocolloid. Xanthan gum solutions maintain all of their viscosity after defrosting in a microwave oven, even at low concentrations [Williams, *et al.*, 1997 Vol 4 Tab 77].

(5) Compatibility

Xanthan is compatible with high concentrations of salts: at a gum concentration of around 0.4%, viscosity is unaffected by electrolytes, but at around 1% there is a significant increase in viscosity in the presence of salts. Xanthan can also be used in the presence of high sugar concentrations (up to 60%). At a given Xanthan gum concentration, viscosity increases with the sugar content. Xanthan is compatible with most of the ingredients in food formulations such as acids, salts, thickeners (starch, carrageenan, cellulose derivatives, gelatin and alginates) and proteins. However, interaction and precipitation may occur with some proteins, such as dairy proteins, if the system is acidic or heat-processed [Williams, *et al.*, 1997 Vol 4 Tab 77].

3. Analyzed Lots of Xanthan Gum Purified by Recovery with Ethanol

ISI and ZZBP have analyzed multiple lots of the various product variations of Xanthan gum purified by recovery with ethanol. These data are presented in the following sections. Particular attention has been paid to those mineral and microbiological contaminants that may be of public health concern. The identity of the various Xanthan product types produced by ZZBP is given below.

a. Product Identity

ZZBP produces several Xanthan gum product variants. All of these products have been purified by recovery with ethanol, and are qualified and registered under ISO 9002. Each product appears as a cream colored powder. The products differ from each other in particle size, ease of dispersibility, and transparency. The descriptions associated with each product are listed below.

b. ZB2

ZB2 is a fine powdered Xanthan (92% through a 200 mesh screen; (75 microns)), which is suitable for use in food, pharmaceutical and cosmetic preparations.

c. ZB3

ZB3 is a coarse powdered Xanthan (95% through an 80 mesh screen; (180 microns)), which is suitable for use in food, pharmaceutical and cosmetic preparations.

d. ZBG

ZBG is a granular Xanthan gum. It is dust free, and disperses easily in aqueous systems. While it may also be used in the food, pharmaceutical and cosmetic markets, its particle size is somewhat larger than that of *ZB2*. Eighty five percent (85%) of the *ZBG* particles are larger than 200 mesh (75 microns).

e. ZBT

ZBT is a transparent grade of Xanthan, which provides clear solutions at low concentrations. It has a particle size of approximately 80 mesh (180 microns).

4. Residual Ethanol

Table 2 shows the residual alcohol levels of 5 lots of ZZBP Xanthan, which was purified by recovery with ethanol. None of the lots contained a detectable amount of isopropanol. Two of the 5 lots of Xanthan gum contained no detectable ethanol, or isopropanol, but did contain 5 ppm of methanol. Three lots contained between 6 and 12 ppm ethanol, as well as 6 ppm of methanol. All values showing the presence of methanol were just above the detectable limit of 4 ppm [ISI Raw data, 2001 Vol 2 Tab 28]. The most likely source of the methanol residual is the manufacturer's ethanol supply. A small amount (0.06%; 600 ppm) of methanol is set as a limit in the company's specifications.

Table 2 - Residual Alcohol Levels in ZZBP Xanthan Purified by Recovery with Ethanol

	Lot Number				
	301290	301295	301296	301301	301302
Methanol	6	6	6	nd*	5
Ethanol	12	6	12	nd*	nd*
Isopropanol	nd*	nd*	nd*	nd*	nd*

nd* - none detected (< 4ppm)

000039

5. Heavy Metals Content

An analysis of the mineral content of Xanthan gum products purified by recovery with ethanol showed that five lots of ZB3 Xanthan gum contained 0.35-0.65% calcium, 0.40-0.56% potassium, and 0.55-0.69% sodium. Both lead and arsenic were below the level of detection, and heavy metals were less than 20 ppm. The results of these analyses are shown in Table 3. Similar results are presented in Tables 4 and 5 for the ZBG and ZBT products.

Table 3 – Heavy Metals and Mineral Analyses of Five Lots of ZB3 Xanthan Gum

Lot No.	200372	200459	300358	300598	300446
Calcium	0.41%	0.49	0.35%	0.39%	0.65%
Potassium	0.40%	0.43%	0.56%	0.49%	0.47%
Sodium	0.55%	0.59%	0.52%	0.69%	0.63%
Lead	ND	ND	ND	ND	ND
Arsenic	ND	ND	ND	ND	ND
Heavy metals	<20ppm	<20ppm	<20ppm	<20ppm	<20ppm
ND = None Detected					

II. Chemical Identity, (continued)

Table 4 – Heavy Metals and Mineral Analyses of Five Lots of ZBG Xanthan Gum

Lot No.	300124	300245	300314	300401	300523
Calcium	0.65%	0.67%	0.44%	0.51%	0.47%
Potassium	0.49%	0.43%	0.47%	0.53%	0.58%
Sodium	0.55%	0.59%	0.52%	0.69%	0.63%
Lead	ND	ND	ND	ND	ND
Arsenic	ND	ND	ND	ND	ND
Heavy metals	<20ppm	<20ppm	<20ppm	<20ppm	<20ppm

ND = None Detected

Table 5 – Heavy Metals and Mineral Analyses of Five Lots of ZBT Xanthan Gum

Lot No.	200339	210022	300223	300303	310031
Calcium	0.48%	0.52%	0.54%	0.42%	0.46%
Potassium	0.54%	0.54%	0.51%	0.59%	0.43%
Sodium	0.65%	0.67%	0.59%	0.71%	0.54%
Lead	ND	ND	ND	ND	ND
Arsenic	ND	ND	ND	ND	ND
Heavy metals	<20ppm	<20ppm	<20ppm	<20ppm	<20ppm

ND = None Detected

000041

a. Specific Heavy Metals Contamination Analyses

ISI conducted analyses on specific heavy metal contamination of Xanthan gum purified by extraction with ethanol, using procedures with lower limits of detection than those shown in Tables 3-5. Results showed that Cadmium was present at levels less than 0.005 mg/kg; Mercury was less than the limits of detection at 0.002 mg/kg; and lead was below the limits of detection at 0.03 mg/kg [ISI, Raw data, 2001 Vol 2 Tab 26]. These data indicate that Xanthan gum purified by recovery with ethanol does not contain appreciable levels of toxicant heavy metals.

Table 6 - Heavy Metal Contamination in ZZBP Xanthan[1] (mg/kg)

	Lot Number				
	#301301	NX1302	#301295	#30125	#301290[2]
Cd	0.005	0.004	0.004	0.003	0.010 / 0.007
Hg	<0.002	<0.002	<0.002	<0.002	<0.002/<0.002
Pb	<0.03	<0.03	<0.03	<0.03	<0.03/ <0.03

[1]Sample preparation was done on a hot plate with $HNO_3/HClO_4$ according to prescribed procedures.

[2]Sample 301290 was run in duplicate.

000042

II. Chemical Identity, (continued)

b. Analysis of Five Lots of ZZBP Xanthan Gum

ZZBP has analyzed five lots of each of the four product variants discussed above. The data for the several chemical and microbiological variables tested are shown in Tables 7 through 10.

Table 7 - Summary of Analytical Results of Five Lots of ZB2 Xanthan Gum

Lot No.	200287	200441	300366	300413	300497
pH	6.48	6.98	6.92	7.21	7.3
Viscosity (cps)	1630	1670	1660	1420	1620
V1:V2:	1.02	1.04	1.03	1.02	1.04
Ash (%)	7.95	8.32	8.21	8.52	8.54
Moisture (%)	11.59	11.09	10.11	10.14	10.24
Pyruvic acid (%)	3.80	3.70	3.90	3.80	3.90
Nitrogen (%)	<1.5	<1.5	<1.5	<1.5	<1.5
Lead (ppm)	<3	<3	<3	<3	<3
Arsenic (ppm)	<5	<5	<5	<5	<5
Heavy metals (ppm)	<20	<20	<20	<20	<20
Nominal Particle size (Through 200 Mesh)	≥92%	≥92%	≥92%	≥92%	≥92%
Standard Plate Count (CFUs/g)	<250	500	<250	400	<250
Yeast and Mold (CFUs/g)	<100	<100	<100	<100	<100
Salmonella sp. (CFUs/g)	negative	negative	negative	negative	negative
E.coli (CFUs/g)	negative	negative	negative	negative	negative

II. Chemical Identity, (continued)

Table 8 - Summary of Analytical Results of Five Lots of ZB3

Lot No.	200372	200459	300358	300598	300446
pH	6.89	7.36	7.26	7.23	7.33
Viscosity (cps)	1500	1550	1510	1680	1600
V1:V2:	1.03	1.04	1.05	1.03	1.04
Ash (%)	8.65	8.67	8.66	8.62	8.63
Moisture (%)	11.26	12.15	11.22	10.38	10.02
Pyruvic acid (%)	3.10	3.40	3.50	3.20	3.30
Nitrogen %)	<1.5	<1.5	<1.5	<1.5	<1.5
Lead (ppm)	<3	<3	<3	<3	<3
Arsenic (ppm)	<5	<5	<5	<5	<5
Heavy metals (ppm)	<20	<20	<20	<20	<20
Nominal Particle size (Through 80 Mesh)	≥95%	≥95%	≥95%	≥95%	≥95%
Standard Plate Count (CFUs/g)	<250	500	<250	<250	<250
Yeast and Mold (CFUs/g)	<100	<100	<100	<100	<100
Salmonella sp. (CFUs/g)	negative	negative	negative	negative	negative
E.coli (CFUs/g)	negative	negative	negative	negative	negative

II. Chemical Identity, (continued)

Table 9 – Summary of Analytical Results of Five Lots of ZBG Xanthan Gum

Lot No.	300124	300245	300314	300401	300523
pH	6.78	6.87	6.92	7.19	7.34
Viscosity (cps)	1580	1570	1540	1520	1600
V1:V2:	1.02	1.04	1.02	1.03	1.04
Ash (%)	8.21	8.15	8.42	7.92	7.86
Moisture (%)	10.37	9.42	10.37	9.57	11.24
Pyruvic acid (%)	3.90	3.70	3.80	3.60	3.80
Nitrogen (%)	<1.5	<1.5	<1.5	<1.5	<1.5
Lead (ppm)	<3	<3	<3	<3	<3
Arsenic (ppm)	<5	<5	<5	<5	<5
Heavy metals (ppm)	<20	<20	<20	<20	<20
Nominal Particle size (Granular)	Granular	Granular	Granular	Granular	Granular
Standard Plate Count (CFUs/g)	<250	300	<250	500	<250
Yeast and Mold (CFUs/g)	<100	<100	<100	<100	<100
Salmonella sp. (CFUs/g)	negative	negative	negative	negative	negative
E.coli (CFUs/g)	negative	negative	negative	negative	negative

000045

II. Chemical Identity (continued)

Table 10 – Summary of Analytical Results of Five Lots of ZBT Xanthan Gum

Lot No.	200339	210022	300223	300303	310031
pH	7.18	6.74	6.69	7.34	7.3
Viscosity (cps)	1490	1560	1590	1520	1630
V1:V2	1.02	1.03	1.04	1.02	1.04
Ash (%)	8.95	8.92	8.34	8.89	7.93
Moisture (%)	11.29	10.13	9.87	10.16	10.86
Pyruvic acid (%)	3.80	3.70	3.80	3.70	3.90
Nitrogen (%)	<1.5	<1.5	<1.5	<1.5	<1.5
Lead (ppm)	<3	<3	<3	<3	<3
Arsenic (ppm)	<5	<5	<5	<5	<5
Heavy metals (ppm)	<20	<20	<20	<20	<20
Nominal Particle size (Through 60 Mesh)	100%	100%	100%	100%	100%
Standard Plate Count (CFUs/g)	<250	600	<250	400	<250
Yeast and Mold (CFUs/g)	<100	<100	<100	<100	<100
Salmonella sp. (CFUs/g)	negative	negative	negative	negative	negative
E.coli (CFUs/g)	negative	negative	negative	negative	negative

Table 11 lists the mean values (n=5) for the various Xanthan gum product variants. Standard Plate Counts and colony forming units per gram (CFUs/g) for *Salmonella sp.*, *E. coli*, and yeast and mold were <250, negative, negative, and < 100 respectively. Particle size varied by product from approximately 200 mesh to granular. Lead, arsenic, and heavy metals were below the level of detection, at <3, <5, and <20 ppm, respectively. The nitrogen component of all products was <1.5%.

000046

The analytical means for the products ranged from 3.30 to 3.82% for pyruvic acid, and from 10.46 to 11.01% for moisture. Ash levels, and viscosity measurements did not vary significantly between the products. The mean ash values ranged from 8.11 to 8.65%. The viscosity (measured according to the procedure given in 21 CFR 172.695) in centipoise ranged from 1558 to 1600. pH levels between the various products were nearly neutral to slightly alkaline (6.98 to 8.38).

Table 11 - Mean Values of Analytical Variables for Xanthan Gum Purified by Recovery with Ethanol (Means of 5 Lots)

	ZB2	ZB3	ZBG	ZBT
pH	6.98	7.21	8.38	7.05
Viscosity (cps)	1600	1568	1562	1558
V1:V2	1.03	1.04	1.03	1.03
Ash (%)	8.31	8.65	8.11	8.61
Moisture (%)	10.63	11.01	10.19	10.46
Pyruvic acid (%)	3.82	3.30	3.76	3.75
Nitrogen (%)	<1.5	<1.5	<1.5	<1.5
Lead (ppm)	<3	<3	<3	<3
Arsenic (ppm)	<5	<5	<5	<5
Heavy metals (ppm)	<20	<20	<20	<20
Nominal Particle size	≥92 % (Through 200 mesh)	≥95% (Through 80 Mesh)	Granular	100% (Through 60 Mesh)
Standard Plate Count (CFUs/g)	<250	<250	<250	<250
Yeast and Mold (CFUs/g)	<100	<100	<100	<100
Salmonella sp.(CFUs/g)	Negative	Negative	Negative	Negative
E.coli (CFUs/g)	Negative	Negative	Negative	Negative

c. Microbiological Profiles of Xanthan Gum Products Purified by Recovery with Ethanol

ZZBP has tested five lots its Xanthan gum products for Standard Plate Count, Yeast and Mold counts, and the presence of *Salmonella, sp., E. coli, Staphylococcus aureus, Clostridium sp., Streptococcus sp.,* and *Pseudomonas aeruginosa.* No organisms of public health significance were detected in any of the 20 lots tested. Further, Standard Plate counts remained below 250 organisms per gram, and Yeast and Mold counts remain less than 100 colony forming units per gram. This type of data indicates that the products have an exceptionally clean microbiological profile. The data for each product type is presented in Tables 12 through 15.

Table 12
Microbiological Profile of Five Lots of ZB2

Lot No.	200287	200441	300366	300413	300497
Standard Plate Count	<250/g	500/g	<250/g	400/g	<250/g
Yeast and Mold	<100/g	<100/g	<100/g	<100/g	<100/g
Salmonella sp.	negative/25 g	negative/25 g	negative/25 g	negative/25 g	negative/25 g
E.coli	negative/25 g	negative/25 g	negative/25 g	negative/25 g	negative/25 g
Staphylococcus aureus	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g
Clostridium sp.	absent	absent	absent	absent	absent
Streptococcus sp.	absent	absent	absent	absent	absent
Pseudomonas aeruginosa	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g

II. Chemical Identity, (continued)

Table 13
Microbiological Profile of Five Lots of ZB3 Xanthan Gum

Lot No.	200372	200459	300358	300598	300446
Standard Plate Count	<250/g	250/g	<250/g	<250/g	<250/g
Yeast and Mold	<100/g	<100/g	<100/g	<100/g	<100/g
Salmonella sp.	negative/25 g	negative/25 g	negative/25 g	negative/25 g	negative/25 g
E coli	negative/25 g	negative/25 g	negative/25 g	negative/25 g	negative/25 g
Staphylococcus aureus	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g
Clostridium sp.	absent	absent	absent	absent	absent
Streptococcus sp.	absent	absent	absent	absent	absent
Pseudomonas aeruginosa	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g

Table 14
Microbiological Profile of Five lots of ZBG

Lot No.	300124	300245	300314	300401	300523
Standard Plate Count	<250/g	300/g	<250/g	500/g	<250/g
Yeast and Mold	<100/g	<100/g	<100/g	<100/g	<100/g
Salmonella sp.	negative/g	negative/g	negative/g	negative/g	negative/g
E coli	negative/g	negative/g	negative/g	negative/g	negative/g
Staphylococcus aureus	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g
Clostridium sp.	absent	absent	absent	absent	absent
Streptococcus sp.	absent	absent	absent	absent	absent
Pseudomonas aeruginosa	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g

000049

Table 15
Microbiological Profile of Five lots of ZBT

Lot No	300124	210022	300223	300303	310031
Standard Plate Count	<250/g	600/g	<250/g	400/g	<250/g
Yeast and Mold	<100/g	<100/g	<100/g	<100/g	<100/g
Salmonella sp.	negative/g	negative/g	negative/g	negative/g	negative/g
E.coli	negative/g	negative/g	negative/g	negative/g	negative/g
Staphylococcus aureus	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g
Clostridium sp.	absent	absent	absent	absent	absent
Streptococcus sp.	absent	absent	absent	absent	absent
Pseudomonas aeruginosa	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g	absent in 0.5g

d. Food Grade Specifications

ZZBP has provided food grade specifications for its various product categories. These specifications are based on the company's demonstrated ability to manufacture consistently, as suggested by the data shown above covering five lots for each product type. Specifications for each of the Xanthan gum products purified by recovery with ethanol are given in Tables 16-19.

000050

II. Chemical Identity, (continued)

Table 16
ZZBP Xanthan Gum Specifications - Product Type: *ZB2*

Food Grade	
Chemical Specifications	
Appearance:	creamy white, free flowing powder
pH:	6.0 - 8.0
Viscosity:	1300 - 1800cps
V1:V2	1.02 - 1.45
Ash:	<13%
Moisture:	<13%
Pyruvic acid:	>1.5%
Nitrogen:	<1.5%
Lead:	<0.1 ppm
Arsenic:	<3 ppm
Particle size:	100% to pass through 80 mesh (180 micron)
	Min. 92% to pass through 200 mesh (75 micron)
Microbiological Specifications	
Total plate count:	<2000/g
Yeast & mold:	<100/g
Salmonella sp:	negative in 1.0 g
E.coli:	negative in 1.0 g
Coliforms	negative in 1.0 g
Staphylococcus aureus:	absent in 0.5g
Clostridium sp:	absent in 1.0 g
Streptococcus sp:	absent in 0.5g
Pseudomonas aeruginosa:	absent in 0.5g
Packaging	
Packaging:	cardboard drums or multi-ply paper bags:
Net 20 kg	carton: net 20kg

II. Chemical Identity, (continued)

Table 17
ZZBP Xanthan Gum Specifications - Product Type: *ZB3*

Food Grade	
Chemical Specifications	
Appearance:	**creamy white, free flowing powder**
pH:	**6.0 - 8.0**
Viscosity:	**1300 - 1800cps**
V1:V2	**1.02 - 1.45**
Ash:	**<13%**
Moisture:	**<13%**
Pyruvic acid:	**>1.5%**
Nitrogen:	**<1.5%**
Lead:	**<0.1 ppm**
Arsenic:	**<3 ppm**
Particle size:	**100% to pass through 60mesh (250 micron)** **Min. 95% to pass through 80mesh (180 micron)**
Microbiological Specifications	
Total plate count:	**<2000/g**
Yeast & mold:	**<100/g**
***Salmonella sp*:**	**negative in 1.0 g**
***E.coli*:**	**negative in 1.0 g**
Coliforms	**negative in 1.0 g**
***Staphylococcus aureus*:**	**absent in 0.5g**
***Clostridium sp*:**	**absent in 1.0 g**
***Streptococcus sp*:**	**absent in 0.5g**
***Pseudomonas aeruginosa*:**	**absent in 0.5g**
Packaging	
Packaging:	**cardboard drums or multi-ply paper bags:**
Net 20 kg	**carton: net 20kg**

000052

II. Chemical Identity, (continued)

Table 18

ZZBP Xanthan Gum Specifications - Product Type: ZBG

Food Grade	
Chemical Specifications	
Appearance:	**creamy white, free flowing powder**
pH:	**6.0 - 8.0**
Viscosity:	**1300 - 1800cps**
V1:V2	**1.02 - 1.45**
Ash:	**<13%**
Moisture:	**<13%**
Pyruvic acid:	**>1.5%**
Nitrogen:	**<1.5%**
Lead:	**<0.1 ppm**
Arsenic:	**<3 ppm**
Particle size:	**Min. 97% to pass through 60 mesh (250 micron)** **Max. 95% to pass through 200 mesh (75 micron)**
Microbiological Specifications	
Total plate count:	**<2000/g**
Yeast & mold:	**<100/g**
***Salmonella sp*:**	**negative in 1.0 g**
***E.coli*:**	**negative in 1.0 g**
Coliforms	**negative in 1.0 g**
***Staphylococcus aureus*:**	**absent in 0.5g**
***Clostridium sp*:**	**absent in 1.0 g**
***Streptococcus sp*:**	**absent in 0.5g**
***Pseudomonas aeruginosa*:**	**absent in 0.5g**
Packaging	
Packaging:	**cardboard drums or multi-ply paper bags:**
Net 20 kg	**carton: net 20kg**

000053

II. Chemical Identity, (continued)

Table 19
ZZBP Xanthan Gum Specifications - Product Type: *ZBT*

	Food Grade
	Chemical Specifications
Appearance:	**creamy white, free flowing powder**
pH:	**6.0 - 8.0**
Viscosity:	**1300 - 1800cps**
V1:V2	**1.02 - 1.45**
Ash:	**<13%**
Moisture:	**<13%**
Pyruvic acid:	**>1.5%**
Nitrogen:	**<1.5%**
Lead:	**<0.1 ppm**
Particle size:	**100% through 60 mesh (250 micron)**
	Min. through 80mesh (175 micron)
Total plate count:	**<2000/g**
Yeast & mold:	**<100/g**
***Salmonella sp*:**	**negative in 1.0 g**
***E.coli*:**	**negative in 1.0 g**
Coliforms	**negative in 1.0 g**
***Staphylococcus aureus*:**	**absent in 0.5g**
***Clostridium sp*:**	**absent in 1.0 g**
***Streptococcus sp*:**	**absent in 0.5g**
***Pseudomonas aeruginosa*:**	**absent in 0.5g**
	Packaging
Packaging:	**cardboard drums or multi-ply paper bags:**
Net 20 kg	**carton: net 20kg**

000054

G. Characteristic Properties of Xanthan Gum

1. Introduction

Xanthan gum products, which have been purified by recovery with ethanol. Xanthan gum is a heteropolysaccharide produced by pure-culture fermentation using the non-pathogenic organism *Xanthomonas campestris* [Imeson, ed., 1997 Vol 3 Tab 26]. Suitable carbon sources, such as cornstarch are used as sources of energy for the organism. During processing, the gum is sterilized, and therefore, the source organism is not passed on to the final product [Imeson, ed., 1997 Vol 3 Tab 26 and Morris, 2001 Vol 3 Tab 45]. The polymer was discovered by the US Department of Agriculture (USDA) and commercial production of Xanthan gum began in the 1960s in the USA [Imeson, ed., 1997 Vol 3 Tab 26 and Whistler, *et al.*, 1993 Vol 4 Tab 73].II. Chemical Identity, (continued)

2. Xanthan Gum as a Food Additive

In most countries, food legislative authorities recognize Xanthan gum as a safe and valuable food additive. Market research firms report that approximately 50 million pounds are used worldwide in food applications on an annual basis [IMR Report, 1998 Vol 3 Tab 27]. The Xanthan gum that is the basis of this GRAS Report differs from that, which was approved as a Food Additive in the US at 21 CFR 172.695, only in the fact that it is purified by recovery with ethanol, rather than isopropanol.

3. Physical and Chemical Structure of Xanthan Gum

000055

The primary structure of the Xanthan gum molecule is composed of a backbone of 1,4-linked β-D-glucose units, as is cellulose [BeMiller, 1993 Vol 2 Tab 4]. Xanthan gum differs from cellulose, in that every second β-D-glucopyranosyl unit is substituted with a trisaccharide unit. Each trisaccharide unit is composed of two mannose and one glucuronic acid residues, and approximately one half the side chains carry a terminal pyruvic acid cyclic acetal group; the non-terminal D-mannose unit is stoichiometrically sub- stituted at *O-6* with an acetyl group [BeMiller, 1991 Vol 2 Tab 4 and Jansson *et al.,* 1975 Vol 3 Tab 29]. The side chains represent about 60% of the molecule, and give Xanthan gum many of its unique properties. Xanthan gum has a high molecular weight of about 2-4 million daltons with a low polydispersity. The molecular conformation was interpreted by Moorhouse *et al.,* 1977 using X-ray diffraction studies on Xanthan fibers.

Aqueous solutions of Xanthan gum exhibit a very high viscosity, even at low concentrations, and very strong pseudoplasticity with no evidence of thixotropy [Whitcomb *et al.*, 1978 Vol 4 Tab 75]. Xanthan solutions are stable over a wide range of pH. This stability is dependent on the gum concentration: the higher the concentration, the more stable the solution. Xanthan can be used in formulations containing acetic, citric or phosphoric acid [Harris, ed., 1990 Vol 2 Tab 23].

H. Summary of Chemical Identity

The preceding Section discusses the chemical identity of Xanthan gum products, which have been purified by recovery with ethanol. Xanthan gum is a heteropolysaccharide produced by pure-culture fermentation using the non-pathogenic organism *Xanthomonas* [Urlacher, *et al.,*1997 Vol 4 Tab 71]. Suitable carbon sources, such as cornstarch are used as sources of energy for the organism. During processing, the gum is sterilized, and therefore, the source organism is not passed on to the final product [Urlacher, *et al.,*1997 Vol 4 Tab 71 and Morris, 2001 Vol 3 Tab 47]. The polymer was discovered by the US Department of Agriculture (USDA) and commercial production of Xanthan gum began in the 1960s in the USA [Urlacher, *et al.,*1997 Vol 4 Tab 71 and Whistler, *et al.,* 1993 Vol 4 Tab 79].].

In most countries, food legislative authorities recognize Xanthan gum as a safe and valuable food additive. Market research firms report that approximately 50 million pounds are used worldwide in food applications on an annual basis [IMR Report, 1998 Vol 3 Tab 30]. The Xanthan gum that is the basis of this GRAS Notification differs from that, which was approved as a

Food Additive in the US at 21 CFR 172.695, only in the fact that it is purified by recovery with ethanol, rather than isopropanol.

The primary structure of the Xanthan gum molecule is composed of a backbone of 1,4-linked β-D-glucose units, as is cellulose [BeMiller, 1993 Vol 2 Tab 5]. Xanthan gum differs from cellulose, in that every second β-D-glucopyranosyl unit is substituted with a trisaccharide unit. Each trisaccharide unit is composed of two mannose and one glucuronic acid residues, and approximately one half the side chains carry a terminal pyruvic acid cyclic acetal group; the non-terminal D-mannose unit is stoichiometrically substituted at *O-6* with an acetyl group [BeMiller, 1991 Vol 2 Tab 5 and Jansson *et al.,* 1975 Vol 3 Tab 33]. The side chains represent about 60% of the molecule, and give Xanthan gum many of its unique properties.

Xanthan gum has a high molecular weight of about 2-4 million daltons with a low polydispersity. The molecular conformation was interpreted by Moorhouse *et al.,* 1977 using X-ray diffraction studies on Xanthan fibers [Moorhouse *et al.,* 1977 Vol 3Tab 46].

Aqueous solutions of Xanthan gum exhibit a very high viscosity, even at low concentrations, and very strong pseudoplasticity with no evidence of thixotropy [Whitcomb *et al.*, 1978 Vol 4 Tab 80]. Xanthan solutions are stable over a wide range of pH. This stability is dependent on the gum concentration: the higher the concentration, the more stable the solution. Xanthan can be used in formulations containing acetic, citric or phosphoric acid [Morris, 2001 Vol 3 Tab 47].

The manufacturer has provided food grade specifications for its various product categories. These specifications are based on the company's demonstrated ability to manufacture consistently, as indicated by the data shown above covering five lots for each product type. Food grade specifications for each of four ethanol purified product variants have been given. The products represent a range of particle sizes and properties in solution.

ZZBP has designed 12 Critical Control Points into its process. The Critical Control Points cover receipt of raw materials, mixing, sterilization, fermentation, and precipitation, milling, sieving, and packaging. The company has also provided written analytical methods in accordance with 21 CFR 172.695 for the testing of its Xanthan gum products. These procedures assure that the product is tested consistently against specification parameters (See Appendix III).

ZZBP's manufacturing process is organized batch-wise into a series of fermentation and purification steps. Each finished lot is assigned a 5-digit number. All finished products and their raw materials can be traced to a given production period. In the event of a complaint or food-borne illness resulting from use of the company's Xanthan gum products, a written policy guides an investigation procedure (See Appendix III).

The manufacturing process for Xanthan gum purified by recovery with ethanol, as executed by ZZBP, is well controlled, and produces a product, which is both free of contaminants of public health concern, and desirable for its intended uses in foods.

Section III

Section III: Information on Self-Limiting Levels of Use and Probable Consumption

A. *Physiochemical Properties of Xanthan Gum Which Form the Basis for its Potential Functionality in Food*

1. Introduction

The use of Xanthan gum as a food ingredient and fiber supplement in human nutrition has been investigated for several decades [Sutherland, 1986 Vol 4 Tab 66]. While previous investigations focused on the technical effects of Xanthan gum, more recent research has shown that Xanthan gum can have a dual role in foods. That is, when Xanthan gum is incorporated into foods, it performs specific functions within the food matrix and functions physiologically as a source of soluble fiber [Ou, *et al.*, 2001 Vol 3 Tab 49 and Eastwood, 1993 Vol 2 Tab 22].

ISI, its associates and others in the edible gum industry have developed food formulations in which Xanthan gum may be utilized across a wide range of food categories [Kelco Product Literature, undated Vol 3 Tab 36]. In most of these formulations Xanthan gum is used as a technical ingredient to improve the quality of the finished product. Its use provides the food formulator a route to modifying the texture, viscosity, appearance, or shelf life of a given food. In this respect Xanthan gum purified by recovery with ethanol is expected to be identical in its technical effects as that purified by recovery with isopropanol.

Example formulations are provided in this section for the use of Xanthan gum [shown as a weight percentage of the formulation] in sauces and dressings (0.3 - 0.75%), baked goods (0.05 - 0.2%), as an ingredient of the flavoring or topping of snack foods (0.05%), in vegetable and fruit juices (0.05 – 0.75%), in dairy products (0.1 – 0.2%), in processed meats (0.1 – 0.2%), glazes and gravies (0.15 – 0.5%), soft candies (0.1%), soy milks (0.1%), and non-alcoholic beverages (0.05%). In these formulations Xanthan gum has a number of technical effects, which are presented below.

2. *Potential Uses of Xanthan Gum in Foods*

Xanthan gum purified by recovery with ethanol is a multiple-use direct food additive. Food formulations containing Xanthan gum recovered with isopropanol have been in use for several decades, and the uses for which this type of Xanthan gum are approved are currently listed under 21 CFR 172.695. The applications for Xanthan gum have been summarized by food category in Table 21.

However, the Xanthan gum regulated under 21 CFR 172.695 and recovered with isopropanol, may contain as much as 750 ppm residual alcohol. As has been stated in Section I, the Xanthan gum, which is the subject of this submission is purified by recovery with ethanol, and recent analyses have shown that this product contains alcohol residuals ranging from non-detectable to 12 ppm. Therefore, the Xanthan gum purified by recovery with ethanol may be appropriate for use over a wider range of food categories, than that which is now common to industry. Table 20 lists the major food categories in which Xanthan gum purified by recovery with ethanol is expected to be used, the food industry application, and the functional effects. The functional effects presented correlate to a list of 32 physical or technical functional effects for which direct food ingredients may be added to food. These are codified at 21 CFR § 170.3 (o) (1 - 32). The applications for Xanthan gum purified by recovery with ethanol are covered under the following terms as listed under 21 CFR 170.3 (o).

(8) "Emulsifiers and emulsifier salts": Substances, which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(11) "Flavor enhancers": Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.

(14) "Formulation Aids": Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers plasticizers, film-formers, and tableting aids, etc.

(16) "Humectants ": Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and anti-dusting agents.

(20) "Nutritional supplement": Substances added to food to supplement the diet, or increase the nutritional value of a food.

(28)"Stabilizers and thickeners": Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(31) "Synergists": Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) "Texturizers": Substances, which affect the appearance or feel of the food.

All of these effects apply in one way or another to current applications of Xanthan gum purified by recovery with isopropanol except for (20) "Nutritional Supplement". While this is a relatively new category of use for natural ingredients, the availability of Xanthan gum purified by recovery with ethanol, with its lower levels of residual alcohol, may accelerate market penetration for this use of Xanthan gum.

III. Probable Consumption, (continued)

Table 20
Current applications for Xanthan Gum Purified by Recovery with Ethanol

Food Type	Application	Functional Effects
Baked Goods and Confectionery	Improvement in dough characteristics	♦ Shear thinning solutions ♦ Suspendability, ♦ Constant viscosity with heat
	Fillings	♦ Shear thinning solutions ♦ Suspendability, ♦ Constant viscosity with hot temperatures, ♦ Resistance in acid systems ♦ Shear thinning solutions ♦ Suspendability,
Milk and Milk Products	Liquid Preparation for milk shakes, Reconstituted dairy products, Soy milk, Whipped Cream	♦ Constant viscosity with hot temperatures, ♦ Heat stability, especially during sterilization
	Light custards, Dessert creams,	♦ Constant viscosity with hot temperatures, ♦ Heat stability, especially during sterilization, ♦ Freeze/thaw stability ♦ Resistance in acid systems, ♦ Heat stability, especially during sterilization
	Puddings, Mousses	
	Caramel covering	

000063

III. Probable Consumption, (continued)

Food Type	Application	Functional Effects
Dry Mixes	Light custards, Puddings, Mousses, Yogurts, Dairy beverages, Sweetened water gels	♦ Disperses readily in cold systems ♦ Disperses readily in cold systems, ♦ Resistance in acid systems
Fruit Preparations	Jellied fruit for yogurt Low-calorie jams Fruit sauces	♦ Shear thinning solutions, ♦ Suspendability, Resistance in acid systems
Meat and Meat Products	Canned products, Meat and fish pates, Comminuted meat and fish products	♦ Disperses readily in cold systems, ♦ Heat stability, especially during sterilization, ♦ Constant viscosity with hot temperatures
Sauces, Soups, and Dressings	Mayonnaise, Sauce emulsions, Salad dressings, Acid sauces, Tomato sauce, Seasonings, Hot sauces, Soups	♦ Disperses readily in cold systems, ♦ Heat stability, especially during sterilization, ♦ Constant viscosity with hot temperatures ♦ Disperses readily in cold systems, ♦ Shear thinning solutions, ♦ Suspendability, ♦ Resistance in acid systems ♦ Heat stability, especially during sterilization, ♦ Constant viscosity with hot temperatures ♦ Resistance in acid systems

III. Probable Consumption, (continued)

Food Type	Application	Functional Effects
Sauces, Soups, and Dressings, (cont'd)	Frozen and ready to eat foods	♦ Constant viscosity with hot Temperatures ♦ Resistance in acid systems ♦ Heat stability, especially during sterilization, ♦ Freeze/thaw stability
Ices, Water-Ices	Ice creams, Ice milks;	♦ Freeze/thaw stability
	Water-ices, Sorbets,	♦ Resistance in acid systems, ♦ Freeze/thaw stability
	Liquid mixes for water-ices	♦ Resistance in acid systems ♦ Heat stability, especially during sterilization, ♦ Freeze/thaw stability
	Dry mixes for ice cream and water-ices	♦ Disperses readily in cold systems, ♦ Freeze/thaw stability
Beverages	Pulp suspension	♦ Shear thinning solutions, ♦ Suspendability, ♦ Resistance in acid systems
	Powdered beverages	♦ Disperses readily in cold systems, ♦ Shear thinning solutions, ♦ Suspendability, ♦ Resistance in acid systems

3. Xanthan Gum Applications

In order to be used as an ingredient in foods, Xanthan gum must first be prepared as a solution. The following information is provided regarding the procedure for preparation of the gum. This information would apply to Xanthan gum as purified by recovery with either isopropanol or ethanol.

a. Solution preparation and use

Xanthan is a very hydrophilic product, and problems have been known to arise during hydration. Certain researchers indicate that a distinction needs to be drawn between hydration and dispersibility:

- Dispersibility has been defined as the ease of separation of the individual gum particles when Xanthan is introduced into a liquid
- Hydration has been defined as the ease with which these individual particles swell and develop viscosity [Morris, 1990 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

Workers in the field of edible gums indicate that it is necessary to find a compromise between dispersibility and hydration. For instance an easily dispersible product will hydrate very slowly and vice versa. A very fine powder is difficult to disperse, but once dispersed it is quick to hydrate [Morris, 1990 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71]. The hydration time depends on several factors:

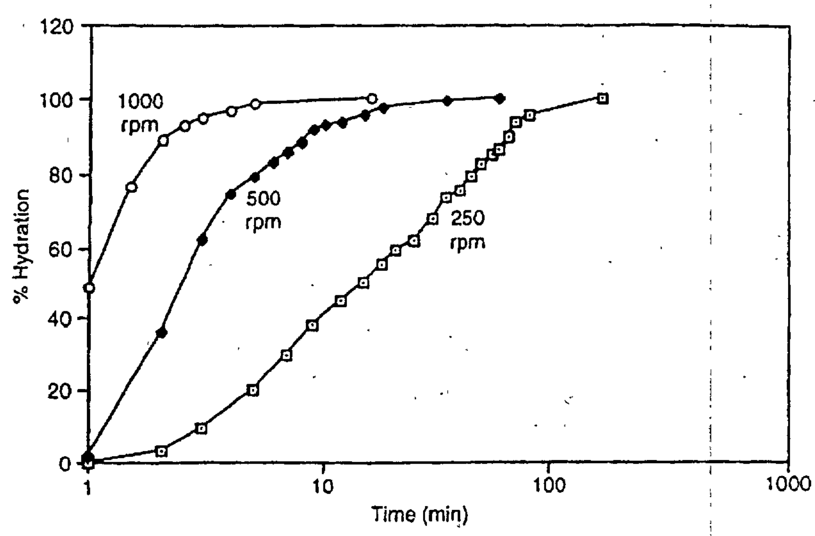
- The effectiveness of the method of dispersion
- The size of the gum particles
- The other components of the formulation.

III. Probable Consumption, (continued)

Figures 9 - 12 below illustrate the percentage hydration (viscosity at time t / final viscosity) as a function of time under different experimental conditions for 0.5% Xanthan gum solutions:

- Variation of the stirring speed (Figure 9): a higher stirring speed improves dispersion and shortens hydration time
- Variation of the size of the particles (Figure 10) under good predispersion conditions: a finely ground material hydrates more rapidly when properly dispersed
- Variation of the salt (NaCl) content (Figure 11): the presence of salt reduces the hydration speed
- Variation of the sugar content (Figure 12): hydration is hardly modified at sugar contents up to 40%, whereas hydration is slower for higher sugar contents [Morris, 1990 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

Figure 9 - Hydration of Xanthan Gum at Different Stirring Speeds[1]

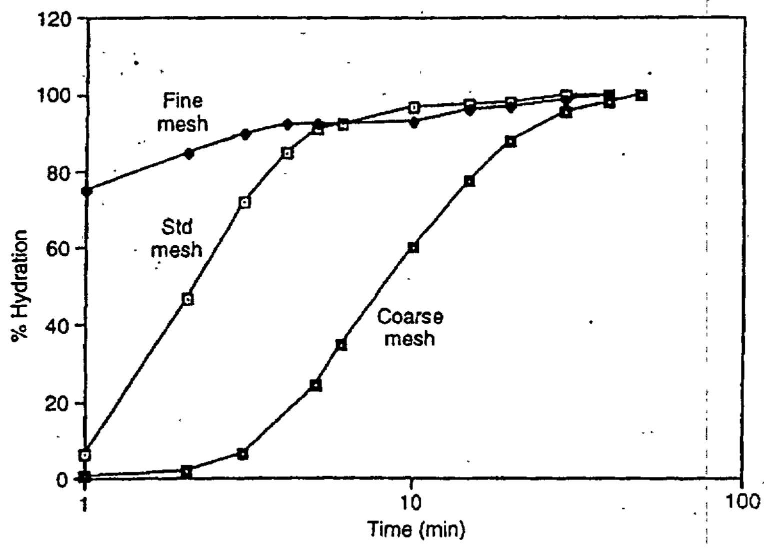


[1]Standard mesh in a 1% NaCl solution

000067

II. Chemical Identity, (continued)

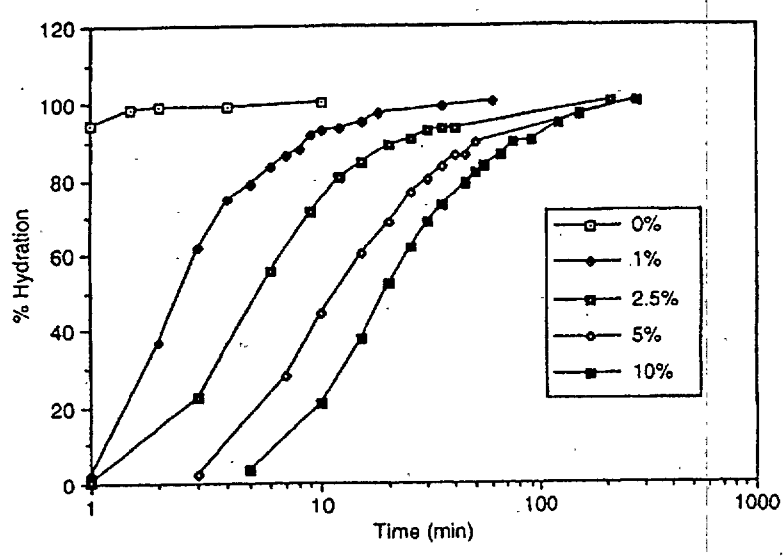
Figure 10 - Hydration of Xanthan Gum of Varying Particle Sizes[1]



[1]In distilled water; predispersion followed by stirring at 500 rpm

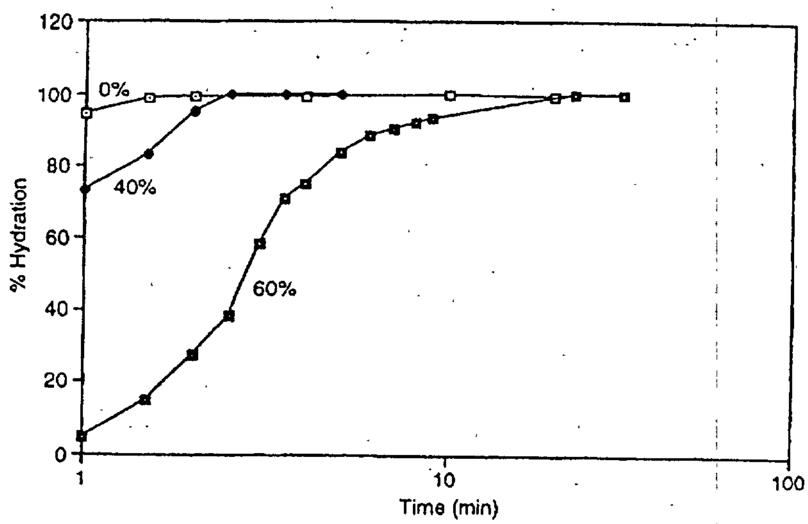
II. Chemical Identity, (continued)

Figure 11 - Hydration of Xanthan Gum in Varying Concentrations of NaCl[1]



[1]Standard mesh; Stirring at 500 rpm

Figure 12 - Hydration of Xanthan Gum in Various Sugar Solutions[1]



[1]Standard mesh; Stirring at 500 rpm

Suggested procedures for the preparation of Xanthan solutions have been published. Those listed by Urlacher, *et al.*, in Thickening and Gelling Agents for Food are given below [Urlacher, *et al.*, 1997 Vol 4 Tab 71].

1. Use a high-speed mixer (1500 rpm) if possible and slowly sprinkle Xanthan onto the upper surface of the vortex.
2. If possible disperse Xanthan with another component of the formulation such as:
   - a non-aqueous liquid, such as vegetable oil or ethyl alcohol, in which Xanthan does not hydrate
   - other dry ingredients, such as sugar and flour.

The author provides the example of salad dressing preparation, in which good hydration can be obtained either by mixing Xanthan gum powder with other dry ingredients (sugar, salt) or by dispersing the gum in vegetable oil. On the industrial scale, rapid dispersion can be achieved by:

1. Dispersion funnels, as shown in Figure 13: In this illustration water rushes through the Venturi tube of the disperser and evenly draws Xanthan from the funnel into the water by a vacuum action.
2. The use of continuous process systems, which produce colloidal solutions without entrapping air and which have a high process throughput. Powder and liquid phases are brought together in a cyclone chamber in metered amounts, and then completely dispersed and hydrated in an in-line flow section [Urlacher, *et al.*, 1997 Vol 4 Tab 71]. An aspirator is also inserted in the water line to allow recirculation of the partially hydrated Xanthan gum solution through the vortex mixer to accelerate and improve the hydration.

III. Probable Consumption, (continued)

Figure 13 - Dispersion Funnel for the Preparation of Xanthan Gum

[redacted]

4. Applications of Xanthan Gum Purified by Recovery with Ethanol

Applications for Xanthan gum purified by recovery with ethanol will be essentially the same as those that have been developed for Xanthan gum recovered with isopropanol (See Table 21). However, as mentioned above, Xanthan gum purified by recovery with ethanol may also be used in food applications, where less alcoholic residue is a desirable feature. The following descriptions provide further detail as to the action of Xanthan gum in certain categories, where the use of the gum has become wide spread [Urlacher *et al.*, 1997 Vol 4 Tab 71, Sworn, 2000 Vol 4 Tab 67, and Povey, 2001 Vol 4 Tab 51].

a. Dressings

According to Urlacher, *et al.*, the primary objective in making dressings is to be able to stabilize the oil/water emulsion for periods of storage as long as 1 year. The ideal stabilizer for this type of application should provide a high yield value for good emulsion stabilization and strong pseudoplasticity to facilitate the manufacturing operations of mixing, pumping, and filling, yielding finished products, which flow easily. Xanthan gum, provides a high viscosity at rest and a high pseudoplasticity, and therefore, has advantages for this application. Emulsions stabilized with Xanthan gum are not affected by pH (around 3.5 in some dressings), salts (as high as 15% in barbecue sauces) or thermal treatments (UHT or pasteurization) [Urlacher, *et al.*, 1997 Vol 4 Tab 71 and Morris, 1990 Vol 3 Tab 47]. Another advantage is that Xanthan gum exhibits a uniform viscosity between 5 and 70°C, which allows a product to maintain its original stability and texture under different storage conditions.

The high yield value of Xanthan makes it possible to suspend spices, herbs and vegetables in the product, allows the salad dressing to cling to the salad and to appear to have 'body'. The level of use is dependent on the oil content in the product:

- Approximately 0.2-0.3% in a high oil formulation (50-60% oil)
- Approximately 0.3-0.4% in a medium oil formulation (around 30% oil)
- Approximately 0.4%-0.6% in a low oil product (10-20% oil) [Morris, 1990 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

In some formulations, the use of high concentrations of Xanthan becomes self-limiting, causing very elastic or 'gloppy' solutions with an irregular flow. This is thought to be due to the elasticity of the Xanthan in solution. According to researchers, this problem can be solved by the use of starch or depolymerized guar in combination with the existing amount of Xanthan.

b. Sauces, Gravies, Relishes and Canned Soups

Even at low concentrations, Xanthan gum imparts a high viscosity to sauces and gravies. In these products, the viscosity is maintained across a wide temperature range and is resistant to different formulation changes. Sauces and gravies stabilized with Xanthan gum are especially resistant to thawing and heating in a microwave oven. The pseudoplasticity of Xanthan gives sauces and gravies a clean mouthfeel and good flavor release [Povey, 2001 Vol 4 Tab 51 and Urlacher, *et al.*, 1997 Vol 4 Tab 371].

Since many of these products are starch-based, Xanthan can be used as a very efficient complement to them. A small addition of Xanthan (0.1-0.2%) can dramatically improve the stability of the starch solution and also improve the texture and appearance of the finished product. The starch provides a special texture and mouthfeel and the Xanthan provides stability to the different formulations [Morris, 1990 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

c. Dairy Products

In dairy products, Xanthan gum may be used in combination with other hydrocolloids including carrageenan, guar gum and locust bean gum. The role of Xanthan is essentially to stabilize or modify and improve certain textures. A small amount of Xanthan with carrageenan in milk gels reduces the brittleness and syneresis of this gel. In this latter application, the level of use is typically between 0.05 and 0.2% depending on the gelling system used and the texture required [Morris, 1990 Vol 3 Tab 47 Urlacher, *et al.*, 1997 Vol 4 Tab 71].

d. Whipped creams and mousses

The high yield value of Xanthan produces improved stabilization of the air cells in whipped products. The whipping process is made easier because of the high pseudoplasticity of Xanthan gum. In addition, with Xanthan or Xanthan-locust bean gum combinations, the stability of whipped creams can be maintained even in contact with other food ingredients, such as bakery fillings [Morris, 1990 Vol 3 Tab 47, Urlacher, *et al.*, 1997 Vol 4 Tab 71, and Povey, 2001 Vol 4 Tab 51].

e. Instant mixes: drinks, soups and desserts

Because of its very fast hydration in different media, especially at room temperature, Xanthan gum is very effective in instant mixes. Its role is essentially to thicken, suspend and give body to the product. The concentration of Xanthan in the final food product, is generally between 0.1 and 0.2%. In instant beverages, Xanthan gum can be used in combination with carboxymethylcellulose or guar gum. To achieve complete dispersion of the Xanthan in the finished product, and very rapid hydration, special grades of Xanthan are used, which can combine the features of good dispersion (even when not premixed with high amounts of other dry ingredients) with the very fast hydration necessary in instant products [Morris, 1990 Vol 3 Tab 47, Urlacher, *et al.*, 1997 Vol 4 Tab 71, and Povey, 2001 Vol 4 Tab 51].

f. Bakery products

Because of the pseudoplasticity of Xanthan gum, dough processing operations, including pumping, kneading and molding become easier to carry out, when low levels of the gum, (between 0.05 and 0.2%) are included in formulations. Xanthan gum prevents lump formation during kneading and improves the homogeneity of the dough, because of its water-retention properties. Furthermore, Xanthan reduces the loss of water during cooking and storage of the final food product [Morris, 1990 Vol 3 Tab 47, Urlacher, *et al.,* 1997 Vol 4 Tab 71, and Povey, 2001 Vol 4 Tab 51]. Another advantage of Xanthan gum in bakery applications, is that the volume of the product, such as sponge cake, is greater and the distribution and the size of the air cells are more uniform. Because of its ability to hydrate rapidly, fine-mesh Xanthan is very efficient in instant cake mixes: it can act as texturizing agent at the beginning of the mixing step due to its cold solubility and it contributes to the final texture through its highly regarded stabilizing properties [Morris, 1990 Vol 3 Tab 47].

g. Syrups, toppings and fillings

Xanthan gum can be used in chocolate syrups in order to keep cocoa particles in suspension. In this particular application, a small amount of Xanthan (0.05-0.1%) is sufficient to obtain acceptable stabilization, and yet the gum does not affect the texture of the product itself. In toppings and fillings, Xanthan improves texture, controls syneresis, and helps to improve freeze-thaw stability [Morris, 1990 Vol 3 Tab 47].

h. Fruit preparations

Since Xanthan gum is versatile under different conditions, it is one of the few products to be fully effective in fruit preparations. Several reviewers listed the following properties, which allow the use of Xanthan gum in fruit preparations:

- Xanthan can hydrate in solutions with up to 65% sugar and is therefore efficient in formulations with very low to very high sugar concentrations
- Xanthan is very stable to changes in pH above pH 3 [Morris, 1990 Vol 3 Tab 47, Urlacher, *et al.,* 1997 Vol 4 Tab 71, and Povey, 2001 Vol 4 Tab 51].

Traditional fruit preparations contain up to 50 or 60% sugar and consist of a more or less gelled texture. These types of products have traditionally been stabilized mainly with pectins. This is no longer the case for 'second generation' products. These new products contain less sugar (20-30%), more fruit, which has to be stabilized, and they have a fluid/non-gelled texture. Xanthan is reported to be one of the best materials to efficiently bind the higher water content, stabilize the fruit pieces in solution, and provide a much more fluid texture. Typically, Xanthan is not used as a single component in fruit preparations, but is usually formulated in combination with other texturizing agents such as pectins, locust bean gum and guar [Morris, *et al.,*. 2001 Vol 2 Tab 47, Morris, 1990 Vol 3 Tab 47, Urlacher, *et al.*, 1997 Vol 4 Tab 71, and Povey, 2001 Vol 4 Tab 51].

Table 21 summarizes the current use levels developed by industry for the various food categories [Kelco Product Literature, undated Vol 3 Tab 36 and ISI shopping basket surveys, 2001 Vol 3 Tab 32].

III. Probable Consumption, (continued)

Table 21
Recommended Usage Levels for Xanthan Gum Purified by Recovery with Etahnol

Food Type	Application	Functional Effects
Baked Goods and Confectionery	Improvement in dough characteristics	0.1-0.3%
	Fillings	0.1-0.5%
Milk and Milk Products	Liquid Preparation for milk shakes,	0.1-0.2%
	Reconstituted dairy products,	0.1-0.2%
	Soy milk,	0.1-0.2%
	Whipped Cream	0.1-0.2%
	Light custards,	0.1-0.2%
	Dessert creams,	0.1-0.2%
	Puddings,	0.1-0.2%
	Mousses	0.1-0.2%
	Caramel covering	0.1-0.2%
Dry Mixes	Light custards,	0.1-0.3%
	Puddings,	0.1-0.3%
	Mousses,	0.1-0.3%
	Yogurts,	0.1-0.3%
	Dairy beverages,	0.1-0.5%
	Sweetened water gels	0.1-0.3%
Fruit Preparations	Jellied fruit for yogurt	0.1-0.3%
	Low-calorie jams	0.1-0.3%
	Fruit sauces	0.1-0.5%
Meat and Meat Products	Canned products,	0.1-0.3%
	Meat and fish pates,	0.1-0.3%
	Comminuted meat and fish products	0.1-0.5%

III. Probable Consumption, (continued)

Food Type	Application	Functional Effects
Sauces, Soups, and Dressings	Mayonnaise,	0.2-1.0%
	Sauce emulsions,	0.2-1.0%
	Salad dressings,	0.2-1.0%
	Acid sauces,	0.2-1.0%
	Tomato sauce,	**0.2-1.0%**
	Seasonings,	0.2-1.0%
	Hot sauces,	0.2-1.0%
	Soups,	0.2-1.0%
	Frozen and ready to eat foods	0.2-1.0%
Ices, Water-Ices	Ice creams,	0.05-0.1%
	Ice milks,	0.05-0.1%
	Water-ices,	0.05-0.1%
	Sorbets,	0.05-0.1%
	Liquid mixes for water-ices	0.05-0.1%
	Dry mixes for ice cream and water-ices	0.1-0.3%
Beverages	Pulp suspension	0.05-0.1%
	Powdered beverages	**0.05-0.1%**

000078

5. Gum associations

Many gum combinations have proven to be of use in industry, because the rheological and functional properties are complementary. In this area gum combinations containing Xanthan gum have not yet been fully exploited by the food industry. In addition, many specific and strong interactions occur between Xanthan gum and different hydrocolloids. These interactions generally yield positive synergistic effects, such as enhancement of the viscosity or gelation, which is especially important and useful with galactomannan and the glucomannans [Morris, 2001 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

a. Xanthan-galactomannan interactions

All galactomannans, including guar gum, locust bean gum (LBG), tara gum and cassia gum, interact synergistically with Xanthan gum. The best known and commercially most valuable interactions involve guar gum and locust bean gum [Morris, 2001 Vol 3 Tab 47, Dea, *et al.*, 1972 Vol 2 Tab 19 and Urlacher, *et al.*, 1997 Vol 4 Tab 71].

Galactomannans are composed of mannose chains with galactose side units. The mannose to galactose ratio is an important parameter. Guar gum, which has a mannose to galactose ratio of around 2:1, exhibits weak synergism, whereas LBG with a ratio of about 4:1 reacts more strongly with Xanthan gum.

b. Xanthan – Guar Interaction

Interactions between Xanthan and guar are important to the food industry, because of the development of an increase in elastic modulus [Morris, 2001 Vol 3 Tab 47 and Urlacher, *et al.*, 1997 Vol 4 Tab 71]. Knowledge of the parameters apparent viscosity and elastic modulus is important because some foods require a high elastic modulus to stabilize the emulsion or suspension (for example, salad dressings). In some other food applications, a high apparent viscosity is required and a high degree of elasticity is undesirable, for example in some sauces or soups [Morris, 2001 Vol 3 Tab 47 and Urlacher, *et al.,* 1997 Vol 4 Tab 71].

The maximum viscosity synergism is achieved for blends containing approximately 40-60% Xanthan gum. Unfortunately, the synergism strongly decreases in the presence of salts and, consequently, the viscosity synergism is generally lower in most food applications, The synergism is also dependent on the total gum concentration: the higher the gum concentration, the higher the synergism [Morris, 2001 Vol 3 Tab 47 and Urlacher, *et al.,* 1997 Vol 4 Tab 71].

In a salty medium and at 1% total gum concentration, all blend ratios have lower values than Xanthan gum alone, but blends containing up to 30% guar gum possess rheological properties similar to those of pure Xanthan gum. Thus, some Xanthan-guar blends have very valuable applications as stabilizers.

Another advantage of using Xanthan-guar gum blends is an improvement, in the thermal stability of guar gum. The thermal stability of guar is dramatically increased in the presence of Xanthan, but the thermal stability of all blends is lower than that of Xanthan gum alone. In summary, Xanthan-guar blends are widely used in the food industry as very efficient thickening agents. Compared with Xanthan alone, these blends are generally less efficient in term of stabilizing emulsions and similar products and providing good thermal stability, but because of their smooth, even-flow properties and their low cost they have very widespread application in foods [Morris, 2001 Vol 3 Tab 47, Povey, 2001 Vol 4 Tab 51, and Urlacher, *et al.,* 1997 Vol 4 Tab 71].

c. Xanthan-LBG interaction

As mentioned above, the interaction between Xanthan and LBG is strong and it is possible, above a certain concentration, to obtain gels. At low concentrations, there is a strong increase in the yield value and viscosity. At concentrations above about 0.2%, Xanthan/LBG combinations produce strong, cohesive, thermoreversible gels with very low syneresis. The optimum ratio is between 40:60 and 60:40. However, because the Xanthan-LBG mixed gel is so elastic, cohesive and non-brittle, it is not pleasant to eat. The texture of the mixed gel can be improved by the addition of another biopolymer, such as starch or protein, but there are few food applications for this kind of gel. For the moment this gelling, system is only widely used in pet food products [Morris, 2001 Vol 3 Tab 47 and Urlacher, *et al.,* 1997 Vol 4 Tab 71].

Because of the yield value of Xanthan-LBG solutions, stable suspensions can be attained at a very low gum concentration. The stability of the blend under different conditions of pH, temperature and salt is lower than Xanthan but higher than LBG alone. Unfortunately this very effective combination is especially difficult to control because of the instability between the solution and gel states.

d. Xanthan-glucomannan (konjac flour-guar) interactions

Xanthan interacts with glucomannan (konjac flour-gum) in a very similar way to its interaction with LBG. The synergism is very strong and provides gels at concentrations above about 0.2%. The optimum ratio is between 40:60 and 30:70 Xanthan-konjac. However, the interaction is decreased in the presence of salt. At temperatures below 50°C, the system shows well-defined elastic properties, the elastic modulus *G'* being greater than the viscous modulus *G"*. At about 55°C, a critical temperature is reached with collapse of the gel structure and a sharp decrease in the value of *G'*. Above this temperature, the behavior is typical of a liquid, with *G"* significantly higher than *G'* [Urlacher, *et al.,* 1997 Vol 4 Tab 71].

Maximum gel strength is reached at about 1% total gum concentration and further increases in concentration do not give additional increases in gel strength. An identical phenomenon of a gel strength plateau has been observed with LBG-Xanthan gels. [Dalbe, 1992 Vol 2 Tab 17]. The mechanical properties of Xanthan-konjac gels are somewhat similar to those of Xanthan-LBG and, likewise, these gels are also unpleasant to eat.

e. Xanthan-starch interactions

As starch is the most commonly used hydrocolloid, there is great interest in improving its storage properties, including preventing retrogradation, water release, and instability. Xanthan gum has little effect on the gelatinization of starch, but is capable of improving its properties considerably. Small amounts of Xanthan help to stabilize starch solutions during storage, even at low gum concentrations. Solutions of starch at 1.5 or 3% (native or modified) are not stable at room temperature, but adding 0.1% or 0.2% Xanthan prevents starch from retrograding and makes the solution stable to storage. Starch is not stable at low pH but 0.1-0.2% Xanthan can stabilize the starch paste at pH around 3. Starch is not stable after a freeze-thaw cycle, especially if the product is thawed in a microwave oven. However, 0.1 or 0.2% Xanthan can make these solutions stable to such treatments. In summary, in many cases, small amounts of Xanthan improve the stability of starch when it is the primary thickener of a formulation [Urlacher, *et al.* 1997 Vol 4 Tab 71].

Table 22 shows various potentially desirable associations between Xanthan gum and other polysaccharides.

III. Probable Consumption, (continued)

Table 22
Potential Associations for Xanthan Gum Purified by Recovery with Ethanol

Food Type	Potential Hydrocolloid Associations
Baked Goods and Confectionery	♦ Galactomannans ♦ Gelatin ♦ Alginates
Milk and Milk Products	♦ Galactomannans ♦ Carrageenans
Dry Mixes	♦ Galactomannans ♦ Gelatin ♦ Carrageenans ♦ Pectins
Fruit Preparations	♦ Galactomannans ♦ Carrageenans ♦ Pectins
Meat and Meat Products	♦ Galactomannans ♦ Gelatin ♦ Carrageenans
Sauces and Soups	♦ Galactomannans ♦ Carrageenans ♦ Alginates
Ices, Water-Ices	♦ Galactomannans ♦ Carrageenans ♦ Alginates ♦ Pectins ♦ Gelatin
Beverages	Alginates

III. Probable Consumption, (continued)

Table 23 below compares various hydrocolloids by functional effect.

Table 23
Hydrocolloid Use and Function

Type	Source	Function	Physiological Effects
Alginate (ionic)	Brown Seaweed	Stabilizer Suspender	No known risk except in excess consumption as a soluble fiber
Pectin	Plant Cell Walls	Emulsifier Gelling Agent	No risk; Reduction blood Cholesterol; Flatulence
Agar	Red Seaweed	Gelation Thickening Stabilizing Humectant	Flatulence Soluble fiber
Locust Bean Gum	Carob Tree	Thickening Gelling Stabilizing Emulsifying	No risk. Possible reduction of blood Cholesterol Soluble fiber
Guar	Annual Plant	Thickener Emulsion stabilizer Suspending agent	No risk Reduction of cholesterol Sugar control in diabetics
Arabic (acacia)	Tree Exudate	Thickener Emulsifier	No risk. slight blood cholesterol reduction
Carrageen	Red Seaweed	Stabilizer Suspender	No risk Dietary fiber
Xanthan	Fermentation	Thickener Emulsifier Pseudoplasticizer Stabilizer	No risk Reduced serum glucose

[from Povey, 2001, Vol 3 Tab 51]

6. Sample Formulations

The following sample formulations illustrate the use of Xanthan gum in various food preparations. These formulations have been taken from food industry recommendations [Kelco Product Literature, undated Vol 3 Tab 36].

a. Heavy Ketchup

To thicken the product and supplement the natural, full-bodied tomato texture, permitting reductions in the level of tomato paste if desired. The product displays superior texture retention compared to natural tomato pulp during heat processing and pumping operations.

Ingredients

Grams	%	
Water	216.00	43.20
Tomato paste (29-30% solids)	131.00	26.20
Sugar	78.50	15.70
Malt vinegar	44.50	8.90
Salt	15.50	3.10
Waxy maize cook-up starch	5.50	1.10
MANUCOL DH (Sodium Alginate)	4.00	0.80
KELTROL T (Xanthan gum)	2.00	0.40
Calcium chloride hexahydrate	2.00	0.40
Citric acid anhydrous	0.50	0.10
Potassium sorbate	0.25	0.05
Sodium benzoate	0.25	0.05
Total	500.00	100.00

000085

Preparation

1. Mix together the tomato paste and 3/4 of the water.
2. Dissolve a dry blend of the MANUCOL DH, KELTROL T, starch, sugar, salt and preservatives into this mixture using a high speed mixer.
3. Heat to 85-40°C with constant stirring.
4. Prepare a solution of calcium chloride and citric acid in the remaining water and vinegar.
5. Mix the vinegar solution with the tomato blend, using an electric mixer fitted with a whisk at the fastest speed.
6. Bottle and store.

This formulation has a target pH of 3.7
[Kelco International Limited, 1994 Vol 3 Tab 36]

b. Heavy Pizza Sauce

The inclusion of gums in this pizza sauce ensures that the product maintains a full body, good texture and flavor while remaining free from syneresis. The sauce does not show boilout, run-off or spitting, when it is cooked in either a conventional or microwave oven.

III. Probable Consumption, (continued)

Ingredients

	Grams	%
Tomato paste (20-30% solids)	224.00	44.00
Water	147.50	29.50
Sugar	56.00	11.20
Malt Vinegar	45.00	9.00
Salt	8.25	1.65
Waxy maize cook-up starch	6.00	1.20
MANUCOL DH (Sodium Alginate)	4.00	0.80
KELTROL T (Xanthan gum)	2.00	0.40
Calcium.chloride hexahydrate	2.00	0.40
Garlic powder	2.50	0.30
Onion powder	1.10	0.22
Sweet basil	1.00	0.20
Citric Acid anhydrous	O.55	0.11
Oregano powder	0.35	0.07
Ground black pepper	0.25	0.05
Potassium sorbate	0.25	0.05
Sodium benzoate	0.25	0.05
Total	500.00	100.00

Preparation

1. Mix together the tomato paste with 3/4 of the water.
2. Make a dry mix of the sodium alginate, Xanthan, starch, sugar, salt and herbs, and disperse in the tomato paste and water using a high-speed mixer.
3. Heat to 85-90°C with good stirring.

[Kelco International Limited, 1994 Vol 3 Tab 36]

000087

c. Peach Vinaigrette Dressing

This combination of KELTROL SF Xanthan gum and KELCOLOID LVF propylene glycol alginate provides complementary functionality to this peach-flavored vinaigrette dressing. KELTROL SF provides exceptional stability and solids suspension to this dressing. KELCOLOID LVF contributes stability, excellent mouthfeel and smooth flow properties.

Ingredients

Grams	%	
Red wine vinegar (5%acidity)	333.03	33.303
Canola oil	305.96	30.596
Water	183.58	18.358
Fructose, granular	91.79	9.179
Peach concentrate (Sabroso)	76.49	7.649
Salt	4.89	0.489
Peach flavor #23303 (California Brands Flavors)	2.00	0.200
KELTROL SF Xanthan gum	1.50	0.150
KELCOLOID LVF propylene glycol alginate	0.70	0.070
EDTA	0.06	0.006
Total	1000.00	100.000

Procedure

1. Disperse gum blend in a small amount of the oil (~1:5).
2. Add the above slurry to water under high shear. Mix for ~5 minutes or until a homogeneous consistency is obtained.
3. Combine red wine vinegar, fructose, salt, EDTA, peach flavor and peach concentrate and mix for 15 minutes.
4. Add gum solution to red wine blend and mix for 5 minutes.
5. Add oil and mix for one minute.
6. Process in a colloid mill at 0.1 gap setting.

[Kelco International Limited, 1994 Vol 3 Tab 36]

III. Probable Consumption, (continued)

d. Low-Calorie, Low Sodium Red Wine Vinegar Dressing

This diet dressing has very low caloric value and sodium content. Xanthan gum provides excellent suspension stability, while KELCOLOID LVF improves the flow property by imparting a smooth flowing texture to the dressing. Two versions are shown below: #1 is the higher quality formulation, while #2 is a cost-saving variation.

	#1		#2	
Ingredients	Grams	%	Grams	%
Water	564.80	56.48	684.30	68.43
Vinegar, red wine, 5% (50-grain)	400.00	40.00	200.00	20.00
Vinegar, white, 10% (100 grain)	—	—	80.00	8.00
Potassium chloride, powdered	10.00	1.00	10.00	1.00
Dill relish, drained	10.00	1.00	10.00	1.00
Xanthan gum	5.00	0.50	5.00	0.50
Propylene glycol alginate	5.00	0.50	5.00	0.50
Garlic powder	2.00	0.20	2.50	0.25
Onion powder	2.00	0.20	2.00	0.20
Sodium benzoate	0.50	0.05	0.50	0.05
Potassium sorbate	0.50	0.05	0.50	0.05
Calcium saccharin	0.20	0.02	0.20	0.02
Color	to suit	to suit	to suit	to suit
	1000.00	100.00	1000.00	100.00

Procedure

1. Thoroughly blend all dry ingredients, except the potassium chloride.
2. Add the dry blend to the available water under vigorous agitation.
3. Mix for 5-10 minutes.
4. Add the vinegar. Mix for 5 minutes.
5. Add the potassium chloride. Mix for 5 minutes.
6. Add the drained dill relish. Mix slowly for 1-2 minutes.
7. Bottle.

[Kelco International Limited, 1994 Vol 3 Tab 36]

III. Probable Consumption, (continued)

B. Current Usage of Xanthan Gum in the Food Industry

A study published by Industrial Market Research has indicated that approximately 34,409 metric tonnes of Xanthan gum are produced annually worldwide [Industrial Market Research, 1998 Vol 3 Tab 30]. Of that amount about 22,475 metric tonnes or 65% is used in the food industry. Table 24 shows the percentage of Xanthan gum used by the food industry, in comparison to that used by other industries.

Table 24
Worldwide Xanthan Gum Production

	Metric Tonnes/Yr	MM lbs.	%
Food	22,475	49.4	65
Industrial	6,341	14.0	18
Oilfield	5,593	12.3	16
Total	34,409	75.7	100

Table 25 lists the usage of Xanthan gum by Application in the United States and Western Europe as of 1998 [Industrial Market Research, 1998 Vol 3 Tab 30].

III. Probable Consumption, (continued)

Table 25

Food Xanthan Consumption by Application Western Europe & the USA

Application	%
Sauces & Dressings	38%
Dairy	12%
Bakery	12%
Prepared Meals	20%
Other	17%
Pet Foods	1%
Total	100%

These data confirm that Xanthan gum has been consumed in significant quantities without adverse effect on human health or well being.

C. Nutritional Profile of Xanthan Gum Purified by Recovery with Ethanol and its Potential Use as a Dietary Fiber

1. Nutritional Profile of ZZBP Xanthan Gum

The manufacturer of Xanthan gum purified by recovery with ethanol, ZZBP, has provided a nutritional analysis on its product. As presented in Table 26, the Xanthan gum comprises approximately 73.2% carbohydrate, of which nearly 100% is dietary fiber. Protein levels range from 5-6%, and fat content is zero. The acetyl and pyruvic acid content of the product is approximately 20%, and there are significant quantities of calcium (0.3-0.7%), potassium (0.4-0.6%), and sodium (0.5-0.8%) present. Energy values for the gum are very low, at <0.6 kcal/g [ZZBP Raw data, 2000 Vol 4 Tab 82].

III. Probable Consumption, (continued)

Table 26
Typical Nutritional Profile of Xanthan Gum[1]
Manufactured by: Zibo Zhongxuan Biological Product Co., Ltd

Energy Kcals:	<0.57kcal/G(2.37kj/G)
Total Carbohydrate:	73.2%
Dietary Fiber:	73%
Digestible Carbohydrate:	<0.2%
Protein:	5-6%
Fat:	0
Acetyl and Pyruvic Acid	20%
Mineral Content:	
Calcium:	0.3-0.7%
Potassium:	0.4-0.6%
Sodium:	0.5-0.8%

[1]All values are calculated on a dry weight basis.

2. Potential Use of Xanthan Gum as a Dietary Fiber

While Xanthan gum has traditionally been used in the food industry for its functional properties, rather than as a dietary supplement, researchers have established that it provides beneficial physiological effects, in the human gastrointestinal tract [Eastwood, *et al.,* 1987 Vol 2 Tab 23 and Daly, 1993 Vol 2 Tab 18]. Since Xanthan gum provides viscosity in the human colon, and is fully or partially fermentable, it meets the newly revised definition of dietary fiber, published the Institute of Medicine [Institute of Medicine, Dietary Reference Intakes, 2001 Vol 3 Tab 31].

III. Probable Consumption, (continued)

In its report, the committee charged with reviewing the definition of dietary fiber suggested that the terms soluble and insoluble dietary fiber be phased out, and that the terms *Dietary Fiber* (meaning derived from plants) and *Added Fiber* (meaning isolated polysaccharides that provide beneficial effects in the human gastrointestinal tract) be used instead [Institute of Medicine, Dietary Reference Intakes, 2001 Vol 3 Tab 31]. Xanthan gum falls under the *Added Fiber* definition.

The committee also discussed the impact of its definition on the food industry and new product development [Institute of Medicine, Dietary Reference Intakes, 2001 Vol 3 Tab 31]. Citing a study by Alaimo, *et al.*, 1994, the committee stated that dietary fiber intakes in the United States remain at half the recommended level [Alaimo, *et al.*, 1994 Vol 2 Tab 1]. The members felt that the new definition, which includes certain ingredients not previously recognized as fibers for purposes of nutritional labeling would encourage manufacturers to use *Added Fibers* and to promote their health benefits.

It is currently difficult to determine whether these changes in labeling will significantly effect the usage level of Xanthan gum. What is being established in this discussion, is that Xanthan gum qualifies for labeling under the proposed *Added Fiber* definition.

D. Other Uses of Xanthan Gum

Over the last two decades, scientists on a worldwide basis have continued to develop uses for Xanthan gum. Certain of these uses may result in modest exposures to Xanthan gum beyond that contributed from a normal diet.

1. Natural Gums and Modified Natural Gums as Sustained-Release Carriers

Bhardwaj, *et al.*, of the University Institute of Pharmaceutical Sciences, Panjab University, India noted in a recent review, that although natural gums and their derivatives are used widely in pharmaceutical dosage forms, their use as biodegradable polymeric materials to deliver bioactive agents has not been thoroughly studied because of competition from synthetic materials. The authors stated that natural polysaccharides held advantages over the synthetic polymers, generally because they are nontoxic, less expensive, and freely available. Natural gums can also be modified to accommodate unique substance delivery systems and thus can compete with the synthetic biodegradable excipients available in the market [Bhardwaj, *et al.*, 2000 Vol 2 Tab 7].

2. Possible Role of Dietary Fiber in Lowering Postprandial Serum Glucose

Ou, *et al.*, 2001 reported that there have been many studies published concerning the role of dietary fiber in lowering postprandial serum glucose, and that the primary mechanism postulated for the effect involved the viscosity of different dietary fibers. The natural viscosity provided by the fibers was thought to hamper the diffusion of glucose into the blood stream, and postpone the absorption and digestion of carbohydrates. In their study, two kinds of water-insoluble dietary fibers, wheat bran and enzyme-resistant starch, and four types of water-soluble dietary fibers, including: the soluble portions of wheat bran, carboxymethylcellulose, guar gum, and Xanthan gum, were investigated at low concentrations *in vitro* to determine the mechanism by which they lowered postprandial serum glucose.

The results showed that at least three mechanisms were involved. First, dietary fibers increased the viscosity of the small intestinal contents and hindered diffusion of glucose; second, they bound glucose and decreased the concentration of available glucose in the small intestine; and, third, they retarded alpha-amylase action through encapsulating starch, and hence directly inhibited the enzyme. All of these mechanisms synergistically decreased the absorption rate of glucose and the concentration of postprandial serum glucose [Ou, *et al.*, 2001 Vol 3 Tab 49].

Cameron-Smith, *et al.*, publishing in the *British Journal of Nutrition* reported on the effect of soluble dietary fiber on the viscosity of gastrointestinal contents and the acute glycemic response in the rat. The study showed that postprandial glycemic response following a meal was reduced with the addition of soluble dietary fiber. The reductions in the glycemia were thought to be due largely to the increased viscosity of the gastrointestinal (GI) contents, thereby retarding digestion and absorption. The goals of the study were to determine the effect that the GI tract has on the viscosity of meals containing different soluble fibers and to determine whether the glycemic response of a meal (containing soluble fiber) could be predicted by the viscosity of the digesta in the small intestine. High carbohydrate diets containing 70 g of soluble fiber in the form of guar gum, Xanthan gum or methylcellulose/kg or 70 g of insoluble fiber from wheat bran)/kg were diluted in water to a final fiber concentration of 18 g/kg (1.8%). Following dilution the wheat bran diet had no measurable viscosity, while the viscosities of the soluble fiber diets were elevated. Results showed that when the diets were fed to male Sprague-Dawley rats for 2 weeks the viscosities of the stomach and small intestinal digesta could not be predicted by the viscosity of the diets measured before ingestion.

The action of the GI tract on the viscosity of the soluble fibers was investigated *in vitro* by dilution of the diets with acidic and neutralizing solutions, mimicking gastric and duodenal secretions. Dilution of the diets with either acidic and neutralizing solutions or saline control significantly lowered the viscosity of all diets, while alterations in the pH of the diets had little impact on the resultant viscosity. Nonetheless, postprandial glycemic response following a meal was reduced with the addition of soluble dietary fiber [Cameron-Smith, *et al.,* 1994 Vol 2 Tab 11].

3. Biodegradability of Xanthan Gum and Use for the Protection of Lactic Acid Producing Organisms

Ruijssenaars *et al.*, of The Netherlands studied exopolysaccharides (EPSs) produced by lactic acid bacteria, which are common in fermented foods, and are claimed to have various beneficial physiological effects on humans. Although the biodegradability of EPSs is important in relation to their bioactive properties, specific knowledge on this topic has been limited. Therefore, authors studied the biodegradability of eight EPSs, six of which were produced by lactic acid bacteria. Biodegradability was measured using with microorganisms from human feces or soil. EPS-degradation was determined from the decrease in polysaccharide-sugar concentration and by high-performance size exclusion chromatography (HPSEC). Xanthan gum, clavan, and the EPSs produced by *Streptococcus thermophilus* SFi 39 and SFi 12 were readily degraded, in contrast to the EPSs produced by *Lactococcus lactis ssp. cremoris* B40, *Lactobacillus sakei 0-1, S. thermophilus* SFi20, and *Lactobacillus helveticus* Lh59. The authors concluded that the susceptibility of exopolysaccharides to biological breakdown could differ greatly, implying that the physiological effects of these compounds may also differ [Ruijssenaars *et al.*,1999 Vol 4 Tab 57].

Sun *et al.*, studied the survival of *Bifidobacteria* in yogurt and simulated gastric juice following immobilization in gellan-Xanthan beads. A novel acid-stable bead made of gellan gum and Xanthan gum was used to immobilize *Bifidobacteria*. The beads (0.75% gellan and 1% Xanthan gum) had an average diameter of 3 mm and did not shrink in a 25% lactic acid solution, with a pH of 1.5. Nor, did they shrink in a 20% acetic acid solution, also with a pH of 1.5, even after storage at 4 degrees C for 4 weeks. *Bifidobacterium infantis* ATCC 15697, the most acid-tolerant strain tested, was immobilized in gellan-Xanthan beads and its survival in peptone water, pH 4, pasteurized yogurt, and simulated gastric juice was monitored by the authors. In peptone water, pH 4, the reduction in cell count of immobilized cells of *B. infantis* ATCC 15697 was not significantly different from that obtained with free cells during 6 weeks of storage at 4 degrees C. However, counts of immobilized cells of *B. infantis* remained significantly higher than free cells ($P < 0.0001$) when both were exposed to simulated gastric juices at pH 2.5, 2.0 and 1.5. At pH 2.5, the viable count of free cells dropped from 1.23×10^9 CFU/ml to an undetectable level (< 10 CFU/ml) in 30 min, while the viable count of immobilized cells decreased by only 0.67 log cycle in the same time period. Immobilized cells also survived significantly better than free cells ($P < 0.05$) in pasteurized yogurt after refrigerated storage for 5 weeks. The investigators concluded that their results held significance for food processors attempting to maintain viable cultures in fermented foods [Sun *et al.*, 2000 Vol 4 Tab 64].

4. Polymers for Use in Saliva Substitutes

van der Reijden, *et al.*, of the Department of Oral Biochemistry, Academic Centre for Dentistry, in Amsterdam studied the rheological properties of a number of natural and synthetic polysaccharides for potential use in saliva substitutes. These polysaccharides were compared with porcine gastric mucin (PGM), a mucin-containing saliva substitute (Saliva Orthana) and with clarified human whole saliva (CHWS). The effects of ionic strength, pH and calcium and fluoride ions on the viscoelastic properties of these polymers were investigated.

Of the polysaccharides tested, Xanthan gum and scleroglucan appeared to resemble CHWS most in viscoelastic behavior and the authors speculated that they may be potential candidates for use in artificial saliva. Both PGM and Saliva Orthana, however, did not show any elastic behavior, whereas a viscosity comparable to human saliva was only observed in highly concentrated solutions. Of the polysaccharides tested, scleroglucan also had mucin-adhesive properties resulting in rheological synergism. The authors concluded, that this information may provide a first step in developing a product capable of mucoadhesion, which may protect underlying oral surfaces *in vivo* [van der Reijden, *et al.*, 1994 Vol 4 Tab 77].

In a second study van der Reijden, *et al.*, investigated the influence of polymers for use in saliva substitutes on de- and remineralization of enamel *in vitro*. The scientists reported on the caries-protective properties of a number of polymers, which have previously been tested for their applicability as thickening agents in saliva substitutes. These polymers studied were: polyacrylic acid, carboxymethylcellulose, Xanthan gum, guar gum, hydroxyethylcellulose and porcine gastric mucin. The polymers were tested for their effects on: (1) growth of hydroxyapatite crystals in a supersaturated calcium phosphate solution, (2) dissolution of hydroxyapatite crystals in 50 mM acetic acid, pH 5.2 and (3) demineralization and remineralization of bovine enamel in a pH-cycling model.

Growth of hydroxyapatite crystals was strongly inhibited by polyacrylic acid and carboxymethylcellulose at very low concentrations (0.005% w/v). Interestingly, hydroxyapatite dissolution was inhibited by all polymers except by hydroxymethylcellulose and Xanthan gum. Hydroxyapatite crystal growth occurred both in the presence of the polymers as well as after a 30-min preincubation. In a pH-cycling experiment, bovine enamel specimens with preformed lesions were alternately exposed to a demineralization buffer and a remineralization buffer containing the polymers hydroxyethylcellulose, carboxymethylcellulose, Xanthan gum, polyacrylic acid, or porcine gastric mucin. A remineralization buffer containing 1 ppm NaF was used as a positive control. Under the experimental conditions, the control experiment (without additives) resulted in a net mineral loss (30.6 μmol Ca/cm^2 after 14 days of pH cycling). In the presence of the positive control, 1 ppm NaF, a small mineral gain was observed (8.6 μmol/cm^2). All polymers tested inhibited further demineralization to large extent (1.2-12.3 μmol/cm^2), except polyacrylic acid. This polymer inhibited growth of hydroxyapatite crystals because of its high calcium-binding capacity. It caused demineralization, especially in the remineralization buffer (17.1 μmol/cm^2). The conclusions from the study were that, the polymers tested, except for polyacrylic acid, reduced the demineralization of enamel *in vitro*. The precise mechanism of the protective effect was not yet clear, but it was hypothesized that the formation of an absorbed polymer layer on the hydroxyapatite or enamel surface may provide protection against acidic attacks [van der Reijden, *et al.*,1997 Vol 4 Tab 77].

E. Exposure to Xanthan Gum Purified by Recovery with Ethanol

Exposure to Xanthan gum purified by recovery with ethanol was estimated in accordance with the agency's guidance document, ***Estimating Exposure to Direct Food Additives and Chemical Contaminants in the Diet*** **[FDA, September 1995].** Usage of the material was estimated for the NAS food categories, shown in Appendix IV titled "GRAS Food Additive Categories and Sub-Categories". Usage levels as percent of the final food products were then averaged across food sub-categories to yield averages for the major food groups. For instance, all of the 01 sub-categories in "GRAS Food Additive Categories and Sub-Categories" (A through P) are averaged to yield a "Baked Goods" usage level.

This value is then entered into Table 27, which lists the 43 Food Categories at 21 CFR §170.3 (n). These average usage levels for the sub-food categories are re-averaged if necessary to align with the food categories from USDA's Continuing Survey of Food Intakes by Individuals (CSFII) [Enns, *et al.*, 1997