Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to an application on the use of partially depolymerised guar gum as a food additive

Question N° EFSA-Q-2006-122

Adopted on 4 July 2007

SUMMARY

The European Food Safety Authority has been asked to provide a scientific opinion on the safety in use of partially depolymerised guar gum as a thickener, emulsifier and stabiliser in food.

Guar gum (E412) is authorised for use as a food additive in the European Union (EU) by European Parliament and Council Directive 95/2/EC. It is currently used as a thickener, emulsifier and stabiliser in a range of food categories.

A ‘not limited’ ADI was originally set for guar gum by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1973, which was further confirmed by JECFA in 1975.

Specifications for guar gum have been established by the Commission and are laid down in Commission Directive 96/77/EC. The description included within the specification for guar gum in this Directive states that guar gum is the ground endosperm of the seeds of the natural strains of the guar plant, *Cyamopsis tetragonolobus* (L.) *Taub.* (family *Leguminosae*). It consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan.

A manufacturer has made a request to use partially depolymerised guar gum as a food additive. Partially depolymerised guar gum is produced from guar gum by one of three manufacturing processes which consist of heat treatment, acid hydrolysis or alkaline oxidation, which all exert a partial depolymerisation of the native guar gum. The result is guar gum which is chemically cut into smaller molecular weight sizes and has different viscosity properties.

Partially depolymerised guar gums have been shown to be very similar to native guar gum with respect to the structure of the galactomannan polysaccharide and the composition of the final products, except for the level of salts present in the samples made by acid hydrolysis and alkaline oxidation because of the neutralisation step involved in the manufacturing process. The resulting salts, either sodium citrate (E311) or sodium phosphate (E339) have well established safety records when used as a food additive in food products (Directive 95/2/EC Annex IV).
Data have been provided by the petitioner from which it follows that all depolymerised guar gum preparations have average molecular weights that match the criteria set for the molecular weight of food grade guar gum specified to be between 50 000 g/mol and 8 000 000 g/mol by the EU and FAO/WHO/JECFA.

Based on detailed analysis of the polydispersity, the petitioner also provided estimates of the percentage of components with molecular mass below 50 000 g/mol. For the preparations produced by heat treatment or acid hydrolysis this percentage was reported to be 0%. For the depolymerised guar gum prepared by alkaline oxidation this percentage amounts to 7.6 %. Taking into account that the specifications for guar gum defined by JECFA indicate that the molecular weight of food grade guar gum should be mainly between 50 000 g/mol and 8 000 000 g/mol it would appear that the depolymerised guar gum prepared by alkaline oxidation matches these specifications.

Potential products resulting from the production process, including furfural, organic peroxides and small molecular weight organic acids, are controlled below specific levels and are not of safety concern.

The safety of native guar gum has been documented. Since the molecular weight of partially depolymerised guar gum appears to fall within the specifications of native guar gum, which is the guar gum already accepted for food use, the Panel concludes that there is no safety concern for the partially depolymerised guar gum prepared by either heat treatment, acid hydrolysis or alkaline oxidation at estimated levels of intake.

The safety of the partially depolymerised guar gum is also supported by the outcome of a 90-day study in rats with a depolymerised guar gum prepared by alkaline oxidation which revealed no adverse effect up to dose levels of 50 g/kg diet estimated to amount to 2500 mg/kg bw/day.

The Panel considers that the specifications for guar gum may need to be modified to take account of the increased level of salts and the possible undesirable byproducts e.g. furfural and peroxides, that may result from the described processes for the production of partially depolymerised guar gum.

**KEY WORDS**

Partially depolymerised guar gum, food additive, CAS Registry Number 9000-30-0.
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BACKGROUND

Guar gum (E412) is authorised for use as a food additive in the European Union by European Parliament and Council Directive 95/2/EC. It is currently used as a thickener, emulsifier and stabiliser in a range of food categories.

Specifications for guar gum have been established by the Commission and are laid down in Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners (as amended). The description included within the specification for guar gum in this Directive states that ‘guar gum is the ground endosperm of the seeds of the natural strains of the guar plant, *Cyamopsis tetragonolobus* (L.) *Taub*. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan’.

In the absence of any description of further specific treatments which may alter the structure of the guar gum it is considered that partially hydrolysed guar gum (PHGG) does not meet this specification.

A manufacturer has made a request to use PHGG as a food additive. PHGG is produced from guar gum by one of three manufacturing processes which are described further in the supporting documents. These manufacturing processes consist of heat treatment, acid hydrolysis or alkaline oxidation, which all exert a partial depolymerisation of the native guar gum. The result is guar gum which is chemically cut into smaller molecular weight sizes and has different viscosity properties.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the safety of partially hydrolysed guar gum produced through the described production processes.

ASSESSMENT

In the original dossier submitted by the petitioner, and in the background and the terms of reference from the European Commission, the material is refered to as partially hydrolysed guar gum. However, considering the nature of the methods used for the depolymerisation the Panel notes that it would be preferable to name the product partially depolymerised guar gum instead of partially hydrolysed guar gum. Therefore the material is referred to as partially depolymerised guar gum throughout the opinion.

Chemistry

Guar gum (CAS number 9000-30-0) is the ground endosperm of the seeds of the natural strains of the guar plant, *Cyamopsis tetragonolobus* (L.) *Taub*. (family *Leguminosae*). Chemically, it is
a high molecular weight hydrocolloid consisting of a (1→4)-linked beta-D-mannopyranose backbone with branch points from their 6-positions linked to alpha-D-galactose (i.e. 1→6-linked-alpha-D-galactopyranose). There are between 1.5 to 2 mannose residues for every galactose residue.

The galactomannan content is not less than 75%. The molecular weight of food grade guar gum is specified between 50 000 g/mol and 8 000 000 g/mol by the EU and FAO/WHO/JECFA. The chemical structure can be presented as follows:

According to the petitioner partially depolymerised guar gum is produced from guar gum by one of three manufacturing processes which consist of an heat treatment (two preparations), a mild acid hydrolysis (two preparations) or a mild alkaline oxidation (one preparation), all exerting a partial depolymerisation of the native guar gum. The production process gives rise to reaction products of smaller molecular weight.

The composition of acid-hydrolysed guar gum is identical to native guar gum, except for the fact that the galactomannan polymers are of shorter chain length, resulting in altered viscosity properties. The petitioner indicates that the guar gum depolymerised by acid hydrolysis complies with EU and JECFA specifications with respect to the molecular weight range. The relatively high salt content of the final product, which results from the neutralisation of the acid, meets the Food Chemical Codex (FCC) specifications (FCC 5th Edition, 2003).

Another partially depolymerised guar gum product is produced by treatment with a mixture of sodium hydroxide and hydrogen peroxide. The petitioner indicates that this chemical oxidation of guar gum by hydrogen peroxide in alkaline medium represents a mild oxidative process. The petitioner also indicates that although this treatment causes some oxidation of the polysaccharide, it leads to guar gum products with a similar mannose-galactose ratio than the native gum, thus indicating that the ring structure of the mannose and galactose units were not affected by the treatment.

Table 1 presents the molecular weights of the different depolymerised guar gums, including native guar gum, as derived from viscosity data.
Table 1. Determination of molecular weight (viscosimetric method) of guar gum.

<table>
<thead>
<tr>
<th>Guar gum sample</th>
<th>Viscosity [η] (dl/g)</th>
<th>Calculated viscosimetric average molecular weight (Mv) (g/mol)</th>
<th>Theoretical viscosimetric average molecular weight (Mv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native guar gum</td>
<td>14.58</td>
<td>2 200 000</td>
<td>2 000 000 to 3 000 000</td>
</tr>
<tr>
<td>Heat treated</td>
<td>13.77</td>
<td>2 022 450</td>
<td>2 000 000 to 3 000 000</td>
</tr>
<tr>
<td>Heat treated</td>
<td>13.68</td>
<td>2 004 190</td>
<td>2 000 000</td>
</tr>
<tr>
<td>Acid hydrolysed</td>
<td>10.48</td>
<td>1 386 360</td>
<td>1 200 000</td>
</tr>
<tr>
<td>Acid hydrolysed</td>
<td>8.98</td>
<td>1 120 000</td>
<td>900 000</td>
</tr>
<tr>
<td>Alkaline oxidized</td>
<td>4.64</td>
<td>230 000</td>
<td>250 000</td>
</tr>
</tbody>
</table>

The petitioner also provides results from molecular weight determinations by Gel Permeability Chromatography (GPC) and these are presented in Table 2.

Table 2. Determination of guar gum molecular weight by GPC

<table>
<thead>
<tr>
<th>Guar gum sample</th>
<th>Weight average molecular weight Mw</th>
<th>Number average molecular weight Mn</th>
<th>Polydispersity Mw/Mn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native guar gum</td>
<td>2 570 000</td>
<td>2 320 000</td>
<td>1.11</td>
</tr>
<tr>
<td>Heat treated</td>
<td>2 660 000</td>
<td>2 340 000</td>
<td>1.14</td>
</tr>
<tr>
<td>Heat treated</td>
<td>2 480 000</td>
<td>2 040 000</td>
<td>1.22</td>
</tr>
<tr>
<td>Acid hydrolysed</td>
<td>1 640 000</td>
<td>1 100 000</td>
<td>1.48</td>
</tr>
<tr>
<td>Acid hydrolysed</td>
<td>1 410 000</td>
<td>899 000</td>
<td>1.57</td>
</tr>
<tr>
<td>Alkaline oxidized</td>
<td>423 000</td>
<td>137 000</td>
<td>3.09</td>
</tr>
</tbody>
</table>

From these data it follows that all depolymerised guar gum preparations have average molecular weights that match the criteria set for the molecular weight of food grade guar gum specified to be between 50 000 g/mol and 8 000 000 g/mol by the EU and FAO/WHO/JECFA.

Based on a detailed analysis of the polydispersity the petitioner also provided estimates of the percentage of components with molecular weight below 50 000 g/mol. For all preparations this percentage was reported to be 0% except for the depolymerised guar gum prepared by alkaline oxidation for which this percentage amounts to 7.6%.

Taking into account that the specifications for guar gum defined by JECFA indicate that the molecular weight of food grade guar gum should be mainly between 50 000 g/mol and 8 000 000 g/mol (JECFA 1975) it would appear that the depolymerised guar gum prepared by alkaline oxidation matches these specifications.

The petitioner indicates that the partially depolymerised guar gum products are very similar to native guar gum with respect to structure and composition, and that the chemical processes used to obtain the reduction in molecular weight are sufficiently mild as not to introduce residual contaminants and/or to result in a significant difference in the quality and quantity of residual contaminants that are found in native guar gum.
The petitioner also indicates that partially depolymerised guar gum products have been shown by analysis to be similar to native guar gum with regard to structure of the galactomannan polysaccharide and the composition of the final products.

Table 3 provides the results from a determination of the global composition of the different depolymerised guar gums compared to native guar gum.

<table>
<thead>
<tr>
<th>Percent composition</th>
<th>Native guar gum</th>
<th>Heat treated</th>
<th>Heat treated</th>
<th>Acid hydrolysed</th>
<th>Acid hydrolysed</th>
<th>Alkaline oxidized</th>
</tr>
</thead>
<tbody>
<tr>
<td>moisture</td>
<td>8.5</td>
<td>8.5</td>
<td>7.0</td>
<td>7.5</td>
<td>8.5</td>
<td>7.0</td>
</tr>
<tr>
<td>Gum content</td>
<td>84.5</td>
<td>85.0</td>
<td>86.5</td>
<td>84.0</td>
<td>83.5</td>
<td>81.0</td>
</tr>
<tr>
<td>solubles</td>
<td>66.5</td>
<td>69.5</td>
<td>73.5</td>
<td>71.0</td>
<td>70.0</td>
<td>75.5</td>
</tr>
<tr>
<td>insolubles</td>
<td>18.0</td>
<td>15.5</td>
<td>13.0</td>
<td>13.0</td>
<td>13.5</td>
<td>5.5</td>
</tr>
<tr>
<td>Salts</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>2.0</td>
<td>2.0</td>
<td>5.5</td>
</tr>
<tr>
<td>sugars</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>1.5</td>
<td>2.5</td>
</tr>
<tr>
<td>proteins</td>
<td>5.0</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>G/M ratio*</td>
<td>0.57</td>
<td>0.59</td>
<td>0.58</td>
<td>0.58</td>
<td>0.58</td>
<td>0.60</td>
</tr>
<tr>
<td>G/M ratio after washing</td>
<td>0.56</td>
<td>0.58</td>
<td>0.58</td>
<td>0.59</td>
<td>0.59</td>
<td>0.59</td>
</tr>
</tbody>
</table>

* Galactose to Mannose ratio

From Table 3 it follows that the neutralisation step carried out at the end of the process in the manufacture of products with a higher degree of partial hydrolysis results in salt formation in the final product. This is sodium citrate for the acid hydrolysed samples and sodium phosphate for the depolymerised guar gum made by alkaline oxidation. As a result the ash content is somewhat different for the depolymerised gums amounting to not more than 5.5 % as compared to not more than 1.5 % for native guar gum.

The galactose to mannose (G/M) ratio of all preparations is typically between 0.5 and 0.66 and there was no difference in G/M ratio between the native and the depolymerised gums. The petitioner indicates that also chromatograms of the sugars after complete hydrolysis of the guar gum indicate that the sugar profile is identical in native and depolymerised guar gum.

Mild alkaline hydrolysis can be expected to result in modification of the end moieties of the guar gum polymers but this is expected to affect only a limited number of sugar residues.

**Manufacturing Process**

The manufacturing process has been adequately described by the petitioner.

**Specifications**

Specifications for guar gum have been established by the Commission and are laid down in Commission Directive 96/77/EC laying down specific purity criteria on food additives other
Guar gum partially hydrolyzed

than colours and sweeteners (as amended). These specifications include the following: galactomannans not less than 75%, loss on drying not more than 15% (105 °C, 5 hours), ash not more than 1.5% (determined at 800 °C), acid insoluble matter not more than 7%, protein not more than 10%, starch not detectable by a iodine method, arsenic not more than 3 mg/kg, lead not more than 5 mg/kg, mercury not more than 1 mg/kg, cadmium not more than 1 mg/kg.

The petitioner suggests specifications for the depolymerised guar gums that are similar except for ash not more than 5.5% (determined at 800 °C).

The petitioner also quantified some reaction products in the partially depolymerised guar gums, with special focus on the product prepared by oxidation under alkaline conditions, which is considered to be the most extensively treated grade. Peroxide residues, furfural and volatile organic compounds were checked as potential oxidation markers. The petitioner indicates that peroxide levels resulting from the production process in two out of three batches cannot be detected in the partially depolymerised guar gum with a quantification limit of <0.1 meq/kg, and indicates that this is less than in unmodified guar gum. One sample contained peroxide levels of 0.1 meq/kg. The petitioner concludes that this shows that neither detectable amounts of organic peroxides nor inorganic peroxides are generated during the manufacturing process in which oxidative conditions are applied.

Levels of furfural, selected as a marker for the formation of oxidised derivatives of sugars, were analysed in three different batches of depolymerised guar gum produced under alkaline oxidative conditions and were shown to be <0.16 mg/kg.

Volatile organic compounds, detected as indicators for possible carbohydrate degradation were also quantified by the petitioner and were shown to be unmodified by the oxidation under alkaline conditions as compared to native guar gum. Minor differences were observed in the free acids, and to some extent in the aldehydes and some gamma-lactones. But altogether apart from the acetic acid content in one sample, the profiles of volatile organic compounds in the samples were quite similar.

The petitioner concludes that processing conditions do not lead to any significant formation of undesirable compounds, i.e. peroxide residues or furfural or organic volatile compounds in the most extensively degraded grade, the depolymerised guar gum produced by alkaline oxidation. The petitioner concludes that this also indicates that there is no need for additional characterisation of less degraded products.

Given the processing conditions of the depolymerised guar gum, certain amounts of salts are formed as a result of the neutralization step in the process. The use of sodium hydroxide to neutralise citric acid used for the acid hydrolysis step results in formation of sodium citrate. The use of phosphoric acid to neutralise sodium hydroxide used for the oxidative alkaline hydrolysis step results in the formation of sodium phosphate. These salts are permitted for use as food additives in various foods. Sodium citrate is permitted quantum satis while sodium phosphate is permitted in certain food categories with the following restrictions:

- Partly dehydrated milk with less than 28% solids: 1g/kg
- Partly dehydrated milk with more than 28% solids: 1.5 g/kg
- Dried milk and dried skimmed: 2.5 g/kg
- Pasteurised, sterilised and UHT creams: 5 g/kg
- Whipped cream and vegetable fat analogues: 5 g/kg
- Unripened cheese (except Mozzarella): 2 g/kg
The maximum percentage of sodium phosphate in guar gum is 5.5%. Given the maximum estimated exposure to guar gum (57 mg/kg bw/day), the related maximum exposure to sodium phosphate would be 3 mg/kg bw/day and this should not give rise to safety concern.

The petitioner proposes to modify the specifications for guar gum for ash from not more than 1.5 % (determined at 800 °C) to not more than 5.5% (determined at 800 °C) because the residual salt contents increase the ash specification of the samples.

The petitioner also proposes to extend the definition of guar gum with the following sentence: “The gum may be partially depolymerised by either heat treatment or mild acid or alkaline oxidative treatment for viscosity adjustment.”

### Methods of analysis in foods

Qualitative and quantitative methods of analysis are available to assay guar gum in food systems.

There are several different AOAC methods for analyzing galactomannans in foods (AOAC, 2003). These methods are based on analyzing the sugars formed from the hydrolyzed gum; or the precipitation of the gums in concentrated alcohol solution; or comparison of the IR spectrum of the separated and purified gum to known standard spectra. The specific method used depends on the particular food matrix and the ease of removing potentially interfering substances.

The petitioner indicates that as guar gum is frequently used in combination with locust bean gum, another galactomannan, more sophisticated methods need to be carried out to differentiate between the two gums.

### Case of need and proposed uses

Thickening properties, hydration kinetics and synergy with other hydrocolloids are the key properties underlying guar gum functionally in food systems (Ellis et al. 2001). The flow properties of guar gum in water solutions are dependent on molecular size and shape. Such properties can be modified through manipulating the molecular weight as well as the particle size of the product in order to meet industry needs in terms of a broader range of product functionally (Kök et al., 1999; Evans and Marrs, 1997).

### Reaction and fate in foods, stability

The behaviour and possible degradation of guar gum under food processing conditions has been mostly studied in response to high temperature treatments under various pH conditions. The petitioner indicates that guar gum is known to be reasonably stable under an acidic environment even at high temperature. Limited depolymerisation of the guar gum takes place.

Therefore mild hydrolysis processing allowing to selectively decrease molecular weight, ending in different flow characteristics in solution, without affecting the chemical nature of the gum have been developed (Rao et al., 1981; Donnelly, 1999; Cheng et al., 2002).

Guar gum is typically used as an emulsifier or a stabiliser at different gum concentrations either alone or in combination with other thickeners or stabilisers. It is typically used in for example...
sauces, salad dressings, instant noodles, processed meats, bread improvers and beverages. Partial depolymerisation influences the thickening properties of guar gum and allows better control of viscosity, flow characteristics, and stabilisation properties in a number of selected applications. It also helps in achieving better mouthfeel characteristics in bakery applications (Ellis and Dawoud 1991; Blake et al., 1997).

The petitioner indicates that partially depolymerised guar gum is intended for use in conventional foods in replacement of native guar gum and/or in combination with it or other hydrocolloids, especially in food categories where rheology control through processing and mouthfeel characteristics of the finished products are critically important.

Table 4 presents the proposed food uses and appropriate use levels provided by the petitioner.

Table 4: Summary of proposed food uses and use levels for partially depolymerised guar gum in the EU.

<table>
<thead>
<tr>
<th>Food category</th>
<th>Proposed food use</th>
<th>Use level %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>min</td>
</tr>
<tr>
<td>Non alcoholic beverages</td>
<td>Fruit juice based beverages</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Instant powder drinks</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Diary based drinks</td>
<td>0.05</td>
</tr>
<tr>
<td>Fruits preparations</td>
<td>Fruits preparations, toppings, fillings, fruit soups</td>
<td>0.1</td>
</tr>
<tr>
<td>Soups and broths</td>
<td></td>
<td>0.1-0.3*</td>
</tr>
<tr>
<td>Sauces and dressings</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Fine bakery wares</td>
<td>Frozen doughs (rolls)</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>Toast bread (prepacked)</td>
<td>0.1</td>
</tr>
<tr>
<td>Edible ices</td>
<td>Ice creams, sorbets, sherbet ice</td>
<td>0.05</td>
</tr>
</tbody>
</table>

* in ready-to-eat products

**Exposure**

The ADI of guar gum is “not specified” and therefore its use is permitted in all food applications on a *quantum satis* basis.

Estimates for the intake of partially depolymerised guar gum in the EU were provided by the petitioner based on the proposed uses and use levels and food consumption data from France and the United Kingdom. As a worst case scenario all estimates were based on the assumption that partially depolymerised guar gum totally replaces the native guar gum in all food products. In addition the petitioner provided data on the potential daily intake of partially depolymerised guar gum based on the proposed applications for the US population.

For the UK population, food consumption data collected as part of the United Kingdom (UK) Food Standard Agency’s Dietary Survey programme (DSP) were used to calculate the mean average daily intake for each of the selected food categories (Henderson *et al.*, 2002). For the estimates for the French population intake data were taken from the INCA database (Volatier, 2000).
For the US population, data from the USDA Continuing Survey of Food Intakes by Individuals (CSFII) were used to calculate the mean average daily intakes for each of the selected food categories (USDA, 1997).

The proposed maximum use levels for partially depolymerised guar gum were combined with the consumption data for a selection of foods from the eight broad food categories to which partially depolymerised guar gum may be added.

In France the overall mean exposure was estimated to be approximately 3.45 g/person/day. Assuming a 60 kg body weight the daily average exposure to partially depolymerised guar gum would be 57 mg/kg bw/day.

In the UK, the overall mean exposure was estimated to be approximately 2.92 g/person/day. Assuming a 60 kg body weight the daily average exposure to partially depolymerised guar gum would be respectively 48 mg/kg bw/day.

In the USA, the overall mean exposure was estimated to be approximately 2.46 g/person/day. Assuming a 60 kg body weight the daily average exposure to partially depolymerised guar gum would be 41 mg/kg bw/day.

It can be concluded, based on this worst case scenario, that the average daily exposure of the overall consumer can be estimated between 41 and 57 mg/kg bw/day. The Panel noted that the estimates are based on average exposure over both consumers and non-consumers. The data make no allowance for the high level consumer.

**TOXICOLOGICAL DATA**

Guar gum as a food additive was first evaluated by JECFA in 1969 and also by the Scientific Committee for Food in the European Union in 1978 (JECFA, 1970, 1974 and 1975, SCF, 1978).

Since then significant safety data on guar gum have been published. These include a 103-week carcinogenicity study in rats and mice up to 50 g/kg in the diet, which was preceded by a subchronic study at doses up to 100 g/kg diet, and a developmental toxicity study in rats up to 150 g/kg diet (NTP 1982a; Melnick et al. 1983; Track et al., 1984). Guar gum when given to F344/N rats or B6C3F1 mice at dietary levels of 25 or 50 g/kg (amounting to about 1250 or 2500 mg/kg bw/day for rats and 3600 and 7200 mg/kg bw/day for mice) for 103 weeks did not induce cancer (NTP, 1982a). The No Observed Adverse Effect levels for each of these studies was the highest dose tested.

Other related galactomannan gums, including locust (carob) bean and tara gum, were not carcinogenic when fed to mice and rats. When locust (carob) bean gum was given to F344/N rats or B6C3F1 mice at dietary levels of 25 or 50 g/kg (equal to about 1250 or 2500 mg/kg bw/day for rats and 3600 and 7200 mg/kg bw/day for mice) for 103 weeks it did not induce cancer (NTP, 1981). F344/N rats fed diets containing tara gum at 0, 25 or 50 g/kg diet (equal to about 0, 1250 or 2500 mg/kg bw/day for rats and 0, 3600 and 7200 mg/kg bw/day for mice) for 2 years exhibited no tumorigenic effects related to the test material (Borzelleca et al., 1993; NTP, 1982b).
A human clinical study examined the effects of feeding a daily dose of 30 g of guar gum for 16 weeks to non-insulin dependent diabetic patients (McIvor et al., 1985). No changes in haematologic, hepatic, or renal function were observed, nor did serologic screening reveal any changes in lipid, protein or mineral metabolism.

In another study, 16 non-insulin dependent diabetic patients were randomized in two groups (McIvor et al., 1985). One group received a placebo, while the other group received an average of 31.7 ± 2.3 g/day guar gum for six months. There were no changes in haematological parameters, or in hepatic or renal function as measured by serum urea nitrogen, creatinine and serum enzyme levels, and serologic screening revealed no change in lipid, protein or mineral metabolism. Measurements of iron, copper, zinc, calcium, magnesium, and manganese were taken pre- and post-study. Administration of guar gum did not significantly change the balance of these minerals. Side effects in the groups exposed to guar gum at 31.7 mg/kg bw/day included gastrointestinal discomfort, flatulence and increased stool frequency. The petitioner indicated that in most patients these effects subsided after a few days.

In the following sections, the information available on partially depolymerised guar gum is described.

**Absorption, Bioavailability and Metabolism**

No data provided.

**Acute Oral Toxicity**

No data provided.

**Short-term and sub-chronic toxicity**

The petitioner described data from a 90-day toxicity study for two oxidised depolymerised guar gums prepared by alkaline hydrolysis. Although these studies were performed using guar gum products produced under different conditions of manufacture than those of the present opinion the petitioner indicates that the very similar structure of the depolymerised guar gum products to native guar gum suggests that toxicological evaluations of the products manufactured much earlier are still relevant for the current product.

Specifications on these two preparations were provided by the petitioner and included moisture (11.8 and 13.7%), crude protein (3.6 and 2.8%), crude fibers (2.2 and 1.7%), ash (1.7 and 4.7%) lipids (0.11 and 0.09%), gum content (91.4 and 89.5%) and negative for peroxide.

These partially depolymerised guar gums prepared by alkaline hydrolysis were added to the daily diet of male and female weanling rats at levels of 0 (control), 20 or 50 g/kg food estimated to amount to doses of respectively 0, 1000 or 2500 mg/kg bw/day for a period of 90 days. Growth, food consumption, chemical, clinical and histopathological examination of the exposed animals indicated that no adverse effects were observed that were attributable to the test substance.

**Reproductive and developmental toxicity**

No data provided.
Mutagenicity

No data provided on the depolymerised guar gum.

Carcinogenicity

No data provided on the depolymerised guar gum.

Human data

No data provided.

DISCUSSION

Partially depolymerised guar gums have been shown to be very similar to native guar gum with respect to the structure of the galactomannan polysaccharide and the composition of the final products, except for the level of salts present in the samples made by acid hydrolysis and alkaline oxidation because of the neutralisation step involved in the manufacturing process. The resulting salts, either sodium citrate (E311) or sodium phosphate (E339) have well established safety records when used as a food additive in food products (EC, 1995).

Because the residual salts content increases the amount of ash formed from the samples, the petitioner proposes modification of the specifications for guar gum for ash from not more than 1.5 % (determined at 800 °C) to not more than 5.5% (determined at 800 °C).

The petitioner has stated that in its production processes potential undesirable compounds from the production process such as furfural, organic peroxides and small molecular weight organic acids formed from oxidation are controlled below specific levels. The Panel considers that the specifications for guar gum may need to be modified to take account of the possible production of undesirable byproducts.

In the case of oxidative depolymerisation by treatment with a mixture of sodium hydroxide and hydrogen peroxide, the oxidation of the polysaccharide chain results in shorter chain length. The similarity between the mannose-galactose ratios is indicative that the ring structure of the mannose and galactose units is not affected by the treatment except for the oxidized sugar moieties expected to be present at the ends of the guar gum polymers upon alkaline oxidation. The resulting aldonic acids are normal food constituents.

Data have been provided by the petitioner from which it follows that all depolymerised guar gum preparations have average molecular weights that match the criteria set for the molecular weight of food grade guar gum, specified to be between 50 000 g/mol and 8 000 000 g/mol by the EU and FAO/WHO/JECFA.

Based on detailed analysis of the polydispersity, the petitioner also provided estimates of the percentage of components with molecular mass below 50 000 g/mol. For all preparations this percentage was reported to be 0% except for the depolymerised guar gum prepared by alkaline oxidation for which this percentage amounts to 7.6 %. Taking into account that the
specifications for guar gum defined by JECFA indicate that the molecular weight of food grade guar gum should be mainly between 50,000 g/mol and 8,000,000 g/mol (JECFA 1975) it would appear that the depolymerised guar gum prepared by alkaline oxidation matches these specifications.

The safety of the partially depolymerised guar gum is also supported by the outcome of a 90-day study in rats with a depolymerised guar gum prepared by alkaline oxidation which revealed no adverse effects up to dose levels of 50 g/kg diet estimated to amount to 2500 mg/kg bw/day. The petitioner provides estimated average levels of exposure to the partially depolymerised guar gum which vary between 41 and 57 mg/kg bw/day.

The intake of furfural, resulting from its presence at levels below 1 mg/kg in partially depolymerised guar gum will be below the group ADI of 0-0.5 mg/kg bw/day established for furfural, furfuryl alcohol and other furfuryl derivatives (JECFA 2000; EFSA 2004).

CONCLUSIONS AND RECOMMENDATIONS

The safety of native guar gum has been documented. Since the molecular weight of partially depolymerised guar gum appears to fall within the specifications of native guar gum, which is the guar gum already accepted for food use, the Panel concludes that there is no safety concern for the partially depolymerised guar gum prepared by either heat treatment, acid hydrolysis or alkaline oxidation at estimated levels of intake.

The Panel considers that the specifications for guar gum may need to be modified to take account of the increased level of salts and the possible undesirabe byproducts e.g. furfural and peroxides, that may result from the described processes for the production of partially depolymerised guar gum.

DOCUMENTATION PROVIDED TO EFSA


REFERENCES


Guar gum partially hydrolyzed


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ACKNOWLEDGEMENT

The Panel wishes to thank the members of the Additives working group: