Food and Agriculture Organization of the United Nations

82nd JECFA - Chemical and Technical Assessment (CTA), 2016

CAROB BEAN GUM

Chemical and Technical Assessment (CTA)

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1. Summary

Carob bean gum (locust bean gum, carubin, algarroba, LBG, INS 410, CAS 9000-40-2, EINECS 232-541-5) consists mainly of the high molecular weight (approximately 50-3,000 kDa) polysaccharides composed of galactomannans and is obtained from the endosperm of the seed of the carob (locust) tree. It is used as a thickener, stabilizer, emulsifier and gelling agent, and approved in most areas of the world (e.g. European Union, United States of America, Japan and Australia) for use in many foods and in certain foods for infants.

Carob bean gum was evaluated by the Committee at 13th JECFA (1970), 18th JECFA (1974), 19th JECFA (1975) 24th JECFA (1980). A temporary ADI "not specified" was allocated at 19th JECFA (1975) and extended at 24th JECFA (1980). An ADI "not specified" was allocated at 25th JECFA (1981). The specifications were prepared at 35th JECFA (1989) and published in FNP 49 (1989) and republished in FNP 52 "Compendium of food additive specifications". They were discussed at 42nd, 44th, 51st and 53rd JECFA, and their revised specifications were published in FNP 52 Add 2, 3, 6 and 7, and republished in FAO JECFA Monographs "Combined compendium of food additive specifications". At 67th JECFA the Committee reviewed the specifications of "Carob bean gum" and noted that they covered two grades of product. The Committee decided to prepare two specifications monographs, "Carob bean gum" and "Carob bean gum (clarified)". Both monographs were designated tentative and published in FAO JECFA Monographs 3 (2006). Further information on gum content, solubility in water and a test method for methanol and isopropanol as residual solvents using capillary gas chromatography were required before the end of 2007. The outstanding information was received for consideration at the 69th JECFA and the specifications were published in FAO JECFA Monographs 5 (2008).

Carob bean gum (Locust bean gum, INS 410) is permitted and currently used in dietary foods for special medical purposes (FSMP) in the European Union (EU) up to 10 g/l including infant formula and follow-on formula from birth onwards as part of the dietary management of gastro-esophageal reflux (SCF, 2003)(Commission regulation 1129/2011). Other jurisdictions give comparable provisions for carob bean gum use in infant formula at similar functional use levels up to 10 g/l. This includes China (7g/l, GB2760-2015) and the Russia-Kazakhstan-Belarus Customs Union (10 g/l, CU regulation 029/2012); while in Korea the use of carob bean gum in infant formula and follow-on formula is authorized according to GMP/Quantum Satis principle (Korea Food Additives Code, 2004). In Australia and New Zealand carob bean gum is authorized up to 1 g/l in infant formula, while in the United States the commercialization of carob bean gum-thickened infant formula with levels up to 5 g/l is possible after a pre-market notification.

2. Description

Carob bean gum is obtained from the endosperm of seed of the carob (locust) tree, *Ceratonia siliqua* (L.) Taub (Fam. *Leguminosae)*. The carob tree is a large evergreen tree and its fruit is a long brown pod containing very hard brown seeds. The seeds are dehusked by treatment with dilute sulfuric acid or with thermal mechanical treatment, elimination of the germ followed by milling and screening of the endosperm (native carob bean gum). The gum may be washed with ethanol or isopropanol to control the microbiological load (washed carob bean gum). It may also be further clarified by dispersing in hot water, recovery with isopropanol or ethanol, filtering, drying and milling, which is known as clarified carob bean gum. Carob bean gum (Clarified) in the market is normally standardized with sugars for viscosity and /or reactivity.

Carob bean gum consists mainly of high molecular weight (approximately 50-3,000 kDa) polysaccharides composed of galactomannans. The gum is a white to yellowish white, nearly odourless powder. Carob bean gum is insoluble in most organic solvents including ethanol. It is partially soluble in water at ambient temperature and soluble in hot water. Carob bean gum typically needs to be heated to above 85° for 10 minutes for complete solubility.

The gum may be precipitated from aqueous solution by some electrolytes, typically polyvalent ones such as lead acetate, phosphotungstic acid, and tannic acid. Solutions containing more than 0.3% gum are gelled by the addition of borate at pH 7.5 or greater. The gel is reversed by reducing the pH to less than 7.0, by heating, or by addition of mannitol (a sequestrant for borate).

Carob bean gum has a significant history of use in a wide range of applications as a thickener, stabilizer, or emulsifier in foods for the general population around the world.

The use of carob bean flour or other polysaccharides in the clinical context dates from the early 1950s for the treatment of severe (acute) infantile diarrhea and chronic vomiting (Abella, 1952; Aksit et al., 1998; Beynon, 1949; Fortier et al., 1953; Plowright, 1951; Rivier, 1952). Its use in the more specific context of gastro-esophageal reflux is illustrated by several published pediatric clinical studies dating back more than 20 years, at dosages of 0.35-0.6 g/100 ml (Ainsworth, 2014; Horvath et al., 2008; Meunier et al., 2014).

Carob bean gum-thickened infant formula and follow-on formula on the market must comply with the current permitted use levels in the European Union (EU) (up to 10 g/l in dietary foods for special medical purposes (FSMP), SCF (1998); SCF (2003)), China (up to 7 g/l in infant formula, GB2760-2015), the Russia-Kazakhstan-Belarus Customs Union (up to 10 g/l in specialized dietetic products for children under the age of 3 years, CU regulation 029/2012) and in Korea (GMP/Quantum Satis levels, Korea Food Additives Code, 2004).

3. Manufacturing

The carob seeds are difficult to process, since the seed coat is very tough and hard. By special processes, the seeds are peeled without damaging the endosperm and the germ.

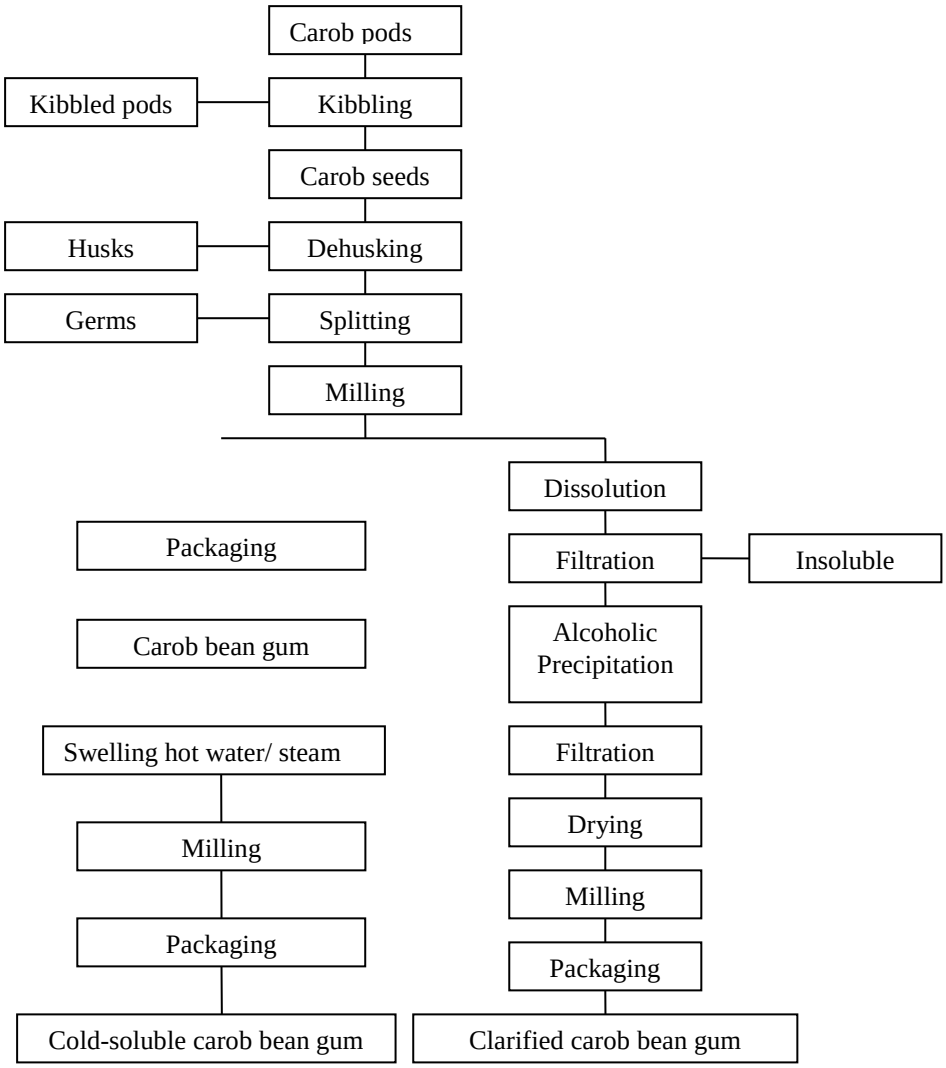
Acid peeling process: The seeds are treated with sulfuric acid at a certain temperature to carbonize the seed coat. The remaining fragments of the seed coat are removed from the clean endosperm in a washing and brushing process. The peeled seeds are dried and cracked and the more friable germ is crushed. The germ parts are sifted off from the unbroken endosperm halves. The carob bean gum produced by this process is “whitish”.

Thermal peeling process: Alternatively, the seeds may be roasted in a rotating furnace where the seed coat more or less pops off from the rest. The endosperm halves are recovered from the burned husk and the crushed germs. This process yields a product of somewhat darker colour. The effect is that no sulfuric acid as processing aid is necessary, and, therefore, no effluent originates from the production process.

Cold-soluble carob bean gum is obtained by swelling carob bean gum with hot water/steam then milling to a powder.

Carob Bean Gum (Clarified)
Carob bean gum is dispersed in water and dissolved by heating. This solution is filtered (with a filter aid) to remove insoluble material. From this clear solution, the Carob Bean Gum is precipitated with isopropanol or ethanol, the precipitate is filtered off, dried and ground to a fine powder.

Carob bean gum processing flow chart

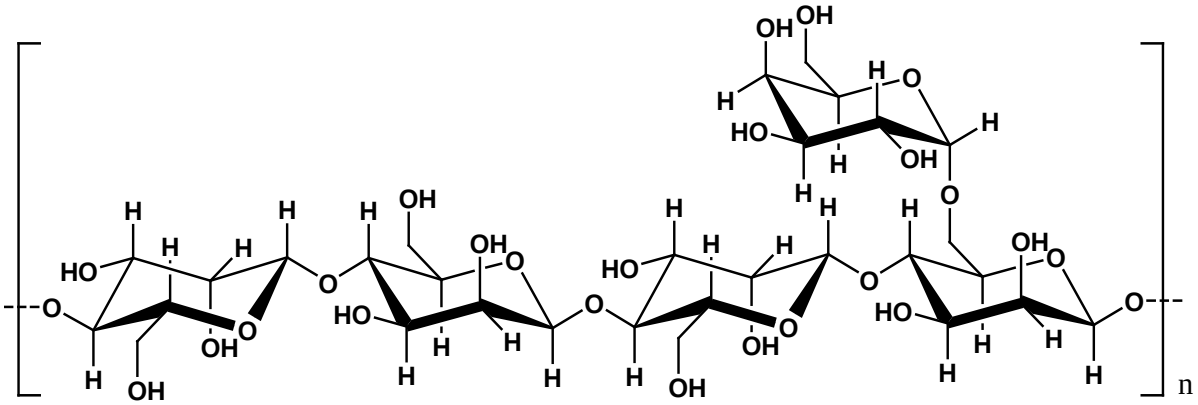


4. Chemical characterization

4.1. Composition and properties

Carob bean gum is comprised of high molecular weight polysaccharides composed of galactomannans with a linear chain of (1→4)-linked β-D-mannopyranosyl units (mannopyranose) with (1→6)-linked α-D-galactopyranosyl residues (galactopyranose) as side chains. It has a molecular weight range of approximately 50,000 to 300,000. The mannose:galactose ratio of carob bean gum is approximately 4:1. The mannose and galactose content has been reported as 73-86% and 27-14%, respectively. Galactomannans are also commonly found in other gums such as guar, tara or cassia gum but with different mannose to galactose ratios.

Carob bean gum has the capacity to form very viscous solutions at relatively low concentrations, which are almost unaffected by pH, salts, or temperature. It is commonly used in various foods as a food additive with thickening, stabilizing, emulsifying or gelling properties.



Commercial carob bean gum contain approximately 5-12% moisture, 1.7-5% acid-soluble ash, 0.4-1.0% ash, and 3-7% protein. Carob bean gum (clarified) contains approximately 3-10% moisture, 0.1-3% acid-soluble matter, 0.1-1% ash, and 0.1-0.7% protein.

4.2. Possible impurities

The possible impurities are:

- Husk (reflected by the Acid-insoluble-matter criterion)
- The germ (adequately reflected by the Protein criterion)
- Residual amounts of ethanol or isopropanol for washing or extraction solvent (limited to 1%, singly or in combination)
- Microbiological contamination
- Metallic impurities

Analytical data from limited batches of carob bean gum indicates: residual solvents ethanol and isopropanol at levels <1 mg/kg (LOQ 1 mg/kg for both); metallic impurities (mg/kg): Pb (0.030 – 0.050), Al (0.205 – 0.279) and arsenic, cadmium and mercury were less than their respective LOQ of 1, 0.005 and 0.005 respectively.

4.3 Analytical methods

At the 82nd JECFA, the Committee updated the method for the determination of lead and the sample preparation for residual solvents in the specifications monographs.

5. Functional uses

5.1 Technological function

Carob bean gum is used as a thickener, stabilizer, emulsifier and gelling agent. Carob bean gum is compatible with xanthan gum and forms gels. It affects the gelling properties of carrageenan and agar.

Carob bean gum (clarified) is mainly used in the manufacture of confections.

5.2. Use of carob bean gum in infant formula and FSMP

Carob bean gum is used as a thickener in powdered infant FSMP formula and follow-on FSMP formula, more particularly in the context of prevention and therapeutic dietary management gastro-esophageal reflux. Gastro-esophageal reflux (GER) is the backward flow of stomach contents up the esophagus and sometimes even into or out the mouth. The use of thickening agents (i.e. cereals, starch, guar gum, soy fibre, carob bean gum) in infant milk formula is recommended by international nutrition paediatric societies (i.e. North American and European Societies for Paediatric Gastroenterology, Hepatology and Nutrition) as a first line measure for the dietary management under medical supervision of frequent gastro-esophageal reflux (NASPGHAN and ESPGHAN, 2009; Vandenplas et al., 1997). The use of carob bean gum- thickened infant formula is demonstrated to reduce the number of reflux episodes and the volume of regurgitation, and to improve the overall quality of life in those patients and their caregivers (Vandenplas et al., 2015; Vandenplas et al., 2013).

In general, thickening agents act upon contact with the acidity (i.e. of the stomach) by thickening and increasing the viscosity of the alimentary bolus, thus making it possible to avoid the refluxes by gravitational effect (Balabaud and Loones, 1995). This is of particular challenge in infants since they display a more alkaline gastrointestinal pH, closer to neutrality. In addition, ready-to-feed infant formula itself has in general a neutral pH. Finally, energy density of infant formula shall be tightly controlled to avoid overfeeding.

Therefore, the main advantages of carob bean gum are that it has the capacity to form adequate viscous solutions at relatively low concentrations, which are almost unaffected by pH, salts, or temperature, making it particularly suitable in the context of infant formula applications. Its use to thicken infant milk formula does also not alter the taste and, given that it is composed of non-digestible polysaccharides it will not add calories to those provided by the common macronutrients present. This allows keeping an isocaloric formula after the addition of carob bean gum.

Carob bean gum is demonstrated in applications for use in infant formula to give adequate thickening properties between 0.3-1% in liquid infant milk formula (i.e. 3-10 g/l) (Balabaud and Loones, 1995). Below 3% (3 g/l) in reconstituted liquid preparations, the thickening effect is insufficient, while above 1% (10 g/l) a more gelled product is obtained which is less adapted for consumption through the teat hole in bottle-fed infants.

Its important thickening properties have been extensively employed in infant formulas in the context of the dietary management of infant regurgitation for more than 20 years in countries of the European Union.

Native carob bean gum has low aqueous solubility of about 20% at a temperature between 10° C and 45° C (Fallourd et al., 2012). As a result, native carob bean gum does not have sufficient solubility in an aqueous media at the usual temperature of infant milk formula reconstitution (i.e. between 30° and 50°). To ensure optimal solubility and effect on viscosity (i.e. thickening effect), the sponsor identified a so-called "cold-soluble" carob bean gum for use to thicken infant formula used in the context of prevention or dietary management of gastro-esophageal reflux. Cold-soluble carob bean gum exhibits a higher viscosity potential at lower concentrations and temperatures conditions compared to the native forms and has solubility in aqueous medium of at least above 60% at a temperature between 10° and 45°. At 82nd JECFA, the committee was not able to consider this product from a chemical and technical point of view because limited information about its manufacture and no data about its composition were received.

5.3 Food categories and use levels

In the United States, carob bean gum is listed for use as a stabilizer and thickener in the following foods:

Food Category	Maximum Use Level (%)
Baked goods & baking mixes	0.15
Non-alcoholic beverages & beverage bases	0.25
Cheeses	0.8
Gelatins, puddings, & fillings	0.75
Jams and jellies	0.75
All other foods	0.50

In the 1977 survey of the United States food industry, carob bean gum was reported as being used as a firming agent, flavouring agent, humectant, stabilizer, and thickener in the following foods:

Food Category	Mean Use Level (%)
Baked goods	
Cakes	0.20
Sweet rolls	0.80
Cookies	0.00055
Grain products & pasta	
Pasta with meat sauce	0.040
Fats & oils	
Dressings	0.023
Dietetic products	0.36
Milk products	
Chocolate milk	0.00015
Eggnog	0.059
Yogurt	0.039
Sour cream	0.073
Buttermilk	0.015
Other (includes evaporated, condensed & imitation milk)	0.099
Cheese	
Processed cheese	0.32
Cottage cheese	0.16
Cream cheese	0.46
Frozen dairy desserts	

Ice cream	0.055
Sherbets	0.10
Mellorine	0.072
Shakes & malts	0.071
Dietetic products	0.17
Other (includes frozen yogurt)	0.0050
Fruits & fruit juices	
Frozen fruit	0.093
Fruit drinks, ades	0.00057
Fruit pie fillings	0.091
Maraschino fruit	0.010
Other (include pickled, fruit salad)	0.075
Fruit & water ices, cup/stick types	0.21
Meat with pasta; hash; spreads	0.17
Egg substitutes	0.089
Fish & seafood	
Processed, unfrozen	0.030
Fabricated, frozen	0.15
Other (include shrimp cocktail, caviar, gefilte fish, etc.)	0.17
Condimental sauces	0.35
Frostings	0.092
Jams & jellies	
Flavoured jellies	0.12
Dietetic products	0.30
Other (include marmalade, conserves)	0.23
Sweet sauces & toppings	
Fruit type	0.23
Other (include nut, fudge, & marshmallow topping)	0.14
Maple syrup	0.0026
Gelatins, puddings, & custards	
Gelatin	0.25
Canned puddings	0.010
Dry puddings, to be cooked	0.12
Custard type pie filling	0.067
Other (include tapioca, rice, & bread puddings)	0.20
Soup & soup mixes	
Dry soup mixes	0.07
Bouillon	0.20
Non-alcoholic beverages	
Carbonated, fruit	0.00085
Diet non-colas	1.1
Alcoholic beverages	
Brandy, whiskey, vodka, mm	0.00039
Cocktails	0.0072
Cordials, liqueurs	0.30
Gravies & sauces	
Meat type	0.12
Milk based	0.12
Dairy product analogs (soy milk & imitation cheese)	0.30

Dietary supplements 5.0

Use as a food thickener in the context of prevention or dietary management of uncomplicated but persistent infantile gastro-esophageal reflux in infant formulae, follow on formulae and formulae for special medical purposes intended for infants (category 13.1). Owing to this functional and clinical use (effective dose level), the typical intended level of use in FSMP formula for infants is at 0.5 mg/100 ml up to a maximum level of 1 g/100 ml for optimal viscosity properties and suitability for use in bottle-fed infants requiring a dietary management of their GER condition.

6. Reactions and Fate in Food

None noted.

7. Nutritional considerations

Carob bean gum is a non-digestible galactomannan polysaccharide and therefore has the advantage to thicken food without providing additional calories. It is also reported not to modify the taste of the food or nutritious liquid to which it is added.

8. Specific considerations related to lead specifications

At 79th JECFA (Ref., 2014) the Committee discussed lead specification for different food additives and re-emphasized that the responsibility for ensuring that the final infant formulas comply with the Maximum Limit for lead remains with infant formula producers. This was confirmed at 82nd JECFA.

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