

The Draft Amendment of Standards for Specification, Scope, Application and Limitation of Food Additives

MOHW Food No. 1071301651, 11 September, 2018

Appendix 2: Standards for Specification of Food Additives

12. Pasting Agent

16. Emulsifiers

§ 12049

§ 16031

Pectins

SYNONYMS

INS No. 440

Definition

Consists mainly of the partial methyl esters of polygalacturonic acid and their sodium, potassium, calcium and ammonium salts; obtained by extraction in an aqueous medium of appropriate edible plant material, usually citrus fruits or apples; no organic precipitants shall be used other than methanol, ethanol and isopropanol; in some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. Sulfur dioxide may be added as a preservative. The commercial product is normally diluted with sugars for standardization purposes. In addition to sugars, pectins may be mixed with suitable food-grade buffer salts required for pH control and desirable setting characteristics. The article of commerce may be further specified as to pH value, gel strength, viscosity, degree of esterification, and setting characteristics.

C.A.S. number

9000-69-5

DESCRIPTION

White, yellowish, light greyish or light brownish powder.

Characteristics

IDENTIFICATION

<u>Test for pectins</u>	Passes test.
<u>Test for amide group</u>	Passes test (amidated pectins only).
<u>Loss on drying</u>	Not more than 12% (105°, 2 h).
<u>Sulfur dioxide</u>	Not more than 50mg/kg.
<u>Residual solvents</u>	Not more than 1% methanol, ethanol and 2-propanol, singly or in combination.
<u>Acid-insoluble ash</u>	Not more than 1%.
<u>Total insolubles</u>	Not more than 3%.
<u>Nitrogen content</u>	Not more than 2.5% after washing with acid and ethanol.
<u>Galacturonic acid</u>	Not less than 65% calculated on the ash-free and dried basis.
<u>Degree of amidation</u>	Not more than 25% of total carboxyl groups of pectin.
<u>Lead</u>	Not more than 2 mg/kg.
Category	Food additives category (12) (16).
Functional uses	Pasting Agent; Emulsifiers.

12. Pasting Agent

16. Emulsifiers

§ 12050

§ 16032

Guar Gum

SYNONYMS

Gum cyamopsis, guar flour; INS No. 412

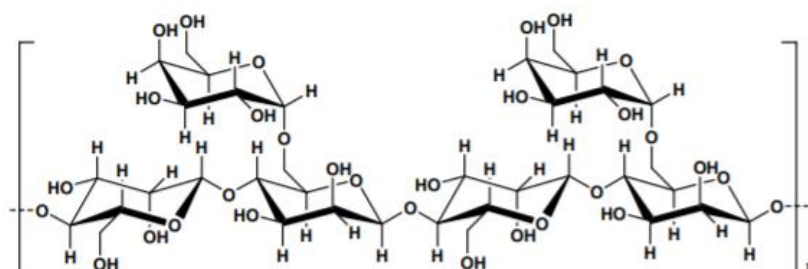
Definition

Primarily the ground endosperm of the seeds from *Cyamopsis tetragonolobus* (L.) Taub. (Fam. *Leguminosae*) mainly consisting of high molecular weight (50,000-8,000,000) polysaccharides composed of galactomannans; the mannose:galactose ratio is about 2:1. The seeds are crushed to eliminate the germ, the endosperm is dehusked, milled and screened to obtain the ground endosperm (native guar gum). The gum may be washed with ethanol or isopropanol to control the microbiological load (washed guar gum).

C.A.S. number

9000-30-0

Structural formula



DESCRIPTION

White to yellowish-white, nearly odourless, free-flowing powder.

Characteristics

IDENTIFICATION

Solubility

Insoluble in ethanol.

Gel formation

Add small amounts of sodium borate TS to an aqueous

dispersion of the sample; a gel is formed.

Viscosity

Transfer 2 g of the sample into a 400-ml beaker and moisten thoroughly with about 4 ml of isopropanol. Add 200 ml of water with vigorous stirring until the gum is completely and uniformly dispersed. An opalescent, viscous solution is formed. Transfer 100 ml of this solution into another 400-ml beaker, heat the mixture in a boiling water bath for about 10 min and cool to room temperature. There is no substantial increase in viscosity (differentiating guar gums from carob bean gums).

Gum constituents

Use galactose and mannose as reference standards. These constituents should be present.

Microscopic examination

Place some ground sample in an aqueous solution containing 0.5% iodine and 1% potassium iodide on a glass slide and examine under a microscope. Guar gum shows close groups of round to pear formed cells, their contents being yellow to brown.

PURITY

Loss on drying

Not more than 15.0% (105°, 5 h).

Borate

Disperse 1 g of the sample in 100 ml of water. The dispersion should remain fluid and not form a gel on standing. Mix 10 ml of dilute hydrochloric acid with the dispersion, and apply one drop of the resulting mixture to turmeric paper. No brownish red colour is formed.

Total ash

Not more than 1.5% (800°, 3-4 h).

Acid-insoluble matter

Not more than 7.0%.

Protein

Not more than 10.0%.

Residual solvents

Not more than 1% of ethanol or isopropanol, singly or in

	combination.
<u>Lead</u>	Not more than 2 mg/kg.
<u>Microbiological criteria</u>	Total (aerobic) plate count: Not more than 5,000 CFU/g. <i>E. coli</i> : Negative. <i>Salmonella</i> : Negative. Yeasts and moulds: Not more than 500 CFU/g.
Category	Food additives category (12) (16).
Functional uses	Pasting Agent; Emulsifiers.

12. Pasting Agent

16. Emulsifiers

§ 12051

§ 16033

Carob Bean Gum

SYNONYMS

Locust bean gum, INS No. 410

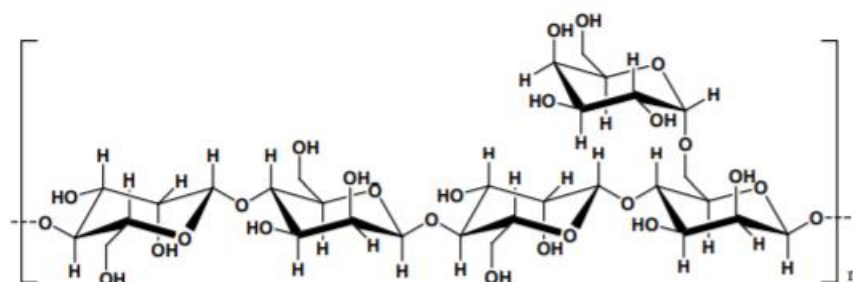
Definition

Carob bean gum, also known as locust bean gum, is a galactomannan polysaccharide obtained from the seeds of *Ceratonia siliqua* (L.) Taub. (Fam. Leguminosae). The ground endosperm of the seeds consists mainly of high molecular weight (approximately 50,000-3,000,000) polysaccharides composed of galactomannans with a mannose:galactose ratio of about 4:1. The seeds are dehusked by treating the seeds with dilute sulfuric acid or with thermal mechanical treatments, elimination of the germ followed by milling and screening of the endosperm to obtain native carob bean gum. The gum may be washed with ethanol or isopropanol to control the microbiological load (washed carob bean gum).

C.A.S. number

9000-40-2

Structural formula



DESCRIPTION

White to yellowish white, nearly odourless powder.

Characteristics

IDENTIFICATION

<u>Solubility</u>	Insoluble in ethanol.
<u>Gel formation</u>	Add small amounts of sodium borate TS to an aqueous dispersion of the sample; a gel is formed.
<u>Viscosity</u>	Transfer 2 g of the sample into a 400-mL beaker and moisten thoroughly with about 4 mL of isopropanol. Add 200 mL of water with vigorous stirring until the gum is completely and uniformly dispersed. An opalescent, slightly viscous solution is formed. Transfer 100 mL of this solution into another 400-mL beaker. Heat the mixture in a boiling water bath for about 10 min and cool to room temperature. There is an appreciable increase in viscosity (differentiating carob bean gums from guar gums).
Gum constituents	Use galactose and mannose as reference standards. These constituents should be present.
<u>Microscopic examination</u>	Disperse a sample of the gum in an aqueous solution containing 0.5% iodine and 1% potassium iodide on a glass slide and examine under a microscope. Carob bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in Guar gum.
PURITY	
<u>Loss on drying</u>	Not more than 14% (105°, 5 h).
<u>Total ash</u>	Not more than 1.2% (800°, 3-4 h).
<u>Acid-insoluble matter</u>	Not more than 4.0%.
<u>Protein</u>	Not more than 7.0%.
<u>Starch</u>	To a 1 in 10 dispersion of the sample add a few drops of iodine TS; no blue colour is produced.
<u>Residual solvents</u>	Not more than 1% of ethanol or isopropanol, singly or in

	combination.
<u>Lead</u>	Not more than 2 mg/kg.
<u>Microbiological criteria</u>	Total (aerobic) plate count: Not more than 5,000 CFU/g. <i>E. coli</i> : Negative. <i>Salmonella</i> : Negative. Yeasts and moulds: Not more than 500 CFU/g.
Category	Food additives category (12) (16).
Functional uses	Pasting Agent; Emulsifiers.

12. Pasting Agent

§ 12052

α -Cyclodextrin

SYNONYMS

α -Schardinger dextrin, α -dextrin, cyclohexaamylose, cyclomaltohexaose, α -cycloamylase, INS No.457

Definition

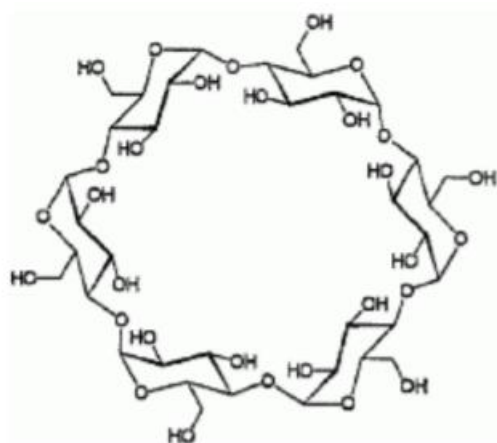
A non-reducing cyclic saccharide consisting of six α -1,4-linked Dglucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolyzed starch. Recovery and purification of α -cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of α -cyclodextrin with 1-decanol, dissolution in water at elevated temperature and reprecipitation, steam-stripping of the complexant, and crystallization of α -cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallization of α -cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis.

Chemical names Cyclohexaamylose

C.A.S. number 10016-20-3

Chemical formula $(C_6H_{10}O_5)_6$

Structural formula



Formula weight 972.85

Assay	Not less than 98% (dry basis).
DESCRIPTION	Virtually odourless, white or almost white crystalline solid.
Characteristics	
IDENTIFICATION	
<u>Melting range</u>	Decomposes above 278°.
<u>Solubility</u>	Freely soluble in water; very slightly soluble in ethanol.
<u>Specific rotation</u>	[α] _{25D} : Between +145° and +151° (1% solution).
<u>Chromatography</u>	The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α-cyclodextrin in a chromatogram of reference α-cyclodextrin.
PURITY	
<u>Water</u>	Not more than 11%.
<u>Residual complexant (1-decanol)</u>	Not more than 20 mg/kg.
<u>Reducing substances</u>	Not more than 0.5% (as dextrose).
<u>Sulfated ash</u>	Not more than 0.1%.
<u>Lead</u>	Not more than 1 mg/kg.
Category	Food additives category (12).
Functional uses	Pasting Agent.

12. Pasting Agent

§ 12053

γ -Cyclodextrin

SYNONYMS

gamma-cyclodextrin, gamma-CD, cyclooctaamylose, cyclomaltooctaose, INS No.458

Definition

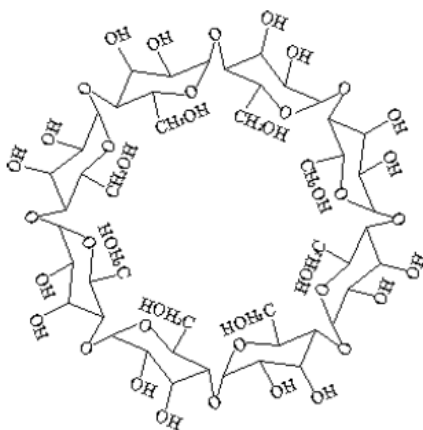
A non-reducing cyclic saccharide consisting of eight alpha-1,4-linked Dglucopyranosyl units manufactured by the action of cyclomaltodextrin glucanotransferase (CGTase, EC 2.4.1.19) on hydrolysed starch followed by purification of the gamma -cyclodextrin. Purification is carried out using one of the following procedures: precipitation of a complex of gammacyclodextrin with a macrocyclic compound and subsequent extraction with n-decane followed by steam-stripping of the solvent; crystallization from the purified mother liquor containing gamma-cyclodextrin obtained by chromatographic methods with ion exchange or gel filtration; membrane separation methods such as ultra filtration and reverse osmosis.

Chemical names Cyclooctaamylose

C.A.S. number 17465-86-0

Chemical formula $(C_6H_{10}O_5)_8$

Structural formula



Formula weight 1297

Assay	Not less than 98% on an anhydrous basis.
DESCRIPTION	Virtually odourless, white or almost white crystalline solid.
Characteristics	
IDENTIFICATION	
<u>Solubility</u>	Freely soluble in water; very slightly soluble in ethanol.
<u>Specific rotation</u>	$[\alpha]_D^{25}$: Between +173 and +180° (1% solution).
<u>Reaction with iodine</u>	To 0.2 g of the sample in a test-tube add 2 ml of a 0.1 N iodine solution. Heat the mixture in a water bath and allow to cool at room temperature. A clear brown solution is formed.
<u>Chromatography</u>	The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for gamma-cyclodextrin in a chromatogram of reference gamma-cyclodextrin.
PURITY	
<u>Water</u>	Not more than 11%.
<u>Volatile organic compounds</u>	Not more than 20 mg/kg.
<u>Reducing substances</u>	Not more than 0.5% (as glucose).
<u>Sulfated ash</u>	Not more than 0.1%.
<u>Lead</u>	Not more than 1 mg/kg.
Category	Food additives category (12).
Functional uses	Pasting Agent.

12. Pasting Agent

15. Carriers

§ 12054

β-Cyclodextrin

SYNONYMS

Beta-cyclodextrin 、βCD 、BCD 、β-Schardinger dextrin 、cyclodextrin B 、INS No. 459

Definition

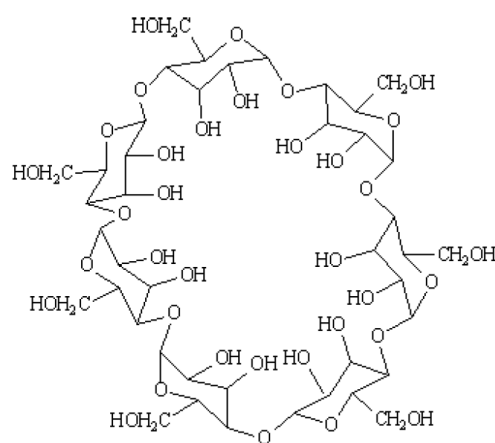
A non-reducing cyclic saccharide consisting of seven alpha-1,4-linked Dglucopyranosyl units manufactured by the action of cyclodextrin transglycolase on hydrolysed starch followed by purification of the β- cyclodextrin; purification is by preparation of a β-cyclodextrin/solvent inclusion compound followed by steam-stripping of the solvent before final purification.

Chemical names Cycloheptaamylose

C.A.S. number 7585-39-9

Chemical formula $(C_6H_{10}O_5)_7$

Structural formula



Formula weight 1135.00

Assay Not less than 98.0% of $(C_6H_{10}O_5)_7$ on an anhydrous basis.

DESCRIPTION Virtually odourless, slightly sweet tasting white or almost white crystalline solid.

Characteristics

IDENTIFICATION

<u>Solubility</u>	Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol.
<u>Specific rotation</u>	[alpha] 25, D: Between +160° and +164° (1% solution).
<u>Infrared absorption</u>	The infrared spectrum of the sample corresponds with that of a reference standard.
<u>Chromatography</u>	The retention time for the major peak in the liquid chromatogram of the sample solution corresponds to that for β-cyclodextrin in the chromatograms of the standard solutions prepared as directed in the Method of Assay.

PURITY

<u>Water</u>	Not more than 14%.
<u>Other cyclodextrins</u>	Not more than 2% on an anhydrous basis.
<u>Residual solvents</u>	Not more than 1 mg/kg of toluene.
<u>Reducing substances</u>	Not more than 1% (as glucose).
<u>Sulfated ash</u>	Not more than 0.1%.
<u>Lead</u>	Not more than 1 mg/kg.
Category	Food additives category (12) (15).
Functional uses	Pasting Agent; Carriers.