## Food and Drug Administration, HHS

the families Gigartinaceae and Solieriaceae of the class Rodophyceae (red seaweed):

Chondrus crispus.
Chondrus ocellatus.
Eucheuma cottonii.
Eucheuma spinosum.
Gigartina acicularis.
Gigartina pistillata.
Gigartina radula.
Gigartina stellata.

- (b) The food additive conforms to the following conditions:
- (1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.
- (2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.
- (c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.
- (d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

# § 172.623 Carrageenan with polysorbate 80.

Carrageenan otherwise meeting the definition and specifications of §172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of §172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of §172.840 (a) and (b) in accordance with the following prescribed conditions:

- (a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.
- (b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.
- (c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in §§172.620(c) and 172.626(b), respectively.
- (d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity

exist unless the standards provide for the use of carrageenan, or salts of carrageenan, combined with polysorbate 80

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the Act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

#### § 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive consists of carrageenan, meeting the provisions of §172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.
- (b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.
- (c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., "sodium carrageenan", "potassium carrageenan", etc.

#### §172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).
- (b) The food additive conforms to the following:
- (1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.
- (2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.
- (c) The food additive is used or intended for use in the amount necessary

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for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

#### § 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive consists of furcelleran, meeting the provisions of §172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.
- (b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.
- (c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., "sodium furcelleran", etc.

## § 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

- (a) The additive is a high molecular weight polysaccharide gum produced from *Pseudomonas elodea* by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters.
- (b) The strain of *P. elodea* is non-pathogenic and nontoxic in man and animals.

- (c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.
- (d) The additive meets the following specifications:
- (1) Positive for gellan gum when subjected to the following identification tests:
- (i) A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.
- (ii) To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.
- (2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the "Gellan gum" monograph in the Food Chemicals Codex, 7th ed. (2010), pp. 425-426, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention. 12601 Twinbrook Pkwy., Rockville, MD (Internet address www.usp.org). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: http:// www.archives.gov/federal-register/cfr/ibrlocations.html.
- (e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter. The additive may be used in foods where standards of identity established under section 401 of