

**§ 172.894**

**21 CFR Ch. I (4–1–14 Edition)**

(h) Food starch may be modified by a combination of the treatments prescribed by paragraphs (a), (b), and/or (i) of this section and any one of the treatments prescribed by paragraph (c), (d), (e), (f), or (g) of this section, subject to any limitations prescribed by the paragraphs named.

(i) Food starch may be modified by treatment with the following enzymes:

Enzyme	Limitations
Alpha-amylase (E.C. 3.2.1.1) .....          Beta-amylase (E.C. 3.2.1.2). Glucoamylase (E.C. 3.2.1.3). Isoamylase (E.C. 3.2.1.68). Pullulanase (E.C. 3.2.1.41).	The enzyme must be generally recognized as safe or approved as a food additive for this purpose. The resulting nonsweet nutritive saccharide polymer has a dextrose equivalent of less than 20.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 11697, Mar. 21, 1978; 46 FR 32015, June 19, 1981; 57 FR 54700, Nov. 20, 1992; 58 FR 21100, Apr. 19, 1993; 66 FR 17509, Apr. 2, 2001]

**§ 172.894 Modified cottonseed products intended for human consumption.**

The food additive modified cottonseed products may be used for human consumption in accordance with the following prescribed conditions:

- (a) The additive is derived from:
  - (1) Decorticated, partially defatted, cooked, ground cottonseed kernels; or
  - (2) Decorticated, ground cottonseed kernels, in a process that utilizes *n*-hexane as an extracting solvent in such a way that no more than 60 parts per million of *n*-hexane residues and less than 1 percent fat by weight remain in the finished product; or
  - (3) Glandless cottonseed kernels roasted to attain a temperature of not less than 250 °F in the kernel for not less than 5 minutes for use as a snack food, or in baked goods, or in soft candy; or
  - (4) Raw glandless cottonseed kernels may be used in hard candy where the kernel temperature during cooking will exceed 250 °F for not less than 5 minutes.
- (b) The additive is prepared to meet the following specifications:
  - (1) Free gossypol content not to exceed 450 parts per million.

(2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:

- (1) The additive identified in paragraph (a)(1) of this section as “partially defatted, cooked cottonseed flour”.
- (2) The additive identified in paragraph (a)(2) of this section as “defatted cottonseed flour”.
- (3) The additive identified in paragraph (a)(3) of this section as “roasted glandless cottonseed kernels”.
- (4) The additive identified in paragraph (a)(4) of this section as “raw glandless cottonseed kernels for use in cooked hard candy”.

(d) The Food and Drug Administration and the Environmental Protection Agency have determined that glandless cottonseed kernels permitted for use by this section are a distinct commodity from glanded cottonseed.

**§ 172.896 Dried yeasts.**

Dried yeast (*Saccharomyces cerevisiae* and *Saccharomyces fragilis*) and dried torula yeast (*Candida utilis*) may be safely used in food provided the total folic acid content of the yeast does not exceed 0.04 milligram per gram of yeast (approximately 0.008 milligram of pteroylglutamic acid per gram of yeast).

**§ 172.898 Bakers yeast glycan.**

Bakers yeast glycan may be safely used in food in accordance with the following conditions:

- (a) Bakers yeast glycan is the comminuted, washed, pasteurized, and dried cell walls of the yeast, *Saccharomyces cerevisiae*. It is composed principally of long chain carbohydrates, not less than 85 percent on a dry solids basis. The carbohydrate is composed of glycan and mannan units in approximately a 2:1 ratio.
- (b) The additive meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead,

0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
(1) In salad dressings as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Not to exceed a concentration of 5 percent of the finished salad dressing.
(2) In frozen dessert analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	In an amount not to exceed good manufacturing practice.
(3) In sour cream analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(4) In cheese spread analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(5) In cheese-flavored and sour cream-flavored snack dips as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.

(e) The label and labeling of the ingredient shall bear adequate directions to assure that use of the ingredient complies with this regulation.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 58836, Sept. 5, 1980]

**PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION**

**Subpart A—Polymer Substances and Polymer Adjuvants for Food Treatment**

- Sec.
- 173.5 Acrylate-acrylamide resins.
  - 173.10 Modified polyacrylamide resin.
  - 173.20 Ion-exchange membranes.
  - 173.21 Perfluorinated ion exchange membranes.
  - 173.25 Ion-exchange resins.
  - 173.40 Molecular sieve resins.
  - 173.45 Polymaleic acid and its sodium salt.
  - 173.50 Polyvinylpyrrolidone.
  - 173.55 Polyvinylpyrrolidone.
  - 173.60 Dimethylamine-epichlorohydrin copolymer.
  - 173.65 Divinylbenzene copolymer.
  - 173.70 Chloromethylated aminated styrene-divinylbenzene resin.
  - 173.73 Sodium polyacrylate.
  - 173.75 Sorbitan monooleate.

**Subpart B—Enzyme Preparations and Microorganisms**

- 173.110 Amyloglucosidase derived from *Rhizopus niveus*.
- 173.115 Alpha-acetolactate decarboxylase ( $\alpha$ -ALDC) enzyme preparation derived from a recombinant *Bacillus subtilis*.
- 173.120 Carbohydase and cellulase derived from *Aspergillus niger*.
- 173.130 Carbohydase derived from *Rhizopus oryzae*.
- 173.135 Catalase derived from *Micrococcus lysodeikticus*.
- 173.140 Esterase-lipase derived from *Mucor miehei*.
- 173.145 Alpha-Galactosidase derived from *Mortierella vinaceae* var. *raffinoseutilizer*.
- 173.150 Milk-clotting enzymes, microbial.
- 173.160 *Candida guilliermondii*.
- 173.165 *Candida lipolytica*.
- 173.170 Aminoglycoside 3'-phosphotransferase II.

**Subpart C—Solvents, Lubricants, Release Agents and Related Substances**

- 173.210 Acetone.
- 173.220 1,3-Butylene glycol.
- 173.228 Ethyl acetate.
- 173.230 Ethylene dichloride.
- 173.240 Isopropyl alcohol.
- 173.250 Methyl alcohol residues.
- 173.255 Methylene chloride.
- 173.270 Hexane.
- 173.275 Hydrogenated sperm oil.
- 173.280 Solvent extraction process for citric acid.
- 173.290 Trichloroethylene.