

§ 173.160

21 CFR Ch. I (4–1–12 Edition)

(5) *Aspergillus oryzae* modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene coding for aspartic proteinase from *Rhizomucor miehei* var. *Cooney et Emerson* as defined in paragraph (a)(4) of this section, and classified as follows: Class, Blastodeuteromycetes (Hyphomycetes); order, Phialiales (Moniliales); genus, *Aspergillus*; species *oryzae*.

(b) The strains of organism identified in paragraph (a) of this section are nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the generating organism from the milk-clotting enzyme product.

(d) The additive is used in an amount not in excess of the minimum required to produce its intended effect in the production of those cheeses for which it is permitted by standards of identity established pursuant to section 401 of the Act.

[42 FR 14526, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 62 FR 59284, Nov. 3, 1997]

§ 173.160 *Candida guilliermondii*.

The food additive *Candida guilliermondii* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the viable organism *Candida guilliermondii* and its concomitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic and nontoxicogenic organism descending from strain, American Type Culture Collection (ATCC) No. 20474,¹ is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida*.
Species: *guilliermondii*.
Variety: *guilliermondii*.

(2) The taxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the

¹Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

standard description for *Candida guilliermondii* variety *guilliermondii* listed in “The Yeasts—A Taxonomic Study;” 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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/code_of_federal_regulations/ibr_locations.html.

(c)(1) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid using an acceptable aqueous carbohydrate substrate.

(2) The organism *Candida guilliermondii* is made nonviable and is completely removed from the citric acid during the recovery and purification process.

(d) The additive is so used that the citric acid produced conforms to the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), under “Citric acid,” pp. 86–87, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined 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/code_of_federal_regulations/ibr_locations.html.

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 173.165 *Candida lipolytica*.

The food additive *Candida lipolytica* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the organism *Candida lipolytica* and its concomitant metabolites produced during the fermentation process.