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(2) Free dipeptide acid (N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine), not more than 1.5 percent.
(3) Other related substances, not more than 2.0 percent.
(4) Lead, not more than 2.0 milligrams per kilogram.
(5) Water, not more than 5.0 percent.
(6) Residue on ignition, not more than 0.2 percent
(7) Specific rotation, determined at 20°C [α]D: -49.9° to 43.4° calculated on a dry basis.

(c) The food additive neotame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to accomplish the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) When neotame is used as a sugar substitute tablet, L-leucine may be used as a lubricant in the manufacture of tablets at a level not to exceed 3.5 percent of the weight of the tablet.

§ 172.831 Sucralose.

(a) Sucralose is the chemical 1,6-dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside (CAS Reg. No. 56038-13-2).

(b) The additive meets the specifications of the “Food Chemicals Codex,” 4th ed. (1996), pp. 398–400, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 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/code_of_federal_regulations/ibr_locations.html.

(c) The additive may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

(d) If the food containing the additive purports to be or is represented to be for special dietary use, it shall be labeled in compliance with part 105 of this chapter.


§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of semi- and neutral succinic acid esters of monoglycerides produced by the saponification of a product obtained by the glycerolysis of edible fats and oils, or by the direct esterification of glycerol with edible fat-forming fatty acids.

(b) The additive meets the following specifications:

Succinic acid content: 14.8%–25.6%
Melting point: 50 °C–60 °C
Acid number: 70–120

(c) The additive is used or intended for use in the following foods:

(1) As an emulsifier in liquid and plastic shortenings at a level not to exceed 3 percent by weight of the shortening.
(2) As a dough conditioner in bread baking, when such use is permitted by an appropriate food standard, at a level not to exceed 0.5 percent by weight of the flour used.

(67 FR 45310, July 9, 2002)
§ 172.833 Sucrose acetate isobutyrate (SAIB).

Sucrose acetate isobutyrate may be safely used in foods in accordance with the following prescribed conditions:

(a) Sucrose acetate isobutyrate (CAS Reg. No. 27216–37–1), or SAIB, is the chemical alpha-D-glucopyranoside, O-acetyl-tris-O-(2-methyl-1-oxopropyl) beta-D-fructofuranosyl acetate tris(2-methyl propanoate).

(b) SAIB, a pale, straw-colored liquid, meets the following specifications:

1. Assay: Not less than 98.8 percent and not more than 101.9 percent, based on the following formula:

   \[
   \text{Assay} = \left( \frac{\text{SV} \times 0.10586}{56.1} \right) \times 100
   \]

   Where \( \text{SV} \) = Saponification value


4. Triacetin: Not to exceed 0.10 percent determined by gas chromatography as described in the “Guide to Specifications for General Notices,