

**§ 172.350 Fumaric acid and salts of fumaric acid.**

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) Fumaric acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis.

(2) The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron.

(b) With the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect.

(c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice.

**§ 172.365 Kelp.**

Kelp may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women. The food additive kelp is the dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni*.

**§ 172.370 Iron-choline citrate complex.**

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in foods for special dietary use.

**§ 172.372 N-Acetyl-L-methionine.**

The food additive *N*-acetyl-L-methionine may be safely added to food (except infant foods and foods containing added nitrites/nitrates) as a source of L-methionine for use as a nutrient in accordance with the following conditions:

(a) *N*-Acetyl-L-methionine (Chemical Abstracts Service Registry No. 65-82-7) is the derivative of the amino acid methionine formed by addition of an acetyl group to the *alpha*-amino group of methionine. It may be in the free, hydrated or anhydrous form, or as the sodium or potassium salts.

(b) The additive meets the following specifications:

(1) Purity assay, on a dry basis: Minimum 99 percent.

(2) Residue on ignition: Maximum 0.1 percent.

(3) Specific optical rotation  $[\alpha]_D^{20}$ : Between  $-19^\circ$  and  $-23^\circ$ .

(4) The additive may contain residues of not more than 500 ppm ethyl acetate; 50 ppm ethyl alcohol; 10 ppm methyl alcohol; and 10 ppm acetone, when used as processing solvents.

(c) The additive is used or intended for use as a source of L-methionine to improve significantly the biological quality of the total protein in a food containing naturally occurring primarily intact vegetable protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact vegetable protein.

(2) The additive results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) The use of the additive results in a statistically significant increase in the PER as determined by the method