

§ 172.140

(3) Alone, as a sequestrant in the nonnutritive sweeteners that are listed in §180.37 of this chapter and that, in addition, are designed for aqueous solution: *Provided*, That the amount of the additive, calculated as anhydrous calcium disodium EDTA, does not exceed 0.1 percent by weight of the dry non-nutritive sweetener.

(c) To assure the safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraphs (b) (1) and (2) of this section the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 65 FR 48379, Aug. 8, 2000]

§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§ 573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

5 parts per million in or on the uncooked fat of meat from animals except poultry.

3 parts per million in or on the uncooked liver and fat of poultry.

0.5 part per million in or on the uncooked muscle meat of animals.

0.5 part per million in poultry eggs.

Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical *n*-heptyl *p*-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions:

21 CFR Ch. I (4–1–04 Edition)

(1) In fermented malt beverages in amounts not to exceed 12 parts per million.

(2) In noncarbonated soft drinks and fruit-based beverages in amounts not to exceed 20 parts per million, when standards of identity established under section 401 of the Act (21 U.S.C. 341) do not preclude such use.

§ 172.150 4-Hydroxymethyl-2,6-di-tert-butylphenol.

The food additive 4-hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140 °C–141 °C.

(b) The additive is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total amount of all antioxidants added to such food shall not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.155 Natamycin (pimaricin).

(a) Natamycin (CAS Reg. No. 7681–93–8), also known as pimaricin, is a polyene macrolide antimycotic substance possessing an empirical formula of C₃₃H₄₇NO₁₃ and a molecular weight of 665.7.

(b) The additive shall conform to the following specifications:

Purity: 97 percent ±2 percent on an anhydrous basis.

Arsenic: Not more than 1 part per million.

Heavy metals (as Pb): Not more than 20 parts per million.

(c) The additive may be applied on cheese, as an antimycotic, in amounts not to exceed 20 milligrams per kilogram (20 parts per million) in the finished product as determined by International Dairy Federation (IDF) Standard 140A:1992, “Cheese and Cheese Rind-Determination of Natamycin Content-Method by Molecular Absorption Spectrometry and by High-Performance Liquid Chromatography,” 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. Copies are available from the Division of Product

Food and Drug Administration, HHS

§ 172.170

Policy (HFS-206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

[47 FR 26823, June 22, 1982, as amended at 50 FR 49536, Dec. 3, 1985; 63 FR 66015, Dec. 1, 1998; 66 FR 13847, Mar. 8, 2001]

§ 172.160 Potassium nitrate.

The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed 200 parts per million of the finished roe.

§ 172.165 Quaternary ammonium chloride combination.

The food additive, quaternary ammonium chloride combination, may be safely used in food in accordance with the following conditions:

(a) The additive contains the following compounds: *n*-dodecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139-07-1); *n*-dodecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479-28-3); *n*-hexadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122-18-9); *n*-octadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122-19-0); *n*-tetradecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139-08-2); *n*-tetradecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479-29-4).

(b) The additive meets the following specifications: pH (5 percent active solution) 7.0-8.0; total amines, maximum 1 percent as combined free amines and amine hydrochlorides.

(c) The additive is used as an antimicrobial agent, as defined in §170.3(o)(2) of this chapter, in raw sugar cane juice. It is added prior to clarification when further processing of the sugar cane juice must be delayed.

(d) The additive is applied to the sugar juice in the following quantities, based on the weight of the raw cane:

Component	Parts per million
<i>n</i> -Dodecyl dimethyl benzyl ammonium chloride	0.25-1.0

Component	Parts per million
<i>n</i> -Dodecyl dimethyl ethylbenzyl ammonium chloride	3.4-13.5
<i>n</i> -Hexadecyl dimethyl benzyl ammonium chloride	1.5-6.0
<i>n</i> -Octadecyl dimethyl benzyl ammonium chloride	0.25-1.0
<i>n</i> -Tetradecyl dimethyl benzyl ammonium chloride	3.0-12.0
<i>n</i> -Tetradecyl dimethyl ethylbenzyl ammonium chloride	1.6-6.5

[50 FR 3890, Jan. 29, 1985]

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:

- (i) The name of the additive.
- (ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraph (a) of this section.