

§ 172.868

1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate); 12 IU vitamin D per gram olestra; and 8 µg vitamin K₁ per gram olestra.

(e)(1) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(i) An asterisk shall follow vitamins A, D, E, and K in the listing of ingredients;

(ii) The asterisk shall appear as a superscript following each vitamin;

(iii) Immediately following the ingredient list an asterisk and statement, "Dietarily insignificant" shall appear prominently and conspicuously as specified in §101.2(c) of this chapter;

(2) Olestra shall not be considered as a source of fat or calories for purposes of §§101.9 and 101.13 of this chapter.

[61 FR 3171, Jan. 30, 1996; 61 FR 11546, Mar. 21, 1996, as amended at 68 FR 46402, Aug. 5, 2003; 69 FR 29432, May 24, 2004]

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC₂H₅) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

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

(1) As a binder and filler in dry vitamin preparations.

21 CFR Ch. I (4–1–09 Edition)

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

§ 172.869 Sucrose oligoesters.

Sucrose oligoesters, as identified in this section, may be safely used in accordance with the following conditions:

(a) Sucrose oligoesters consist of mixtures of sucrose fatty acid esters with an average degree of esterification ranging from four to seven. It is produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils (including hydrogenated fats and oils). The only solvents which may be used in the preparation of sucrose oligoesters are dimethyl sulfoxide, isobutyl alcohol, and those solvents generally recognized as safe in food.

(b) Sucrose oligoesters meet the specifications in the methods listed in the table in this paragraph. The methods cited for determining compliance with each specification are incorporated by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the methods may be examined at the Center for Food Safety and Applied Nutrition's Library, room 1C-100, 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. Copies of the methods are available from the sources listed in the table in this paragraph:

Specification	Limit	Method Cited	Source for Obtaining Method
(1) Sucrose esters	Not less than 90%	"Method for Analyzing the Purity of Sucrose Fatty Acid Esters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.
(2) Mono-, di-, and tri-esters ...	Not more than 45%	"Method for Measuring the Ester Distribution of Sucrose Oligoesters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.