

**§ 137.190**

**21 CFR Ch. I (4-1-03 Edition)**

be made on the label for calcium as a nutrient.

(c) The requirements of paragraphs (a) and (b) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to insure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine ...	Thiamine chloride hydrochloride.	C <sub>12</sub> H <sub>17</sub> ClN <sub>4</sub> OS·HCl	337.28
Riboflavin ..	Riboflavin .....	C <sub>17</sub> H <sub>20</sub> N <sub>4</sub> O <sub>6</sub>	376.37
Niacin .....	Niacin .....	C <sub>6</sub> H <sub>5</sub> NO <sub>2</sub>	123.11

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) When calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance;

(f) When calcium is added as carbonate, the method set forth in §137.180(c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof;

(g) All ingredients from which the food is fabricated shall be safe and suitable. The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

[42 FR 14402, Mar. 15, 1977, as amended at 43 FR 38578, Aug. 29, 1978; 46 FR 43414, Aug. 28, 1981; 58 FR 2877, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

**§ 137.190 Cracked wheat.**

Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in §137.200(c)(2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of the moisture as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 7.002 under "Preparation of Sample—Official Final Action," and section 7.003 under "Moisture—Official Final Action. I. Drying in Vacuo at 95–100° (2)," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

**§ 137.195 Crushed wheat.**

Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in §137.200(c)(2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 7.002 under "Preparation of Sample—Official Final Action," and section 7.003 under "Moisture—Official Final Action. I. Drying in Vacuo at 95–100° (2)," which is incorporated by reference. Copies may be obtained from

the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

#### § 137.200 Whole wheat flour.

(a) Whole wheat flour, graham flour, entire wheat flour is the food prepared by so grinding cleaned wheat, other than durum wheat and red durum wheat, that when tested by the method prescribed in paragraph (c)(2) of this section, not less than 90 percent passes through a 2.36 mm (No. 8) sieve and not less than 50 percent passes through a 850  $\mu$ m (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. It may contain harmless preparations of  $\alpha$ -amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier. The moisture content of whole wheat flour is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the whole wheat flour appear to be better or of greater value than it is, the optional bleaching ingredient azodicarbonamide (complying with the requirements of §172.806 of this chapter, including the quantitative limit of not more than 45 parts per million) or chlorine dioxide, or chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) When ascorbic acid is added, the label shall bear the statement "Ascor-

bic acid added as a dough conditioner". When the optional ingredient " $\alpha$ -amylase obtained from *Aspergillus oryzae*" is used, it may alternatively be declared in the list of ingredients as "Fungal *alpha*-amylase," "Fungal  $\alpha$ -amylase", "Enzyme", or "Enzyme added for improved baking". When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trademark or brand, other written, printed or graphic matter, which is also a part of such trademark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trademark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Moisture is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), section 14.002, "Vacuum Oven Method—Official Final Action," and section 14.003, "Determination," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave, suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full-height frames, complying with the specifications set forth in the AOAC, Table 1, "Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)," under the heading "Definitions of Terms and Explanatory Notes," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 gm. of the sample into the No. 8 sieve. Attach cover and hold