

§ 137.185

21 CFR Ch. I (4-1-14 Edition)

number of mL of gas evolved by the factor given in section 52.007, "Correction factors for gasometric determination of carbon dioxide," AOAC, 13th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (c) of this section), for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

(2) Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

(3) Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U.S.P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

(4) Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

(5) Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

[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; 58 FR 2877, Jan. 6, 1993]

§ 137.185 **Enriched self-rising flour.**

Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for self-rising flour by §137.180, except that:

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

(b) It contains added calcium in such quantity that the total calcium content is 960 milligrams per pound. If a calcium compound is added for tech-

nical purposes to give self-rising characteristics to the flour, the amount of calcium per pound of flour may exceed 960 milligrams provided that the excess is no greater than necessary to accomplish the intended effect. However, if such calcium is insufficient to meet the 960-milligram level, no claim may 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 ₁₂ H ₁₇ ClN ₄ OS·HCl	337.28
Riboflavin ..	Riboflavin	C ₁₇ H ₂₀ N ₄ O ₆	376.37
Niacin	Niacin	C ₆ H ₅ NO ₂	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 AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.

[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 AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.

[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 µm (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 α -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