§ 101.108

blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and

(ii) When the variation is in regard to a fill of container standard, "Product Mislabeled. Actual fill may be as low as —% below standard of fill. This Product Not for Retail Distribution".

(3) The statements required by paragraphs (t)(2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

(a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§101.9 and 105.66 of this chapter.

(b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§101.9 and 105.66 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:

(1) A description of the labeling format to be tested;

(2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining "low" and "reduced":

(3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;

(4) The dates on which the experiment will begin and end and on which a written report of analysis of the ex-

perimental data will be submitted to FDA, together with a commitment not to continue the experiment beyond the proposed ending date without FDA approval;

(5) The geographic area or areas in which the experiment is to be conducted:

(6) The mechanism to measure the effectiveness of the experiment;

(7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;

(8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and

(9) A statement of the sections of the regulations for which an exemption is sought.

(c) The written proposal should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under §10.30 of this chapter.

(d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.

(e) Reporting requirements contained in §101.108(b) have been approved by this Office of Management and Budget and assigned number 0910-0151.

[48 FR 15240, Apr. 8, 1983, as amended at 59 FR 14364, Mar. 28, 1994; 62 FR 15343, Mar. 31, 1997]

APPENDIX A TO PART 101—MONIER-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

The AOAC official method for sulfites (Official Methods of Analysis, 14th Edition, 20.123–20.125, Association of Official Analytical Chemists) has been modified, in FDA

Food and Drug Administration, HHS

laboratories to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% H₂O₂ solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the sepa-ratory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K-183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. (A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K-179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, Ε, (Kontes K-431000-2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of ca. 2.5 cm and a depth of 18 cm.

Buret-A 10 ml buret (Fisher Cat. No. 03-848-2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxidefree atmosphere over the standardized 0.01Nsodium hydroxide.

Chilled Water Circulator-The condensor must be chilled with a coolant, such as 20% methanol-water, maintained at 5 °C. A circulating pump equivalent to the Neslab Coolflow 33 is suitable.

Reagents

- (a) Aqueous hydrochloric acid, 4N.—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.
- (b) Methyl red indicator-Dissolve 250 mg of methyl red in 100 ml ethanol.
- (c) $Hydrogen\ peroxide\ solution,\ 3\%$ —Dilute ACS reagent grade 30% hydrogen peroxide to

3% with distilled water. Just prior to use, add three drops of methyl red indicator and titrate to a yellow end-point using 0.01N sodium hydroxide. If the end-point is exceeded discard the solution and prepare another 3% H₂O₂ solution.

(d) Standardized titrant. 0.01N NaOH—Certified reagent may be used (Fisher SO-5-284). It should be standardized with reference standard potassium hydrogen phthalate.

(e) Nitrogen—A source of high purity nitrogen is required with a flow regulator that will maintain a flow of 200 cc per minute. To guard against the presence of oxygen in the nitrogen, an oxygen scrubbing solution such as an alkaline pyrogallol trap may be used. Prepare pyrogallol trap as follows:

1. Add 4.5 g pyrogallol to the trap.

- 2. Purge trap with nitrogen for 2 to 3 minutes
- 3. Prepare a KOH solution prepared by adding 65g KOH to 85 ml distilled water (caution: heat).
- 4. Add the KOH solution to the trap while maintaining an atmosphere of nitrogen in the trap.

Determination

Assemble the apparatus as shown in Fig. 1. The flask C must be positioned in a heating mantle that is controlled by a power regulating device such as Variac or equivalent. Add 400 ml of distilled water to flask C. Close the stopcock of separatory funnel, B, and add 90 ml of 4N hydrochloric acid to the separatory funnel. Begin the flow of nitrogen at a rate of 200±10 cc/min. The condenser coolant flow must be initiated at this time. Add 30 ml of 3% hydrogen peroxide, which has been titrated to a yellow end-point with 0.01N NaOH, to container G. After fifteen minutes the apparatus and the distilled water will be thoroughly de-oxygenated and the apparatus is ready for sample introduction.

Sample preparation (solids)—Transfer 50 g of food, or a quantity of food with a convenient quantity of SO₂ (500 to 1500 mcg SO₂), to a food processor or blender. Add 100 ml of 5% ethanol in water and briefly grind the mixture. Grinding or blending should be continued only until the food is chopped into pieces small enough to pass through the 24/40 point of flask C.

Sample preparation (liquids)—Mix 50 g of the sample, or a quantity with a convenient quantity of SO_2 (500 to 1500 mcg SO_2), with 100 ml of 5% ethanol in water.

Sample introduction and distillation—Remove the separatory funnel B, and quantitatively transfer the food sample in aqueous ethanol to flask C. Wipe the tapered joint clean with a laboratory tissue, apply stopcock grease to the outer joint of the separatory funnel, and return the separatory funnel, B, to tapered joint flask C. The nitrogen flow through the 3% hydrogen peroxide

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solution should resume as soon as the funnel, B, is re-inserted into the appropriate joint in flask C. Examine each joint to ensure that it is sealed.

Apply a head pressure above the hydrochloric acid solution in B with a rubber bulb equipped with a valve. Open the stopcock in B and permit the hydrochloric acid solution to flow into flask C. Continue to maintain sufficient pressure above the acid solution to force the solution into the flask C. The stopcock may be closed, if necessary, to pump up the pressure above the acid and then opened again. Close the stopcock before the last few milliliters drain out of the separatory funnel, B, to guard against the escape of sulfur dioxide into the separatory funnel.

Apply the power to the heating mantle. Use a power setting which will cause 80 to 90

drops per minute of condensate to return to the flask from condenser, E. After 1.75 hours of boiling the contents of the 1000 ml flask and remove trap G.

Titration.—Titrate the contents with 0.01N sodium hydroxide. Titrate with 0.01N NaOH to a yellow end-point that persists for at least twenty seconds. Compute the sulfit content, expressed as micrograms sulfur dioxide per gram of food (ppm) as follows:

ppm= $(32.03xV_B xNx1000)$ ÷Wt

where 32.03=milliequivalent weight of sulfur dioxide; V_B =volume of sodium hydroxide titrant of normality, N, required to reach endpoint; the factor, 1000, converts milliequivalents to microequivalents and Wt=weight (g) of food sample introduced into the 1000 ml flask.

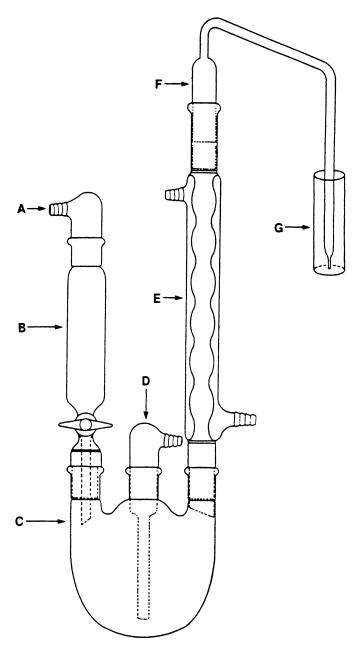


Figure 1. The optimized Monier-Williams apparatus. Component identification is given in text.

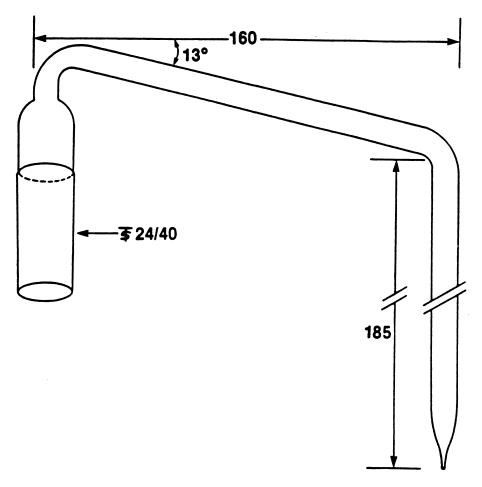


Figure 2. Diagram of bubbler (F in Figure 1). Lengths are given in mm.

[42 FR 14308, Mar. 15, 1977, as amended at 51 FR 25017, July 9, 1986]

APPENDIX B TO PART 101—GRAPHIC ENHANCEMENTS USED BY THE FDA

Examples of Graphic Enhancements used by the FDA

A Overal

 Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral ground.

B. Typeface and size

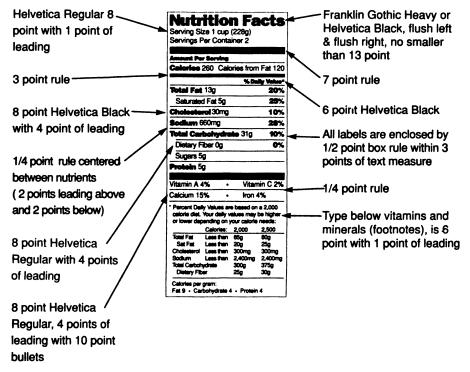
- 1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4, (tighter kerning reduces legibility).
- Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" is set in Helvetica Regular).
- 3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
- "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
- The table labels (for example; "Amount per Serving") are set 6 point Helvetica Black.
- Absolute measures of nutrient content (for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
- 7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
- 8. All type that appears under vitamins and minerals is set in 6 point Helvetica regular with 1 point of leading.

C. Rules

- 1. A 7 point rule separates large groupings as shown in example. A 3 point rule separates calorie information from the nutrient information.
- 2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

1. All labels are enclosed by 1/2 point box rule within 3 points of text measure.



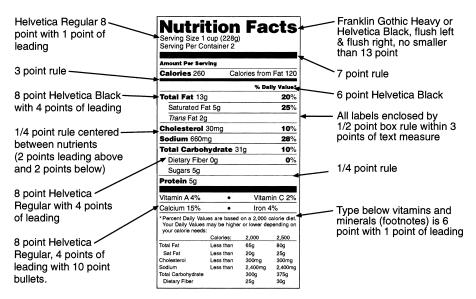
[58 FR 17332, Apr. 2, 1993]

EFFECTIVE DATE NOTE: At $68\ FR\ 41506$, July $11,\ 2003$, Appendix B to Part $101\ was$ amended by revising the sample label following the list of examples, effective January 1, 2006. For the convenience of the user, the revised text is set forth as follows:

APPENDIX B TO PART 101—GRAPHIC ENHANCEMENTS USED BY THE FDA

* * * * * *

Examples of Graphic Enhancements used by the FDA



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APPENDIX C TO PART 101—NUTRITION FACTS FOR RAW FRUITS AND VEGETABLES

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Cucumber, ½ medium (99 g/3.5 oz) Bell pepper, 1 medium (148 g/5.3 oz) ... Cauliflower, ½ medium head (99 g/3.5

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25 30 30 25 10 10 10 15 45 25 50 15 240 35 45 10 o midia Siria Sir % 00 00 0000 270 2 5 Vita-% - 0 0004 F F 0 Pro-tein <u>(</u> 0.40 5 5 0 -5 5 6 1 0 0 8 Sug-ars <u>6</u> 2 4 4 5 12 27 20 20 21 4 4 5 Dietary Fiber <u>(</u> 2 V 88 Z 6 - 2 5 დ ი ဖ က Car-drate Total 27 21 12 16 10 10 16 വ 15 22 24 7 26 യ ഗ 8 13 (g) 3 2 5 9 14 12 12 107 80 7 Potassium % 230 280 280 270 270 270 270 270 270 270 300 310 170 90 115 180 300 480 75 720 120 360 240 (mg) 00 00 00-00000 0000 000 % Sodium 000000 35 0 00 0000 5 5 0 55 8 8 (mg) Cholesterol (%) 00 00 0000 000 00 (mg) 00 2 00 0000 000 00 00 Saturated fat % 000000000 00 - 0 00 0000 000 00 00 (g -10000000 0 0 **®** О 0 -000 0 + 0 00 2 -% fat Total 0.5 0.5 0.5 1 2 <u>(</u> 000500050 0 0 45 00 0000 000 00 00 Cal-ories from fat 80 70 50 90 60 60 45 70 70 50 80 55 15 60 50 8888 15 35 60 35 20 80 45 Cal-ories (30 g/ Tangerine, 1 medium (109 g/3.9 oz) Sweet cherries, 21 cherries, 1 cup Onion, 1 medium (148 g/5.3 oz) Carrot, 7" long, 11/4" diameter (78 g/ Nutrition facts 1 for raw fruits and vege-tables edible portion Lemon, 1 medium (58 g/2.1 oz)
Pineapple, 2 slices, 3" diameter, ¾"
thick (112 g/4 oz) Celery, 2 medium stalks (110 g/3.9 oz) Sweet corn, kernels from 1 medium 'atermelon, 1/18 medium melon; cups diced pieces (280 g/10.0 oz) . Banana, 1 medium (126 g/4.5 oz) Apple, 1 medium (154 g/5.5 oz) ... Fomato, 1 medium (148 g/5.3 oz) 1.1 oz)

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0 4 0 8 23 30 0 440 0 0 16 20 വ 0 0 350 2 0 -0 0 0 00 0 00 00 0 00 00 0 00 0 00 00 0 00 00 00 0 00 00 9 25 15 15 130 Leaf lettuce, 1½ cups shredded (85 g/ 30 oz)

Sweet Potato, medium, 5" long, 2" di- ameter (130 g/4.6 oz)

Mushrooms, 5 medium (84 g/3.0 oz)

Green onion, ¼ cup chopped (25 g/0.9 oz)

Green (snap) beans, ¾ cup cut (83 g/ 3.0 oz)

Radishes, 7 radishes (85 g/3.0 oz)

Summer squash, ½ medium (98 g/3.5 oz) Asparagus, 5 spears (93 g/3.3 oz)

[61 FR 42761, Aug. 16, 1996]

APPENDIX D TO PART 101—NUTRITION FACTS FOR COOKED FISH

<u>10</u>%

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	Cal- cium (%)		Ø	0	0	0	Ŋ	0	0	0	N	9	0	0	10	0	9	9	Ŋ	80	9	4	4	0
	Vita- min (%)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	2
	Vita- min A (%)		0	0	0	0	0	0	N	4	0	0	0	0	0	4	N	9	0	0	4	N	0	2
	Pro- tein (g)		18	20	20	17	22	22	22	23	2	10	16	2	2	21	19	22	2	20	2	23	17	22
	Sug- ars (g)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ary.	(%)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
APPENDIX D TO PART 101—INUTRITION FACTS FOR COOKED FISH	Dietary	(B)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	car-	(%)	0	0	0	0	-	0	0	0	0	_	0	0	0	0	0	0	0	0	0	0	0	0
	Total car-	(a)	0	0	0	0	N	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	_	0
	Potassium	(%)	4	13	9	7	ω	4	12	6	ω	Ξ	6	Ξ	ω	12	6	15	9	9	Ξ	4	6	6
		(gm)	140	450	360	230	280	490	410	320	290	390	330	400	290	430	320	230	340	360	370	490	300	310
	Sodium	(%)	80	က	2	N	Ξ	N	က	N	4	80	က	4	4	က	4	4	4	13	-	က	13	4
		(gm)	190	09	110	40	260	20	92	22	06	190	2	100	92	2	92	92	82	320	32	09	320	100
	Cholesterol	(%)	22	15	27	17	8	17	23	52	50	38	7	50	17	13	23	18	27	30	50	12	50	13
		(mg)	165	45	80	20	22	20	2	75	09	115	20	09	20	40	2	22	80	06	09	32	09	40
	Saturated fat	 (%)	0	0	0	9	0	2	2	ω	က	S	0	ω	0	0	က	0	0	0	9	0	0	2
		(g)	0	0	0	N	0	-	-	7.	0.5	-	0	7.	0	0	0.5	0	0	0	N	0	0	-
	Total fat S	(%)	N	-	N	4	N	Ξ	9	4	N	2	Ŋ	20	က	က	ß	Ŋ	N	N	6	က	_	7
		(g)	-	0.5	-	6	-	7	4	6	5.	3.5	-	13	N	0	က	5.	-	-	9	N	0.5	4.5
	Cal- ories from fat		9	0	9	80	9	09	35	80	4	35	9	120	50	50	52	15	9	9	20	50	0	32
	Cal- ories		80	06	90	140	120	160	130	180	100	100	80	210	110	100	110	100	100	100	140	110	80	130
	Nutrition facts ¹ fish (84 g/3 oz)		Shrimp	Cod	Pollock	Catfish	Scallops, about 6 large or 14 small	Salmon, Atlantic/Coho	Salmon, Chum/Pink	Salmon, Sockeye	Flounder/sole	Oysters, about 12 medium	Orange roughy	Mackerel, Atlantic/Pacific	Ocean perch	Rockfish	Whiting	Clams, about 12 small	Haddock	Blue crab	Rainbow trout	Halibut	Lobster	Swordfish

[61 FR 42761, Aug. 16, 1996]

¹ Raw, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.

¹ Cooked, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.