

NUTRIENT CONTENT CLAIMS ...

- ... describe directly or by implication the level of a nutrient or dietary substance in a serving
- ... are limited to those authorized by FDA regulation; generally, this is limited to nutrients that are mandatory or voluntary in the Nutrition Facts and have an FDA-established Daily Value
- ... are used on labels without review by FDA, but must comply with all FDA definitions and regulations
- ... placed on labels for USDA-regulated products must always be submitted for USDA approval
- ... can be made for both conventional foods and dietary supplements
- ... are not allowed on products for infants and children less than two years of age
- ... must be accompanied by the following disclosure when fat, cholesterol, saturated fat or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT.**

Nutrients that qualify for nutrient content claims include: total calories, total fat, saturated fat, cholesterol, sodium, potassium, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, choline and ALA & DHA omega-3 fatty acids.

Note: Even though there is no Daily Value for choline or ALA & DHA omega-3 fatty acids and these nutrients are not mandatory or voluntary for Nutrition Facts reporting (and cannot be included in Nutrition Facts), they are allowable per specific FDA notification. Choline claims are allowable per FDA's notification under FDAMA; ALA & DHA omega-3 claims are allowable per the "Martek Notification."

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ABSOLUTE NUTRIENT CONTENT CLAIMS are direct statements about the level of a nutrient in the product.

- **Free** means a product's reference amount and labeled serving contains an insignificant amount of: total fat, saturated fat, cholesterol, sodium, sugars or calories. (Insignificant is defined as an amount that may be rounded to zero, per FDA rounding rules.) Synonyms include *zero*, *no*, *without*, *trivial source of*, *negligible source of* and *dietarily insignificant source of*. *Non fat* is a synonym for fat free.
- **Low** means a product could be eaten frequently without exceeding the guidelines for: total fat, saturated fat, cholesterol, sodium or calories. Synonyms include *little*, *few* (for calories), *contains a small amount of* and *low source of*. The term *very low* is also defined, but only with respect to sodium levels.

Notes about *free* and *low* claims:

- » When using *free* or *low* on a product that has not been specifically processed or altered to qualify for the claim, the manufacturer must indicate that the food inherently qualifies for the claim (e.g., peanut butter, a cholesterol-free food).
- » FDA has not defined nutrient content claims for trans fat, therefore it is not permissible to use the words *free* or *low* (or their synonyms) to describe trans fat levels (e.g., trans fat free, no trans fat and zero trans fat are unauthorized nutrient content claims). However, 0g trans fat per serving is allowed as a statement of fact.





- » FDA has not defined nutrient content claims for carbohydrate; therefore, it is not permissible to use the words *free* or *low* (or their synonyms) to describe carbohydrate levels (e.g., no carbs, carb free and low carb are unauthorized nutrient content claims). However Xg carb per serving is allowed as a statement of fact as long as it is simply a repeat of information from the Nutrition Facts and does not imply a level.
- » FDA has not provided a definition for *low sugar*, therefore this claim cannot be used. However, *sugar free*, *reduced sugar* and *no added sugar* claims are allowed as long as the food includes the required calorie and/or disclosure statements adjacent to the claim.
- » If a claim is made about fatty acids or cholesterol, then polyunsaturated fat and monounsaturated fat must be included in the Nutrition Facts (or Supplement Facts) unless the product is fat free. Additionally, specific disclosure about total fat and cholesterol levels must be included directly next to the claim when certain threshold levels are exceeded.
- » For dietary supplements: Claims for total fat, saturated fat and cholesterol can be made only if the product is greater than 40 calories per serving. Claims for calories can be made only when a similar product exists that contains over 40 calories per serving.
- **Lean** may be used to describe meat, poultry, seafood and game meat, and means less than 10g fat, 4.5g or less saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, main dishes and meals.
- **Extra Lean** may be used to describe meat, poultry, seafood and game meat, and means less than 5g fat, less than 2g saturated fat, and less than 95mg cholesterol per reference amount or per 100 grams (whichever is larger). Criteria are different for mixed foods, main dishes and meals.
- **Good Source** means the reference amount of a product contains 10 to 19% of the Daily Value of a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include *contains* and *provides*.
- **High** means the reference amount of a product contains 20% or more of the Daily Value for a particular nutrient (i.e., fiber, protein, or a vitamin or mineral). Synonyms include *excellent source* and *rich in*.

Notes about good source and high claims:

- » *Good source* and *high* cannot be used to describe nutrients and functional components without an FDA-established Daily Value (i.e., cannot be used to describe carotenoids, flavonoids, etc.).
- » The term “antioxidant” can be used in a claim as long as the antioxidant is named, has an FDA-established Daily Value, and qualifies in level for the *good source* or *high* claim (e.g., high in antioxidant vitamin C).
- » If a fiber claim is made and the food does not qualify as a low fat food, then the fiber claim must be accompanied by a disclaimer that discloses the level of total fat per labeled serving.
- » If a protein claim is made, then the Nutrition Facts (or Supplement Facts) must include the % Daily Value from protein based on specific protein quality factors.
- **High Potency** means the vitamin or mineral is present in a product at 100% or more of the RDI per reference amount; the nutrient in the claim must be identified (e.g., high potency vitamin C). *High Potency* can also be used to describe a conventional food or dietary supplement when the product contains 100% or more RDI for at least two-thirds of vitamins and minerals with Daily Values present in the product at 2% or more (e.g., high potency multivitamin/mineral supplement).



Nutrient Content Claim Definitions for *Free and Low*

Nutrient	Claim	Definition
Calories	Free	Less than 5 calories per serving
	Low	40 calories or less per serving Main dish/meal: 120 calories or less per 100 grams
Total Fat	Free	Less than 0.5g fat per serving, and includes no ingredients that contain fat*
	Low	3g or less fat per serving Main dish/meal: 3g or less fat per 100 grams, and not more than 30% of calories from fat
Saturated Fat	Free	Less than 0.5g saturated fat and less than 0.5g trans fat per serving, and includes no ingredients that contain saturated fat*
	Low	1g or less saturated fat per serving, and not more than 15% of calories from saturated fat Main dish/meal: 1g or less saturated fat per 100 grams, and less than 10% of calories from saturated fat
Cholesterol	Free	Less than 2mg cholesterol and 2g or less saturated fat per serving, and includes no ingredients that contain cholesterol*
	Low	20mg or less cholesterol and 2g or less saturated fat per serving Main dish/meal: 20mg or less cholesterol and 2g or less saturated fat per 100 grams
Sodium	Free	Less than 5mg sodium per serving, and contains no sodium chloride (table salt) or other ingredient that contains sodium*
	Very Low	35mg or less sodium per serving Main dish/meal: 35mg or less sodium per 100 grams
	Low	140mg or less sodium per serving Main dish/meal: 140mg or less sodium per 100 grams



“Per serving” means per reference amount or per labeled serving, whichever is larger. However, if a product has a small serving size (i.e., reference amount of 30 grams or less, or 2 Tbsp or less), then the nutrient levels for the claim must be met on a 50 gram basis.

**Exceptions are allowed if the relevant ingredient is asterisked in the ingredient statement and footnoted as required.*



RELATIVE NUTRIENT CONTENT CLAIMS compare the level of nutrients of one product to another.

- **More** means that the reference amount of a product (whether altered or not) contains at least 10% more of the Daily Value of a nutrient than the reference product. This definition also applies to *fortified*, *enriched*, *added*, and *plus* claims but, unlike *more*, these terms can only be used to describe foods that have been altered.
- **Less** means that the reference amount of a product (whether altered or not) contains 25% less of a nutrient than the reference product. This definition also applies to *fewer*, which can be used to describe calories.
- **Reduced** means that the reference amount of a nutritionally-altered product contains 25% less of a nutrient than the reference product. This definition also applies to *lower*.
- **Light** means that the reference amount of a nutritionally-altered product contains 50% less fat or 1/3 fewer calories than the reference product.

Notes about *light* claims:

- » For products with greater than 50% calories from fat, the claim must be met on the basis of 50% less fat (not 1/3 fewer calories). For products with less than 50% calories from fat, the claim can be met on either the calorie or fat basis.
- » A *light* claim is not allowed on products when the reference product is low calorie (40 calories or less) or low fat (3g fat or less), unless the sodium of such a product is reduced by 50%.

FDA has specified **reference products** that may be used as a basis of comparison for each of the four relative claims above. For *more*, *less* and *reduced*, the reference product can be the company's regular brand, a competing regular brand, or a representative value for a broad base of products of that type. For *more* and *less*, the reference product may also be a similar product in the same product category (e.g., pretzels with 25% less fat than potato chips). For *light*, the reference product must be similar and the reference value must be a representative value for a broad base of products of that type. Relative claims trigger many disclosure and footnote requirements.

- The identity of the reference product and the percent/fractional difference for nutrient(s) that are the subject of the claim between the two comparison products must be declared adjacent to the claim. Example: half the calories and 60% less fat than [name of reference product].
- Quantitative information comparing level of nutrients (i.e., calories and fat, or sodium) in the product and reference product must be disclosed, either adjacent to the claim or on the information panel. Example: light soy sauce 500mg sodium per serving; regular soy sauce 1000mg sodium per serving.
- The following disclosure is required when total fat, cholesterol, saturated fat or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT.**



IMPLIED NUTRIENT CONTENT CLAIMS include:

- claims not explicitly stated but implied by association with an ingredient known to contain a particular nutrient or be free of that nutrient. Examples: (1) *good source of oat bran* is an implied fiber claim and is approved for foods that could make a good source of fiber claim, (2) *no tropical oils* is an implied low saturated fat claim and is approved for foods that could make such a claim.
- claims that characterize the level of a nutrient as a little or a lot. Examples: (1) *only* implies a little; therefore, *only 3g carbohydrate* is not allowed because low carbohydrate claims are not allowed, (2) *packed with antioxidants* implies high in antioxidants; this claim is not allowed because a specific antioxidant is not named. However, a statement such as *packed with antioxidant vitamin C* is allowed on a product that reports 20% or more Daily Value for this nutrient within the Nutrition Facts or Supplement Facts.
- equivalency claims such as *contains as much [nutrient] as a [food]*. This claim can be made if both the reference product and the labeled product are a *good source* of the nutrient on a per serving basis. Example: *contains as much vitamin C as an 8 ounce glass of orange juice* is allowed when the statement is truthful and not misleading.

Two common implied nutrient content claims:

- **Healthy** means a food that is low in fat and saturated fat, contains 480mg or less sodium and 60mg or less cholesterol per reference amount or labeled serving (whichever is larger), and provides at least 10% Daily Value per reference amount for one of these beneficial nutrients: vitamin A, vitamin C, calcium, iron, protein or fiber.

Notes and exceptions for *healthy* claims:

- » For products with a small serving size, the food must meet the criteria on a 50 gram basis.
 - » For products that qualify as a main dish or meal, the food must be low in fat and saturated fat, contain 600mg or less sodium, 90mg or less cholesterol, and at least 10% Daily Value per labeled serving of two beneficial nutrients.
 - » For products that qualify as a meal, the food must be low in fat and saturated fat, contain 600mg or less sodium, 90mg or less cholesterol, and at least 10% Daily Value per labeled serving of three beneficial nutrients.
 - » For single ingredient raw meat, poultry, seafood or game meat, the food must contain less than 5g fat, 2g saturated fat, and 95mg cholesterol per reference amount per 100 grams (whichever is larger); it must also contain at least 10% Daily Value of one of the beneficial nutrients. [Note that the criteria for “healthy” in these foods is the same as “extra lean” for fat, saturated fat and cholesterol.]
 - » Raw fruits and vegetables, canned or frozen single ingredient fruits and vegetables, mixtures of single ingredient raw, canned, or frozen fruits and vegetables, and enriched cereal grain products that conform to certain standards of identity are exempt from the requirement of providing at least 10% Daily Value for one of the beneficial nutrients.
- **Percent Fat Free** can be stated on foods which meet the low fat or fat free definition. However, *100% fat free* can be made only on foods that contain less than 0.5g fat per reference amount or per 100 grams (whichever is larger), and include no ingredients that contain fat.



STATEMENTS OF FACT ...

- ... can be made on labels as long as they do not make a nutrient content claim, health claim or other claim that requires specific FDA authorization
- ... are covered by free speech rights
- ... must not characterize the nutrient level by using terms that are defined or implied nutrient content claims (i.e., *free*, *zero*, *no*, *low*, *high*, *good source*, *only*, *packed with*, etc.)
- ... are allowed on conventional foods and dietary supplements as long as they are truthful and not misleading
- ... may be used to describe an amount of a nutrient or a functional component present in a product; this allows manufacturers to inform consumers about the level a nutrient or functional component present when a Daily Value has not been established
- ... taken from the Nutrition Facts panel and repeated elsewhere on the label require the disclosure statement when total fat, cholesterol, saturated fat or sodium threshold levels are exceeded: **SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT**

EXAMPLES AND EXPLANATIONS:

ALLOWED: 0g trans fat per serving (the numeral 0 is not a defined nutrient content claim)

NOT ALLOWED: zero trans fat, trans fat free, no trans fat (the terms *zero*, *free*, and *no* are defined nutrient content claims; there are no allowable defined nutrient content claims for trans fat at this time)

ALLOWED: 200mg isoflavones per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: excellent source of isoflavones (the term *excellent source* is a synonym for the nutrient content claim *high* which means 20% or more Daily Value per serving; since FDA has not established a Daily Value for isoflavones, this is an unauthorized nutrient content claim)

ALLOWED: 3g carb per serving (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 3g carb per serving (the term *only* implies a low level, and low carbohydrate claims are not allowed)

ALLOWED: 100 Calorie Pack (factual statement with no nutrient content claim terms)

NOT ALLOWED: Only 100 Calories (the term *only* implies a low level and the definition for low calorie is 40 calories or less per serving; this statement requires the addition of a disclaimer "Only 100 calories, not a low calorie food.")

ALLOWED: Contains 10mg lutein (factual statement with English use of the word *contains* preceding a quantitative amount)

NOT ALLOWED: Contains lutein (use of the word *contains* without the quantitative amount is a nutrient content claim that means 10% or more Daily Value per serving; since FDA has not established a Daily Value for lutein, this is an unauthorized nutrient content claim)

ALLOWED: Made with oat bran (factual as long as the product contains a significant amount of oat bran in the formulation, generally more than 2% by weight)

NOT ALLOWED: High in oat bran (implies a *high* level of fiber, which means 20% or more Daily Value per serving; if the product contains less than 20% Daily Value then the claim is not valid)

ALLOWED: Glycemic index of this product is 41

NOT ALLOWED: Low glycemic foods help control diabetes (this is an unauthorized health claim)

