Additional Information about High-Intensity Sweeteners Permitted for use in Food in the United States

High-Intensity Sweeteners Main Page (/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm397716.htm)

High-intensity sweeteners are commonly used as sugar substitutes or sugar alternatives because they are many times sweeter than sugar but contribute only a few to no calories when added to foods. High-intensity sweeteners, like all other ingredients added to food in the United States, must be safe for consumption.

- **Saccharin**
- **Aspartame**
- **Acesulfame potassium (Ace-K)**
- **Sucralose**
- **Neotame**
- **Advantame**
- **Steviol glycosides**
- **Luo Han Guo fruit extracts**

Saccharin
Saccharin is **approved (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=180.37)** for use in food as a **non-nutritive** sweetener. Saccharin brand names include Sweet and Low®, Sweet Twin®, Sweet'N Low®, and Necta Sweet®. It is 200 to 700 times sweeter than table sugar (sucrose), and it does not contain any calories.

First discovered and used in 1879, saccharin is currently approved for use, under certain conditions, in beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, as a sugar substitute for cooking or table use, and in processed foods. Saccharin is also approved for use for certain technological purposes.

In the early 1970s, saccharin was linked with the development of bladder cancer in laboratory rats, which led Congress to mandate additional studies of saccharin and the presence of a warning label on saccharin-containing products until such warning could be shown to be unnecessary. Since then, more than 30 human studies demonstrated that the results found in rats were not relevant to humans, and that saccharin is safe for human consumption. In 2000, the National Toxicology Program of the National Institutes of Health concluded that saccharin should be removed from the list of potential carcinogens. Products containing saccharin no longer have to carry the warning label.

Aspartame
Aspartame is **approved (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.804)** for use in food as a **nutritive** sweetener. Aspartame brand names include Nutrasweet®, Equal®, and Sugar Twin®. It does contain calories, but because it is about 200 times sweeter than table sugar, consumers are likely to use much less of it.

FDA approved aspartame in **1981 (/downloads/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/UCM404380.pdf)** (46 FR 38283) for uses, under certain conditions, as a tabletop sweetener, in chewing gum, cold breakfast cereals, and dry bases for certain foods (i.e., beverages, instant coffee and tea, gelatins, puddings, and fillings, and dairy products and toppings). In **1983**

(/downloads/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/UCM404332.pdf) (48 FR 31376), FDA approved the use of aspartame in carbonated beverages and carbonated beverage syrup bases, and in **1996 (http://www.gpo.gov/fdsys/pkg/FR-1996-06-28/pdf/96-16522.pdf)**, FDA approved it for use as a "general purpose sweetener." It is not heat stable and loses its sweetness when heated, so it typically isn't used in baked goods.

Aspartame is one of the most exhaustively studied substances in the human food supply, with more than 100 studies supporting its safety.

FDA scientists have reviewed scientific data regarding the safety of aspartame in food and concluded that it is safe for the general population under certain conditions. However, people with a rare hereditary disease known as phenylketonuria (PKU) have a difficult time metabolizing phenylalanine, a component of aspartame, and should control their intake of phenylalanine from all sources, including aspartame. Labels of aspartame-containing foods and beverages must include a statement that informs individuals with PKU that the product contains phenylalanine.

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Acesulfame potassium (Ace-K)
Acesulfame potassium is **approved (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.800)** for use in food as a **non-nutritive** sweetener. It is included in the ingredient list on the food label as acesulfame K, acesulfame potassium, or Ace-K. Acesulfame potassium is sold under the brand names Sunett® and Sweet One®. It is about 200 times sweeter than sugar and is often combined with other sweeteners.

FDA approved acesulfame potassium for use in specific food and beverage categories in **1988 (/downloads/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/UCM404328.pdf)** (53 FR 28379), and in **2003 (http://www.gpo.gov/fdsys/pkg/FR-2003-12-31/pdf/03-32101.pdf)** approved it as a general purpose sweetener and flavor enhancer in food, **except in meat and poultry**, under certain conditions of use. It is heat stable, meaning that it stays sweet even when used at high temperatures during baking, making it suitable as a sugar substitute in baked goods.

Acesulfame potassium is typically used in frozen desserts, candies, beverages, and baked goods. More than 90 studies support its safety.

Sucralose
Sucralose is **approved (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=c0f4112bab74084d5c7489f8fc3f4489&ty=HTML&h=L&r=SECTION&n=21y3.0.1.1.3.9.1.20)** for use in food as a **non-nutritive** sweetener. Sucralose is sold under the brand name Splenda®. Sucralose is about 600 times sweeter than sugar.

FDA approved sucralose for use in 15 food categories in **1998 (http://www.gpo.gov/fdsys/pkg/FR-1998-04-03/pdf/98-8750.pdf)** and for use as a general purpose sweetener for foods in **1999 (http://www.gpo.gov/fdsys/pkg/FR-1999-08-12/pdf/99-20888.pdf)**, under certain conditions of use. Sucralose is a general purpose sweetener that can be found in a variety of foods including baked goods, beverages, chewing gum, gelatins, and frozen dairy desserts. It is heat stable, meaning that it stays sweet even when used at high temperatures during baking, making it suitable as a sugar substitute in baked goods.

Sucralose has been extensively studied and more than 110 safety studies were reviewed by FDA in approving the use of sucralose as a general purpose sweetener for food.

Neotame
Neotame is **approved (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.829)** for use in food as a **non-nutritive** sweetener. Neotame is sold under the brand name Newtame®, and is approximately 7,000 to 13,000 times sweeter than table sugar.

FDA approved neotame for use as a general purpose sweetener and flavor enhancer in foods (except in meat and poultry), under certain conditions of use, in **2002 (http://www.gpo.gov/fdsys/pkg/FR-2002-07-09/pdf/02-17202.pdf)**. It is heat stable, meaning that it stays sweet even when used at high temperatures during baking, making it suitable as a sugar substitute in baked goods.

In determining the safety of neotame, FDA reviewed data from more than 113 animal and human studies designed to identify possible toxic effects, including effects on the immune system, reproductive system, and nervous system.

Advantame
Advantame is **approved (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=180.37)** for use in food as a **non-nutritive** sweetener. It is approximately 20,000 times sweeter than table sugar (sucrose).

FDA approved advantame for use as a general purpose sweetener and flavor enhancer in foods (except in meat and poultry), under certain conditions of use, in **2014 (https://www.federalregister.gov/articles/2014/05/21/2014-11584/advantame-food-additives-permitted-for-direct-addition-to-food-for-human-consumption)**. It is heat stable, meaning that it stays sweet even when used at high temperatures during baking, making it suitable as a sugar substitute in baked goods.

In determining the safety of advantame, FDA reviewed data from 37 animal and human studies designed to identify possible toxic effects, including effects on the immune system, reproductive and developmental systems, and nervous system. FDA also reviewed pharmacokinetic and carcinogenicity studies, as well as several additional exploratory and screening studies.

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Steviol glycosides
Steviol glycosides are natural constituents of the leaves of *Stevia rebaudiana* (Bertoni) Bertoni, a plant native to parts of South America and commonly known as Stevia. They are **non-nutritive** sweeteners and are reported to be 200 to 400 times sweeter than table sugar.

FDA has received many GRAS Notices for the use of high-purity (95% minimum purity) steviol glycosides including Rebaudioside A (also known as Reb A), Stevioside, Rebaudioside D, or steviol glycoside mixture preparations with Rebaudioside A and/or Stevioside as predominant components. FDA has not questioned the notifiers' GRAS determinations for these high-purity stevia derived sweeteners under the intended conditions of use identified in the GRAS notices submitted to FDA. FDA's response letters on such high-purity steviol glycosides are available at FDA's **GRAS Notice Inventory (http://www.fda.gov/grasnoticeinventory)** website.

The use of stevia leaf and crude stevia extracts is not considered GRAS and their import into the United States is not permitted for use as sweeteners. For details, see **Import Alert 45-06 (http://www.accessdata.fda.gov/cms_ia/impotalert_119.html)**.

Luo Han Guo fruit extracts
Siraitia grosvenorii Swingle fruit extract (SGFE) contains varying levels of mogrosides, which are the **non-nutritive** constituents of the fruit primarily responsible for the characteristic sweetness of SGFE. SGFE, depending on the mogroside content, is reported to be 100 to 250 times sweeter than sugar. *Siraitia grosvenorii* Swingle, commonly known as Luo Han Guo or monk fruit, is a plant native to Southern China.

FDA has received GRAS Notices for SGFE. FDA has not questioned the notifiers' GRAS determination for SGFE under the intended conditions of use identified in the GRAS notices submitted to FDA. FDA's response letters on SGFE are available at the agency's **GRAS Notice Inventory (http://www.fda.gov/grasnoticeinventory)**website.

Sweetener	Regulatory Status	Examples of Brand Names Containing Sweetener	Multiplier of Sweetness Intensity Compared to Table Sugar (Sucrose)	Acceptable Daily Intake (ADI) milligrams per kilogram body weight per day (mg/kg bw/d)	Number of Tabletop Sweetener Packets Equivalent to ADI*
Acesulfame Potassium (Ace-K)	Approved as a sweetener and flavor enhancer in foods generally (except in meat and poultry) **21 CFR 172.800 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.800)**	Sweet One® Sunett®	200 x	15	23

Sweetener	Regulatory Status	Examples of Brand Names Containing Sweetener	Multiplier of Sweetness Intensity Compared to Table Sugar (Sucrose)	Acceptable Daily Intake (ADI) milligrams per kilogram body weight per day (mg/kg bw/d)	Number of Tabletop Sweetener Packets Equivalent to ADI*
Advantame	Approved as a sweetener and flavor enhancer in foods generally (except in meat and poultry) 21 CFR 172.803		20,000 x	32.8	4,920
Aspartame	Approved as a sweetener and flavor enhancer in foods generally **21 CFR 172.804 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.804)**	Nutrasweet® Equal® Sugar Twin®	200 x	50	75
Neotame	Approved as a sweetener and flavor enhancer in foods generally (except in meat and poultry) **21 CFR 172.829 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.829)**	Newtame®,	7,000-13,000 x	0.3	23 (sweetness intensity at 10,000 x sucrose)
Saccharin	Approved as a sweetener only in certain special dietary foods and as an additive used for certain technological purposes **21 CFR 180.37 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=180.37)**	Sweet and Low® Sweet Twin® Sweet'N Low® Necta Sweet®	200-700 x	15	45 (sweetness intensity at 400 x sucrose)
Siraitia grosvenorii Swingle (Luo Han Guo) fruit extracts (SGFE)	SFGE containing 25%, 45% or 55% Mogroside V is the subject of GRAS notices for specific conditions of use **GRAS Notice Inventory (http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices)**	Nectresse® Monk Fruit in the Raw® PureLo®	100-250 x	NS***	ND

Sweetener	Regulatory Status	Examples of Brand Names Containing Sweetener	Multiplier of Sweetness Intensity Compared to Table Sugar (Sucrose)	Acceptable Daily Intake (ADI) milligrams per kilogram body weight per day (mg/kg bw/d)	Number of Tabletop Sweetener Packets Equivalent to ADI*
Certain high purity steviol glycosides purified from the leaves of *Stevia rebaudiana* (Bertoni) Bertoni	≥95% pure glycosides Subject of GRAS notices for specific conditions of use **GRAS Notice Inventory (http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices)**	Truvia® PureVia® Enliten®	200-400 x	4**	9 (sweetness intensity at 300 x sucrose)
Sucralose	Approved as a sweetener in foods generally **21 CFR 172.831 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.831)**	Splenda®	600 x	5	23

* Number of Tabletop Sweetener Packets a 60 kg (132 pound) person would need to consume to reach the ADI. Calculations assume a packet of high-intensity sweetener is as sweet as two teaspoons of sugar.
**ADI established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
*** NS means not specified. A numerical ADI may not be deemed necessary for several reasons, including evidence of the ingredient's safety at levels well above the amounts needed to achieve the desired effect (e.g., as a sweetener) in food.

What is the difference between nutritive and non-nutritive high-intensity sweeteners?
Nutritive sweeteners add caloric value to the foods that contain them, while non-nutritive sweeteners are very low in calories or contain no calories at all. Specifically, aspartame, the only approved nutritive high-intensity sweetener, contains more than two percent of the calories in an equivalent amount of sugar, as opposed to non-nutritive sweeteners that contain less than two percent of the calories in an equivalent amount of sugar.

Why do the intended conditions of use of high-intensity sweeteners sometimes not include use in meat and poultry products?
The intended conditions of use of some high-intensity sweeteners approved for use as food additives do not include use in meat and poultry products because the companies that sought FDA's approval for these substances did not request these uses. In the case of the high-intensity sweeteners that are subjects of GRAS notices (i.e., certain high-purity steviol glycosides and SGFE), the notifiers did not include use in meat and poultry products as an intended condition of use in the GRAS notices that they submitted for FDA's evaluation.

If a high-intensity sweetener is proposed for use in a meat or poultry product through a food additive petition, FDA would be responsible for reviewing the safety of the high-intensity sweetener under the proposed conditions of use, and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) would be responsible for evaluating its suitability. If FDA is notified under the GRAS Notification Program that a high-intensity sweetener is GRAS for use in a meat or poultry product, FDA would evaluate whether the notice provides a sufficient basis for a GRAS determination and whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether the use of the high-intensity sweetener is GRAS. FDA would also forward the GRAS notice to FSIS to evaluate whether the intended use of the substance in meat or poultry products complies with the relevant statutes that are administered by FSIS

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