FACTS ABOUT LOW-CALORIE SWEETENERS

INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION

Low-calorie sweeteners (sometimes referred to as non-nutritive sweeteners, artificial sweeteners, or sugar substitutes) are ingredients added to foods and beverages to provide sweetness without adding a significant amount of calories. In fact, they can also play an important role in a weight management program that includes both good nutrition choices and physical activity.

Low-calorie sweeteners have a long history of safe use in a variety of foods and beverages, ranging from soft drinks to puddings and candies to table-top sweeteners. They are some of the most studied and reviewed food ingredients in the world today and have passed rigorous safety assessments. In the U.S., the most common and popular low-calorie sweeteners permitted for use in foods and beverages today are:

- acesulfame potassium (ace-K)
- advantame
- aspartame
- neotame
- saccharin
- stevia sweeteners
- sucralose

(See Table 1 on p. 6 for more general information on each low-calorie sweetener)

When added to foods and beverages, these low-calorie sweeteners provide a taste that is similar to that of table sugar (sucrose), and are generally several hundred to several thousand times sweeter than sugar. They are often referred to as "intense" sweeteners. Because of their intense sweetening power, these sweeteners can be used in very small amounts and thus add only a negligible amount of calories to foods and beverages. As a result, they can substantially reduce or completely eliminate the calories in certain products such as diet beverages, light yogurt and sugar-free pudding. In addition, many low-calorie sweeteners do not contribute to cavities or tooth decay.

The following are some helpful facts about the safety, benefits, and uses of low-calorie sweeteners.

FACT: Low-calorie sweeteners are reviewed for safety by the federal government before being approved for use in foods and beverages.

Low-calorie sweeteners are thoroughly tested and carefully regulated by U.S. and international regulatory authorities, as well as scientific organizations, to ensure the safety of foods, beverages and other products that contain them. Current findings have documented that low-calorie sweeteners are safe for consumption as part of a balanced diet. Also, food and beverage manufacturers are required to list low-calorie sweeteners in the ingredients list on the product label.

The Acceptable Daily Intake (ADI) must be determined by the U.S. Food and Drug Administration (FDA) prior to approval for any food ingredient, including low-calorie sweeteners, for use in foods and beverages in the U.S. The ADI is the amount of an ingredient (expressed in milligrams per kilogram of body weight) that a person can safely consume every day over a lifetime without risk. The ADI is set at one one-hundredth of the amount that has been found not to produce any adverse health effects in key animal studies. Therefore, it would be very difficult for a person to consume enough of any low-calorie sweetener to reach the ADI. In fact, current intake of each low-calorie sweetener is well below the ADI.

FACT: All approved low-calorie sweeteners can be safely consumed by the general population, including people with diabetes, pregnant women and children.

One exception is people who have a rare hereditary condition called phenylketonuria (PKU), which means they cannot metabolize phenylalanine, a component of aspartame. All products containing aspartame must carry a statement warn-

ing people with PKU of the presence of aspartame on the label. For people with diabetes, who must control their blood-sugar levels through careful monitoring of their sugar and carbohydrate intake, low-calorie sweeteners can offer a sweet alternative that does not affect blood glucose levels.

Substituting caloric sweeteners such as sugar with low-calorie sweeteners allows patients with type 2 diabetes greater flexibility with their health and dietary goals. A 2010 review of nutritive and nonnutritive sweeteners published in the *Journal of the Academy of Nutrition and Dietetics* concluded that consumption of low-calorie sweeteners generally do not affect glucose levels in people with diabetes. According to the American Diabetes Association (ADA) and American Heart Association (AHA) 2013 joint scientific statement, four randomized-control trials (the gold standard in scientific research) found no significant difference in the effects of low-calorie sweeteners on standard measures of glycemic response compared to other sweeteners. The statement also posits, "Monitoring carbohydrate intake...is a key strategy to achieve glycemic control," which includes reduction in overall calorie intake.

Pregnant women and children can safely consume foods and beverages sweetened with low-calorie sweeteners. Current low-calorie sweetener consumption in children is well below the Acceptable Daily Intake (ADI) for all approved low-calorie sweeteners. However, pregnant women and young children are not encouraged to restrict their calorie intake, so they should talk with their healthcare provider and/or dietitian about ensuring that dietary plans including low-calorie sweeteners still meet the desired calorie and nutrient goals.

FACT: Low-calorie sweeteners do not cause or increase the risk of cancer.

Studies have repeatedly shown that low-calorie sweeteners do not cause or increase the risk of developing cancer. The following discusses cancer research conducted on each approved low-calorie sweetener.

Ace-K.

Acesulfame potassium (ace-K) has been thoroughly tested in several long-term animal studies which used amounts of ace-K that were far higher than any person could potentially consume, and no evidence of cancer or tumors was found.

Advantame.

A large body of research on advantame safety and health has been performed. Comprehensive toxicology studies designed to meet the highest scientific standards have clearly demonstrated that advantame does not increase the risk of cancer.

Aspartame.

The vast majority of the research conducted over the last three decades has concluded that aspartame does not cause cancer. The National Cancer Institute (NCI) recently concluded that aspartame is not associated with increased risk of cancer, even among individuals with high aspartame intakes. In September 2007, a panel of experts published a safety report on aspartame which found "no credible evidence that aspartame is carcinogenic" (Magnuson, 2007).

While two recent studies by a group of Italian researchers reported a link between aspartame and cancer in rats, the FDA found "significant shortcomings" in the design and interpretation of both studies. FDA subsequently stated that it does not plan to change its position on the safety of aspartame. Upon reviewing all of the available data, including the Italian cancer studies, the European Food Safety Authority (EFSA) published an official Opinion supporting aspartame's safety in December 2013. Prior to the 2013 risk assessment, EFSA convened a Panel in 2009 to review all available evidence on aspartame safety and concluded that aspartame does not cause cancer.

Neotame.

Prior to its approval as a general-purpose sweetener in 2002, more than 100 scientific studies were conducted on neotame, including cancer studies. Human studies were also conducted and "no significant effects of neotame were observed."

Saccharin.

While saccharin's safety has been the subject of ongoing controversy, the sweetener has been established as safe for many years. Studies conducted several decades ago found a link between saccharin consumption and bladder cancer in rats, which raised concerns. This caused FDA to propose a ban on saccharin in 1977 and require a warning label on products containing saccharin. However, since then, researchers have concluded that the findings on bladder cancer in the rats do not apply to humans. (NCI, 2006) Other human studies on saccharin have found no consistent evidence to link saccharin with bladder cancer in humans. As of 2001, products containing saccharin no longer have to carry a warning label.

Stevia sweeteners.

Several studies conducted on stevia sweeteners since the 1980s have shown that they are not associated with cancer. Recent research confirmed the conclusions of earlier research that steviol glycosides, the primary components of stevia

sweeteners, do not pose a cancer risk. Additionally, in June 2008, the Joint Expert Committee on Food Additives (JECFA) completed a multi-year review of all the available scientific data on high purity steviol glycosides, and concluded that they are safe for use as general purpose sweeteners.

Sucralose.
Extensive research on sucralose and health has been conducted over the last two decades. Comprehensive toxicology studies designed to meet the highest scientific standards have clearly demonstrated that sucralose is not cancerous.

FACT: Low-calorie sweeteners do not cause or increase the risk of other health conditions.

Low-calorie sweeteners are often inaccurately linked to adverse health effects, such as seizures, infertility, stomach ailments, and possible effects on kidney and liver function. However, the existing body of research does not support such effects. Health authorities around the world have verified that low-calorie sweeteners are safe. The following information on each low-calorie sweetener demonstrates that they do not cause or increase the risk of these or other health conditions.

Ace-K.
There is a large body of scientific evidence that supports the safety of ace-K for use in foods and beverages. Throughout more than 15 years of extensive use, there have been no documented health problems in humans from consuming ace-K. The FDA has concluded that the safety of ace-K is consistent with research findings from other countries. EFSA's re-examination of the sweetener in 2000 reaffirmed its safety.

Advantame.
The FDA reviewed data from 37 animal and human studies. The safety studies were designed to identify potential reproductive, neurological, and cancer-causing effects. Results of three clinical studies of human tolerability of advantame found advantame to be well tolerated and not to affect blood glucose levels in both healthy people and people with diabetes, suggesting that advantame is a safe alternative for people with diabetes. After a thorough assessment of the studies, the FDA concluded that advantame is safe for human consumption as classified under the conditions of use.

Aspartame.
In December 2013, EFSA published the results of a full safety assessment of aspartame, concluding that aspartame is safe for the general population (including pregnant women, infants, and children) and recommending no changes to the previously established ADI. A 2007 review by Magnuson, et al examined over 500 scientific studies, articles, and reports published over the last 25 years looking at aspartame metabolism, consumption, and toxicology data. Based on their review, the panel concluded that aspartame does not cause cancer, seizures, or other adverse effects on behavior, cognitive function, or neural function.

Neotame.
Of the more than 100 scientific studies conducted on neotame, no link has been found between neotame consumption and adverse health conditions, including toxicity, developmental and reproductive problems, or cancer.

Saccharin.
Saccharin has been evaluated by credible health and science organizations and confirmed to be safe. The Academy of Nutrition and Dietetics (AND), American Cancer Society (ACS), and American Medical Association (AMA) all agree that saccharin is safe and acceptable for use.

Stevia sweeteners.
The safety of stevia sweeteners for human consumption has been established through rigorous peer-reviewed research, including metabolism and pharmacokinetic studies, general and multi-generational safety studies, intake studies and human studies. This research is consistent with JECFA's review of steviol glycosides, completed in 2008, which concluded that steviol glycosides are safe for human consumption.

Sucralose.
More than 100 scientific studies have been conducted over a 20-year period on sucralose, looking at a variety of health conditions, such as toxicity, cancer, reproductive health, kidney health, brain and blood disorders, children's health, and nutrition. These studies have demonstrated that sucralose does not cause adverse health effects and is safe for use as a sweetening ingredient. The research on sucralose's safety has also been reviewed by scientific and regulatory bodies including JECFA and EFSA, both of which concluded it is safe for human consumption.

FACT: Low-calorie sweeteners can help with weight management and do not cause weight gain.

As Americans face increasing obesity rates, low-calorie sweeteners provide an alternative to caloric sweeteners and may facilitate weight loss or maintenance by limiting calorie intake. In addition, randomized controlled trials suggest that the use of low-calorie sweeteners may increase adherence to low-calorie diets and improve bodyweight and weight loss maintenance over time. Because they are not deprived of sweets, individuals consuming low-calorie sweeteners may feel more satisfied with their eating plans, helping them to lose weight and keep it off.

In one recent study, researchers at Purdue University found that consumption of saccharin led to increased appetite and weight gain in rats. However, many experts agree that there are a number of limitations that prevent the study from being applied to humans, including that rats have a known affinity for saccharin, and that the study had a small sample size, among other design flaws. While a few studies have suggested that low-calorie sweeteners may cause cravings and/or lead to weight gain, these studies have not changed the overall scientific consensus that low-calorie sweeteners can aid in weight management.

In fact, a 2012 review of human studies on low-calorie sweeteners and weight management published in *The Journal of Nutrition* concludes that there is no evidence that low-calorie sweeteners cause higher body weights in adults.

Sound clinical studies conducted in humans over the past 20 years have shown that low-calorie sweeteners can help with weight loss and/or maintenance. The CHOICE (Choose Healthy Options Consciously Everyday) study, published in the *American Journal of Clinical Nutrition* in March 2013, found that people who drink two diet beverages instead of two sugar-sweetened drinks every day enjoyed a healthy change in their overall food preferences and calorie intake. A 2006 review of aspartame's role in weight management demonstrated a weight loss of 0.2 kg/week (or 0.4 lb/week) when aspartame-sweetened products were substituted for those sweetened with sugar.

A 2014 meta-analysis published in *The American Journal of Clinical Nutrition* supported these earlier findings, as it showed that substituting low-calorie sweetened beverages for their full-calorie counterparts can aid in weight loss. In addition, a 2014 randomized control trial published in *Obesity* found that participants in a behavioral weight loss program who drank at least 24 ounces of low-calorie sweetened beverage a day not only lost weight, but lost more weight than participants who drank only water.
Experts agree that successful weight management requires more than just calorie reduction – moderation, along with eating a balanced diet and regular exercise, is key to reaching an optimal weight.

Low-Calorie Sweeteners by Sweetener Type

Each low-calorie sweeter has unique characteristics. *See Table 1 on page 6 for more general information on each low-calorie sweetener.*

Ace-K.

Ace-K is a combination of an organic acid and potassium, and is 200 times sweeter than sugar. It is a popular sweetener used in low-calorie sweetener blends to create an optimal flavor profile in foods and beverages.
Ace-K was approved by the U.S. Food and Drug Administration (FDA) in 1988 for use in numerous food products and as a tabletop sweetener. In 1998, the FDA extended its approval to beverages, and finally as a general purpose sweetener in 2003. Ace-K is approved for use in nearly 90 countries.

Ace-K is not broken down by the body and is eliminated unchanged by the kidneys. It has no effect on serum glucose, cholesterol or triglycerides, and people with diabetes may safely include products containing ace-K in their diet.

Aspartame.

Discovered in 1965, aspartame is used in foods and beverages in more than 100 countries worldwide. FDA approved aspartame for use in foods in 1981, followed by beverages in 1983. In 1996 it received approval as a general purpose sweetener.

Aspartame is a molecule consisting of two amino acids – phenylalanine and aspartic acid. People who have a rare hereditary condition called phenylketonuria (PKU) cannot metabolize phenylalanine; therefore, all products containing aspartame must carry a statement warning people with PKU of the presence of aspartame on the label.

Aspartame provides four calories per gram. However, it is used in very small amounts, contributing negligible calories to the diet. Aspartame is approximately 180 times sweeter than sugar. It is not heat-stable and is not suggested for use in cooking or baking.

Advantame.
The most recent FDA-approved LCS to enter the market is advantame, which was approved in the U.S. as a food additive in May 2014. Advantame has been found to be safe for consumption in foods and beverages by the general population. Advantame is an approved sweetener in the European Union, Australia, New Zealand, and Japan. Advantame is a no-calorie, high intensity sweetener made from vanillin and aspartame. Because it is so sweet, only a very small amount is needed to provide the desired sweetness. While it contains phenylalanine, unlike aspartame, the small amount of advantame needed to sweeten food products means they do not require a warning label for people with PKU.

Advantame can currently be used by food and beverage manufacturers to sweeten a variety of products, including some coffee, iced tea, and powdered beverages. Advantame can also be used as a flavor enhancer in some chewing gum, yogurt, and beverages. It is quite heat stable and therefore can be used in most cooking and baking applications.

Neotame.
Neotame is also a derivative of aspartic acid and phenylalanine. It is approximately 7,000 to 8,000 times sweeter than sugar, although some report a sweetening power of up to 13,000 times that of sugar. It is partially absorbed, but rapidly metabolized and excreted from the body.

Neotame was approved by FDA in July 2002 as a general purpose sweetener. Neotame has also received favorable evaluation by JECFA and is approved for use in other countries, including most parts of Eastern Europe, Australia, Russia, Mexico and several South American countries.

Because of the extraordinary sweetening power of a small amount of neotame, the level of exposure to phenylalanine as it is released into the bloodstream is considered clinically insignificant. Therefore, products sweetened with neotame are not required to carry a statement on the label alerting persons with PKU to the presence of phenylalanine.

Saccharin.
Originally discovered in 1878, saccharin is considered the oldest of the low-calorie sweeteners approved for food and beverage use. Today saccharin is still used safely and widely and often in combination with other sweeteners. Saccharin is 300 times sweeter than sugar, although some reports have indicated it can be up to 700 times sweeter than sugar. It is not broken down by the body and is eliminated without providing any calories. Saccharin is heat stable, therefore making it suitable for cooking and baking.

Stevia sweeteners.
The stevia plant is native to South America, and today, it can be found growing in many countries including China, Brazil, Argentina, Paraguay, India and South Korea. Hundreds of foods and beverages consumed around the world are sweetened with stevia sweeteners.

Stevia sweeteners are highly purified steviol glycosides, which make up the sweetest part of the stevia plant. Since 2008, the FDA has stated, in response to more than 30 notifications, that it has no questions regarding conclusions of expert panels that steviol glycosides as generally recognized as safe (GRAS) for use as general purpose sweeteners. Prior to this, stevia (in its unpurified form) was only permitted for use as a dietary supplement in the U.S. Stevia sweeteners are natural, contain zero calories, and are 200-300 times sweeter than sugar.

Stevia sweeteners are approved for food and beverage use in several countries and can be found in the U.S. in many food and beverage products, including some juice and tea beverages, as well as some tabletop sweeteners.

Sucralose.
In 1998, FDA approved sucralose for use in 15 food and beverage categories – the broadest initial approval ever given to a food additive. In 1999, FDA extended the approval to all categories of foods and beverages as a general-purpose Sweetener.

Six hundred times sweeter than sugar, the intense sweetness of sucralose is made from a process that begins with regular table sugar (sucrose); however, it is not sugar. It is produced through a process whereby three hydrogen-oxygen groups on the sugar molecule are replaced with three chlorine atoms. Sucralose is not recognized by the body as a carbohydrate. It is poorly absorbed and is excreted unchanged from the body. As a result, sucralose provides no calories. Because sucralose is very stable, it can be used almost anywhere sugar is used, including in cooking and baking.

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Table 1.

Low-Calorie Sweeteners At a Glance			
Sweetener	**Date Approved**	**Sweeter Than Sugar**	**Brand Name(s)**
Ace-K	1988	200x	Sunett®, Sweet One®
Advantame	2014	20,000x	n/a
Aspartame	1981	180x	NutraSweet®, Equal®, others
Neotame	2002	7,000x	n/a
Saccharin	Years prior to 1958	300x	Sweet 'N Low®, Sweet Twin, Sugar Twin®, others
Stevia Sweeteners	2008	200x	Truvia™, PureVia™, Sun Crystals®
Sucralose	1998	600x	Splenda®

Sources: *Comprehensive Reviews in Food Science and Food Safety*, 2006; *Food and Chemical Toxicology*, 2008, 2011

For more information on low-calorie sweeteners, visit www.foodinsight.org

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