

INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION

SUCRALOSE

here's no mistaking it: Americans love to eat. Enjoying good food with good company is one of life's great pleasures. And vet, frequent over-indulgences can have a detrimental impact on conditions like obesity and type 2 diabetes, which take a substantial toll on individuals, communities and our healthcare system. Replacing foods and beverages high in calories and added sugars with ones that are lower in sugar is one option to help reduce intake of excess calories. In turn, this may help reduce the risk of obesity and related chronic diseases. One type of low-calorie sweetener, sucralose, has been used in foods and beverages for decades as a way to lower intake of added sugars, while still providing satisfaction from enjoying something sweet. This fact sheet will examine the evidence for many topics of interest around sucralose and health so that you can make informed decisions about its place in your diet.

WHAT IS SUCRALOSE?

Sucralose is a no-calorie sweetener that contributes sweetness to foods and beverages without adding calories or carbohydrates. It is made from a process that begins with regular table sugar (sucrose); however, sucralose is not sugar. Three select hydrogenoxygen groups on a sucrose molecule are replaced with three chlorine atoms, resulting in a no-calorie sweetener that is about 600 times sweeter than sugar. Although sucralose provides sweetness, its structure prevents enzymes in the digestive tract from breaking it down. Most consumed sucralose (about 85 percent) is not absorbed. Of the small amount absorbed (about 15 percent), none is broken down for energy, so sucralose does not provide any calories. All absorbed sucralose is excreted quickly in the urine (Roberts 2000, Magnuson 2016).

Sucralose is the no-calorie sweetener in regular SPLENDA® retail sweeteners and it is also used in other retail sweeteners, such as those sold under store brand names. Sucralose is found in beverages and foods like chewing gum, dairy products, canned fruits, syrups and condiments. Because it is stable at high temperatures, sucralose can be used in baked goods. However, a food containing sucralose may be slightly different than the same food made with sugar, because

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sugar also plays a role in the structure, texture and flavor of foods. Like all noand low-calorie sweeteners, only very small amounts of sucralose are needed to achieve the sweetness of sugar. To make measuring and pouring easier, low-calorie sweeteners like sucralose are typically blended with approved food ingredients. This is why a packet of sucralose sweetener seems equal in quantity to a packet of table sugar, for example.

IS SUCRALOSE SAFE TO CONSUME?

YES. More than 100 safety studies representing over 20 years of research have shown sucralose to be safe. The Food and Drug Administration (FDA) approved its use in specific food categories in 1998 and expanded the approval to all food and beverage categories in 1999. Leading global health authorities such as the European Food Safety Authority (EFSA), the FAO/WHO Joint Expert Committee on Food Additives (JECFA), Japan's Ministry of Health, Labor and Welfare, Food Standards Australia New Zealand and Health Canada have also found sucralose to be safe.

The FDA established an acceptable daily intake (ADI) for sucralose of 5 milligrams per kilogram of body weight (mg/kg) per day. The ADI represents an amount 100 times less than the quantity of sucralose found to be safe in research studies. For a person weighing 150 pounds (68 kg), this equates to 340 mg of sucralose—the amount found in nine cans of diet soda or more than 28 individual packets of sucraloseconsumed, on average, every day over a lifetime. While estimates of dietary exposure to sucralose are limited in the United States, predictions of daily intake are below the ADI (1.3 mg/kg per

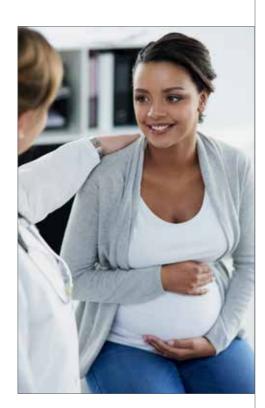
WHAT IS AN ADI?

The acceptable daily intake, or ADI, is the average daily intake over a lifetime that is expected to be safe based on significant research (WHO 2009). It is usually derived by determining the highest intake level found to have no adverse effects in lifetime studies in animal models. These studies are required by FDA and other regulatory agencies around the world before permitting any new food ingredient. That amount is then divided by 100 to determine the ADI (Renwick 1991). The ADI is a conservative number that the vast majority of people will not reach.

day for the average adult and maximal intakes of up to 2.4 mg/kg per day, FDA 1998, FDA 1999). Sucralose has been found safe at levels hundreds of times this amount. Globally, sucralose intake also remains well below the ADI established by JECFA, which is 0-15 mg/kg per day. A 2018 scientific review found that studies conducted since 2008 raise no concerns for exceeding the ADI of the major low- and no-calorie sweeteners, including sucralose, in the general population (Martyn 2018).

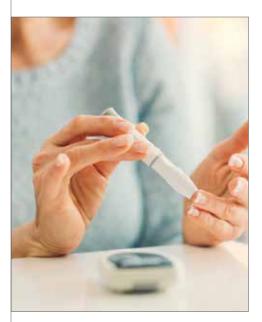
IS SUCRALOSE SAFE FOR CHILDREN?

YES. Foods sweetened with sucralose can add sweetness to a child's diet without contributing to increased calorie intake, sugar intake or risk of cavities. As with adults, current intake of low-calorie sweeteners in children is considered to be well within acceptable levels. Due to limited studies in children, the American Academy of Pediatrics does not have official recommendations on low-calorie sweetener intake.



CAN PREGNANT AND BREASTFEEDING WOMEN CONSUME SUCRALOSE?

YES. Pregnant and lactating women are frequently concerned about the influence of foods. beverages and medications on their babies' health. Research has shown that sucralose has no adverse effects on expecting or nursing mothers or on the fetus, and there are no known side effects of sucralose consumption (Grotz and Munro 2009, Magnuson 2017). Because only small amounts of sucralose are absorbed into the bloodstream, the amount of sucralose present in breast milk is very low (Sylvetsky 2015). All women should try to consume the necessary nutrients and calories for their baby's growth during pregnancy and breastfeeding, while taking care not to exceed their needs. This may include being mindful of all sources of sweeteners, whether they be from sugar or low-calorie sweeteners.



CAN PEOPLE WITH DIABETES CONSUME SUCRALOSE?

YES. Products containing sucralose provide a sweet taste and are often low or lower in carbohydrates, which is important for people who must monitor their carbohydrate intake. Sucralose does not raise blood sugar levels or otherwise affect blood glucose control. The 2018 American Diabetes Association Standards of Medical Care in Diabetes state that, "The use of nonnutritive sweeteners may have the potential to reduce overall calorie and carbohydrate intake if substituted for caloric (sugar) sweeteners and without compensation by intake of additional calories from other food sources. Nonnutritive sweeteners are generally safe to use within the defined acceptable daily intake levels." This statement is supported by the Academy of Nutrition and Dietetics, Diabetes UK, and Diabetes Canada. People with diabetes should talk with a registered dietitian, healthcare professional or a certified diabetes educator for advice on healthy eating to improve blood sugar control.

WILL SUCRALOSE HELP ME LOSE OR MAINTAIN MY WEIGHT?

Substituting foods and beverages sweetened with sucralose for their fullsugar counterparts can play a role in weight loss or weight management. In a survey of members of the National Weight Control Registry, the largest study of successful weight-loss maintainers, over 50 percent of all respondents stated that they regularly consume low-calorie beverages, 78 percent of whom felt that doing so helped control their calorie intake (<u>Catenacci 2014</u>).

Data from randomized controlled trials, considered to be the gold standard for assessing causal effects, support that substituting low-calorie sweetener options for regular-calorie versions leads to modest weight loss (<u>Miller 2014</u>, <u>Rogers 2016</u>). For example, in one study, more than 300 participants were assigned to consume either water or lowcalorie sweetened beverages for one year as part of a weight-loss program. Those who were assigned to the low-calorie sweetener group lost 6.21 kg on average, compared to those in the water group, who lost 2.45 kg (<u>Peters 2016</u>).

Some observational studies have demonstrated an association between low-calorie sweeteners and increased weight and waist circumference (Fowler 2016). Observational studies, which examine the relationship between an exposure (such as sucralose intake) and an outcome (such as body weight or a health condition), are not able to provide direct evidence of cause and effect. Additionally, observational studies are not randomized, so they cannot control for all of the other exposures or factors that may be causing or influencing the results. For example, one hypothesis is that people may compensate for "caloriefree" choices by eating or drinking more calories in other food choices or future meals (Mattes 2009). Think of a person who may justify ordering dessert at a restaurant because they had a diet soda with their meal: The extra calories from the dessert may be greater than the calories saved by ordering the diet beverage.

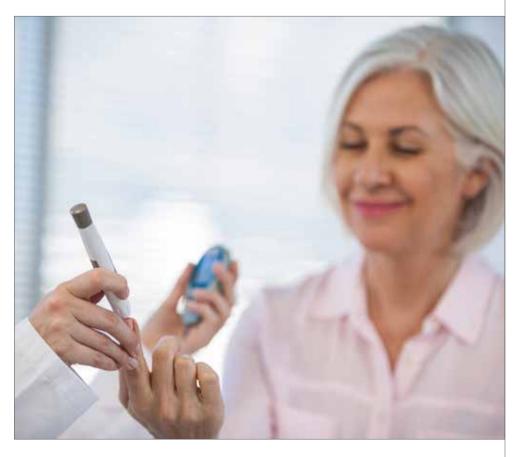


These additional calories may contribute to weight gain or prevent further weight loss. It has also been suggested that people who are already overweight or obese may begin to choose low-calorie sweetened foods and beverages as one method for losing weight (Drewnowski 2016). This makes it difficult to assume that the use of a low-calorie sweetener can be the cause of weight gain. Recent systematic reviews and meta-analyses (a scientific approach that combines findings from many studies into one powerful analysis) have concluded that, overall, findings from observational studies showed no association between low-calorie sweetener intake and body weight, and a small positive association with body mass index (BMI) (Miller 2014, Rogers 2016).

It is important to note that losing and maintaining one's weight often require multiple simultaneous approaches. Making a single change, such as substituting low-calorie sweeteners for full-calorie, sugar-containing products, is just one component. Lifestyle and behavioral practices like eating a healthful diet, exercising regularly, getting enough sleep, and maintaining social support networks are all important factors in achieving weightloss and weight-maintenance goals.

DOES SUCRALOSE AFFECT BLOOD SUGAR CONTROL?

Foods and beverages made with sucralose are frequently recommended to people with diabetes as an alternative to sugar-sweetened foods and beverages. Extensive research shows that sucralose does not raise blood sugar levels or otherwise affect blood glucose control in humans (Nichol 2018, <u>Romo-Romo 2017, Grotz 2017</u>), and a recent consensus statement by experts

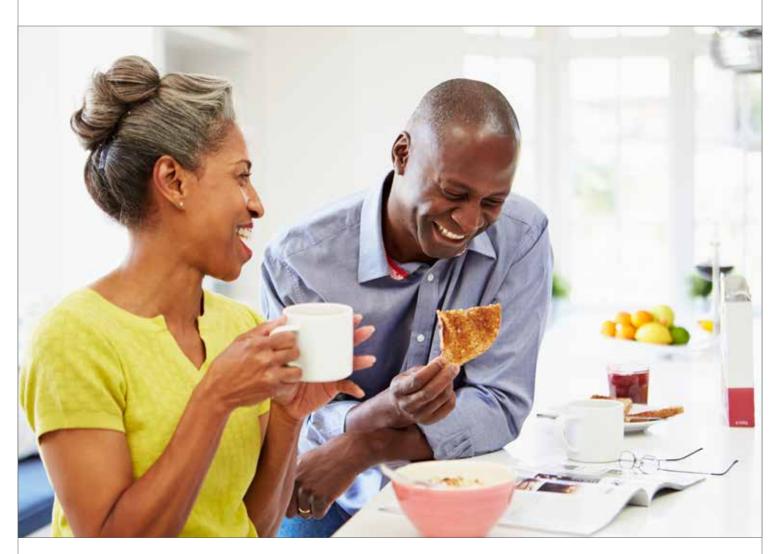


in nutrition, medicine, physical activity and public health concluded that the use of low-calorie sweeteners in diabetes management may contribute to better glycemic control (<u>Serra-Majem 2018</u>).

Despite these conclusions, some studies have periodically raised questions about sucralose and blood glucose control. One randomized trial proposed that sucralose may "prime the pump" to increase blood glucose and insulin concentrations if dietary sugars are eaten with or soon after low-calorie sweeteners (Pepino 2013). Results of many other randomized clinical trials do not support this hypothesis (Temizkan 2015, Grotz 2017). A few observational studies have demonstrated an association between low-calorie sweetener consumption and risk for type 2 diabetes (Sakurai 2014, Imamura 2015) but are not able to directly link cause and effect, and as with the studies on body weight and obesity, they are at risk of confounding.

For instance, many studies do not adjust for obesity status, a direct contributor to developing type 2 diabetes. Given that overweight and obese individuals tend to consume more low-calorie sweetened beverages as compared to lean individuals (<u>Bleich 2014</u>), this is a critical omission.

Many medical, nutrition and public health organizations around the world, backed by a large body of evidence, support the consumption of low-calorie sweeteners in people with diabetes. These individuals, or those who are at risk for developing diabetes, should be mindful of food and beverage intake from all sources, including those containing low-calorie sweeteners and sugars. It is important to discuss nutrition with a doctor or registered dietitian and to eat a healthful, balanced diet to keep blood sugar levels under control.



EMERGING RESEARCH: CAN SUCRALOSE MAKE ME HUNGRIER?

Highly palatable foods activate brain regions of reward and pleasure. This positive association can enhance appetite and, if left unchecked, the resulting increase in food intake can lead to overweight and obesity (<u>Singh 2014</u>). Substituting full-calorie and sugar-containing foods with their counterparts made with low-calorie sweeteners has exhibited a similar effect on reward pathways, but without contributing additional calories.

Some have expressed concern that activating reward pathways without delivering sugar to the body may have unintended consequences, and the role that low-calorie sweeteners play in appetite and food cravings is a developing area of research. As noted in recent reviews (Fowler 2016, Sylvetsky & Rother 2018), some research in animal models has demonstrated changes in food intake and appetiterelated hormones after consuming low-calorie sweeteners. And yet, similar effects have not been seen in humans. To date there is no strong evidence that low-calorie sweeteners, including sucralose, enhance appetite or cravings in humans (Rogers 2017), and some randomized trials have demonstrated the opposite effect—including a decrease in hunger (Peters 2016) and reduced dessert intake compared to those who drank water (Piernas 2013). Others have shown no effect of sucralose on hormones that regulate hunger and fullness (Steinert 2011, Ford 2011) or on total energy intake and selection of sweet foods (Bellisle 2015, Fantino 2018).

These discrepancies underscore an area in which animals and humans are inherently different as research subjects. In humans, the link between physiology, psychology, personal experiences and food is unmistakably complex, and the translation of animal research to this area of study should be viewed with caution.

EMERGING RESEARCH:

WHAT ABOUT THE MICROBIOME?

The microbes living in our intestinal tract have become recognized as potentially significant contributors to our health, though research on the gut microbiome is still in its infancy. In rodents, exposure to sucralose has resulted in wide-ranging, inconsistent effects (Bian 2017, Uebanso 2017). To date there are few studies on sucralose's effect on the human gut microbiome, though it is known that it is not metabolized by the gut microbiota (Magnuson 2017). There are significant differences between the microbiome profiles from one person to another, and research has shown that the gut microbiome changes in response to normal changes in the diet (David 2014). A great deal of research is still needed to identify a microbiome profile and degree of diversity considered to be "optimal" in populations and in individuals.





SUCRALOSE AT A GLANCE

SCIENTIFIC NAME: Sucralose

BRAND NAME: Splenda®

DATE APPROVED BY FDA: 1998 for 15 food categories; 1999 for all food and beverage categories

NUMBER OF TIMES SWEETER THAN SUGAR: 600

SAFE FOR CHILDREN? Yes

SAFE FOR PREGNANT AND BREASTFEEDING WOMEN? Yes

WHAT IS THE BOTTOM LINE?

All types of foods and beverages can have a place in our diets, including those made with sucralose. Sucralose has been FDA-approved for two decades and its safety has been acknowledged by many international health agencies.

Sucralose's impact on and association with chronic conditions like obesity and diabetes have been extensively studied. Observational studies linking low-calorie sweeteners to weight gain inherently cannot demonstrate a causal relationship, while randomized clinical trials consistently support that low-calorie sweeteners like sucralose can be useful in nutritional strategies to assist with weightloss and weight-maintenance goals. Sucralose has no impact on blood sugar or insulin levels in randomized trials and no effect on appetite.

Adopting a healthful, active lifestyle that is tailored to personal goals and priorities is vital to supporting one's well-being. Choosing foods and beverages sweetened with low-calorie sweeteners such as sucralose is one way to control sugar intake and keep calories in check, which are important components of maintaining health and reducing risk for diet-related disease.

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