WHAT IS SUCRALOSE?

Sucralose is a no-calorie sweetener that can be used to lower one’s intake of added sugars while still providing satisfaction from enjoying the taste of something sweet. While some types of sweeteners in this category are considered low-calorie (e.g., aspartame) and others are no-calorie (e.g., sucralose, monk fruit sweeteners and stevia sweeteners), collectively they are often referred to as sugar substitutes, high-intensity sweeteners, nonnutritive sweeteners or low-calorie sweeteners.

Like other no-calorie sweeteners, sucralose is intensely sweet. It is about 600 times sweeter than sugar, so only small amounts of sucralose are used to match the sweetness provided by sugar. Sucralose is permitted by the U.S. Food and Drug Administration (FDA) for use as a general-purpose sweetener, meaning it can be used as an ingredient in any type of food or beverage. Sucralose is exceptionally stable, so foods and beverages sweetened with sucralose stay sweet under a wide range of conditions. This includes frozen foods like ice cream and other frozen desserts, as well as foods that need to be heated to high temperatures, like baked goods and foods that require sterilization. However, a recipe that uses sucralose in place of sugar may turn out slightly different because, in addition to sweetness, sugar plays several roles related to volume and texture in recipes but varies based on the type of recipe.

Sucralose is also used in tabletop sweeteners. There are numerous brands of sucralose-based tabletop sweeteners. The most common brand in the U.S. is Splenda® Original.

HOW IS SUCRALOSE PRODUCED?

Sucralose is made from a process that begins with regular table sugar (sucrose); however, sucralose is not sugar. Three select hydroxyl groups on the sucrose molecule are replaced with three chlorine atoms. Sucralose’s structure prevents enzymes in the digestive tract from breaking it down, which is an inherent part of its safety.
WHAT HAPPENS TO SUCRALOSE AFTER CONSUMPTION?

Most (about 85 percent) of consumed sucralose is not absorbed by the body and is excreted, unchanged, in the feces. Of the small amount that is absorbed (about 15 percent), none is broken down for energy—therefore, sucralose does not provide any calories. All absorbed sucralose is excreted quickly in the urine.

IS SUCRALOSE SAFE TO CONSUME?

YES. More than 100 safety studies representing over 20 years of research have shown sucralose to be safe. In 1998, the FDA approved its use as a sweetener in 15 specific food categories. In 1999, the FDA expanded its regulation to allow sucralose as a “general-purpose sweetener,” meaning that it is approved for use in any type of food or beverage. Leading global health authorities such as the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) have concluded that sucralose is safe for its intended use.

The safety of sucralose has also been confirmed by Japan’s Ministry of Health, Labour and Welfare, Food Standards Australia New Zealand, and Health Canada. Based on the conclusions of these global authorities, sucralose is currently permitted for use in more than 100 countries.

The FDA has established an acceptable daily intake (ADI) for sucralose of 5 milligrams (mg) per kilogram (kg) of body weight per day. The JECFA first established an ADI of 0—15 mg/kg of body weight per day for sucralose in 1991. The European Commission’s Scientific Committee on Food confirmed JECFA’s ADI for sucralose in 2000. The ADI represents an amount 100 times less than the quantity of sucralose found to achieve a no-observed-adverse-effect-level (NOAEL) in toxicology studies. The ADI is a conservative number that the vast majority of people will not reach. Using the ADI established by the FDA, a person weighing 150 pounds (68 kg) would exceed the ADI (340 mg of sucralose) if consuming more than 26 individual tabletop packets of sucralose every day over the course of their lifetime. While precise measurements of the total amount of sucralose people consume in the U.S. is limited, 1.6 mg/kg of body weight per day is a conservative mean estimate of sucralose intake from beverages among adults that has recently been reported. This level of intake is well below the FDA’s ADI. Globally, estimated sucralose intake from foods and beverages also remains well below the ADI established by JECFA. 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. For more on how ADIs are set, see the “What is an ADI?” sidebar.

CAN CHILDREN CONSUME SUCRALOSE?

YES. Health and food safety authorities such as the FDA and JECFA have concluded that sucralose is safe for adults and children to consume within the ADI. Sucralose metabolism is not expected to be different in children than it is in adults.

Sucralose can add sweetness to a child’s foods and beverages without contributing to calories consumed or added sugars intake. Sucralose is not cariogenic or fermentable like sugars, so it does not increase the risk of dental caries. With a focus on reducing consumption of added sugars in recent decades, the number of food and beverage products containing low-calorie sweeteners has increased. While observational research among U.S. children and adults has shown an increase in the percentage of people reporting daily consumption of products containing low-calorie sweeteners, current intake of low-calorie sweeteners is considered to be well within acceptable levels, both globally and in the U.S.

The American Heart Association (AHA) advises against children regularly consuming beverages containing low-calorie sweeteners, instead recommending water and other unsweetened beverages such as plain milk. One of the notable exceptions in the 2018 AHA science advisory is made for children with diabetes, whose blood glucose management may be benefitted by consuming low-calorie-sweetened beverages in place of sugar-sweetened varieties. Citing an absence of data, the 2019 policy statement from the American Academy of Pediatrics (AAP) does not provide...
advice on children under two years of age consuming foods or beverages that contain low-calorie sweeteners.\(^\text{14}\) The 2019 AAP policy statement does, however, acknowledge potential benefits of low-calorie sweeteners for children by reducing calorie intake (especially among children with obesity), incidence of dental caries and glycemic response among children with type 1 and type 2 diabetes. The 2020—2025 Dietary Guidelines for Americans (DGA) do not recommend the consumption of low-calorie sweeteners or added sugars by children younger than two years of age.\(^\text{15}\) This DGA recommendation is not related to body weight, diabetes or the safety of added sugars or low-calorie sweeteners, but is instead intended to avoid infants and toddlers developing a preference for overly sweet foods during this formative phase.

CAN PREGNANT AND BREASTFEEDING WOMEN CONSUME SUCRALOSE?  

**YES.** The consumption of low-calorie sweeteners within their respective ADIs is safe for women who are pregnant or breastfeeding according to the EFSA, FDA and JECFA. 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.\(^\text{2,16}\) Because only small amounts of sucralose are absorbed into the bloodstream, the amount of sucralose present in breast milk is very low.\(^\text{17}\) All women who are pregnant or nursing need the necessary nutrients and calories for their baby’s optimal growth and development, while taking care not to exceed their needs.

CAN PEOPLE WITH DIABETES CONSUME SUCRALOSE?  

**YES.** Foods and beverages made with sucralose are frequently recommended to people with diabetes as an alternative to sugar-sweetened foods and beverages and as a way to help these individuals satisfy their desire for sweet taste while managing carbohydrate intake. Extensive research shows that sucralose does not raise blood glucose levels or otherwise affect blood glucose management.\(^\text{18-21}\) Recent consensus statements by experts in nutrition, medicine, physical activity and public health cite the neutral effects of low-calorie sweeteners on hemoglobin A1C, insulin and fasting and post-prandial glucose, and conclude that the use of low-calorie sweeteners in diabetes self-care may contribute to better glycemic management.\(^\text{22-24}\)

Global health professional organizations have published their own conclusions on the safety and role of low-calorie sweeteners for people with diabetes. The 2021 American Diabetes Association Standards of Medical Care in Diabetes state that, “For some people with diabetes who are accustomed to regularly consuming sugar-sweetened products, nonnutritive sweeteners (containing few or no calories) may be an acceptable substitute for nutritive sweeteners (those containing calories, such as sugar, honey, and agave syrup) when consumed in moderation. Use of nonnutritive sweeteners does not appear
SUCRALOSE

Can Sucralose Help with Weight Loss or Weight Maintenance?

Substituting foods and beverages sweetened with low- and no-calorie sweeteners like sucralose for their full-sugar counterparts can play a role in weight loss and/or weight management, as demonstrated in numerous clinical trials.36-39 The National Weight Control Registry (NWCR) is the largest longitudinal study of successful weight loss maintainers who have lost at least 30 pounds and kept it off for more than one year. In an online survey of 434 NWCR members, over 50 percent reported that they regularly consumed low-calorie beverages; 78 percent of these members reported that doing so helped control their calorie intake.40

Conclusions from observational research studying the impact of low-calorie sweeteners on weight loss and/or weight management, as demonstrated in numerous clinical trials.36-39 The National Weight Control Registry (NWCR) is the largest longitudinal study of successful weight loss maintainers who have lost at least 30 pounds and kept it off for more than one year. In an online survey of 434 NWCR members, over 50 percent reported that they regularly consumed low-calorie beverages; 78 percent of these members reported that doing so helped control their calorie intake.40

Conclusions from observational research studying the impact of low-calorie sweeteners on body weight and waist circumference in adults.41 A systematic review and meta-analysis of observational studies published in 2017 found that consumption of low-calorie sweeteners was also associated with increases in body mass index (BMI) and higher incidence of obesity and cardiometabolic disease in adults.42 In children and adolescents, observational studies have shown an association between consumption of low-calorie-sweetened beverages and increased body weight, while evidence from randomized controlled trials have not.43,44 Other recent systematic reviews and meta-analyses have concluded that findings from observational studies showed no association between low-calorie sweetener intake and body weight and a small positive association with higher BMI.36,37,45

While observational studies can be important for generating hypotheses, it is important to note that they have limitations. By their nature, observational studies cannot prove cause and effect. Instead, observational studies examine......
the association between an exposure (such as reported sucralose intake) and an outcome (such as body weight or a health condition). Associations found in observational studies can be confounded by various factors and/or may be the result of reverse causality. A common example of this is a person changing their food and beverage choices after being diagnosed with a health condition: The disease led to them making these changes; the changes they made did not lead to the disease.

Additionally, observational studies are not randomized, so they cannot control for all of the other exposures or factors that may be causing or influencing results. For example, one hypothesis is that people may compensate for “calorie-free” choices by eating or drinking more calories in other food choices or future meals.46-47 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 will likely be greater than the calories saved by ordering the diet beverage. These additional calories may contribute to weight gain or prevent further weight loss. This behavior is called the “licensing effect” or “self-licensing,” in which an individual justifies giving in to indulgences by finding reasons to make a behavior that is inconsistent with their goals more acceptable.48 Although it may occur in some instances, there is little evidence from scientific studies that people consistently and consciously overconsume calories as a result of consuming low-calorie sweeteners or foods and beverages that contain them.49

It has also been suggested that people who already have overweight or obesity may begin to choose low-calorie-sweetened foods and beverages as one method for losing weight.50-53 This makes it difficult to assume that the use of a low-calorie sweetener can be the cause
of weight gain, since reverse causality may be a factor. A 2019 systematic review and meta-analysis funded by the World Health Organization recommended cautiously interpreting results from observational studies on low-calorie sweeteners and health outcomes while concentrating on plausible confounding and reverse causality.45

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.36-39,45,55,56 In a 2016 randomized clinical trial, over 300 participants were assigned to consume either water or low-calorie-sweetened beverages for one year as part of a program that included 12 weeks of weight loss followed by 40 weeks of weight maintenance interventions. Those who were assigned to the low-calorie-sweetened beverage group lost 6.21 kg on average, while those in the water group lost 2.45 kg.56

While a few systematic reviews have concluded that low-calorie sweetener consumption does not lead to appreciable weight loss or weight gain, such findings appear to be the result of how the studies are compared.42 As stated by Mela, et al.,53 some study designs allow for the analysis of outcomes between caloric and non-caloric alternatives,37,39 while others do not.52

The Scientific Report of the 2020 Dietary Guidelines Advisory Committee (DGAC) included a systematic review of 37 studies (six of which were randomized controlled trials) published between January 2000 and June 2019 on the role of low- and no-calorie-sweetened beverages on adiposity. The DGAC report concluded that low- and no-calorie sweeteners should be considered an option for managing body weight.57

It is important to note that losing and maintaining body weight requires 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 healthfully, exercising regularly, getting enough sleep, and maintaining social support networks are all important factors in achieving weight loss and weight-maintenance goals.

**CAN SUCRALOSE MAKE ME HUNGERIER?**

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.58 Low-calorie sweeteners can also lead to a stimulation of reward pathways by activating sweet taste receptors, but they are not a source of calories.

Some have expressed concern that activating reward pathways without delivering calories to the body may have unintended consequences. Some animal studies have demonstrated changes in food intake and appetite-related hormones after consuming low-calorie sweeteners.41,54 However, other animal studies show that pathways involved in sugar digestion and preference for sugar are not activated by low-calorie sweeteners.59,60
Low- and no-calorie sweeteners, including sucralose, have not been found to enhance appetite or cravings in humans. Some randomized controlled trials have demonstrated the opposite effect—including a decrease in hunger and reduced dessert intake compared with those who drank water. Others have shown no effect of sucralose on hormones that regulate hunger and fullness or on total energy intake and selection of sweet foods.

**WHAT ABOUT THE GUT MICROBIOME?**

Although research on the gut microbiome is still in its infancy, the microbes living in the intestinal tract have become recognized as potentially significant contributors to health. In rodents that have consumed sucralose, changes in the gut microbiota species profile have been reported. However, the clinical meaningfulness of such changes in rodents is not known, and the applicability of animal microbiome studies to humans may be limited.

Currently, no standards exist to define a healthy human microbiome. There are significant differences among the microbiome profiles of different people, and research has shown that the gut microbiome can quickly respond to normal changes in the diet. International experts have noted that huge variabilities in microbiome profiles make it difficult to distinguish normal variation from adverse effects.

Sucralose is not metabolized by gut microbiota, and no adverse health effects on the gastrointestinal system are known from either human or well-controlled toxicology studies. Human studies with repeated sucralose consumption show no meaningful effect on the gut microbiome. Consistent with this, a 2019 literature review found no conclusive evidence that low-calorie sweeteners negatively impact gut microbiota. In 2020, a panel of experts on low-calorie sweeteners came to a similar conclusion that, at this time, data on the effects of low-calorie sweeteners on the human gut microbiota are limited and do not provide adequate evidence that they impact gut health at doses that are relevant to human consumption.

**WHAT’S THE BOTTOM LINE?**

All types of foods and beverages, including those made with sucralose, can have a place in a variety of healthy eating patterns. Sucralose has been FDA-approved as a food additive for two decades, and its safety has been acknowledged by many international health authorities. The impact of low-calorie sweeteners on, and association with, chronic conditions like obesity and type 2 diabetes have been extensively studied. Observational studies linking low-calorie sweeteners to weight gain inherently cannot demonstrate a causal relationship and suffer from methodological issues like confounding and reverse causality. In contrast, randomized controlled trials consistently support that low-calorie sweeteners can be useful in nutritional strategies to assist with weight-loss and/or weight-maintenance goals. Sucralose has no impact on blood glucose or insulin levels in randomized controlled trials, and no effect on appetite. While the role of the gut microbiome in health is still being explored, the available research does not suggest that low- and no-calorie sweeteners such as sucralose adversely affect the gut microbiome.

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- and no-calorie sweeteners such as sucralose is one way to reduce consumption of added sugars and keep calories in check—important components in maintaining health and reducing risk for lifestyle-related disease.
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