BRITISH Nutrition FOUNDATION

Sucralose – all sweetness and light

Nino M. Binns
McNeil Consumer Nutritionals Europe, London, UK

Introduction

Sucralose is a new, high-quality, intense sweetener discovered during a collaborative research programme between Tate & Lyle and Queen Elizabeth College of the University of London during the 1970s. Sucralose received approval by the UK's Food Standards Agency in March 2002 for use in a wide range of foods, ahead of the European Union approval that is anticipated in the next year or so. The sweetener is marketed for home use under the brand name SPLENDA® Low Calorie Sweetener and is available under this name as table top granular and tablet formats. The SPLENDA® brand will also be seen to highlight the use of sucralose as an ingredient in a growing range of low-energy foods and beverages. The sweet taste of sucralose is of excellent quality and the fact that it is highly stable allows it to be used at high temperatures both by the food industry and by the consumer at home. Furthermore, sucralose remains stable in food products throughout extended periods of storage, even at low pH.

What is sucralose?

Sucralose is an intense sweetener made by selective substitution of the hydroxyl groups of sucrose with chlorine. The resultant molecule (Fig. 1) is 600 times sweeter than sugar (sucrose), has taste characteristics very similar to sugar, and is extremely stable to heat and to acid media.

Safety and regulatory aspects

Over a 20-year period more than 100 studies, designed to meet the highest scientific standards, have clearly demonstrated that sucralose is safe. Sucralose does not hydrolyse nor does it dechlorinate after ingestion and it is thus nontoxic. Recently, the major safety studies on sucralose were published in a peer-reviewed journal. Papers can be found in a supplement of *Food and Chemical Toxicology* (2000). The studies include a number of clinical studies in humans.

Following initial tolerance studies, a single blind, randomised controlled study was conducted in healthy adults over a period of 13 weeks. One hundred and eight subjects completed the study in which escalating doses of sucralose were given in aqueous solution to 77 subjects while 31 received fructose. Daily intake of sucralose was 125 mg (weeks 1–3), 250 mg (weeks 4–7), 500 mg (weeks 8–13) giving a dose of 4.8–8.0 mg/kg for the 47 males in the study and 6.4–10.1 mg/kg for the 30 females. This compares with the estimated daily intake (EDI) of 1.1 mg/kg predicted for the normal population. Subjects receiving fructose consumed a dose of 50 g/day. There were no clinically meaningful changes in physical, biochemical, haematological or urinalysis indices and no effect on electrocardiogram in the volunteers in this study (Shepard & Kyffin 1984).

Absorption, distribution, metabolism and excretion (ADME) studies have found that sucralose is poorly absorbed in man and the majority of ingested sucralose is excreted unchanged in the faeces. On average, 15% of a dose is absorbed and then rapidly excreted, for the most part unchanged, in the urine. About 2% of ingested sucralose is excreted in the urine in the form of glucuronide conjugates. Sucralose does not accumulate in the body tissues.

International experts in a variety of scientific disciplines, including toxicology, oncology, teratology, neurology, haematology, paediatrics, diabetology and nutrition, independently evaluated the data from the studies. In 1990, the Joint FAO/WHO Expert Committee on Food Additives, an international body of experts who evaluate food additives, confirmed the safety of sucralose. It has since been approved, as a food additive,

Correspondence: Professor Nino M. Binns, McNeil Consumer Nutritionals Europe, 131–151 Great Titchfield Street, London W1W 5BB, UK.
E-mail: nbinns1@jacgb.jnj.com

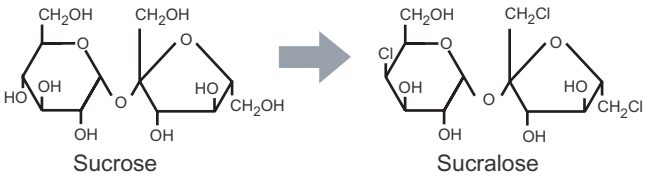

Figure 1 Conversion of sucrose to sucralose.

by the regulatory agencies of more than 50 countries including the UK (2002) and the USA (1998). First approved in Canada (1991) and Australia (1993), sucralose has since been safely consumed by millions of people.

Taste and stability in food applications

Sucralose has a sugar-like taste and is approximately 600 times sweeter than sugar. However, as with other high-intensity sweeteners, the relative sweetness intensity of sucralose compared to sugar varies as a function of concentration. The sweetness factor for sucralose in water ranges from about 500 to 750 times sugar. Sweetness intensity can also be influenced by a number of other factors including pH, temperature and the presence of food ingredients such as gelling agents, starches and fats.

Standard taste panel methods have been used to evaluate the taste characteristics of intense sweeteners and sugars. Most of the sensory testing has been conducted using trained panellists. These are individuals who are trained to recognise and describe various sensory characteristics, who agree on a common language for those characteristics and thus are able to describe and distinguish between different products presented to them. The criteria most commonly used are a measure of perceived sweetness intensity against time (time-intensity measurements) and taste profiling, *i.e.* asking panellists to rate perception not only of sweetness but of other aspects of taste such as bitter, sour, metallic, drying, caramelised, etc.

Time-intensity measurements (Ketelsens *et al.* 1993) have demonstrated that the sweetness profile of sucralose is very similar to that of sugar in that sucralose has a rapid onset of sweetness and similar sweetness duration to sugar (Fig. 2). Subjects in a study by Wiet & Beyts (1992) were trained panellists ($n = 12$) presented randomly, with coded 10 mL samples of sugar or sweeteners in water at a temperature of 22 ± 2°C. The sweeteners were equivalent in sweetness to concentrations of sucrose in the range 1.2–9% w/v. Each sweetener and sucrose were rated for five attributes: bitterness, sourness, body (perceived mouthfeel), residual sweet aftertaste and non-sweet aftertaste, using a 0–10 point scale where 0 meant absence of the attribute and 10 indicated it was extremely intense. Aftertaste was measured 20 s after tasting. The samples (30 samples in all) were tested in triplicate over a 3-day period, the panellists rinsing with water between each sample and having a 15-min break after six samples.

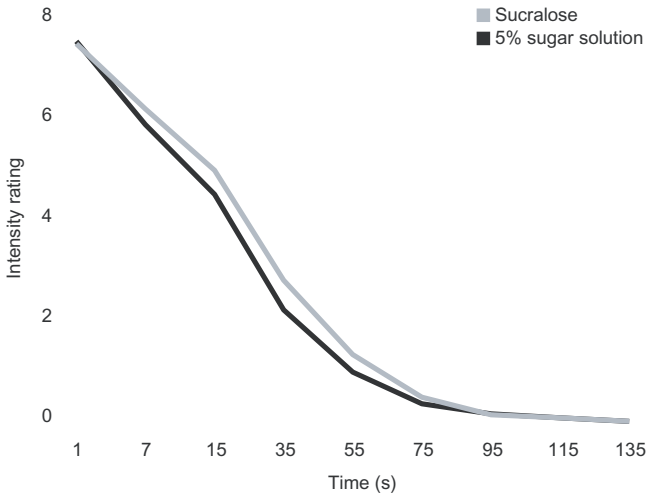

Figure 2 Sweetness profiles of sucralose and sugar.

The results for each attribute were presented as a function of sweetness intensity. Sucralose had very low level of bitterness and sourness at all concentrations and at a level close to that of sucrose (a score of around 1 or less). Both sucrose and sucralose demonstrated an increased body as the sweetness increased but the scores were low overall for this range of concentration with top scores up to only about 3. Sweet aftertaste correlated with initial sweetness intensity and there was no significant difference between sucrose and sucralose. Non-sweet aftertaste was intended to measure any off-flavour or other non-sweet aftertaste. Sucralose and sucrose rated low on non-sweet aftertaste (scores around 1) and did not differ significantly from one another. From this study and other published and unpublished data it can be concluded (Wiet & Miller 1997) that sucralose has a taste profile very close to that of sugar (Fig. 3).

Sucralose blends well with all other intense sweeteners and is synergistic with most, allowing the sweetness and flavour profile of reduced- and low-energy products to be customised. Sucralose also blends well with nutritive sweeteners such as sucrose and glucose syrups, providing some sweetness synergy and is therefore an ideal sweetener for use in 'light' products.

Table 1 Sucralose stability during food manufacturing processes

	pH	Process conditions	Sucralose preprocessing	Sucralose postprocessing
Pasteurisation				
Tropical beverage	2.8	93°C for 24 s	0.0125%	0.0126%
Tomato ketchup	3.8	93°C for 51 min	0.046%	0.047%
Canned pears	3.3	100°C for 12 min	0.037%	0.038%
Sterilisation				
Beans in sauce	5.6	121°C for 80 min	0.0064%	0.0066%
UHT				
Dairy dessert	6.7	140°C for 15 s	0.012%	0.012%
Vanilla milk	6.5	141°C for 3.5 s	0.0075%	0.0075%

UHT, ultra-heat treatment.

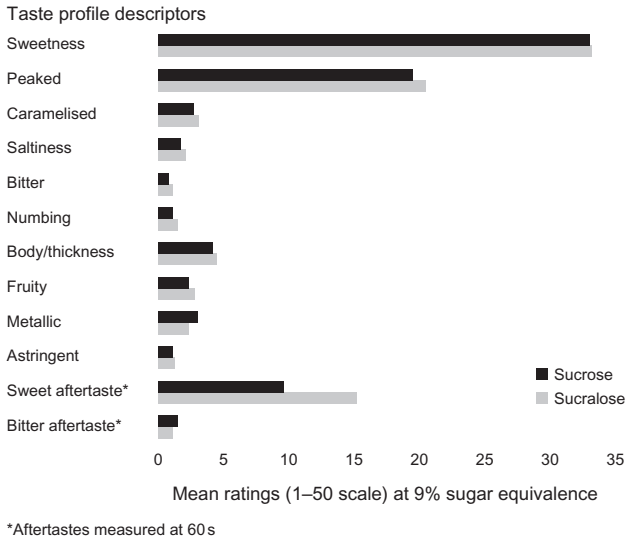

Figure 3 Taste profiles of sucralose and sugar.

Sucralose does not interact with other ingredients in the food. Specific studies have confirmed that it is unlikely to undergo interactions with commonly used food ingredients such as preservatives and added nutrients (Goldsmith & Merkel 2001). The stability of sucralose has been shown to be unaffected by the presence of ethanol. Sucralose may therefore be used in alcoholic beverages, depending also on regulatory requirements.

The major technical advantage of sucralose is its stability to high-temperature food processing and long-term storage, even when used in low-pH products. Studies have confirmed the stability of sucralose in baking (Barndt & Jackson 1990) and under other high-temperature processes (Table 1). Sucralose will hydrolyse very slowly to its component monosaccharides under acidic conditions. For example, a sucralose solution at pH 3, held at 25°C for 1 year, will still have over 99% of the original sweetener.

It follows from the stability and taste qualities of sucralose that food manufacturers now have more opportunities to create a wide range of tasty low-energy and energy-reduced products, including baked goods and products made by heat extrusion. It also follows that sucralose-sweetened products will have a very long shelf life. Furthermore, the availability of granular SPLENDA® Low Calorie Sweetener means that consumers can create their own recipes at home.

Nutritional aspects

Sucralose is resistant to both mammalian and oral bacterial enzymes which means that, unlike sugars, it is not broken down and is therefore both energy-free and non-cariogenic.

Obesity and diabetes

The prevalence of obesity is still on the increase in many countries in Europe. According to the Health Survey for England (1999) 17% of men and 21% of women in the UK are classed as clinically obese, *i.e.* have a body mass index (BMI) over 30 and nearly 50% of men are overweight (BMI over 25). The fundamental cause of overweight and obesity is an imbalance between energy intake and energy expenditure but addressing either side of the equation is clearly proving a challenge (WHO 2000). Sucralose offers new opportunities for palatable, low-energy, sweetened beverages and foods – although, as with all reduced- and low-energy products, they can

only have an impact on bodyweight if users also restrict their total energy intake and/or increase their physical activity.

Type 2 diabetes is also becoming an increasing public health concern in many parts of the world and is now a major contributor to morbidity and mortality (http://www.who.int). Diabetes results in a greater risk of premature death, cardiovascular disease, peripheral vascular disease, kidney and eye problems and in later stages of the disease, neuropathological conditions (Rifkin & Porte 1990). In the UK, there are estimated to be approximately 2.4 million people with diabetes (of which 1 million are undiagnosed), which is about 4% of the population (Diabetes UK). WHO estimated that in 2000, 200 million people worldwide had type 2 diabetes.

Of the two types of diabetes, type 2 is the most prevalent form and usually occurs in older, often obese individuals. In its early stages it is characterised by 'insulin resistance', *i.e.* the muscle and fat cells have a lower than normal sensitivity to insulin so that the pancreas produces more and more insulin in order to overcome the resistance. The cause of type 2 diabetes is not precisely known, but there is a tendency for it to run in families and there is now overwhelming evidence that obesity is a key risk factor (National Audit Office 2001; WHO 2000).

People with diabetes frequently consume low-energy products containing high-intensity sweeteners in an attempt to reduce their sugar and/or energy intake. This is because the dietary management of diabetes often includes a reduction in sugar and energy intake, especially for overweight or obese individuals with type 2 diabetes. As a result, it is likely that the consumption of sucralose-sweetened products by this patient population will be both long term and above average.

Clinical studies in diabetes

A series of short-term (Mezitis *et al.* 1996) and long-term studies was conducted in people with diabetes and in normal healthy volunteers in order to assess the safety of sucralose and to provide a thorough evaluation of glucose control.

A 12-week study (McNeil 1996) was designed specifically to investigate the possible effect of sucralose on glucose homeostasis in healthy male volunteers following prolonged exposure at elevated doses (1000 mg/day). Forty-eight healthy, non-diabetic males with a BMI of between 18 and 28, with normal glucose tolerance based on repeated screening evaluations were recruited. The double blind, randomised parallel-design study was conducted in a single centre in the UK and involved subjects consuming capsules containing either sucralose or a cellulose placebo. The study was divided into three phases: (1) a screening phase consisting of four visits separated by a 1-week interval; (2) a test phase consisting of 12 visits over a 12-week period; and (3) a follow-up phase.

Changes from baseline were determined for all fasting glucose homeostasis parameters including blood glucose, blood insulin and haemoglobin A1c (HbA1c). These were analysed statistically using a repeated measures analysis of variance to test for between- and within-group differences.

The results showed that 1000 mg sucralose per day was well tolerated throughout the test phase and resulted in a mean daily intake of 13.22 mg/kg/day. This daily intake was considerably higher than would be expected from 'normal' everyday usage (estimated to be 1.1 mg/kg/day). The results of this study were consistent with previous preclinical and clinical studies as well as consistent with the fact that sucralose is not treated by the body as a carbohydrate or other energy source. Sucralose had no effect on insulin secretion and was shown to have no adverse effect on measures of insulin sensitivity. Likewise, the doses of sucralose used in this study caused no adverse effects on glucose control since there were no statistically significant differences between the sucralose and placebo treatment groups in overall HbA1c, or fasting blood glucose, or serum c-peptide or insulin changes from baseline.

A second study was conducted in subjects with type 2 diabetes to assess the effect of a daily high dose (667 mg/day) of sucralose on blood glucose homeostasis (Grotz *et al.* 2002). This was a randomised, double blind, placebo-controlled, parallel group, multicentre study conducted over 3 months in five clinical centres across the USA. One hundred and thirty-six patients completed the study. The study was divided into three phases: (1) a screening phase; (2) a test phase; and (3) a follow-up phase, with a single poststudy examination conducted 4 weeks after the final dose administration. During the screening phase and follow-up phase, all subjects received a cellulose placebo capsule and baseline levels were determined for the parameters selected to evaluate blood glucose control including blood glucose, c-peptide and HbA1c. During the test phase, half the subjects received sucralose-containing capsules while the placebo group continued to take the placebo capsules. Measurements of the blood glucose homeostasis parameters were made every other week over the 3 months of the test phase. The effect of sucralose vs. placebo on long-term blood glucose control was assessed by statis-

tical evaluation. The glucose homeostasis parameter results were tested by analysis of variance using repeated measures.

The results showed that there were no significant differences between the sucralose and placebo groups in their baseline demographic, anthropometric or diabetes characteristics. Likewise, there were no significant differences between the sucralose and placebo groups in blood glucose control before, during or after treatment or when analysed over the entire study period. The mean, daily sucralose dose achieved, based on the patients bodyweight, was 7.5 mg/kg/day. Again, this was much higher than the average EDI for the UK population of 1.1 mg/kg/day providing additional reassurance of safety.

In terms of diabetes management, people with either type 1 or type 2 diabetes are currently encouraged to eat carbohydrate-rich diets, including moderate levels of sucrose and to reduce the proportion of fat in their diet (Kunar 2002). Because research has shown sucralose to be safe for both healthy individuals and individuals with diabetes and since it does not affect glucose homeostasis or diabetic control, sucralose can therefore be recommended for use by this group. SPLENDA® tablets are essentially free of energy (0.2 kcal per tablet) and in the case of SPLENDA® Granular, the product contains just 2 kcal and 0.5 g carbohydrate per teaspoon (one teaspoon providing sweetness equivalent to one 5-g teaspoon of sugar) so that both products can be incorporated into a healthy diet for people with diabetes.

Dental health

A series of studies has shown that sucralose is non-cariogenic and that SPLENDA® Granular Low Calorie Sweetener, which is a blend of sucralose and maltodextrin, can be predicted to be of reduced cariogenicity compared to sucrose. *In vitro* and animal studies have clearly shown that plaque bacteria are unable to metabolise sucralose and that sucralose is non-cariogenic (for a review see Mandel & Grotz 2002).

Studies in healthy human volunteers confirmed the non-cariogenicity of sucralose. Using the *in situ* plaque pH model, Steinberg *et al.* (1995, 1996) conducted two studies and found that neither sucralose in water nor sucralose in coffee resulted in any fall in plaque pH over a 60-min period. A third study by Meyerowitz and colleagues confirmed these results for iced tea sweetened with sucralose (Meyerowitz *et al.* 1996; see Fig. 4). When sucralose is combined with maltodextrin to create a product that measures and sweetens spoon-for-spoon like sugar, the maltodextrin can be metabolised by plaque bacteria. The studies cited above used sucralose blended with maltodextrin to sweeten water, hot coffee or iced tea and in each case the beverage was significantly less acidogenic (*i.e.* less acid was produced by the plaque bacteria) than the same beverage sweetened with sucrose.

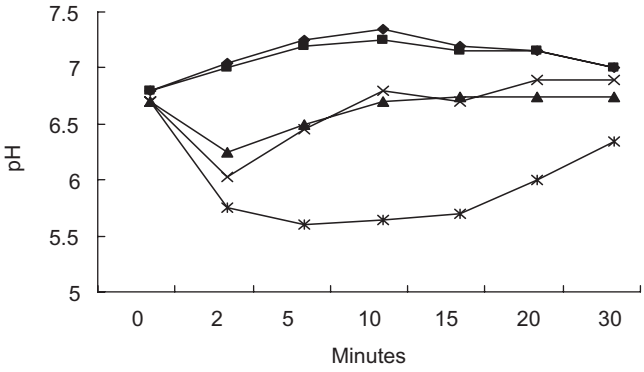

Figure 4 Comparison of effects on plaque pH of iced tea sweetened with: sucralose (■), sucralose + maltodextrin (▲), sucralose + maltodextrin + dextrose (×), sucrose (✱) and unsweetened tea (◆) (Meyerowitz *et al.* 1996).

Thus, energy- and carbohydrate-free soft drinks sweetened with sucralose are non-cariogenic. It would also be expected that plain tea and coffee sweetened only with SPLENDA® tablets, which contain the sweetener sucralose and a small amount (0.04 g) of lactose (added to give bulk), would have less cariogenic potential than plain tea or coffee sweetened with sucrose. Again, sucralose is non-cariogenic, while lactose appears to have significantly less cariogenic potential than sucrose (Department of Health 1989). Similarly, studies show that coffee or tea sweetened with the home-use granular form of SPLENDA® with its content of maltodextrin, has less cariogenic potential than coffee or tea sweetened with sucrose. However, the cariogenicity of other foodstuffs prepared at home with the granular product will of course depend on the composition and matrix of the whole food. Likewise, the cariogenicity of manufactured foods containing sucralose will depend on the specific composition of each food.

Conclusion

Sucralose is a high-quality intense sweetener that can be used in cooking and baking and in soft drinks, tea, coffee and chilled desserts. Sucralose is non-caloric, non-cariogenic and has no effect on blood glucose or insulin levels nor on other measures of glucose control such as HbA1c. It is therefore ideal for people with diabetes as

well as anyone trying to reduce their sugar intake to meet current healthy eating guidelines or to control their energy intake. The safety of sucralose has been thoroughly evaluated and its safety endorsed by experts advising governments worldwide.

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