

SUCRALOSE

IMPORTANT NOTE

The information and studies listed below are based on pure sucralose, the form of the ingredient used in E⁷. The tabletop version, Splenda[®] contains other ingredients and bulking agents that have some carcinogenic potential and should not be confused with pure sucralose.

AN OUTSTANDING SAFETY PROFILE

Sucralose, a high-intensity sweetener, is made from sugar so it tastes like sugar. This is accomplished using a patented multi-step process that selectively replaces three hydrogen-oxygen groups on the sugar molecule with three chlorine atoms. The result is an exceptionally stable sweetener that keeps sugars' taste without sugars' calories and carbohydrates. After consumption it passes through the body without being metabolized or broken down. Sucralose is approximately six hundred times sweeter than sugar, and as a result, only small amounts are necessary in a product.

Sucralose underwent the FDA's rigorous food additive approval process, and in 1998, the FDA approved sucralose for use in 15 food and beverage categories, the broadest initial approval ever given to a food additive. The FDA has never required any warning label or information statements on products containing sucralose.

SUCRALOSE IN OTHER COUNTRIES

Sucralose has been approved for use in more than 40 countries worldwide. Canada approved sucralose in 1991, Australia and Mexico in 1993. Regulatory agencies have also approved the use of sucralose in Brazil, China, Japan, in various Latin American, Asian, Caribbean, and Middle Eastern countries. In 1990, the safety of sucralose was confirmed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA is an international body of experts whose safety evaluation of food additives is relied upon by the regulatory agencies of many smaller countries.

SAFETY STUDIES SHOW THAT SUCRALOSE IS SAFE

Safety studies show that sucralose is a safe and essentially inert ingredient. Conclusions from the studies include the following:

- No known side effects

- Not toxic: No adverse effects seen in test animals, even in amounts equivalent in sweetness to 40+ pounds of sugar per day per life

- No bioaccumulation

- Not carcinogenic

- Not genotoxic: Does not cause genetic mutations

- No effects on fetal or neonatal development

Not neurotoxic: No evidence of effects on the central nervous system
Not cariogenic
No effect on carbohydrate metabolism
No calories or carbohydrate: Sucralose is not hydrolyzed or otherwise broken down for energy
No effect on short- or long-term blood glucose or on serum insulin levels.
Sucralose is suitable for people with diabetes and may be used as part of an overall healthy diet designed to meet their unique dietary needs

USE OF SUCRALOSE BY PEOPLE WITH DIABETES

The FDA has approved the use of sucralose by everyone, including people with diabetes. Although made from sugar, sucralose is not recognized by the body as a carbohydrate. Therefore, it is not broken down for energy and provides no calories. Studies in humans with and without diabetes have shown no effect of sucralose on insulin levels, fasting or postprandial blood glucose levels, or long-term blood glucose control.

ABSORPTION, DISTRIBUTION, METABOLISM, AND ELIMINATION OF SUCRALOSE

Absorption: Studies have shown that about 15% of ingested sucralose is passively absorbed through the small intestine. Most ingested sucralose passes through the digestive system unchanged and without causing gastrointestinal side effects.

Distribution: The small amount of sucralose that is absorbed is distributed to essentially all tissues. Studies show that there is no active transport of sucralose across the blood-brain barrier, across the placental barrier, or from the mammary gland into milk.

Metabolism: Although derived from sucrose, sucralose is not perceived by the body as a carbohydrate. Unlike carbohydrates, sucralose is not broken down during its passage through the body. In humans, approximately 2% of the amount consumed is biotransformed into toxicologically insignificant components that are rapidly excreted in urine.

Elimination: Most ingested sucralose is excreted unchanged in feces, without gastrointestinal effects. Of the small amount that is absorbed, most is eliminated unchanged in urine within about 24 hours.