SUCRALOSE

Level 1 Module

1 CPE

Calorie Control Council

HEALTHY EATING & EXERCISE FOR LIFE™

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Learning Objectives:

1. List the characteristics of sucralose that relate to its use as a sweetener and its safety as a food additive.
2. Discuss the FDA approval process for sucralose as a food additive
3. Explain safe levels of consumption of foods and beverages sweetened with sucralose within the context of the Acceptable Daily Intake (ADI) level for sucralose.
4. Advise patients and the public on the appropriate use of sucralose based on age, life stage, and health status of the individual.
5. Advise patients and the public on the appropriate use of sucralose in packaged food and beverages and in cooking.

Sucralose Module Outline

- Sucralose: What is it?
- Safety and Regulation of Sucralose
- Sucralose and Health Outcomes
- Putting it Into Practice

SUCRALOSE: WHAT IS IT?

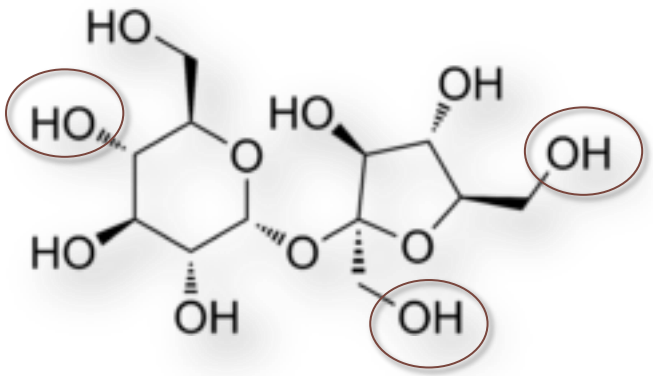
Sucralose: What is it?

- Sucralose is classified as a nonnutritive sweetener.
- 600+ times as sweet as white sugar
  - Twice as sweet as saccharin
  - Three times as sweet as aspartame
- Splenda® is the common brand name of sucralose
  - Yellow colored packaging
- Other sucralose-based sweeteners include
  - Sukrana, SucraPlus, Candys, Cukren and Nevella.

Sucralose in Food and Beverages

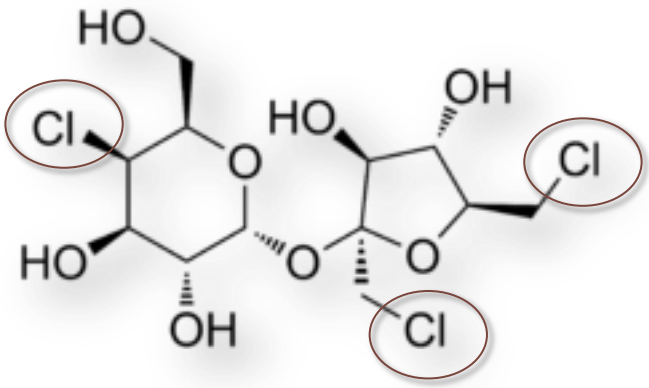
- Sucralose can be found in:
  - Diet drinks
  - Low carbohydrate meal replacements
  - Reduced carbohydrate foods
  - Pre-prepared dairy foods
  - Condiments
  - Candy and gums

Chemical Structure



Sucrose

3 hydroxyl (OH) groups replaced with 3 chlorine atoms



Sucralose

- Distinctive sweetness profile
- Sweetness stable over prolonged periods of storage
- Heat and pH stable (stable in cooking, baking)
- Not readily absorbed in the small intestine

Sucralose: Absorption and Metabolism

- Metabolism is well understood
- Stimulates taste receptors and hormone secretions
- Approximately 85% of ingested sucralose is not absorbed
- About 15% of ingested sucralose is passively absorbed
- Absorbed sucralose is not recognized as a carbohydrate and provides no energy to the body
- Sucralose does not accumulate in body compartments
- Most sucralose is eliminated, unchanged in feces.

Sucralose: Metabolism

- Consumption, even at very high levels, has virtually no impact on blood constituents, such as:
  - Amino acids
  - Methanol
  - Glucose
- Research shows that sucralose has no negative gastrointestinal effects:
  - No gas or bloating
  - No osmotic effect (diarrhea)

SAFETY & REGULATION OF SUCRALOSE

FDA Safety Standards

A reasonable certainty of no harm under the intended conditions of use.

FDA Food Additive Regulations

- Authorized by the Food Additives Amendment of 1958 to the Federal Food, Drug and Cosmetic Act
- Defined in Title 21 of the Code of Federal Regulations
- Based on the law, chemistry, toxicology, risk and safety assessment
- Requires premarket review and approval of food additives before use, and use may be limited to specific categories of foods or beverages

FDA Safety Evaluation: Intake Levels

- EDI: Estimated Daily Intake
  - Conservative estimation of probable consumer exposure to the additive
- HNEL: Highest No Effect Level
  - Animal studies data
  - The highest level that can be consumed without negative consequences
- ADI: Acceptable Daily Intake
  - HNEL x 1/100 = ADI

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FDA Safety Evaluation and Regulatory Decision

- FDA compares the EDI and ADI.
  - If EDI > ADI, FDA will NOT allow safety conclusions
  - If EDI < ADI, FDA *may* issue a safety decision consistent with "reasonable certainty of no harm"
- Additional research may be required
- Other risk assessment techniques may be applied
- An advisory committee may be consulted
- Published in Federal Register with adequate and reasonable time for public's right to review and respond

Sucralose Discovery and Approval History

- 1976: Discovered, and patented
- 1987: Original FDA petition filed
- 1998: Approved for use in United States
- 1991: Approved for use in Canada
- 2004: Approved for use in European Union (EU)

- Sucralose is permitted for use in more than 100 countries

Chronology of FDA Food Additive Approval or GRAS Affirmation of Nonnutritive Sweeteners

Sweetener	Approved
Saccharin	1977 (GRAS) 2000 (all warnings repealed) (general use)
Aspartame	1981 (specific foods) 1983 (soft drinks) 1996 (general use)
Acesulfame potassium (Ace-K)	1988 (dry foods) 1998 (nonalcoholic beverages) 2003 (general purpose)
Sucralose	1998 (general use)
Neotame	2002 (general use)
Stevia	2008 (GRAS)
Luo han guo (monk fruit)	2010 (GRAS)
Advantame	2014 (general use)

Sucralose Review by FDA

- 11-year FDA Review
- After initial application, FDA required from the petitioner:
  - 6 new studies addressing growth rate and weight gain impacts
  - 5 new studies addressing blood glucose homeostasis
- Further evaluation
- FDA set ADI for sucralose and estimated EDI
- FDA concluded “reasonable certainty of no harm”
- FDA approval of sucralose as sweetener in wide variety of foods, including beverages - 1998
- FDA approval expanded to include general use in food - 1999

Sucralose and the Estimated Daily Intake (EDI) for Adults

- Sucralose Estimated Daily Intake (EDI)
  - 1.6 g/kg/d
- Sucralose Acceptable Daily Intake (ADI)
  - 5 mg/kg bw/day
- EDI < ADI → contributed to FDA safety conclusion

How Much Sucralose Can an Individual Safely Consume?

Sweetener	ADI (mg/kg/d)	132 lb. (60 kg) person	
		mg/d	packets/d
Acesulfame K	15	900	23
Aspartame	50	3,000	75
Saccharin	15	900	45
Sucralose	**5**	**300**	**23**
Advantame	32.8	1,968	4,920

Sucralose Safety Summary

- Over 110 studies conducted that address safety and use of sucralose
  - Safe and essentially inert ingredient
  - No known side effects
  - No toxicity, carcinogenicity, genotoxicity, neurotoxicity, cariogenicity
  - No bioaccumulation
  - No effect on fetal or neonatal development
  - No effect on carbohydrate metabolism or glycemic control

Safety & Healthful Diets: Children

- Unique considerations with children:
  - Smaller body size
  - Periodic tendency to eat a limited number of foods
- Risk reduced by
  - Food producers use of sweetener blends versus only one type
  - Parents continued promotion of variety and decreasing proportion of sweet-tasting foods in children's diets
- Used in nutrient-dense foods, nonnutritive sweeteners can encourage key nutrient intakes without extra kcal

Safety & Healthful Diets: Pregnant/Nursing Women & Infants

- Research has shown that sucralose does not have harmful effects on pregnant women or their babies.
- FDA specifically evaluates sucralose for its effect on embryo-fetal development.
  - No birth defects or any other effects that would compromise normal development.
- Sucralose can be safely consumed as part of a healthful prenatal and postnatal diet.
- RDNs should counsel patients to ensure nonnutritive sweeteners do not interfere with adequate intake of energy and key nutrients

Reviewed by Other Regulatory and Scientific Agencies

- The following third party and regulatory agencies have conducted independent evaluations for use of sweeteners, and uphold their appropriate and reasonable use.
  - U.S. Food and Drug Administration
  - U.S. National Institutes of Health, National Cancer Institute
  - Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives
  - European Union's Scientific Committee on Food
  - Health Protection Branch of Health and Welfare Canada
  - Food Standards Australia and New Zealand

Extensive Review by Third Party Organizations

- American Diabetes Association
- National Cancer Institute
- Academy of Nutrition and Dietetics
- American Heart Association
- Canadian Diabetes Association

Academy of Nutrition and Dietetics Evidence Analysis Library (EAL) Process

- Formed Nutritive and Nonnutritive Sweeteners Workgroup
- Conducted independent and systematic review
  - Peer reviewed, well designed, human studies, published in English
- Graded evidence to support conclusions to specific questions, based on number and quality of evidence
  - Grade I: Good
  - Grade II: Fair
  - Grade III: Limited
  - Grade IV: Expert Opinion Only
  - Grade V: Not Assignable (no evidence to support or refute the conclusion)
- Formulated official position based on the evidence-based analysis conclusions

What is a Conclusion Statement?

- Conclusion statements address specific questions and claims relating to a topic.
- Each Conclusion Statement is assigned a grade based on the results of a systematic analysis and evaluation of the supporting research evidence.
  - Grade I: Good
  - Grade II: Fair
  - Grade III: Limited
  - Grade IV: Expert Opinion Only
  - Grade V: Not Assignable (no evidence to support or refute the conclusion)
- Criteria for grades, and evidence considered, can be found at www.andevidencelibrary.com

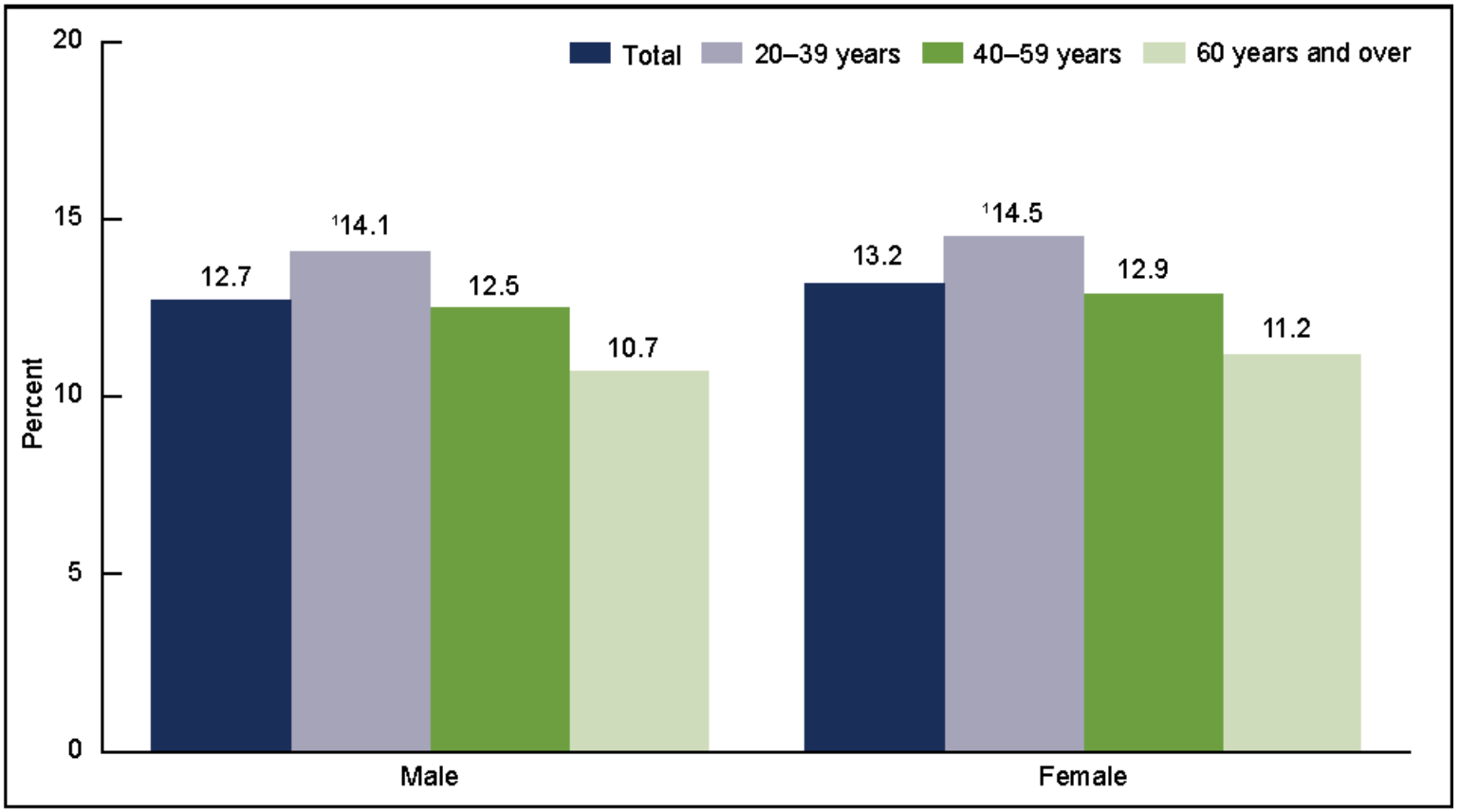
EAL Conclusion on Adverse Events Related to Sucralose in Humans

“Limited research in humans, from peer-reviewed journals, did not find an association between adverse effects and the intake of sucralose in the general population. No data from longitudinal cohort studies were available for review.”

SUCRALOSE AND HEALTH

Percentage of Kilocalories From Added Sugars

Figure 2. Mean percentage of kilocalories from added sugars among adults aged 20 and over, by age group and sex: United States, 2005–2010



[1]Significant linear trend by age, $p < 0.05$.
NOTE: Estimates that were not age-specific were age adjusted to the 2000 U.S. standard population using the three age groups shown.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey, 2005–2010.

Added Sugar Intakes & Recommendations

Added Sugars	Dietary Guidelines	American Heart Association	World Health Organization
	2015-2020	2009	2015
%kcal/d	< 10	N/A	≤ 10
g/d	< 50*	25-38	≤ 50*
tsp/d*	<12*	6-9	≤ 12*

*Calculated based on 2,000 kcal/d diet

Adults: Weight Management

- Studies are limited
- Does not affect appetite or directly affect food intake in adults (two studies)
- Creates energy deficit only if sucralose displaces caloric sweeteners and not compensated with other caloric intake
    - + increased physical activity to improve weight loss efforts
    - In place of added sugars to meet Dietary Guidelines for Americans

Children: Weight Management

- Studies are limited
- Does not increase food intake in children
- Overweight children who increased walking by 2000 steps/day and eliminated 100 kcal/day by using sucralose prevented further weight gain
- Long-term studies needed to assess impact of sucralose use on achieving and maintaining healthy weight in children

Glycemic Management & Diabetes

- Does not significantly impact carbohydrate metabolism
- Not recognized as a carbohydrate by the body
- Healthy adults
  - Little or no impact on blood glucose, insulin, or glycemic response
  - One study found lower post-prandial glucose and GLP-1 response
- Adults with diabetes
  - Lower HbA1c and fasting plasma glucose over 3 months (one study)
  - Lower post-prandial glycemic response with soluble fiber compared to sugar (one study)
  - Similar post-prandial glycemic response compared to water (one study)

Cancer

- The FDA has found no evidence that sucralose causes cancer or leads to an elevated risk of cancer.
- The National Cancer Institute 2009 Fact Sheet:
  - “…no clear evidence that Nonnutritive Sweeteners that are commercially available in the US are associated with cancer risk in human beings.”

Potential Interaction with Gut Microbiome

- Gut microbiome linked to risk factors for chronic disease
  - Metabolic syndrome, obesity, diabetes, etc.
  - Proportion of bacterial species important
  - Metabolites of bacterial digestion of food components may be more important
  - Sucralose reaches colon (microbiome) intact
- However:
  - Early studies document sucralose excreted intact in feces
  - Limited human studies on sucralose and gut microflora
  - Gut microflora respond to many food components, foods, and dietary patterns

Potential Interaction with Gut Microbiome

- One animal study documented microflora changes with sucralose
  - Both good and bad bacterial species increased
  - No observed health effects
  - Methodological flaws
- One animal study claimed: “artificial sweeteners induce glucose intolerance by altering gut microbiota”
  - Three different sweetener-fed groups were combined for statistical analysis, suggesting that all three sweeteners had similar effects
  - Gut microbiome in mice fed sucralose was unchanged
- Exploration of dietary impacts on the gut microbiome is ongoing.

PUTTING IT INTO PRACTICE

Recommendations Regarding Intake of Nonnutritive Sweeteners

- Dietary Guidelines for Americans 2015-2020
  - Potential for “high-intensity sweeteners” to replace added sugars, reducing calories in short term
  - Recommendation for added sugars < 10% total kcal
  - Need more long-term research to evaluate effectiveness for weight management
- World Health Organization
  - No direct mention of nonnutritive sweeteners

Terms used on Food Labels to Identify Sweeteners

Nonnutritive Sweeteners
Acesulfame Potassium/K
Aspartame
Neotame
Saccharin
Sucralose
Luo han guo (Monk Fruit) Extract
Stevia
Advantame

Nutritive Sweeteners
Fruit juice concentrates, Nectars
Date sugar, Honey
Syrups: Corn, High Fructose Corn, Sorghum, Maple, Malt
Molasses
Dextrose & Anhydrous Dextrose
Sugars: Brown, Confectioner's, Invert, Raw, White granulated
Lactose, Maltose, Sucrose, Fructose
Polyols (Sugar Alcohols): Sorbitol, Mannitol, Xylitol, Maltitol syrup, Lactitol, Erythritol, Isomalt, Hydrogenated Starch Hydrolysates

Kilocalories Saved with Substitutions of Nonnutritive Sweeteners

Product	kcal	In Place of	kcal saved
Table top sweetener (one packet)	0	2 tsp. sugar	32
Fat-free, light yogurt (6 oz.)	80	Fat-free yogurt (6 oz.)	95
Sugar-free syrup (1/4 cup)	20	Regular Syrup (1/4 cup)	180
Sugar-free preserves (1 tbsp.)	10	Regular preserves (1 tbsp.)	40
Sugar-free pudding (1/2 cup)	60	Regular Pudding (1/2 cup)	70
Diet Soda (12 oz.)	0	Regular soda (12 oz.)	127

Working with Clients and Consumers

- Read, review, and discuss the literature.
- Translate research for clients and consumers.
- Remind clients that sucralose must displace intake of nutritive sweeteners in order to create an energy deficit.
- Provide practical tips for creating an energy deficit:
  - Replace nutritive with non-nutritive sweeteners in beverages and recipes, keeping serving sizes the same.
  - Reduce food intake throughout the day.
  - Help those with diabetes to account for carbohydrates versus sugar on labels.

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SUMMARY

Sucralose Summary

- The unique chemical structure of sucralose prevents its absorption, therefore it can be used to sweeten without imparting calories to foods.
- Sucralose was thoroughly reviewed by the FDA before approval as a safe food additive, and has also been deemed safe by several other regulatory and scientific organizations.

Sucralose Summary

- For weight management:
  - Use of sucralose has not been shown to independently affect food intake or appetite.
  - Using nonnutritive sweeteners, such as sucralose, can contribute to decreased energy and added sugars intakes when they are used to substitute for added sugars.
  - Long-term studies in various human populations are warranted to provide further depth of evidence.
- For those with diabetes:
  - Sucralose has largely been shown to have no effect on glycemic control in adults.
  - Some preliminary evidence suggests a potential glucose lowering effect that warrants further study.

Nonnutritive Sweeteners Summary

- Dietetics professionals can use this information, along with continued review of evolving science, to help clients and consumers make educated decisions about the use and value of sweeteners as a part of their daily diets.
  - For all nonnutritive sweeteners, learning to make substitutions is the key.

References