



November 19, 2018

Mr. Andrew Smith, Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
Via fax: (202) 326-3799

RE: Request for Investigation of Deceptive Advertising of Sucralose

Dear Director Smith:

U.S. Right to Know, a nonprofit consumer and public health group, requests the Commission to investigate possibly deceptive advertising of the organochlorine artificial sweetener sucralose. Some advertising and marketing claims about sucralose may be deceptive under section 5 of the Federal Trade Commission Act,¹ as interpreted by the Commission in its “Statement on Deception,”² because emerging evidence suggests, contrary to some advertising and marketing, that sucralose may metabolize and bioaccumulate.³ These findings are important because they point to new uncertainties about the health risks of sucralose. In short, we know almost nothing about the new sucralose metabolites, and bioaccumulation of sucralose in adipose tissue may pose health risks.

Sucralose is sold by Tate & Lyle PLC under the brand name Splenda. According to Tate & Lyle, “SPLENDA® Sucralose is a leading non-sugar, zero-calorie sweetener, trusted in the development of more than 5,000 products in over 80 countries”.⁴ Many common food products sucralose, including Diet Coke with Splenda, Powerade Zero, Diet Pepsi with Splenda, Diet Mountain Dew, Lipton Diet Iced Tea with Lemon, among others.

Because U.S. Right to Know is based in the Bay Area, I request a meeting with your San Francisco office to more fully explain our complaint and to answer questions; hence I cc Thomas Dahdhoh, director of the FTC Western Regional Office.

¹ 15 U.S.C. §§ 41-58, as amended.

² Federal Trade Commission, [Policy Statement on Deception](#). October 14, 1983. Appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984).

³ Volker Bornemann, Stephen C. Werness, Lauren Buslinger & Susan S. Schiffman, “[Intestinal Metabolism and Bioaccumulation of Sucralose In Adipose Tissue In The Rat](#).” Journal of Toxicology and Environmental Health, Part A, August 21, 2018, DOI: 10.1080/15287394.2018.1502560. Susan S. Schiffman & Kristina I. Rother, “[Sucralose, A Synthetic Organochlorine Sweetener: Overview Of Biological Issues](#).” Journal of Toxicology and Environmental Health, Part B, November 12, 2013. 16:7, 399-451, DOI: 10.1080/10937404.2013.842523

⁴ <http://www.sucralose.com/our-sucralose/specifications>

Exposing what the food industry *doesn't* want us to know

The Federal Trade Commission Act declares that “unfair or deceptive acts or practices in or affecting commerce” are “unlawful,”⁵ and that it is “unlawful” to disseminate any false advertisement “for the purpose of inducing” the purchase of food.⁶ The FTC Act defines a “false advertisement” as one that is “misleading in a material respect.”⁷

To determine whether an advertisement is deceptive in violation of section 5, “the Commission engages in a three-step inquiry, considering: (i) what claims are conveyed in the ad, (ii) whether those claims are false, misleading or unsubstantiated, and (iii) whether the claims are material to prospective consumers.” *Pom Wonderful, LLC v Federal Trade Commission*, 777 F.3d 478, 490 (D.C. Cir. 2015). As the Commission’s own policy explains, the Commission applies a three-pronged test to determine whether advertising is deceptive: First, “there must be a representation, omission or practice that is likely to mislead the consumer.... Second, we examine the practice from the perspective of a consumer acting reasonably in the circumstances. If the representation or practice affects or is directed primarily to a particular group, the Commission examines reasonableness from the perspective of that group. Third, the representation, omission or practice must be a ‘material’ one. The basic question is whether the act or practice is likely to affect the consumer’s conduct or decision with regard to a product or service. If so, the practice is material and consumer injury is likely because consumers are likely to have chosen differently but for the deception.”⁸

In this situation, as explained below, sucralose is being advertised and marketed as not metabolized or bioaccumulated by humans. The claim may well be deceptive under and within the meaning of section 5, given research suggesting that sucralose metabolizes and bioaccumulates in rats, and perhaps it does so in humans as well.

A: Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and the International Food Information Council Foundation Claim that Sucralose Neither Metabolizes nor Bioaccumulates

Sucralose manufacturers Tate & Lyle and Heartland Food Products Group, along with their trade group the Calorie Control Council and the food industry public relations group International Food Information Council Foundation, as well the beverage company Coca-Cola make statements that sucralose does not metabolize or bioaccumulate. See, for example:

- “SPLENDA® Sucralose is not recognized by the body as a carbohydrate and is not metabolized by the body,” according to the Tate & Lyle website [sucralose.com](http://www.sucralose.com).⁹

⁵ 15 U.S.C. § 45(a)(1).

⁶ 15 U.S.C. § 52(a).

⁷ 15 U.S.C. § 55(a)(1).

⁸ Federal Trade Commission, [Policy Statement on Deception](#). October 14, 1983. Appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984).

⁹ <http://www.sucralose.com/our-sucralose/faqs>

- “The small amount of sucralose that is absorbed is not metabolized, but is rapidly eliminated in urine as sucralose. Sucralose does not accumulate in the body,” according to a primer on sucralose on The Coca-Cola Company’s website.¹⁰
- “Sucralose is not recognized by the body as a carbohydrate and is not metabolized or otherwise broken down for energy,” according to the Calorie Control Council website sucralose.org.¹¹
- “[S]ucralose does not break down in the body. It is not affected by the body’s digestive processes. The chlorine in sucralose does not separate in the body, nor does sucralose accumulate in the body,” according to the Calorie Control Council website sucralose.org.¹²
- “Sucralose enters and leaves the body as sucralose. It is not broken down in the body and does not provide any calories,” according to the Calorie Control Council website sucralose.org.¹³
- “Although sucralose is made from sugar, the body does not recognize it as sugar or a carbohydrate. It is not metabolized by the body for energy, so it is calorie-free. The vast majority of ingested sucralose is not absorbed and simply passes through the digestive system. The small amount of sucralose that is absorbed is rapidly eliminated in urine as sucralose,” according to the Calorie Control Council website sucralose.org.¹⁴
- “Most importantly to me personally and professionally, SLENDA® doesn’t get metabolized as a carbohydrate and is quickly excreted...” writes dietitian Toby Smithson on the “Splenda living” website.¹⁵
- “Sucralose is water soluble and it does not accumulate in the body and is not broken down for energy - so it has no calories. About 85% of the sucralose we consume is excreted in our stool unchanged, while the remaining 15% is passively absorbed then excreted quickly in the urine. It is eliminated rapidly from the body with no tendency for increased plasma concentrations with continued consumption (or use),” according nutrition consultant Robin Flipse, on the “Splenda living” website.¹⁶

¹⁰ <https://www.coca-colacompany.com/stories/0000013e-a36b-d44b-af7e-bf6b8b5f0000>

¹¹ <https://sucralose.org/sucralose-facts/>

¹² <https://sucralose.org/faqs/>

¹³ <https://sucralose.org/faqs/>

¹⁴ <https://sucralose.org/faqs/>

¹⁵ <https://blog.splenda.com/thankful-sweetness-managing-diabetes#sthash.Ejjjnfhu.dpbs>

¹⁶ <https://blog.splenda.com/fact-vs-fiction-sucralose-side-effects-and-dangers#sthash.dswOLkt7.dpbs>

- “SPLENDA® Brand Sweetener does not build up in the body, nor is it broken down to yield any free chlorine or smaller chlorinated molecules,” according to the Heartland Food Products Group website Splenda Truth.¹⁷
- “After it [sucralose] is ingested, most (about 85%) is not absorbed and passes through the body unchanged in the stool. Of the small amount that is absorbed, most leaves the body unchanged in the urine within 24 hours,” according to the Heartland Food Products Group website Splenda Truth.¹⁸
- “SPLENDA® Brand Sweetener does not build up in the body, nor is it broken down to yield any free chlorine or smaller chlorinated molecules,” according to the Heartland Food Products Group website Splenda Truth.¹⁹
- “All absorbed sucralose is excreted quickly in the urine,” according to the International Food Information Council Foundation fact sheet “Everything You Need to Know About Sucralose.”²⁰

B: A Recent Study Suggests that Sucralose Does, In Fact, Metabolize in the Gastrointestinal Tract of Rats and Bioaccumulate in Their Bodies

On August 21, 2018, the Journal of Toxicology and Environmental Health published a study by researchers from Avazyme, Inc. and North Carolina State University, who tried to determine whether rats metabolize sucralose in their gastrointestinal tract, and whether sucralose bioaccumulates in rat adipose tissue. Contrary to regulatory filings by sucralose manufacturers, the study found that sucralose in fact metabolizes and bioaccumulates in rat adipose tissue. According to the researchers,

Analysis of the urine and fecal extracts by ultra-high performance liquid chromatography tandem mass spectrometry (UHPLC–MS/MS) revealed two new biotransformation products that have not previously been reported. These two metabolites are both acetylated forms of sucralose that are less polar and hence more lipophilic than sucralose itself. These metabolites were present in urine and feces throughout the sucralose dosing period and still detected at low levels in the urine 11 days after discontinuation of sucralose administration and 6 days after sucralose was no longer detected in the urine or feces. The finding of acetylated sucralose metabolites in urine and feces do not support early metabolism studies, on which regulatory approval was based, that claimed ingested sucralose is excreted unchanged (i.e. not metabolized).

¹⁷ <http://www.splendatruth.com/health/splenda-dangers-myths>

¹⁸ <http://www.splendatruth.com/splenda-safety-faqs>

¹⁹ <http://www.splendatruth.com/splenda-safety-faqs>

²⁰ <https://www.foodinsight.org/articles/everything-you-need-know-about-sucralose>

The researchers explain why previous studies failed to find the sucralose metabolites:

The historical metabolic studies apparently failed to detect these metabolites in part because investigators used a methanol fraction from feces for analysis along with thin layer chromatography and a low-resolution linear radioactivity analyzer.

The researchers explain the discovery of sucralose bioaccumulation in rat adipose tissue:

Further, sucralose was found in adipose tissue in rats two weeks after cessation of the 40-day feeding period even though this compound had disappeared from the urine and feces. Thus, depuration of sucralose which accumulated in fatty tissue requires an extended period of time after discontinuation of chemical ingestion.

The researchers conclude with a warning about the significance of their findings:

These new findings of metabolism of sucralose in the gastrointestinal tract (GIT) and its accumulation in adipose tissue were not part of the original regulatory decision process for this agent and indicate that it now may be time to revisit the safety and regulatory status of this organochlorine artificial sweetener.²¹

Other studies have also suggested that sucralose may metabolize in rats and humans.²² For example, an article in the Journal of Toxicology and Environmental Health states:

Although early studies asserted that sucralose passes through the GIT [gastrointestinal tract] unchanged, subsequent analysis suggested that some of the ingested sweetener is metabolized in the GIT, as indicated by multiple peaks found in thin-layer radiochromatographic profiles of methanolic fecal extracts after oral sucralose administration. The identity and safety profile of these putative sucralose metabolites are not known at this time.

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²¹ Volker Bornemann, Stephen C. Werness, Lauren Buslinger & Susan S. Schiffman, "[Intestinal Metabolism and Bioaccumulation of Sucralose In Adipose Tissue In The Rat.](#)" Journal of Toxicology and Environmental Health, Part A, August 21, 2018, 81:18, 913-923, DOI: 10.1080/15287394.2018.1502560.

²² Susan S. Schiffman & Kristina I. Rother, "[Sucralose, A Synthetic Organochlorine Sweetener: Overview Of Biological Issues.](#)" Journal of Toxicology and Environmental Health, Part B, November 12, 2013. 16:7, 399-451, DOI: 10.1080/10937404.2013.842523. J. Sims; A. Roberts; A. G. Renwick; J. W. Daniel, "[The Metabolic Fate of Sucralose in Rats.](#)" Food and Chemical Toxicology, 2000; 38 Suppl 2:S115-21. DOI: 10.1016/S0278-6915(00)00034-X. Roberts A, Renwick AG, Sims J, Snodin DJ, "[Sucralose Metabolism and Pharmacokinetics in Man.](#)" Food and Chemical Toxicology, 2000;38 Suppl 2:S31-41. DOI: 10.1016/S0278-6915(00)00026-0.

The finding of multiple peaks in the TLC [thin-layer chromatogram] traces of fecal extracts from rats and humans is consistent with the finding by Abou-Donia et al. (2008) that oral consumption of sucralose increases the expression of CYP [cytochrome P-450] isozymes in the intestine known to metabolize xenobiotics including drugs and other foreign substances. The identity of the metabolites has not yet been established, but known sucralose reaction products include its two hydrolysis products (e.g., the organochlorine monosaccharides 4-chloro-4-deoxygalactose [4-CG] and 1,6-dichloro-1,6-dideoxyfructose [1,6-DCF]; Grice and Goldsmith, 2000), an unsaturated aldehyde of sucralose (Labare and Alexander, 1994), and 3',6'-anhydro-4,1'-dichlorogalactosucrose, which is gradually produced under aqueous, alkaline conditions (Barndt and Jackson, 1990). Overall, the TLC and CYP findings in aggregate do not support the historical contention that sucralose is not metabolized in the GIT...²³

C: Request for Investigation into Whether Advertising and Marketing by Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and International Food Information Council Foundation that Sucralose Does Not Metabolize or Bioaccumulate are Deceptive and in Violation of the FTC Act

As noted, according to the FTC Policy Statement on Deception, three elements “undergird all deception cases.”

First, there must be a representation, omission or practice that is likely to mislead the consumer....

Second, we examine the practice from the perspective of a consumer acting reasonably in the circumstances. If the representation or practice affects or is directed primarily to a particular group, the Commission examines reasonableness from the perspective of that group.

Third, the representation, omission, or practice must be a "material" one. The basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception. In many instances, materiality, and hence injury, can be presumed from the nature of the practice. In other instances, evidence of materiality may be necessary.

²³ Susan S. Schiffman & Kristina I. Rother, “[Sucralose, A Synthetic Organochlorine Sweetener: Overview Of Biological Issues.](#)” *Journal of Toxicology and Environmental Health, Part B*, November 12, 2013. 16:7, 399-451, DOI: 10.1080/10937404.2013.842523.

Thus, the Commission will find deception if there is a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment.²⁴

Next, we will examine these elements.

i: Representations that Sucralose is Neither Metabolized nor Bioaccumulated Seems Likely to Mislead Reasonable Consumers

In the Policy Statement on Deception, the Commission writes that:

The Commission believes that to be deceptive the representation, omission or practice must be likely to mislead reasonable consumers under the circumstances. The test is whether the consumer's interpretation or reaction is reasonable....

To be considered reasonable, the interpretation or reaction does not have to be the only one. When a seller's representation conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation. An interpretation will be presumed reasonable if it is the one the respondent intended to convey.²⁵

Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and International Food Information Council Foundation state in their advertising and marketing materials that sucralose does not metabolize or bioaccumulate.

However, new scientific evidence in a rat model, as well as some older evidence, appears to contradict those representations.²⁶ We ask the FTC to investigate and determine whether those representations are likely to mislead reasonable consumers regarding whether sucralose metabolizes or bioaccumulates.

ii: Is There Consumer Detriment from Possible Misrepresentations of Sucralose by Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and International Food Information Council Foundation?

²⁴ [FTC Policy Statement on Deception](#), October 14, 1983. Appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984).

²⁵ [FTC Policy Statement on Deception](#), October 14, 1983. Appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984).

²⁶ Volker Bornemann, Stephen C. Werness, Lauren Buslinger & Susan S. Schiffman, "[Intestinal Metabolism and Bioaccumulation of Sucralose In Adipose Tissue In The Rat.](#)" *Journal of Toxicology and Environmental Health, Part A*, August 21, 2018, DOI: 10.1080/15287394.2018.1502560.

The premise behind the supposed safety of sucralose is that it is poorly absorbed, and what little is absorbed is not metabolized and rapidly excreted. A recent study in the Journal of Toxicology and Environmental Health contradicts this premise in a rat model. The implications for the human health risks of sucralose are unknown. If sucralose metabolizes in humans similarly as in rats, we do not know the hazard potential or human health risk of the newly-discovered acetylated forms of sucralose.

The health effects of any bioaccumulation of sucralose are not known. But bioaccumulation in adipose tissue would lead to greater exposure, which could promote or bring adverse health effects, including metabolic dysregulation, upregulation of adipogenic genes and inflammation.

In a study presented to the Endocrine Society's 2018 annual meeting, researchers found that sucralose promotes metabolic dysregulation. The study concludes that:

Analysis of in vitro human MSCs [mesenchymal stem cells] exposed to sucralose, data along with subjects' fat biopsy sample analysis data from consumers and subject's biochemistry indicates that sucralose promotes metabolic dysregulation (by increased glucose uptake, inflammation and adipogenesis) which is associated with increased intra-cellular ROS [reactive oxygen species] accumulation and high TG [triglyceride].²⁷

One account of the Endo study, in Practice Update, reported that:

Sucralose, a popular artificial sweetener, promotes metabolic dysregulation, including fat cell genesis, dysregulation of response to insulin and glucose, inflammation, and increases in plasma triglycerides, particularly among those who are obese, according to a study presented at the annual meeting of the Endocrine Society (ENDO)...

* * * * *

The investigators found that sucralose exposure resulted in upregulation of adipogenic genes, such as *CEBPA* and *FABP4*, in human MSCs [mesenchymal stem cells], which occurred in a dose-dependent fashion. Analysis of fat samples from obese individuals showed significant upregulation of glucose transporter type 4, which is responsible for cellular uptake of glucose mediated by the presence of insulin. There was also significant upregulation in taste receptor type 1 member 3 and taste receptor type 2 member 3, which play roles in the detection of sweet and bitter tastes. Finally, they observed upregulation in

²⁷ Nabanita Kundu, Cleyton Domingues, Mohammed Aljishi, Brent Samuel Abel, Neeki Ahmadi, Allison Sylvestsky, Monica C. Skarulis, Kristina Rother and Sabyasachi Sen, "[Sucralose Promotes Metabolic Dysregulation and Intracellular ROS Accumulation.](#)" Endocrine Society, Endo 2018, March 18, 2018.

genes associated with the generation of adipose cells and obesity, including perilipin-1, peroxisome proliferator-activated receptor gamma, and *CEBPA*.²⁸

The point is that misrepresentation to consumers about whether sucralose metabolizes or bioaccumulates could lead to consumer detriment, by increasing consumer acceptance and consumption of a product that may pose human health risks.

iii: Are the Possible Misrepresentation About Sucralose by Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and International Food Information Council Foundation Material Ones that Will Likely Affect Consumer Decision-making?

The premise underlying manufacturers' claims of safety of sucralose is that it neither metabolizes nor bioaccumulates. It is hardly a stretch of the imagination that some consumers – especially health-conscious ones -- might not wish to consume sucralose if they were told that this premise is false, and that sucralose may metabolize and bioaccumulate.

D: Action Requested: The FTC Should Investigate Tate & Lyle, Heartland Food Products Group, Coca-Cola, Calorie Control Council and International Food Information Council Foundation Because Their Advertising and Marketing Materials on Sucralose May Be Deceptive

We request that the Commission investigate whether it is deceptive within the meaning of the FTC Act for companies or their trade groups to claim, in advertising, marketing and promotions, that sucralose neither metabolizes nor bioaccumulates.

Sincerely,



Gary Ruskin
Co-Director

CC: Thomas N. Dahdouh, FTC Regional Director, Western Region

²⁸ [“Sucralose Promotes Metabolic Dysregulation and Inflammation.”](#) Practice Update, March 27, 2018. See also Kristen Monaco, [“Artificial Sweeteners Impact Metabolic Health Even on Cellular Level.”](#) Medpage Today, March 20, 2018.