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The Trials of Olestra: The Health Safety Issue

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## Introduction

Olestra, brand name olean®, is a non-absorbable, non-digestible, fat substitute that has found itself in savory snack foods on the consumer market. One would think the public would welcome the development of such a product that contributes zero calories to the foods prepared with it. But such is not the case. Olestra has come under fire vehemently over the last decade. In 1987, Procter and Gamble (P&G) petitioned the Food and Drug Administration (FDA) to approve olestra as a substitute for up to 35% of the fat in shortenings and cooking oils, and up to 75% of the fat used for commercial deep frying and in fried snack foods (1). What is it about this wonder product olestra that has members of the scientific community and consumer advocacy groups up in arms?

Olestra was developed in 1968 and Procter and Gamble (P&G) obtained patent in 1971. The FDA, on Jan 24, 1996, finally approved Olestra as a non-digestible substitute for fat in snack foods. However, after twenty-five years of research and repeated formulations of this product, and a financial investment of over 200 million by P&G, olestra remains mired in controversy (2). Consumer advocacy groups and nutritionists are appalled at the FDA's approval of olestra as a food additive in savory snacks. Has not the FDA any concerns about consumer health safety of a product that is saddled with problems from gastrointestinal symptoms such as "anal leakage", abdominal cramping, and diarrhea, to the decreased absorption of important fat-soluble vitamins (1,3) into the body?

This paper evaluates the pros and cons of olestra as a fat substitute: its effect on the gastrointestinal system, fat and fat-soluble molecule absorption, daily energy intake and fat reduction. Perhaps, with this information, an informed decision can be made regarding its dietary consumption.

## Properties of Olestra

Olestra is a sucrose polyester made by esterifying sucrose with six or more triglycerides (long chain fatty acids) derived from edible fats and oils (2,4). Olestra is neither absorbable nor digestible, and it provides no calories to the diet (4). The physical properties of olestra are similar to that of triglyceride with the same constituent fatty acids. It is liquid at room temperature if it is made from highly unsaturated fatty acids, and solid if made from highly saturated fatty acids. It has the organoleptic and thermal properties of fat but it is not hydrolyzed by gastric or pancreatic enzymes (4,5) and is eliminated intact in the feces (6). For this reason olestra can be used to modify dietary fat and caloric intake. Because olestra is lipophilic and non-absorbed, it has the ability to interfere with the absorption of dietary components, especially the lipophilic ones (4,5). The evidence indicates that olestra can have pharmacokinetic interactions with molecules that have high octanol-water partition coefficients, greater than approximately 7.5 (6,7). The water-octanol partition coefficient of the molecule, that is, its equilibrium distribution between an aqueous phase (water) and an oil phase (octanol) determines whether olestra will interfere with it (4,5).

## Olestra and nutrient absorption

Numerous studies with both animals and humans have shown that olestra decreases the absorption of the phytochemicals and carotenoids, cholesterol, and vitamins A and E, all of which have high octanol-water partition coefficients (4,5). Conflicting evidence exists for

vitamins D and K (8,9). Vitamin E is an important anti-oxidant in the body, and the carotenoids (e.g.  $\beta$ -carotene) have been identified as cancer fighters and preventive agents against heart disease, stroke, cataracts, and macular degeneration, the leading cause of age-related, irreversible blindness (1,5).

The tendency of olestra to interact with lipophilic compounds is consistent with current concepts of fat absorption. As digestion proceeds, fats and fat-soluble nutrients move to intestinal micelles, where they are absorbed and incorporated into chylomicrons. They then enter the gastrointestinal circulation via the lymphatic system (4). Since edible oils enhance the absorption of fat-soluble nutrients, such as  $\beta$ -carotene, it is expected that a portion of these fat-soluble nutrients would partition into olestra in the GI tract, and not be incorporated into intestinal micelles. They would be carried out of the body with the non-absorbed olestra, thereby decreasing their absorption (4,6).

Studies have shown decreased serum levels of fat-soluble vitamins when olestra is used as a fat replacement. Over a 16 week period, patients who co-ingested olestra with  $\beta$ -carotene (and other carotenoids) showed a decline in carotenoid absorption by 27%, vitamin E declined 6%, and a decreased serum cholesterol was also noted, 4.5% (6,8). One must take into account also that the grams of olestra used in these studies are far more than is expected to be consumed under free-living dietary patterns, that is, 18g versus about 7g (4,5), so the effects will likewise be reduced. However, it should be noted that olestra can affect absorption of another substance only if both are present in the GI tract together. This is because the mechanism of interaction is a physical one that occurs in the lumen of the gut (4). It is believed that the effects of olestra on the fat-soluble vitamins can be offset by adding specified amounts of the vitamins to olestra foods (4,5) and by increasing the dietary levels of these vitamins (9).

#### Olestra and the gastrointestinal tract

The effect of olestra on the gastrointestinal system is one of the major issues olestra has come up against over the years. Subjects who ingested olestra-containing foods reported mild to moderately severe gastrointestinal symptoms that included abdominal cramping, diarrhea, loose stools, flatulence, nausea, and "anal leakage" (1,3,4,5). Numerous studies have shown that individuals who consume large quantities of olestra may experience transient mild to moderate GI symptoms. When these symptoms are experienced, they resolve in 1-2 days, but may recur (4,5). The GI symptoms experienced are believed to result from the presence of non-digestible oil in the gastrointestinal tract (3). Research studies show that as an unabsorbed lipid, olestra can cause symptoms similar to those produced by other foods we eat (e.g. foods rich in fiber, beans) or by a change in diet. Although mild to moderate GI discomfort may ensue after ingesting olestra, studies indicate that these GI symptoms are not increased with olestra consumption (10).

Researchers contend that the nature and intensity of the GI symptoms experienced do not represent a serious health risk to the consumer (4,5,11). This was evident in subjects whose GI function was compromised by disease. Olestra does not exacerbate GI problems associated with inflammatory bowel disease (12), or gastric acid regurgitation (13). Further assessments indicate that olestra does not significantly alter the microflora population of the GI tract (3); does not alter the physiology of GI system; does not significantly affect gastrointestinal or colonic transit in healthy subjects (14); and does not affect health status in a clinically significant way (3).

## Olestra and obesity

Obesity has been linked to a number of serious and life-threatening illnesses such as coronary heart disease, diabetes, stroke, hypertension, and other cardiovascular problems (16). In the United States today, 35% of women and 31% of males over 20 years are considered obese which is up from 30% and 25% respectively, in 1980 (15). The incidence of obesity has been linked to fat intake and total energy intake in the diet. According to the World Health Organization, a high dietary fat intake accounting for more than 30 % of dietary energy intake will soon lead to positive energy balance, and can have detrimental effects on health.

Olestra is proposed for use as an aid to weight loss and dietary fat reduction (1). It can be used to reduce weight among obese people; it can prevent weight gain among populations at risk for conditions associated with obesity; and it can reduce caloric intake (2). Studies have shown that with a fat reduction of about 10% in the diet obtained by substituting with olestra foods, people can reduce their fat intake without the likelihood of provoking a compensatory increase in appetite (16). However, if a more dramatic reduction, greater than 10%, is made too quickly, bio-behavioral responses will be evoked. An energy deficit will be created which will cause a compensatory increase in appetite, that is, you will eat more over the course of the day to make up for the deficit (16).

Olestra has been approved for up to 100% replacement of the fats and oils used in the preparation of savory snack foods. These include salty and piquant foods such as potato chips, tortilla chips and crackers (2,17). Olestra is not digested or absorbed by the GI system, so it contributes no calories to the diet (13). This property of olestra allows it to be substituted for conventional triglycerides in a variety of foods while remaining palatable (3,13). The fatty acids used to make olestra impart the same physical properties, taste, and cooking characteristics to olestra as the starting triglycerides (17). Individuals who want or need to lower their total energy intake and body weight, may find it easier to change dietary habits and to maintain healthful nutritional practices when they use olestra foods (5). Consumption of olestra can also reduce fat intake and increase carbohydrate intake without affecting total daily energy intake or usual patterns of hunger and fullness (18).

## Conclusion

There are several conditions that come with the FDA's approval of olestra. First, the use of olestra is confined to savory snack foods such as potato and tortilla chips and crackers. Second, compensatory amounts of vitamins A, D, E, and K must be added to the snacks. Third, olestra products must carry a label stating "This product contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added". (2).

Some experts believe that olestra's potential benefit as an aid to weight loss and dietary fat reduction outweigh its possible downside with respect to vitamin absorption and gastrointestinal discomfort (1). The evidence has been clearly presented here. Perhaps now we will be able to assess olestra's potential benefits and negative effects and make an informed decision regarding its daily dietary role.

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