Think about the most popular topics of discussion at any social gathering. Diet and nutrition surely make the list. Why? One reason is that Americans fight an ongoing battle with excess weight. More than one-half of American adults are overweight or obese, a condition that not only raises the risk of poor self-esteem and social segregation, but one that substantially increases the chances of high blood pressure, diabetes, heart disease, stroke, and some cancers.

Although dietary fat may have topped the list of diet concerns in recent years, the calorie never really went away. Surveys show that Americans today are paying more attention to the caloric contents of foods, whether their intention is to lighten up or just get healthier. In recent years, there has been a steady and significant increase in consumer demand for low-calorie products. People look to low-calorie foods to help them manage their weight, maintain an attractive physical appearance, and stay in better overall health.

This IFIC Review examines how intense, or low-calorie, sweeteners are used to help reduce the caloric content of foods. It also reviews research that explores the role of low-calorie sweeteners in helping people maintain a diet that supports good health and healthy weights.

**The Benefits of Low-Calorie Sweeteners**

Low-calorie sweeteners add to foods a taste that is similar to that of sucrose (table sugar). Intense sweeteners, however, are generally several hundred to several thousand times sweeter than sucrose. Most do not contain any calories. Those that do contain calories, such as aspartame, are used in very small amounts because of their concentrated sweetening power. Thus, they also add essentially no calories to foods and beverages. As a result, intense sweeteners practically eliminate or substantially reduce the calories in some foods and beverages such as carbonated soft drinks, light yogurt, and sugar-free pudding.

Intense sweeteners also do not affect insulin levels. Hence, they may be used to provide sweet-tasting foods and beverages for people who must restrict carbohydrate intake, such as people with diabetes.

A variety of low-calorie sweeteners have been approved for use in the U.S. food supply, and the Food and Drug Administration (FDA) is currently considering petitions to approve others. Because low-calorie sweeteners have different functional
properties, the availability of a variety of low-calorie sweeteners for use in foods expands the capability to develop reduced-calorie products that better meet consumer needs and desires.

Blends of some low-calorie sweeteners in foods and beverages may also act synergistically to produce the desired level of sweetness with smaller amounts of each sweetener. The resulting taste often better meets consumer expectations of a sweetness profile close to that of sugar. The products may also have longer sweetness shelf lives.

The Safety of Blends

Individually, each of the approved low-calorie sweeteners has a long history of chemical stability. Additionally, an exhaustive safety database exists on each of these sweeteners. The only known and anticipated interaction between the various blends of sweeteners is the physical interplay with sensory taste buds. Individually, among the low-calorie sweeteners only aspartame is metabolized, and it is rapidly digested and converted into other components that are further metabolized normally. On the basis of the information presented above, health authorities around the world have reasonably concluded that there is no scientific basis to expect any physiological effects to emerge from blended sweetener systems separate and apart from those that occur with the individual sweeteners, and none have been reported. Indeed, the blending of sweeteners further reduces the already safe levels of use and dietary intake.

Low-Calorie Sweeteners in the United States

Before being approved by FDA for use in the United States, all low-calorie sweeteners must undergo extensive safety evaluation in tests with humans and animals. All FDA-approved low-calorie sweeteners meet the same standard of safety and are safe for consumption by pregnant women and children. However, as diet and caloric intake are important for both of these segments of the population, the advice of a physician or registered dietitian is recommended.

Four intense sweeteners are currently approved for use in the United States: acesulfame potassium, aspartame, saccharin, and sucralose.

Acesulfame potassium, or acesulfame-K (6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide), is 200 times sweeter than sugar, and because it is not metabolized by the body, it is calorie-free. Acesulfame potassium is excreted unchanged by the kidneys.

Approved for use by FDA in 1988 and expanded for use in beverages in 1998, acesulfame potassium is available as a tabletop sweetener. It is also used in many prepared foods, including carbonated and noncarbonated beverages, chewing gum, baked goods, dairy products, confections, desserts, sauces, and alcoholic beverages. It is highly stable and can therefore withstand high cooking and baking temperatures.

The Acceptable Daily Intake (ADI) for acesulfame potassium is 15 milligrams (mg) per kilogram (kg) of body weight (see the sidebar Anatomy of a Sweetener Approval). Approximate consumption of acesulfame potassium in the United States is less than 20 percent of the ADI over a lifetime.

Acesulfame potassium is approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia. It requires no health warning or information on the label and may be used by all population segments.

Aspartame (N,N'-aspartyl-L-phenylalanine 1-methyl ester) is composed of aspartic acid and the methyl ester of phenylalanine. Although its taste is similar to that of sucrose and it provides the same number of calories (4 kilocalories per gram [kcal/g]), aspartame is 200 times sweeter. Thus, aspartame can be used in much smaller amounts. For example, a tiny amount of aspartame (19 mg) with 1/10 of a calorie produces the same level of sweetness as a teaspoon of sugar (4 grams) with 16 calories. In actual use, then, aspartame contributes negligible calories to the diet.

Upon digestion, aspartame breaks down to aspartic acid, phenylalanine, and a small amount of methanol, all of which are metabolized normally.

Approved for use in the United States in 1981, aspartame can be used in tabletop sweeteners, carbonated and noncarbonated beverages, juices, chewing gum, dairy products, confections, desserts, puddings, jams, jellies, and breakfast cereals. In 1996, aspartame received FDA approval for general use and can be used in all foods.
Although it loses its sweetness when it is exposed to high heat for extended periods of time, it can be added to foods at the end of the cooking cycle.

The ADI in the United States for aspartame is 50 mg/kg of body weight. Approximate consumption in the United States is less than 10 percent of the ADI over a lifetime.³

Products made with aspartame must bear on their labels a statement that they contain phenylalanine. The statement is important for individuals with phenylketonuria, a rare hereditary disease, because they cannot properly metabolize the essential amino acid phenylalanine. Phenylalanine is consumed in greater amounts from common protein-containing foods such as chicken, beef, milk, and vegetables than from aspartame.

Aspartame is approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia.

**Saccharin** (1,2-benzisothiazol-3(2H)-one-1,1-dioxide) has a taste 300 to 500 times sweeter than that of sucrose. Suitable for use in cooking and baking, saccharin is highly stable and contains no calories. It is absorbed almost completely but is excreted unchanged in the urine.

Saccharin has been used to sweeten foods and beverages since 1900 and has received interim approval from FDA since 1970. FDA proposed a ban on saccharin in 1977 on the basis of animal research that suggested that it was a weak bladder carcinogen. In the study, researchers administered unrealistically high doses of saccharin, equivalent to 750 cans of soft drinks or 10,000 saccharin tablets per day, every day, for a lifetime.

A congressional moratorium was subsequently placed on the ban to allow more research on saccharin's safety. The moratorium on the ban has been extended numerous times on the basis of the need for further scientific study and continued consumer demand for the sweetener. Because FDA has withdrawn the ban, the moratorium will not be necessary after 2002.

More than 20 studies with humans, including the largest bladder cancer survey ever undertaken in the United States, have shown no overall association between saccharin consumption and cancer incidence.⁴ In addition, more recent research indicates that the mechanism that causes cancer to develop when high levels of saccharin are consumed is unique to the male rat and is not relevant to humans.⁵ Still, labels on products with saccharin must continue to bear a statement that it has caused cancer in laboratory animals. The National Toxicology Program of the U.S. Department of Health and Human Services (DHHS) has delisted saccharin from a list of potential carcinogens; however, removal of the warning label will require action by either the U.S. Congress or FDA (DHHS).⁶ ⁷

In the United States, saccharin may be used in tabletop sweeteners, carbonated and noncarbonated beverages, juice, chewing gum, dairy products, confections, desserts, puddings, jams, and jellies.

The ADI for saccharin is 15 mg/kg of body weight. Approximate consumption in the United States is about 12 percent of the ADI over a lifetime.

Saccharin is approved for use in major countries in North and South America, Europe, Africa, and Asia and in Australia.

**Sucralose**, or trichlorogalacto-sucrose (1,6-dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-degalactopyranoside), is approximately 600 times sweeter than sucrose. Although sucralose is made from sugar, it is not recognized by the body as a carbohydrate, is not metabolized by the body, and therefore does not contribute to calories in the diet. Like other high-intensity sweeteners, sucralose does not cause dental caries. The majority of sucralose is not absorbed, and it is excreted unchanged in the urine. Approximately 15 percent is passively absorbed, of which most is excreted in the urine unchanged. About 2 percent is changed to more water-soluble components and is excreted in the urine.

Sucralose is highly stable and can be used in cooking and baking. Approved for use in 1998, sucralose can be used in tabletop sweeteners, baked goods and desserts, dairy products, carbonated beverages, processed fruit products such as juices, jams, and pie fillings, and chewing gum.

The ADI for sucralose is 5 mg/kg of body weight. Approximate consumption in the United States is less than 20 percent of the ADI over a lifetime.

Sucralose requires no health warning or information on the label.

Sucralose has been approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia.
Waiting in the Wings

FDA is currently considering petitions to approve other intense sweeteners including neotame, alitame, and cyclamate.

Neotame is a versatile, new no-calorie sweetener composed of two elements of protein, the amino acids l-aspartic acid and l-phenylalanine, combined with two organic functional groups, a methyl ester group and a neohexyl group. It is approximately 7,000 to 13,000 times sweeter than sugar and as such captures the “essence of sweetness,” with only a very small amount required for use. The chemical composition of neotame makes it stable for use in baking.

Aside from its use as a sweetener, another potential application for neotame is as a flavor enhancer. Like other high-intensity sweeteners, although it contributes no sweetness functionality when used at very low levels, it can modify the flavor of a food or beverage.

Alitame is another sweetener made from amino acids (l-aspartic acid, d-alanine, and a novel amide [a specific arrangement of chemical bonds between carbon, nitrogen, and oxygen]). It offers a taste that is 2,000 times sweeter than that of sucrose and can be used in a wide variety of products including beverages, tabletop sweeteners, frozen desserts, and baked goods.

Only the aspartic acid component of alitame is metabolized by the body. As a result, alitame contains 1.4 kcal/g. Since alitame is such an intense sweetener, however, it is used at very low levels and thus contributes negligible amounts of calories. It is highly stable, can withstand high temperatures in cooking and baking, and has the potential to be used in almost all foods and beverages in which sweeteners are presently used.

Alitame has been approved for use in all food products, including beverages, in Australia, Mexico, and New Zealand. The Joint Expert Committee on Food Additives of the World Health Organization’s Food and Agriculture Organization has established an ADI for alitame of 1 mg/kg of body weight.

Cyclamate is approved for tabletop use in Canada and more than 50 countries in Europe, Asia, South America, and Africa. It is 30 times sweeter than sucrose, calorie-free, and heat stable and works synergistically with other sweeteners. Since 1970, however, the use of cyclamate has been banned in the United States on the basis of a study that suggested that cyclamates may be related to the development of bladder tumors in rats. Although 75 subsequent studies have failed to show that cyclamate is carcinogenic, the sweetener has yet to be reapproved for use in the United States.

Polyols

Polyols are another type of sweetener used in reduced-calorie foods. They differ from intense sweeteners in that they are considered nutritive; that is, they do contribute calories to the diet. Polyols are incompletely absorbed and metabolized, however, and consequently contribute fewer calories than sucrose.

The polyols commonly used in the United States include sorbitol, mannitol, xylitol, maltitol, maltitol syrup, lactitol, erythritol, isomalt, and hydrogenated starch hydrolysates. Most are approximately half as sweet as sucrose; maltitol and xylitol are about as sweet as sucrose.

Polyols are found naturally in berries, apples, plums, and other foods. They also are produced commercially from carbohydrates such as sucrose, glucose, and starch for use in sugar-free candies, cookies, and chewing gum.

Along with adding a sweet taste, polyols perform a variety of functions such as adding bulk and texture, providing a cooling effect or taste, preventing the browning that occurs during heating, and retaining the moisture in foods.

When consumed in excess, some polyols such as sorbitol may produce abdominal gas and discomfort in some individuals. As a result, foods that contain certain sugar alcohols and that are likely to be eaten in amounts that could produce such an effect must bear the statement “Excess consumption may have a laxative effect.”

Low-Calorie Sweeteners and Weight Management

Data from national health and food intake surveys, although not completely comparable, show that Americans, on average, increased their caloric intake by 9.64 percent in the past 20 years. That fact, combined with an aging and increasingly sedentary population, points to a continued, and perhaps heightened, struggle on the part of Americans to achieve and maintain healthy weights.
The following discussion highlights research into the specific effects of foods sweetened with low-calorie sweeteners on weight management. Because of the widespread use of aspartame and its ability to replace sugars, most investigations have involved this low-calorie sweetener.

**Weight Maintenance and Weight Loss.** When low-calorie sweetened foods and beverages are substituted for their full-calorie counterparts and no additional food is eaten to replace the calories saved, caloric reduction may be achieved. Pioneering work by Porikos and colleagues and by other investigators confirmed this effect, showing that study subjects consumed approximately 15 percent fewer calories over time when they consumed foods and beverages in which aspartame had been covertly substituted for sugar.12-15

Tordoff and Alleva found a similar effect when comparing the consumption of regular or aspartame-sweetened soda or no soda at all.16 Individuals who drink low-calorie sodas consumed significantly fewer calories than those who drink regular sodas or no soda. As in the previously mentioned studies, the subjects were not informed of the caloric content of the soda being consumed.

The question has been raised, however, whether people knowingly compensate for the calories saved by using a low-calorie sweetened product when they are aware that they are consuming such foods. For example, because they choose a diet soda, do people then feel freer to consume it with a piece of cake?

The examination of food intake records from national nutrition surveys provides a way to indirectly answer this question. Using U.S. Department of Agriculture nutrition survey data, Smith and Heybach compared the caloric intake records of persons consuming aspartame-sweetened foods and beverages with the caloric intake records of persons consuming foods and beverages not containing aspartame.17 Aspartame users consumed an average of 167 fewer calories per day than nonusers. Female aspartame users aged 35 to 50 years consumed 215 fewer calories per day than their study counterparts.

Other research has shown that the use of aspartame may help increase compliance with weight management programs. Kanders et al. measured weight loss, perceived feelings of energy and well-being, and other quality-of-life parameters among 59 free-living obese men and women who were knowingly on a weight-control program for 12 weeks.18 The experimental group was encouraged to use aspartame, whereas the control group was told to avoid all products sweetened with aspartame. Both groups participated in a weight-loss program that includes support groups, behavior modification, and exercise instruction.

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**Facts about Low-Calorie Sweeteners**

Given that so many Americans use low-calorie sweeteners and foods that contain them, it is probably natural that misperceptions abound. Here are some of the facts about low-calorie sweeteners and their effects on weight, eating behavior, and health.

- **FACT:** Americans face an increasing problem with obesity that foods and beverages sweetened with low-calorie sweeteners may help manage. Research shows that people who use foods and beverages sweetened with low-calorie sweeteners consume fewer calories than those who do not. Experts agree, however, that successful weight management requires more than just calorie reduction; it also involves a three-pronged approach of sensible eating, regular physical activity, and behavior management.

- **FACT:** Low-calorie sweeteners do not increase appetite and cravings for sweet foods. Indeed, studies show not only that low-calorie sweeteners do not affect appetite but also that they may even help people be more satisfied with eating plans that help them lose weight and keep it off.

- **FACT:** Foods and beverages sweetened with low-calorie sweeteners do not cause disease. These ingredients are some of the most closely studied ingredients in the food supply. A wealth of research confirms that they are safe for human consumption.

- **FACT:** Pregnant women can safely use low-calorie sweeteners unless otherwise advised by their physician. All Food and Drug Administration-approved low-calorie sweeteners are safe for consumption by pregnant women and children. Because diet and caloric intake are important for both of these groups, however, the advice of a physician or a registered dietitian is recommended.

- **FACT:** Low-calorie sweeteners do not cause cancer. Studies show that low-calorie sweeteners do not initiate or promote cancers. Although the level of low-calorie sweetener use has increased in the last several decades, no increase in cancer rates can be attributed to any sweetener.
In a larger study, these investigators placed 163 obese women on a 19-week multidisciplinary weight-loss program that included a balanced deficit diet and behavior modification. The women were randomly assigned to groups that either consumed or abstained from foods sweetened with aspartame.

Although both groups lost an average of 10 percent of their initial body weight, those who consumed aspartame were more successful in keeping the weight off in the long term. After 3 years, the no-aspartame group had, on average, regained all the weight. The aspartame group, however, had kept off about half of the lost weight, maintaining a medically significant average weight loss of 5 percent of their initial body weight.19, 20

An epidemiological study published in 1986 was widely publicized for its finding that saccharin users gained an average of 0.6 to 1.5 pounds more than nonusers over the course of a year.21 Significant methodological problems with the study, however, raise questions about the findings.22 The methodological problems include failure to determine subjects’ caloric intakes and exercise habits, reliance on memory to determine weight changes and sweetener use, and exclusion of women who had followed a weight-loss regimen. Furthermore, it is possible that the weight gain by saccharin users, which was statistically significant but biologically irrelevant, might have been greater without the use of the intense sweetener.

Low-Calorie Sweeteners and Appetite. Several years ago it was suggested that low-calorie sweeteners may stimulate appetite, thereby increasing food intake and promoting weight gain. To test this hypothesis, studies were conducted with intense sweeteners both in foods and beverages and in capsules. Several of these studies have also examined whether the knowing use of low-calorie foods and beverages encourages the consumption of larger amounts of foods and, hence, excess calories.

Food and Drink Studies. The appetite stimulation theory first drew widespread media attention when Blundell and Hill of the University of Leeds in the United Kingdom reported in 1986 that persons who were consuming highly sweetened solutions perceived themselves to be hungrier than when they were consuming water alone.23 The study, however, relied only on subjects’ hunger rat-
ings and did not measure their actual food intake, which is considered essential by psychologists and obesity experts. The impact of having persons consume intense sweeteners in unflavored solutions instead of in familiar and palatable beverages such as low-calorie sodas has also been questioned.

Blundell and colleagues conducted a subsequent study using solutions sweetened with aspartame, saccharin, and acesulfame potassium. Although increased appetite ratings were again observed for all three types of solutions, there were no increases in actual food intakes when they were measured 1 hour later.

Subsequent research has failed to confirm that intense sweeteners promote increased food intake. Canty and Chan found that high-intensity sweeteners did not raise hunger levels or the level of food consumption. Birch et al. found that 2- to 5-year-old children decreased their level of snack consumption 30 minutes after consuming an aspartame-sweetened beverage compared with the level of snack consumption of those who drank water. Anderson et al. found that aspartame consumption did not affect hunger or food intake in 9- to 10-year-old children compared with the effect of sodium cyclamate or sucrose consumption.

Several studies with adults have also shown that familiar aspartame-sweetened beverages do not affect short-term appetite or food intake when they are consumed before lunch or with meals compared with the effects of water. Although Black et al. found that consuming two cans of aspartame-sweetened soft drink significantly reduced appetite ratings but not actual food intake, a follow-up study revealed that the total volume of fluid consumed, not aspartame, was responsible for suppressing short-term hunger in adult males. Mattes found that neither aspartame nor sucrose alone, consumed as part of a breakfast cereal, significantly affected hunger ratings, intake of the next meal, daily calories consumed, or food selections. That study also showed that awareness of the caloric content of the cereal—whether it was the low-calorie or regular cereal—did not significantly affect intake.

Similarly, Rolls et al. studied the effect of awareness of the caloric content of regular or low-calorie puddings and gelatins containing sugar or aspartame, with a difference of about 200 calories, on the appetite and intake of nondieting, normal-weight adults. The study showed that awareness did not affect appetite or food consumption at the time of eating, nor did it affect food consumption from a buffet 2 hours later.

Drewnowski and colleagues studied the effects of aspartame on caloric intake in both normal-weight men and women and, in a similar study, in obese and lean women. They divided the subjects into four groups, each of which received different breakfast preloads: two provided 700 calories and contained either sucrose or aspartame with maltodextrin, and the other two provided 300 calories and either contained aspartame or were unsweetened. By this method, Drewnowski et al. were able to test both the effect of substituting aspartame for sucrose while maintaining sweetness and the effect of adding aspartame for sweetness.

In the study with obese and lean women, there were no significant differences in lunchtime food intakes among the groups that received the different breakfast preloads. In the study with normal-weight subjects, a slight increase in food intake at lunch was recorded for those who consumed the low-energy preloads. However, no overall compensation was observed, so those who consumed the low-energy preloads had lower caloric intakes for the day than those who consumed the high-energy preloads.

The investigators concluded that neither the addition of aspartame nor the substitution of aspartame for sucrose increased overall hunger ratings or food intake.

In a comprehensive scientific literature review, Rolls concluded that “Intense sweeteners have never been found to cause weight gain in humans... Although several investigators have reported increases in rating of hunger associated with aspartame, most have found that aspartame is associated with decreased or unchanged ratings of hunger.”

Capsule Studies. It has also been suggested that intense sweeteners may alter food intake not by affecting the sweet taste but by affecting certain hormones involved in appetite regulation. Blundell and colleagues found that subjects who consumed aspartame (235 or 470 mg) in capsules consumed less food than subjects who consumed a placebo capsule.

Other studies involving encapsulated aspartame at much higher doses, however, have not...
replicated such findings. Anderson and colleagues administered aspartame capsules with water 60 to 105 minutes before lunch and found that they had no effect on food intake or ratings of mood or hunger. Leon and Hunninghake gave healthy adults aspartame or placebo capsules daily for 24 weeks as part of a long-term aspartame safety study. The body weights of those who took the aspartame capsules did not differ significantly from those at the baseline after 6 months.

**The Role of Low-Calorie Sweeteners in a Healthful Diet**

The growing availability of affordable and palatable foods in combination with an increasingly sedentary lifestyle in industrialized countries underscores the important role that low-calorie sweeteners can play in achieving a healthful diet that supports healthy weights. Because they do not affect insulin levels, intense sweeteners also play an important role in the diets of people with diabetes.

The use of low-calorie sweeteners results in a wide range of food choices that can aid individuals in managing their caloric and carbohydrate intakes. Research shows that intense sweeteners can play a useful role in helping people achieve or maintain a healthy weight by providing good-tasting alternatives to foods and beverages that are typically higher in calories. According to Adam Drewnowski, Ph.D., professor at the University of Washington, “Low-calorie sweeteners offer the best method to date of reducing calories while maintaining the palatability of the diet.”

Although the theory has been put forth that intense sweeteners may have a paradoxical effect and stimulate appetite and hence promote weight gain, a variety of studies both in controlled laboratory environments and with free-living populations do not support this effect.

It is clear, however, that intense sweeteners or any food alone cannot make people succeed at weight management or the management of diseases such as diabetes. Such success involves a multidisciplinary approach of diet, physical activity, and behavior management. However, because they provide the pleasure of sweetness without adding calories or carbohydrates, low-calorie sweeteners can facilitate compliance with restricted eating plans. Within a sensible program for weight or disease management, intense sweeteners can play an important role in helping Americans achieve goals for weight and overall health.
## Low-Calorie Sweeteners Matrix

Extensive safety testing is conducted prior to FDA approval in the United States with mandated animal and human testing. All FDA-approved low-calorie sweeteners meet the same standard of safety.

<table>
<thead>
<tr>
<th></th>
<th>Acesulfame potassium</th>
<th>Aspartame</th>
<th>Saccharin</th>
<th>Sucralose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Composition</strong></td>
<td>Acesulfame potassium (6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide)</td>
<td>The amino acids aspartic acid and phenylalanine (N-L-aspartyl-L-phenylalanine 1-methyl ester)</td>
<td>1,2-benzenothiazol-3(2H)-one-1,1-dioxide</td>
<td>Trichlorogalacto-sucrose (1,6-dichloro-1,6-dideoxy-β-D-fructosuranosyl-4-chloro-4-deoxy-α-degalactopyranoside)</td>
</tr>
<tr>
<td><strong>Approximate Sweetening Power Compared with that of Sucrose</strong></td>
<td>200 times sweeter</td>
<td>200 times sweeter</td>
<td>300 times sweeter</td>
<td>600 times sweeter</td>
</tr>
<tr>
<td><strong>Caloric Value</strong></td>
<td>Calorie-free</td>
<td>4 kcal/g</td>
<td>Calorie-free</td>
<td>Calorie-free</td>
</tr>
<tr>
<td><strong>Metabolism/Excretion</strong></td>
<td>Not metabolized; excreted by the kidneys unchanged</td>
<td>Upon digestion, breaks down to aspartic acid, phenylalanine, and small amount of methanol, all of which are metabolized normally</td>
<td>Not metabolized; excreted by the kidneys unchanged</td>
<td>Not metabolized; excreted in the feces and urine</td>
</tr>
<tr>
<td><strong>ADI (Acceptable Daily Intake)</strong></td>
<td>15 mg/kg</td>
<td>50 mg/kg</td>
<td>15 mg/kg or 1 g/day</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td><strong>Approximate Consumption as percentage of ADI</strong></td>
<td>Less than 20%</td>
<td>Less than 10%</td>
<td>Approximately 12%</td>
<td>Less than 20%</td>
</tr>
<tr>
<td><strong>Additional Labeling Requirements</strong></td>
<td>None</td>
<td>Must bear a label statement that product contains phenylalanine</td>
<td>Must bear a label statement that saccharin has caused cancer in laboratory animals</td>
<td>None</td>
</tr>
<tr>
<td><strong>Date Received Initial FDA Approval for Safe Use in Foods</strong></td>
<td>1988</td>
<td>1981</td>
<td>1900—since 1970s interim approval</td>
<td>1998</td>
</tr>
<tr>
<td><strong>Foods/Beverages Approved for Use in the United States</strong></td>
<td>Tabletop sweeteners, beverages, processed foods</td>
<td>Tabletop sweeteners, beverages, processed foods</td>
<td>Tabletop sweeteners, beverages, processed foods</td>
<td>Tabletop sweeteners, beverages, processed foods</td>
</tr>
<tr>
<td><strong>Other Regions Where Approved for Use</strong></td>
<td>Approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia</td>
<td>Approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia</td>
<td>Approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia</td>
<td>Approved for use in major countries in North and South America, Europe, Africa, and Asia, and in Australia</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Highly stable; can be used in cooking and baking</td>
<td>Loses sweetness when exposed to high heat; add to foods at end of cooking cycle</td>
<td>Highly stable; can be used in cooking and baking</td>
<td>Highly stable; can be used in cooking and baking</td>
</tr>
</tbody>
</table>


References


7. Federal Food, Drug and Cosmetic Act, Section 403(o).


43. Memorandum from M. DiNovi, Chemistry Review Branch, to P. Hansen, Biotechnology Policy Branch, Food and Drug Administration; Apr 28, 1994.