

Ten Facts about Aspartame

Unsettling people about a safe and beneficial food ingredient has its own public health consequences. Each year in the United States, approximately 41,000 new cases of cancer are attributable to obesity. About 14% of deaths from cancer in men and 20% of deaths from cancer in women are due to overweight and obesity.

Here are ten key facts about aspartame:

1. Aspartame enables food and drink manufacturers to deliver against commitments to tackle the health challenges of overweight and obesity.
2. An extensive body of scientific research shows that aspartame helps people to control their weight.
3. Aspartame is digested naturally to small amounts of common dietary components. It brings nothing new or different to our diets.
4. Aspartame is considered among the most thoroughly tested ingredients in our food supply.
5. There is no substance to allegations that the result of studies on aspartame are influenced by their source of funding.
6. Aspartame has been scrutinized repeatedly by regulatory authorities in the United States and around the world for more than 30 years. There is no basis for the allegation that aspartame has been approved improperly.
7. Claims about aspartame made by the Ramazzini Institute have been assessed and rejected by the Food & Drug Administration, the European Food Safety Authority and other regulatory authorities.
8. The Food and Drug Administration's conclusion that aspartame is safe for special population groups, including women who are pregnant, remains valid.
9. Production of aspartame is a much more efficient and sustainable use of natural resources than production of sugar.
10. Aspartame cannot simply be replaced by other low calorie sweeteners. Of all of the low calorie sweeteners, aspartame has a sweetness that most closely replicates the taste of sugar. It is, therefore, integral to many of the low calorie and no sugar products people in the United States and all over the world choose and enjoy.

Further details about each of these 10 facts appear on the following pages.

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1. Aspartame enables food and drink manufacturers to deliver against commitments to tackle the health challenges of overweight and obesity.

- Records from the earliest civilizations show that man has always valued foods that taste sweet. For several hundred years, sugar has been used to sweeten many of the foods and drinks that we consume, and with the invention of saccharin at the end of the nineteenth century, low calorie sweeteners offered a limited alternative.
- The introduction of aspartame 30 years ago, however, meant that the taste of low calorie products became acceptable to many more people. By providing an excellent sweet taste without the calories of sugar, aspartame makes a significant contribution to the efforts that food manufacturers are making to provide lower calorie alternatives to their regular products. Typical calorie savings are as follows:

Product	Serving size	Calories	
		With sugar	With aspartame
Sparkling soft drinks	12 oz	156	1
Powdered soft drinks	8 oz	86	5
Desserts	8 oz	150	75
Fruit yogurts	6 oz	196	81
Table top sweeteners	1 packet	16	<1

- The National Cancer Institute points out that daily physical activity, *balanced with appropriate calorie intake*, is one of the most effective ways of to avoid weight gain.
- In a recent survey conducted by the International Food Information Council, 60% of Americans said that they use products with low calorie/artificial sweeteners. When aspartame was first introduced, just one in five sparkling soft drinks were low calorie. Today, that figure is nearly one in three.

2. An extensive body of scientific research shows that aspartame helps people to control their weight.

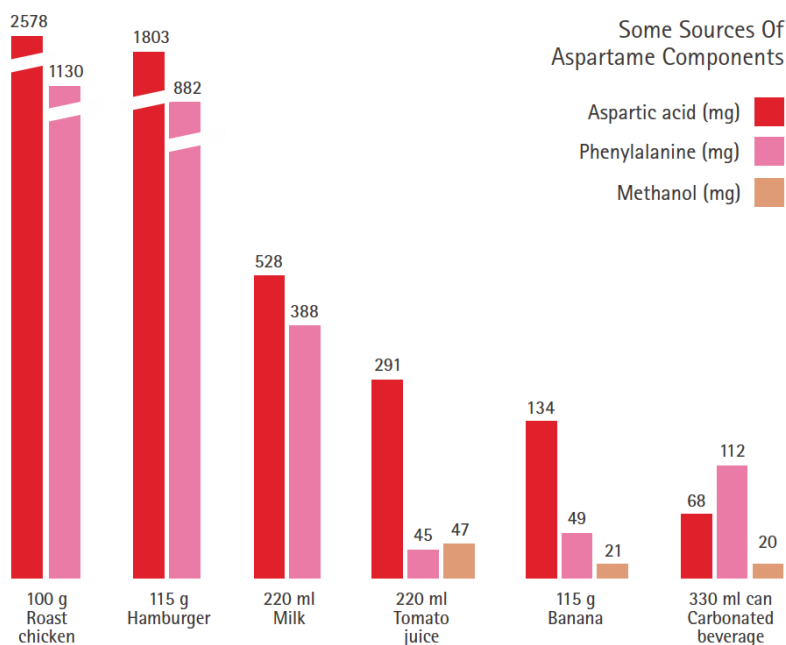
- Key evidence includes:
 - A study by Astrup et al published in the *American Journal of Clinical Nutrition* in 2002. This study showed that overweight subjects who supplemented their diets with sugar-containing foods and beverages for a ten-week period gained weight, while those who supplemented their diet with foods and beverages containing low-calorie sweeteners did not.
 - A study by Ludwig et al published in *The Lancet* in 2001. This study of schoolchildren showed that the more low calorie soft drinks were consumed, the less likely the children were to be obese.
 - A study by Fantino et al published in *Appetite* in 1998. This study showed that participants who drank a sugar-sweetened beverage consumed as many calories at a subsequent meal as those who drank an aspartame-sweetened beverage. The participants who consumed the aspartame-sweetened beverage therefore consumed substantially fewer calories overall.
 - A study by Blackburn et al published in the *American Journal of Clinical Nutrition* in 1997. This study showed that when aspartame was used as part of a 19-week weight control program, the sweetener helped participants to reduce their weight. Two years after the start of the study, aspartame users retained more of their weight loss than non-aspartame users.
 - A study by Tordoff and Alleva published in the *American Journal of Clinical Nutrition* in 1990. This study showed that normal weight subjects lost weight when they drank aspartame-sweetened cola rather than 'regular' cola every day for a period of 3 weeks.
 - A systematic review of studies on aspartame and weight by de la Hunty et al published in *Nutrition Bulletin* in 2006 concluded, "*The meta-analyses demonstrate that using foods and drinks sweetened with aspartame instead of sucrose results in a significant reduction in both energy intakes and bodyweight. The meta-analyses both of energy intake and of weight loss produced an estimated rate of weight loss of about 0.2 kg/week.*"
- When all of the scientific evidence that is available is considered, it is clear that, as would be expected, providing sweetness without calories is beneficial.

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3. Aspartame is digested naturally to small amounts of common dietary components. It brings nothing new or different to our diets.

- In 2002, the European Commission's Scientific Committee on Food stated:
"Aspartame is unique among the intense sweeteners in that the intake of its component parts can be compared with intakes of the same substances from natural foods."
- The two amino acids in aspartame are aspartic acid and phenylalanine. Phenylalanine is an essential amino acid, which means that we need to obtain it from our diet in order to remain healthy. Our bodies produce aspartic acid. Phenylalanine and aspartic acid are found in eggs, meat, cheese, fish, cereals, fruit and milk. When we consume aspartame, it is broken down in the digestive system to very small quantities of common dietary components. Aspartame does not, therefore, bring anything new to our diet.
- The phenylalanine in aspartame is present as the methyl ester. When we consume products sweetened with aspartame, it is broken down in the digestive system to small amounts of aspartic acid, phenylalanine and methanol, which comes from the methyl ester. Methanol is a common dietary constituent, occurring in fresh fruits and vegetables. There is as much methanol in a banana (21mg) and more than twice as much in a 220ml (8 oz) serving of tomato juice (47mg) as there is in a 330ml (12 oz) soft drink sweetened with aspartame (20mg). Traces of methanol also occur naturally in our blood, in our saliva, and on our breath. Our bodies themselves produce 300-1200mg of methanol per day.

It is true that, like many other components of our food, methanol in large quantities is toxic.



These quantities are at least hundreds of times higher than those found in bananas, tomato juice or an aspartame-sweetened beverage. The amount of methanol in foods and drinks is not harmful. Nevertheless, some scaremongers have sought to unsettle people about aspartame by claiming that the very small amount of methanol represents a health hazard, which is simply untrue.

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4. Aspartame is considered among the most thoroughly tested ingredients in our food supply.

- Aspartame has been the subject of over 200 scientific studies, many of which have been conducted at internationally renowned research institutes and universities.
- Aspartame was first approved in the United States and Canada in 1981. The Canadian Health Protection Branch wrote in its Information Letter, *"The data on the safety of aspartame are the most comprehensive ever received by the Health Protection Branch in support of a food additive."*
- The science on aspartame has been reviewed by the Joint Expert Committee on Food Additives of the World Health Organization and the United Nations Food and Agriculture Organization, by the European Food Safety Authority and the European Commission's Scientific Committee on Foods, and by the regulatory authorities in more than 100 countries around the world. All of these bodies have found aspartame to be safe and have approved its use as a food ingredient.
- Aspartame is approved for use in foods and beverages all around the world. Contrary to myths which circulate from time to time, aspartame is not "banned" anywhere.
- There is extensive evidence from studies conducted with human volunteers that aspartame has no adverse effects. For example, Professors Leon and Hunninghake working at the University of Minnesota published a study in the *Archives of Internal Medicine* in which they gave volunteers the amount of aspartame equivalent to that found in 30 cans of diet soft drink, every day for a period of six months. There were no adverse effects.
- A comprehensive review of every scientific study ever conducted on aspartame, published in the September 2007 edition of *Critical Reviews in Toxicology*, reaffirmed the safety of aspartame. A panel of internationally renowned experts in relevant scientific disciplines reviewed more than 500 studies, articles and reports on aspartame, concluding:

"The weight of existing evidence is that aspartame is safe at current levels of consumption... No credible evidence was found that aspartame is carcinogenic, neurotoxic, or has any other adverse effect on health."

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5. There is no substance to allegations that the result of studies on aspartame are influenced by their source of funding.

- Allegations that industry-funded studies have shown aspartame to be safe while "independent" research has shown adverse effects date back to claims made by Dr Ralph Walton that were circulated on the internet in 1999. Walton claimed that of 166 articles published in medical journals between 1980 and 1985, 74 studies that were financed by the industry showed aspartame to be safe, while of 92 independently funded articles, 84 identified adverse health effects.
- Careful reading of Walton's material, however, shows that, of the 92 pieces of "research", 85 (not 84) were identified as showing an adverse reaction to aspartame. However, of the 85:
 - 10 studies actually involved aspartate and not aspartame. Aspartate is the salt of aspartic acid. Aspartic acid is a very common component of food. These studies are irrelevant to aspartame safety.
 - 18 of the studies did not actually draw any negative conclusions about aspartame.
 - 5 were review articles, not peer-reviewed studies.
 - 2 were "brief reports" or "case reports", not peer-reviewed studies.
 - 5 were anecdotes, based on the writers' observations of patients.
 - 11 were conference proceedings, which are not peer-reviewed studies.
 - 19 were letters to various medical journals.
 - 3 were different reports of the same study.
 - 2 were exact duplicates of other documents appearing in the list.
 - 3 were different reports of the same allegations.
- There are methodological and other questions relating to the remaining documents, such as the use of abuse doses of aspartame in animal trials. In some of the studies, the animals were fed in a single day the amount of aspartame equivalent to that which a human being would ingest in 1,000 liters of soft drink.

In conclusion, it is clear that Walton's allegations have little relevance to the facts.

6. Aspartame has been scrutinized repeatedly by regulatory authorities around the world for more than 30 years. There is no basis for the allegation that aspartame has been approved improperly.

- The first product with aspartame to be marketed was a tabletop sweetener that was sold in pharmacies in France from 1979.
- The United States Food & Drug Administration (FDA) approved aspartame for use in dry products in 1981 and for use in carbonated beverages in 1983. Before the FDA approved aspartame in 1981, the studies on the sweetener were evaluated independently by the FDA and by the Universities Associated for Research and Education in Pathology (UAREP). In addition, shortly after the approval of aspartame for use in dry products, Dr. Nauta, chairman of a Public Board of Inquiry that had been set up in 1980 to resolve some remaining questions, wrote to the Commissioner of the FDA and stated: "We wish to express our endorsement of your final decision in this matter."
- In 1987, the General Accounting Office of the US Congress reviewed the process, which led to the FDA's 1981 approval of aspartame in dry products, and concluded that the Administration had acted properly. The FDA affirmed the safety of aspartame no fewer than twenty-six times leading up to the agency's approval of aspartame as a general purpose sweetener in 1996.
- Aspartame has been reviewed and found safe by the Joint Expert Committee on Food Additives of the United Nations Food and Agriculture Organization and the World Health Organization, by the European Food Safety Authority and by regulatory agencies in more than 100 countries, including:

Food Standards Australia New Zealand

Health Canada

Ministry of Health, China

Danish Food Institute

National Board of Trade and Consumer Interests, Finland

Ministere d'Affaires sociales et de l'Emploi, de la Santé et de la Famille, France

Bundesministerium für Jugend, Familie, Frauen und Gesundheit, Germany

National Centre for Hygiene, Food Control and Environmental Protection, Iceland

Ministero della Sanita, Italy

Ministry of Public Health, The Netherlands

Directorate of Health, Norway

Ministerio de Sanidad y Consumo, Spain

Statens Livmedelsverk, Sweden

Bundesamt für Gesundheitswesen, Switzerland

Department of Health and the Ministry of Agriculture, Fisheries and Food, United Kingdom

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7. In May 2006, the European Food Safety Authority (EFSA) unequivocally rejected claims by Morando Soffritti of the Ramazzini Institute (ERF) based on a rat study that aspartame was unsafe.

- In April 2007, the Food & Drug Administration issued a statement which included the following comments:

"FDA could not conduct a complete and definitive review of the study because ERF did not provide the full study data. Based on the available data, however, we have identified significant shortcomings in the design, conduct, reporting, and interpretation of this study. FDA finds that the reliability and interpretation of the study outcome is compromised by these shortcomings and uncontrolled variables, such as the presence of infection in the test animals.

"Additionally, the data that were provided to FDA do not appear to support the aspartame-related findings reported by ERF."

In April 2007, Dr Soffritti made further allegations and referred to a second rat study on aspartame. This material was reviewed by EFSA, who again concluded that there was no reason to change its opinion. In 2010, Dr Soffritti published a paper based on a mouse study on aspartame. In February 2011, EFSA announced its conclusion that the validity of the study could not be assessed and its results could not be interpreted.

In addition, the design and conduct of work at the Ramazzini Institute has been criticized by the United Kingdom Department of Health Committee on Carcinogenicity and by the French food safety agency (L'Agence Française de Sécurité Sanitaire des Aliments).

- The following points are relevant to evaluation of claims about aspartame safety by the Ramazzini Institute:
 - The laboratory at which the Ramazzini work is conducted does not follow internationally recognized Good Laboratory Practice (GLP) procedures. The rat colony is not specific pathogen free.
 - The Ramazzini Institute does not reveal the source of its funding.
 - The Ramazzini Institute refuses to provide government regulators with full access to its results. For example, only 70 pathology slides were provided to EFSA following the first Ramazzini rat study on aspartame in 2005. This compares with approximately 39,000 slides from carcinogenicity studies on aspartame that were submitted to the Food and Drug Administration before aspartame was first approved in the United States.

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8. The Food and Drug Administration's conclusion that aspartame is safe for special population groups, including women who are pregnant, remains valid.

- Experts have cautioned changing aspartame recommendations based on a paper by Halldorsson et al, which alleges a link between preterm births and consumption of low calorie soft drinks.
- On February 28, 2011, EFSA announced that, following its review of the paper by Halldorsson et al, it saw no evidence to support a causal relationship between the consumption of low calorie soft drinks and preterm delivery.
- The paper and its conclusions have been criticized by epidemiologists for multiple reasons. These include:
 - Studies conducted using multiple generation animal models have concluded that aspartame is safe for mothers and developing babies. No adverse effects have ever been found.
 - In studies with large sample sizes, weak associations appear significant in statistical analyses due to the sheer numbers of subjects. The observed associations in this study are all weak (i.e., odds ratios are less than 2.0).
 - Despite the very large sample size (59,334 women), the authors had to merge three high intake subgroups into one to demonstrate statistical significance. If there had been a clear dose-response relationship, the merging of these categories would not have been necessary.
 - Only beverages with low calorie sweeteners were considered – not other sources of low calorie sweeteners. Intake was assessed only once during the entire pregnancy. All low calorie sweeteners, despite the fact that they have very different properties, were lumped together as a single variable in the study.
 - As with many fruits and vegetables, a small amount of methanol is produced and immediately broken down after aspartame is consumed. The authors speculate that this production could be related to their findings. But the amount of methanol produced from the aspartame in a 12 oz soft drink is the same as that contained in a medium-size banana, and less than half that in 6 oz of tomato juice. A link to methanol is implausible.
 - In its speculations about aspartame, the paper ignores the fact that aspartame brings nothing new to our diets.
 - The researchers themselves state in the paper, "*We cannot exclude that our findings may be a result of unidentified and unadjusted confounders.*" Dr Halldorsson has expressed the opinion that this study does not provide evidence of a causal relationship.

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9. Production of aspartame is a much more efficient and sustainable use of natural resources than production of sugar.

- To make the sugar that we eat, the raw materials, including sugar beet, sugar cane and corn starch, are harvested and shipped for refining. The refining process entails extracting the sugar from the crop by crushing, chopping or grinding and treatment with water.
- Aspartame is made using a fermentation process to produce amino acids from a feedstock of molasses (a thick syrup from sugar cane or beet), soy and corn. The amino acids are then combined to form aspartame crystals. These crystals are purified and converted into finished aspartame.
- Aspartame is almost 200 times sweeter than sugar, which means that much less is required to sweeten foods and drinks. As a result:
 - Less packaging is needed;
 - Emissions from manufacturing and transportation are reduced;
 - Natural resources are conserved;
 - The carbon footprint is reduced; and
 - Less space is required for storage.
- The farming of sugar impacts heavily on the land, with topsoil being lifted with the crop during harvest. This causes extra carbon emissions during manufacturing, adds to weight during transportation and requires further resources during cleaning. Much less arable land is required to produce aspartame, meaning that the average productivity of the land is greatly increased and soil erosion is reduced.
- The agrochemical consumption associated with aspartame is between 0.4 and 1% of that associated with sugar. It is 0.4% when compared to sugar from cane, 0.9% when compared to high fructose corn syrup, and 1% when compared to sugar from beets.
- The amount of water used to produce aspartame is less than 2% of that used in the production of sugar.
- Aspartame has a longer storage life than sugar, which means that it's less prone to degradation and that waste is decreased. Further, no temperature controlled storage facilities are required for aspartame, unlike some sweetening systems, so energy consumption is reduced.

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10. Aspartame cannot simply be replaced by other low calorie sweeteners. Of all of the low calorie sweeteners, aspartame has a sweetness that most closely replicates the taste of sugar. It is, therefore, integral to many of the low calorie and no sugar products people in the United States and all over the world choose and enjoy.

- Aspartame has a taste profile that closely matches that of sugar. Numerous taste tests have shown that most people cannot tell the difference between products sweetened with aspartame and those sweetened with sugar. In one test, consumers were asked to taste two equally sweet samples of water. One sample was sweetened with aspartame, the other with sugar. When asked which sample was sweetened with sugar, 57% picked the sample actually sweetened with aspartame.
- Per capita consumption of low calorie sparkling beverages is highest in those countries where leading products are sweetened with aspartame alone (such as the United States) or with blends that include a high proportion of aspartame (as in the United Kingdom). In the United States, per capita consumption of low calorie sparkling drinks is almost 16 gallons per annum, in Belgium more than 9 gallons, in the UK almost 8 gallons and in the Netherlands and Ireland almost 6 gallons. In all of these markets, the leading low calorie beverage brands are sweetened with aspartame alone or with aspartame-rich blends.

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