



## Q&A'S ON ASPARTAME

### 1. What is aspartame?

- Aspartame is a low/no calorie sweetener, approved by global food safety authorities, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA).
- Aspartame contains two amino acids (compounds that combine to make proteins); aspartic acid and phenylalanine, which are found naturally in most protein-containing foods, including meats, dairy products and vegetables, and used by consumers on a daily basis.

### 2. Is aspartame safe?

- Yes. Aspartame has been the subject of an overwhelming number of scientific studies and has been thoroughly researched and approved for global use. In fact, food safety authorities including the Food and Drug Administration (FDA), the Joint Expert Committee on Food Additives (JECFA) of the World Health Organization (WHO) and Food and Agriculture Organization (FAO) and the European Food Safety Authority (EFSA) have reviewed aspartame and found that its use is safe.
- In 2013, EFSA re-confirmed the safety of aspartame after undertaking the most comprehensive risk assessment of aspartame to date.
- Moreover, aspartame, along with all approved low/no calorie sweeteners, offer benefits that further public health objectives on sugar intake reduction and ultimately assist in weight and diabetes management, as well as with dental health – and has been safely used for more than 40 years.
- Aspartame is a simple compound made from two amino acids and a methyl group, all of which occur naturally in the diet and are consumed in larger amounts from other normal dietary sources.
  - Upon digestion, aspartame breaks down in our gut to phenylalanine, aspartic acid and a small amount of the organic compound methanol. Phenylalanine is an essential amino acid. Methanol is found naturally in the body and in many foods.
  - The level of methanol in aspartame is insignificant compared to that found in many natural foods. For example, tomato juice contains six times as much methanol as a comparable serving of soft drink sweetened with aspartame.
- Like all ingredients, low/no calorie sweeteners, like aspartame, should be consumed, in moderation, as part of an overall balanced diet and healthy lifestyle.
- Research has shown that our intake of aspartame is well below the acceptable daily intake (ADI) level set by the authorities (Magnuson et al, 2016; Martyn et al, 2018; Carvalho et al, 2022). The ADI is a measure of the amount – of low/no calorie sweeteners in this case – which we can consume on a daily basis, over a lifetime, without an appreciable health risk. It is based on the amount of a sweetener that was found to have no adverse effects in animal studies, divided by a safety factor of 100. The 100-fold safety factor takes into account potential differences between animals and humans, as well as among different population groups ensuring the safety of the most vulnerable including children and pregnant women.



### **3. What are the key benefits of aspartame and other similar low/no calorie sweeteners?**

- Aspartame, along with all approved low/no calorie sweeteners, offer benefits that further public health objectives on sugar intake reduction and ultimately assist in weight and diabetes management, as well as with dental health. These sweeteners are used on a daily basis, and have been approved by global safety authorities, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA).
- And given that aspartame is one of the most thoroughly researched ingredients in the world, there is significant evidence that shows that, as other low/no calorie sweeteners, does not raise blood glucose levels or affect blood glucose control. Importantly, low/no calorie sweeteners have made it possible for a wider range of lower-sugar products to be available, providing people with diabetes with a greater choice of foods and drinks that are suitable for them.
- All approved low/no calorie sweeteners offer individuals benefits that help reduce overall calorie intake and meet the dietary guidelines recommendations for reduction of excessive sugar consumption while still enjoying sweet taste. When consumed in moderation, low/no calorie sweeteners can help achieve lower calorie intake and help with reducing excess body weight.
- Additionally, low/no calorie sweeteners can be beneficial also to oral health as they do not contribute to tooth decay. Indeed, low/no calorie sweeteners are non-fermentable ingredients, meaning that they cannot be broken down by oral bacteria and thus do not contribute to tooth decay. Due to their non-fermentable nature, low/no calorie sweeteners are frequently used in sugar free chewing gums, which have been shown to contribute to the neutralisation of plaque acids. Plaque acids are a risk factor in the development of dental caries.

### **4. Why is there a review of aspartame by two international bodies?**

- In an unprecedented step, aspartame is being reviewed simultaneously by two international bodies - the Joint FAO/ WHO Expert Committee on Food Additives (JECFA) and WHO's International Agency for Research on Cancer (IARC).
- JECFA first evaluated aspartame in 1981 and found it to be safe. In 2021, upon the request of Codex Alimentarius Commission and with the endorsement of all Codex member countries, JECFA scheduled aspartame for 're-review' at the forthcoming meeting of 27th June – 6th July 2023, where it will evaluate all the new safety data available.
- IARC is a research organisation. It is not a food safety agency, nor does it make health recommendations. Its objective is to promote international collaboration in cancer research.
- While JECFA will update its risk assessment exercise, IARC will review aspartame's potential carcinogenicity. An overview of IARC's classification system is available [here](#).
- The result of the summary evaluations of IARC and JECFA will be made available together, on July 14, 2023, and is confidential until the summary of the evaluations of IARC Monographs Volume 134 is published online, at 00:30 CEST, 14 July, by The Lancet Oncology, and simultaneous publication of the JECFA findings on the WHO website.
- ISA joins global food safety agencies in trusting the scientific rigor of the comprehensive food safety review of aspartame by the World Health Organization's Joint FAO/WHO Expert Committee on Food Additives (JECFA) and we look forward to the full publication of those findings.



## 5. Do we need more research on aspartame's safety?

- Aspartame is one of the most thoroughly researched ingredients in history, reviewed by over 90 food safety agencies across the globe, including the European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA).
- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) in the recent review reconfirmed aspartame's safety and found no need to change the Acceptable Daily Intake (ADI) based on this wealth of scientific evidence.

## 6. Should people consume low/no calories sweeteners in moderation?

- All food and drink should be consumed in moderation and be part of balanced diet that includes a variety of products from all food groups.
- Our intake of low/no calorie sweeteners is well below the acceptable daily intake (ADI) - which is the amount we can consume daily in our diet, over a lifetime, without any adverse health effect - which has been set by safety authorities around the world. (Martyn et al, 2018) The ADI is calculated to leave a substantial margin of safety. It also takes into account sensitive sub-populations, such as children or pregnant women. These safety authorities have also repeatedly confirmed that low/no calorie sweeteners are safe to consume.
- Moreover, low/no calorie sweeteners are used in very small amounts in foods, drinks and tabletop sweeteners to provide sweet taste with fewer or virtually no calories. As regulated ingredients, the amount of low/no calorie sweeteners used in such food and drink products is determined by their acceptable daily intake, to ensure we avoid overconsumption.

## 7. Do low/no calorie sweeteners such as aspartame, cause cancer?

- No. Aspartame is one of the most thoroughly researched ingredients in the world and approved by global food safety authorities, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA).
- Moreover, EFSA has reviewed aspartame twice, including the most comprehensive risk assessment of aspartame ever undertaken in 2013, and based on the extensive scientific evaluation of all available data, EFSA ruled out **any potential risk of causing cancer and reconfirmed that aspartame is safe.**

## 8. Are low/no calorie sweeteners such as aspartame safe also for pregnant women?

- Yes. Consumption of low/no calorie sweeteners, within the acceptable daily intake (ADI) set by the regulatory authorities, is safe during pregnancy.
- Specific safety studies looking at consumption of sweeteners during pregnancy are required as part of the approval process for food additives including sweeteners. As such, if a sweetener was found to cause adverse effects in pregnancy it would not be approved for use.
- The variety of foods and drinks sweetened with low/no calorie sweeteners can help satisfy a pregnant woman's taste for sweetness while adding few or no calories.
- Pregnant and breastfeeding women, however, do need to consume adequate calories to nourish the foetus or infant and should consult with a physician about their nutritional needs. It is important to remember that weight control remains a priority in pregnancy.



## 9. Are low/no calorie sweeteners such as aspartame safe also for children?

- Yes, low/no calorie sweeteners are also safe for children. In fact, aspartame is one of the most thoroughly researched ingredients in the world and approved by global food safety authorities, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA), European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA).
- Moreover, the safety testing required before a food additive such as a sweetener can be approved includes the period of growth seen in children. As such, **if sweeteners were found to cause adverse effects during this life stage, they would not be approved for use.**
- It is important, however, to keep in mind that children, particularly young children, need ample calories for rapid growth and development. For this reason, in the European Union, low/no calorie sweeteners are not approved for use in foods for infants (defined as children under the age of 12 months) and young children (defined as children between 1-3 years).

## 10. Can aspartame and other low/no calorie sweeteners enable manufacturers to support public health objectives by reformulating products to reduce sugar and thus contribute to healthy food environments?

- Yes. At a time when the rates of obesity and NCDs continue to increase worldwide and the global Covid-19 pandemic has further exacerbated the burden of these health conditions, public health authorities are encouraging food manufacturers to replace sugar and reduce calories as part of their reformulation goals. Low/no calorie sweeteners, including aspartame, represent a helpful and necessary tool for creating such products.
- Manufacturers have responded with innovation and product development and have brought to the market foods and drinks with less calories.
  - To sustain and scale up these efforts, industry relies on low/no calorie sweeteners, including aspartame, as approved food ingredients which provide the consumer with choice.
  - The collective scientific evidence supports such strategy, as it has consistently demonstrated the safety and benefits of aspartame and other low/no calorie sweeteners. This is all the more important as we are facing a global pandemic which has led to changes in lifestyle, including eating behaviour, and is increasing the burden of NCDs.
  - To advance the efforts to tackle NCDs and their risk factors, the recognition of low/no calorie sweeteners, including aspartame, as a safe and useful alternative to sugar is helpful.
- Consuming a low/no calorie sweetened food or beverage sweetened with aspartame or another low/no calorie sweetener instead of the sugar-sweetened version can help reduce overall daily sugar intake. In turn, when used as part of a balanced diet and healthy lifestyle, this can help achieve lower energy intakes and help with lowering excess body weight.
- Thorough evidence shows that low/no calorie sweeteners, including aspartame, do not raise blood glucose levels or affect blood glucose control. The European Commission permits the following health claim, on the basis of the scientific evidence: *“consumption of foods/drinks containing low/no-calorie sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks”.*
- The availability of the approved low/no calorie sweeteners, including aspartame, has made possible the development of a wider range of lower sugar products that can



provide a greater choice for people with diabetes. As they provide no calories, low/no calorie sweeteners can also help in lowering excess body weight, which is a risk factor for diabetes.

- Aspartame and other low/no calorie sweeteners can be beneficial to oral health due to their properties. The European Commission has authorised the health claim that the consumption of foods containing low/no calorie sweeteners instead of sugar contributes to the maintenance of tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates.
  - *For example*, sugar free gum helps to stimulate the saliva flow in the mouth without providing any carbohydrates for the oral plaque bacteria to metabolize.

## 11. What is the Acceptable Daily Intake (ADI) and how is it established?

- The ADI is derived from the daily maximum intake that can be given to test animals throughout life without producing any adverse biological effects, known as the No-Observed Adverse Effect Level (NOAEL). The NOAEL is then divided by a 100-fold safety factor to establish the ADI. This ensures a margin of safety covering differences between test animals and humans and variation within the human population.
- The use of the ADI principle for toxicological evaluation and safety assessment of food additives is accepted by all regulatory bodies worldwide.
- The ADI is not intended to set a maximum safe level on a given day. Instead, it confers a guideline for daily consumption up to a maximum intake level that is safe. On the basis of the ADI, regulators additionally set usage levels of low/no calorie sweeteners in foods and beverages to further help ensure that consumption stays within safe levels. Since the ADI covers lifetime consumption of low/no calorie sweeteners, its margin of safety is sufficiently large not to cause concern in case a consumer's short-term intake, e.g., on a given day, is exceeding it.

## 12. Are low/no calorie sweeteners over-consumed?

- No. In fact, in 2018, a published review of the global literature regarding the intake of the most commonly used low/no calorie sweeteners concluded that, overall, the studies conducted to determine the exposures of low/no calorie sweeteners over the last decade **raise no concerns with respect to exceedance** of the individual sweetener ADIs among the general population globally (Martyn et al, 2018).
- The most refined and analytical exposure assessments of low/no calorie sweeteners to date have been conducted in Europe. The majority of the studies in Europe were conducted for the general population, with intakes calculated for the mean and high-level consumers.
- This research found that consumption of **low/no calorie sweeteners did not exceed the ADI**, even among high consumers (Huavere et al, 2012; Le Donne et al. 2017; Buffini et al, 2018; Tennant 2019; Tennant and Vlachou, 2019; Carvalho et al, 2022).
- Furthermore, several studies examined intakes in specific subgroups, including young children and people with diabetes (Dewinter et al, 2016; Martyn et al. 2016; Le Donne et al. 2017; Carvalho et al, 2022).