

Low calorie sweeteners factsheet: Safety

Low calorie sweeteners (LCS) are regulated within the European Union (EU) and are subject to rigorous safety assessments before being permitted for use in foods or drinks.

How are LCS assessed for safety in the EU?

The European Food Safety Authority (EFSA), Panel on Food Additives, and Nutrient Sources Added to Food (ANS) Panel carries out risk assessments, and provides scientific advice on all food additives (including sweeteners) and the amounts that can be used. Safety studies need to show that the sweetener in question:

- does not cause any adverse effects, including cancer
- does not affect reproduction
- is not stored within the body or metabolised into other potentially unsafe products
- does not cause allergic reactions

An **E number** means that the additive has passed safety tests and has been approved for use in the UK and in the rest of the EU. Even after approval, additives with E numbers are re-tested regularly to ensure they are still safe.

EU legislation also sets out the rules for the sale and use of LCS, the food categories in which they are permitted to be used and the maximum permitted levels allowed.

Are there safe consumption levels set for LCS?

As part of the approval process for the safety of each LCS, an **Acceptable Daily Intake (ADI)** level is set.

The ADI is: *“the estimated amount per kilogram of body weight that a person can consume, on average, every day over a lifetime without risk”.*

The ADI has a large inbuilt safety margin making it unlikely that the diet of any individual will provide this level. For example, an adult would have to consume around 14 cans of an aspartame-sweetened drink every day before reaching the ADI, assuming the sweetener was used in the drink at the maximum permitted level. In practice most drinks use aspartame in combination with other sweeteners, so the level is considerably lower.

What are some examples of ADIs?

Sweetener	E number	Acceptable Daily Intake (ADI) level
Acesulfame-K	E950	9 mg/kg body weight
Aspartame	E951	40 mg/kg body weight
Saccharin	E954	5 mg/kg body weight
Sucralose	E955	15 mg/kg body weight
Stevia	E960	4 mg/kg body weight

What about safety amongst the highest consumers?

Studies show that the average intake of LCS amongst adults in the EU is well below the ADI. In most cases, and as indicated in the relevant safety evaluations carried out by EFSA, even in high consumers, LCS intakes typically remain below the ADI.

Are there any concerns about use of LCS amongst vulnerable groups?

- **Pregnant women and children** – current scientific reviews have suggested LCS to be safe for children and pregnant women if consumed within the ADIs. Researchers have reported it is unlikely even in children that intakes will exceed the ADIs because of the variety of LCS on the market, resulting in a reduction in the intake of individual LCS, unless only one LCS is preferred.
- **Infants up to 3 years old** – sweeteners, like all food additives, are not permitted for use in foods for young children aged up to 3 years. Infants need enough calories for adequate growth and development, therefore low calorie options using sweeteners may not be suitable, and should not replace more nutritious foods such as fruit juice, milk and whole milk yogurts.
- **Phenylketonuria (PKU)** – this is a rare genetic disorder, that is screened for (heel prick test) at around 5 days after birth. People with PKU can't break down the amino acid phenylalanine, which can accumulate to harmful levels if not controlled with diet. Aspartame is metabolised to produce phenylalanine, aspartic acid and a small amount of methanol. Therefore in the UK, labelling of aspartame is mandatory in order to inform consumers with PKU of the presence of phenylalanine.



Where a food contains aspartame (aspartame or aspartame-acesulfame salt) it must be labelled:

"a source of phenylalanine"

Where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E-number, it must be labelled:

"contains aspartame (a source of phenylalanine)"

We cover some of the information above in the following FAQ document, which you may find helpful.

BNF answers some common questions on low calorie sweeteners...

What are low calorie sweeteners?

- LCS provide a sweet taste to food or drinks with the benefit of few or no calories. They can be added to foods or drinks (in tea, coffee or baking) and are used in many low calorie and sugar-free foods and beverages such as soft drinks, chewing gum, confectionery, frozen desserts, dessert mixes, yogurts and puddings.

What are the main types of low calorie sweeteners?

- There are two main types of LCS. Intense sweeteners include saccharin, sucralose, acesulfame K (ace-K) and aspartame. These are typically used as table top sweeteners and in low calorie soft drinks, and are so intensely sweet that only a tiny amount is needed. They are also used in sugar-free gum and low calorie yogurts. Bulk sweeteners provide fewer calories weight for weight compared to sugar, but have a similar bulk or volume. These are useful, for example, when preparing low calorie confectionery products. Examples of bulk sweeteners include the polyols (sugar alcohols) sorbitol, mannitol and xylitol.

What are the potential benefits of using low calorie sweeteners?

- The use of LCS may offer benefits in relation to weight management, diabetes management and dental health.

Do foods and drinks have to specify whether they contain low calorie sweeteners on their labels?

- By law, the addition of LCS to food or drink products must be clearly labelled as 'with sweetener(s)' on the packaging. Sweeteners will also be listed in the ingredients list where provided. Table top sweeteners containing polyols must carry the warning "excessive consumption may induce laxative effects".

How is the safety of low calorie sweeteners assessed?

- All LCS used in food and drinks sold in the EU have to undergo rigorous safety testing before being approved by the European Commission.

As part of the approval process for each sweetener, an Acceptable Daily Intake (ADI) level is set. The ADI is the estimated amount per kilogram of body weight that a person can consume, on average, every day over a lifetime without risk. This has a large inbuilt safety margin making it very unlikely that the diet of any individual will ever provide this level.

Are low calorie sweeteners safe for children to consume?

- Low calorie sweeteners are safe for children to consume. Children are very unlikely to have intakes near the ADI even if they regularly consume drinks or food products containing sweeteners. However, in the EU the use of sweeteners is prohibited in all foods specifically made for infants and young children aged up to three years, partly due to their increased energy requirements for optimal growth.

Are low calorie sweeteners safe for pregnant women?

- Consumption of approved LCS below the ADI level is safe during pregnancy. There is no evidence of any risks to the mother or her unborn child.

Are there any individuals who cannot consume low calorie sweeteners?

- There is a rare genetic condition known as phenylketonuria (PKU) that prevents the amino acid phenylalanine (a component of protein) from being broken down. Phenylalanine can accumulate to harmful levels if not controlled. Phenylalanine is found in many protein-containing foods. In addition, phenylalanine is a component of aspartame. All products that contain aspartame must, by law, clearly state on the label that they 'contain a source of phenylalanine'.