

Facts About Neotame

FDA Approved.

- On July 9, 2002, the U.S. Food and Drug Administration (FDA) affirmed neotame's safety and functionality by granting general use approval as a sweetener and flavor enhancer in foods and beverages.
- FDA has a detailed and extensive process for evaluating the safety and functionality of new food additives. This rigorous process included the review of more than 100 scientific studies and provides a high level of confidence in the safety of neotame.

Safe for use by the general population.

- The results of extensive research confirm that neotame is safe for use by the general population, including children, pregnant and lactating women, and people with diabetes.
- This research was done in both humans and animals using amounts of neotame that far exceed expected consumption levels.
- In addition, FDA has determined that no special labeling for phenylketonuric individuals is needed.

Handled through normal body processes.

- Neotame (N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester) is a derivative of the dipeptide composed of the amino acids, aspartic acid and phenylalanine.
- In humans, neotame is rapidly metabolized. The major metabolic pathway is hydrolysis of the methyl ester by esterases that are present throughout the body. This yields de-esterified neotame and methanol.
- Peptidases, which would typically break the peptide bond between the aspartic acid and phenylalanine moieties, are essentially blocked by the presence of the 3,3-dimethylbutyl moiety, thus reducing the availability of phenylalanine.
- The amount of methanol derived from neotame is exceedingly small relative to the amount of methanol derived from common foods such as fruits and vegetables and their juices. For example, the amount of methanol provided by tomato juice is about 200 times greater than that from neotame in a beverage.
- Neotame is completely eliminated in the urine and feces and does not accumulate in the body.

Meets consumer demand for great taste.

- Neotame will provide food and beverage companies with greater flexibility and value in developing new products because it can be used alone or in combination with other non-nutritive or nutritive sweeteners.
- As a sweetener, neotame can reduce or replace the sugar and caloric content of products while maintaining great taste.