

ASPARTAME - INFORMATION SHEET

THE COMPOUND

Aspartame is a non-nutritive intense sweetener. It is used as an alternative to sugar as a sweetener, but is added at much lower concentrations as aspartame is approximately 200 times sweeter than sugar. For this reason aspartame is particular used in 'diet' and 'low calorie' products. Aspartame is metabolised by gut esterases and peptidases to three common chemicals; the amino acids, aspartic acid and phenylalanine, and small amounts of methanol.

SOURCES

In New Zealand and Australia, approximately 70% of dietary aspartame exposure is estimated to come from consumption of carbonated beverages, with about 10% of exposure from consumption of tabletop sweeteners (Food Standards Australia New Zealand, 2003). Other foods contributing significantly to dietary exposure in New Zealand include confectionery, chocolate/cocoa/cappuccino drink bases, cordials/fruit drinks, flavoured yoghurts and mousses, jellies and milk-based puddings, flavoured milks, sweet biscuits, and sports, energy and weight management products.

POTENTIAL HEALTH EFFECTS

Aspartame has been claimed to cause a vast range of adverse health effects. However, consistent claims have mainly related to cancer, particular brain tumours (Olney *et al.*, 1996; Soffritti *et al.*, 2006; Soffritti *et al.*, 2007), neurological effects (epileptic seizures, headaches, changes in behaviour, cognition and moods) (Scientific Committee on Food, 2002) and allergic-type reactions (Geha *et al.*, 1993).

While debate still continues, anecdotal claims of adverse health effects due to aspartame have generally not been substantiated by rigorous scientific investigation. A representative example of this is:

Allergic-type reactions made up 15% of anecdotal complaints associated with aspartame evaluated by the Centers for Disease Control and Prevention (CDC) (Butchko *et al.*, 2002). Following an extensive multi-centre recruitment effort over four years, 21 subjects who were convinced that aspartame caused their allergic-type reaction, were included in a randomised, double-blind, placebo-controlled clinical study (Geha *et al.*, 1993). Subjects were evaluated in a clinical research unit over a five day period, receiving, in random order, capsules containing aspartame or placebo. Two subjects reacted to aspartame, but not placebo, two subjects reacted to placebo, but not aspartame, and 17 subjects reacted to neither aspartame nor placebo.

ESTIMATES OF DIETARY EXPOSURE



Average daily dietary exposures to aspartame have been estimated for New Zealand (1.69 mg/kg body weight) and Australia (2.56 mg/kg body weight) (Food Standards Australia New Zealand, 2003). Estimates for high consumers (90th percentile) were 3.9 mg/kg body weight for New Zealand and 5.3 mg/kg body weight for Australia.

Estimates of daily intakes of aspartame in the US were made on a regular basis from its approval in 1984 until 1992. High (90th percentile) intakes increased from 1.6 to 3.0 mg/kg body weight for the general population, while for 2-5 year children high intakes increased from 3.1 to 5.2 mg/kg body weight (Butchko *et al.*, 2002). A recent study of cancer incidence in the US estimated average aspartame intakes at 111 mg/day (1.9 mg/kg body weight for a 60 kg adult) (Lim *et al.*, 2006). Estimates of average daily aspartame intake from European countries were in the range 2.4-3.4 mg/kg body weight, while high consumer intakes were in the range 2.8-10.1 mg/kg body weight (Scientific Committee on Food, 2002). Average aspartame intakes in Korea were estimated to be in the range 0.06-0.9 mg/kg body weight, depending on age, with high (90th percentile) consumers having intakes of 4.6 mg/kg body weight (Chung *et al.*, 2005).

All estimates are well below ADI levels (40-50 mg/kg body weight/day).

FACTORS INFLUENCING RISK

Aspartame is unstable under conditions of prolonged heating and is inappropriate for use in cooking and baking (Kroger *et al.*, 2006). Aspartame also decomposes in liquids during prolonged storage. Aspartame-containing products are labelled to reflect these issues. Breakdown products include the metabolic breakdown products (aspartic acid, phenylalanine and methanol) and diketopiperazine. Breakdown results in loss of sweetness.

SAFETY ASSESSMENTS

The safety of aspartame has been considered by a range of regulatory organisations, their expert advisory groups and interested scientists.

Aspartame has been considered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1975, 1976, 1977, 1980 and 1981. The most recent assessment concluded that neither aspartame nor its breakdown product, diketopiperazine, caused brain tumours in rats (JECFA, 1981). An acceptable daily intake (ADI) of 40 mg/kg body weight was established for aspartame, while an ADI of 7.5 mg/kg body weight was established for diketopiperazine.

The European Commission's Scientific Committee on Food (SCF) expressed opinions on the safety of aspartame in 1984, 1988 and 2002 (SCF, 1985;1989;2002). On each occasion the Committee assessed any new data and reaffirmed the safety of aspartame. ADIs for aspartame and diketopiperazine were set at the same level as those set by JECFA.

The US Food and Drug Administration approved aspartame for use in 1984 and have subsequently reaffirmed its safety in 1996 (FDA, 1996). The FDA established a slightly higher ADI for aspartame of 50 mg/kg body weight.

Specific investigation into the carcinogenicity of aspartame have also been conducted by the European Commission's Scientific Committee on Food (SCF, 1997), the UK Committee on Carcinogenicity (COT) (COT, 1996), the European Food Safety Authority's Scientific Panels (Panel on Food Additives and Nutrient Sources added to Food, 2009; Scientific Panel on Food Additives Flavourings Processing Aids and Materials in Contact with Food, 2006) and the US FDA (FDA, 2007). In all cases it was concluded that aspartame is not carcinogenic. It is worth noting that, while the potential carcinogenicity of most food additives involves assessment through one and two long-term rodent studies, aspartame has been assessed as non-carcinogenic in four long-term rodent studies (Scientific Panel on Food Additives Flavourings Processing Aids and Materials in Contact with Food, 2006).

A number of non-regulatory safety assessments of aspartame have also been published in the scientific literature with equivalent conclusions drawn (Butchko *et al.*, 2002; Kroger *et al.*, 2006; Magnuson *et al.*, 2007).

SAFETY AND REGULATORY LIMITS

Safety limits are levels of dietary exposure that are without appreciable risk for a lifetime of exposure. Regulatory limits define the maximum amount of a substance that is permitted in a particular food.

Source	Limit Type	Limit
<i>Safety Limits</i>		
JECFA	Acceptable Daily Intake	40 mg/kg body weight/day
<i>Regulatory Limits</i>		
Australia New Zealand Food Standards Code*	Maximum Permitted Level	Confectionery 10,000 mg/kg Electrolyte drink and electrolyte drink base 150 mg/kg Brewed soft drink 1,000 mg/kg Formulated beverages GMP# Other processed foods, except where expressly excluded GMP#

* Standard 1.3.1 of the Australia New Zealand Food Standards Code also includes Maximum Permitted Levels for a related additive, aspartame-acesulphame salt. For concision these have not been included here, but can be viewed at:

http://www.foodstandards.gov.au/srcfiles/Standard_1_3_1_Additives_Part_2_v103.pdf

Aspartame is permitted in a range of processed foods at levels consistent with Good Manufacturing Practice. For aspartame, this means at the minimum level necessary to wholly or partially replace the sweetness due to sugars normally present in the food, or to act as a flavour enhancer in the food

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