



# **SÜSSSTOFFE IN DER KRITIK** **SICHERHEIT VON ASPARTAM & CO**

Jürgen König, Department für Ernährungswissenschaften der  
Universität Wien

# Was sind Süßstoffe?

Entsprechend den EU-Regelungen  
sind Süßstoffe

Lebensmittelzusatzstoffe, die

- verwendet werden, um  
Lebensmitteln einen süßen  
Geschmack zu verleihen oder
- als Tafelsüßen verwendet  
werden.

E-Nummer	Zusatzstoff
E 420	Sorbit
E 421	Mannit
E 953	Isomalt
E 965	Maltit
E 966	Lactit
E 967	Xylit
E 968	Erythrit
E 950	Acesulfam K
E 951	Aspartam
E 952	Cyclohexansulfamidsäure
E 954	Saccharin
E 955	Sucralose
E 957	Thaumatococcus
E 959	Neohesperidin DC
E 960	Steviolglykoside
E 961	Neotam

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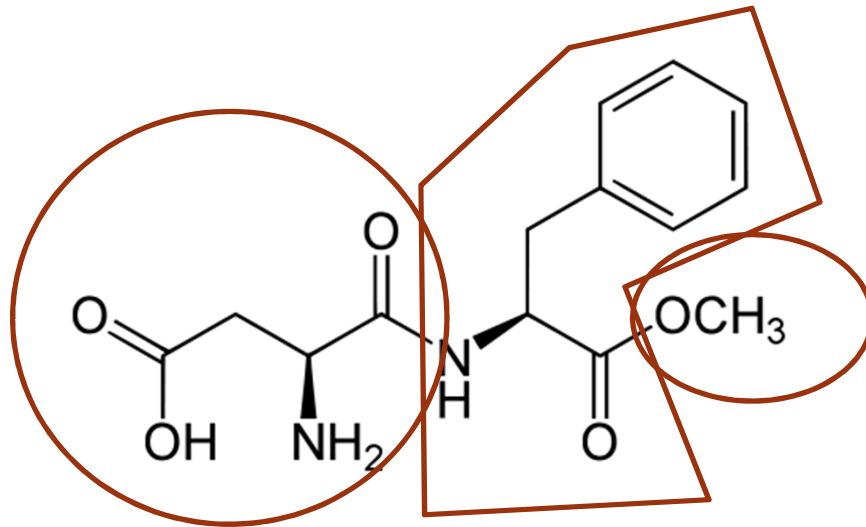
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# Aspartam



Asparagyl- Phenylalanin- methylester

Süßkraft: etwa 200 mal süßer als  
Saccharose



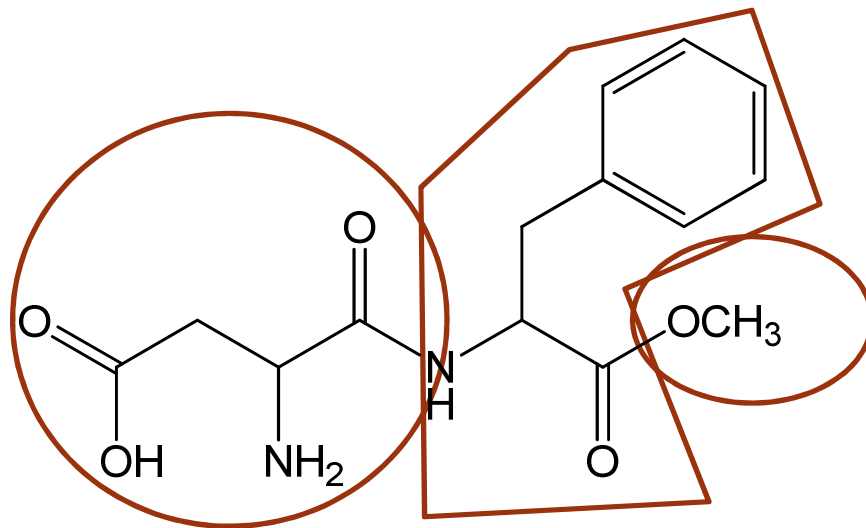
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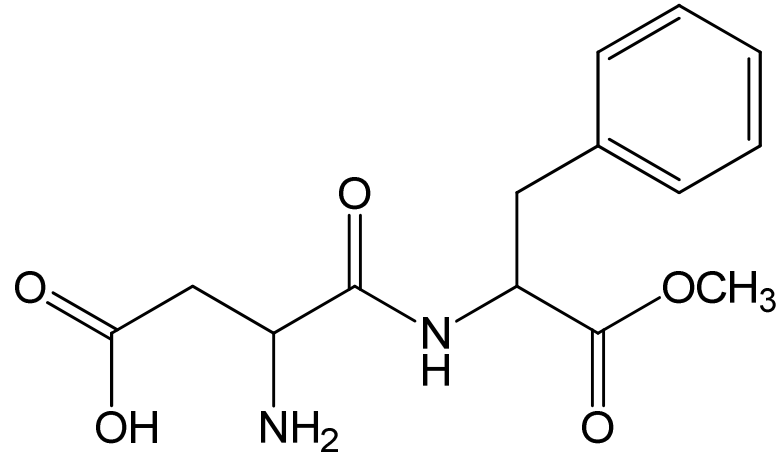


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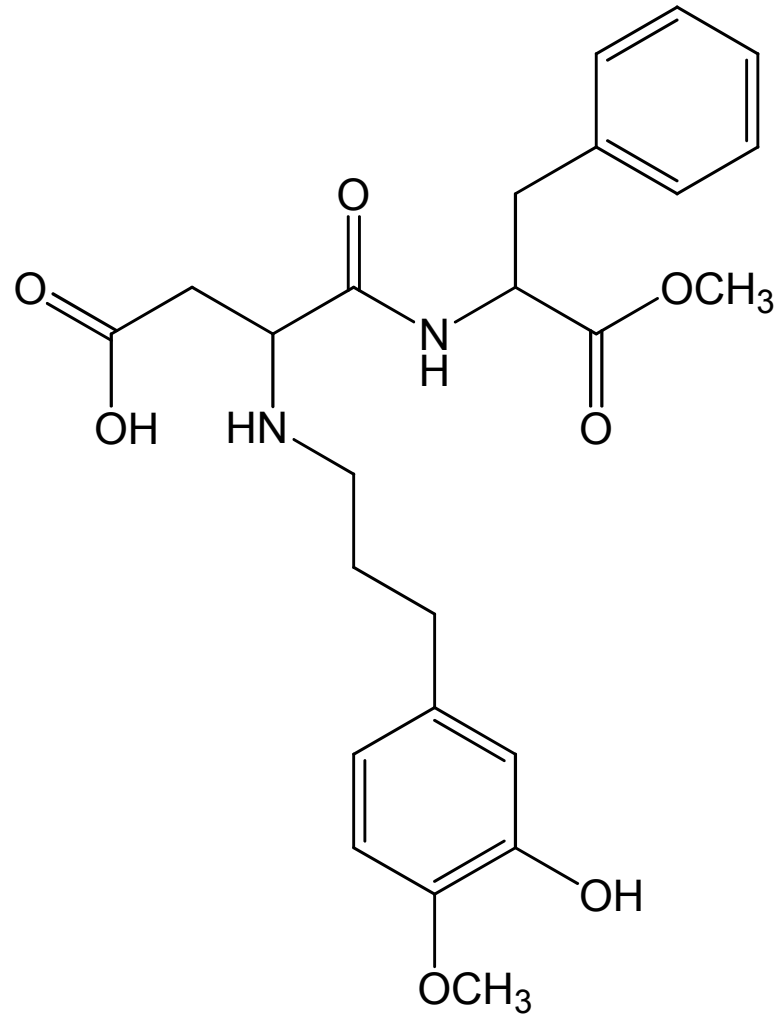


# Aspartam

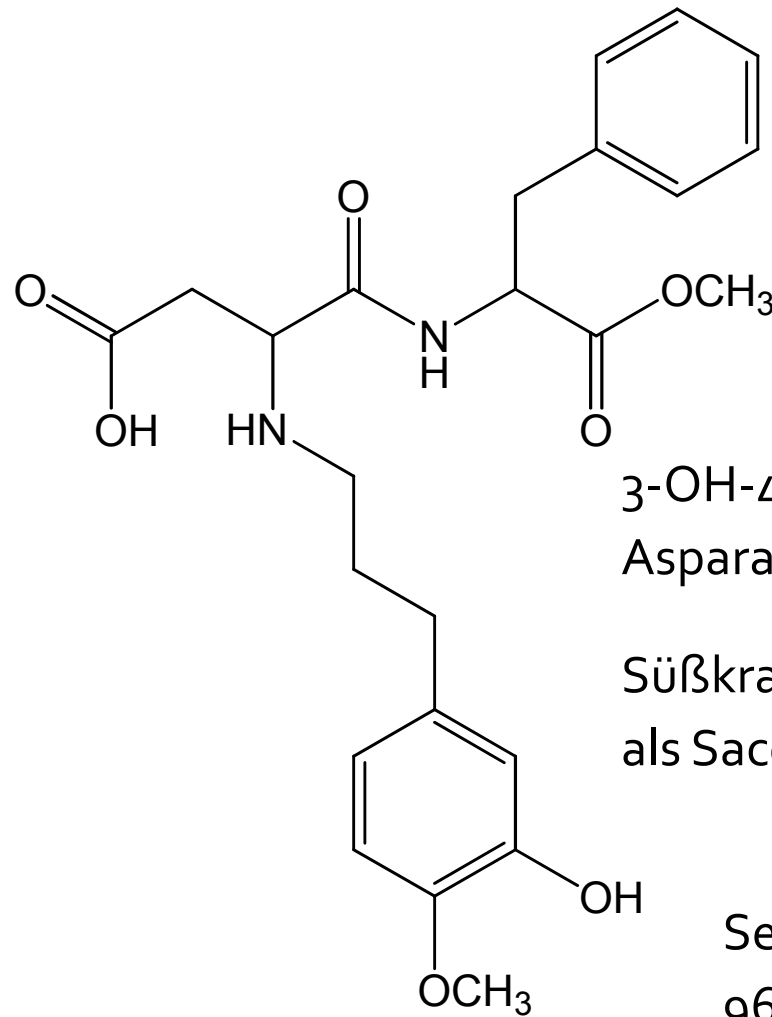




# Aspartam



# ■ Advantame



3-OH-4-Methoxyphenylpropan-  
Asparagyl-Phenylalanin-Methylester

Süßkraft: etwa 37000 (!) mal süßer  
als Saccharose

Seit 4. Juni 2014 in der EU als E  
969 zugelassen

# Aspartam: Zulassungen

Category number	Foods	restrictions/exception	Maximum level (mg/L or mg/kg as appropriate)
1.4	Flavoured fermented milk products including heat-treated products	only energy-reduced products or with no added sugar	1000
3	Edible ices	only energy-reduced or with no added sugar	800
4.2.2	Fruit and vegetables in vinegar, oil, or brine	only sweet-sour preserves of fruit and vegetables	300
4.2.3	Canned or bottled fruit and vegetables	only fruit energy-reduced or with no added sugar	1000
4.2.4.1	Fruit and vegetable preparations excluding compote	only energy-reduced	1000
4.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	only energy-reduced jams, jellies and marmalades	1000
4.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	only energy-reduced jams, jellies and marmalades	1000
4.2.5.3	Other similar fruit or vegetable spreads	only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar	1000
5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	only energy-reduced or with no added sugars	2000
5.2	Other confectionery including breath refreshing micro-sweets	only cocoa or dried fruit based, energy reduced or with no added sugar	2000
5.2	Other confectionery including breath refreshing micro-sweets	only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar	1000
5.2	Other confectionery including breath refreshing micro-sweets	only starch based confectionary energy reduced or with no added sugar	2000
5.2	Other confectionery including breath refreshing micro-sweets	only confectionary with no added sugar	1000
5.2	Other confectionery including breath refreshing micro-sweets	only breath-freshening micro-sweets, with no added sugar	6000
5.2	Other confectionery including breath refreshing micro-sweets	only strongly flavoured freshening throat pastilles with no added sugar	2000
5.3	Chewing gum	only with added sugars or polyols, as flavour enhancer	2500
5.3	Chewing gum	only with no added sugar	5500
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only starch based confectionary energy reduced or with no added sugar	2000
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only confectionary with no added sugar	1000
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only cocoa or dried fruit based, energy reduced or with no added sugar	2000
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only sauces	350
6.3	Breakfast cereals	only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy reduced or with no added sugar	1000
7.2	Fine bakery wares	only essoblaten - wafer paper	1000
7.2	Fine bakery wares	only fine bakery products for special nutritional uses	1700
9.2	Processed fish and fishery products including molluscs and crustaceans	only sweet-sour semi-preserves of fish and marinades of fish, crustaceans and molluscs	300
11.4.1	Table-top Sweeteners in liquid form		quantum satis
11.4.2	Table-top Sweeteners in powder form		quantum satis
11.4.3	Table-top Sweeteners in tablets		quantum satis
12.4	Mustard		350
12.5	Soups and broths	only energy-reduced soups	110
12.6	Sauces		350
12.7	Salads and savoury based sandwich spreads	only Feinkostsalat	350

Category number	Foods	restrictions/exception	Maximum level (mg/L or mg/kg as appropriate)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	Products in this category can also use additives that are allowed in the corresponding food counterparts categories	1000
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		800
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	only energy-reduced or with no added sugar	600
14.1.4	Flavoured drinks	only energy reduced or with no added sugar	600
14.2.1	Beer and malt beverages	only alcohol-free beer or with an alcohol content not exceeding 1.2 % vol; 'Bière de table/Tafelbier/Table beer' (original wort content less than 6 %) except for 'Oborgärges Einfachbier'; Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH; Brown beers of the 'oud bruin' type	600
14.2.1	Beer and malt beverages	only energy-reduced beer	25
14.2.3	Cider and perry		600
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol		600
15.1	Potato-, cereal-, flour- or starch-based snacks		500
15.2	Processed nuts		500
16	Desserts excluding products covered in category 1, 3 and 4	only energy-reduced or with no added sugar	1000
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms		2000
17.2	Food supplements supplied in a liquid form		600
17.3	Food supplements supplied in a syrup-type or chewable form		5500



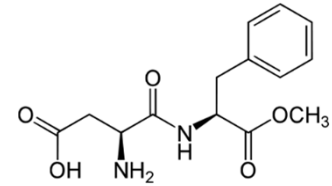
# Aspartam: Zulassungen

Lebensmittelkategorie	Einschränkungen	Höchstgehalt (mg/kg)
Aromatisierte fermentierte Milchprodukte, auch wärmebehandelt	Nur brennwertverminderte oder ohne Zuckerzusatz hergestellte Produkte	1000
Speiseeis	Nur brennwertverminderte oder ohne Zuckerzusatz hergestellte Produkte	800
Obst und Gemüse in Essig, Öl oder Lake	Nur süßsaure Obst- und Gemüsekonserven	300
Kaugummi	Nur ohne Zuckerzusatz	5500
Senf		350
Soßen		350
Aromatisierte Getränke	Nur brennwertverminderte oder ohne Zuckerzusatz hergestellte Produkte	600
Apfelwein und Birnenwein		600
Knabbereien auf Kartoffel-, Getreide-, Mehl- oder Stärkebasis		500
Nahrungsergänzungsmittel in fester Form, einschließlich Kapseln, Komprimaten und ähnlichen Formen, ausgenommen kaubare Formen		2000
Nahrungsergänzungsmittel in Form von Sirup oder in kaubarer Form		5500



# SICHERHEIT VON ASPARTAM

# Aspartam: Sicherheit



Derzeit erfolgt durch die EFSA eine Neubewertung (im Rahmen der Regulation 493 (EU) No 257/2010) aller zugelassenen Zusatzstoffe, somit auch Aspartam.

Aufgrund neuer Daten wurde die Neubewertung von Aspartam vorgezogen, ein Entwurf wurde einem öffentlichen Stellungnahmeverfahren unterzogen.

Die endgültige Stellungnahme liegt seit November 2013 vor.



EFSA Journal 2013;11(12):3496

## SCIENTIFIC OPINION

### Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive<sup>1</sup>

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)<sup>2, 3</sup>

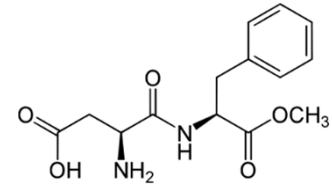
European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

The EFSA ANS Panel provides a scientific opinion on the safety of aspartame (E 951). Aspartame is a sweetener authorised as a food additive in the EU. In previous evaluations by JECFA and the SCF, an ADI of 40 mg/kg bw/day was established based on chronic toxicity in animals. Original reports, previous evaluations, additional literature and data made available following a public call were evaluated. Aspartame is rapidly and completely hydrolysed in the gastrointestinal tract to phenylalanine, aspartic acid and methanol. Chronic and developmental toxicities were relevant endpoints in the animal database. From chronic toxicity studies in animals, a NOAEL of 4000 mg/kg bw/day was identified. The possibility of developmental toxicity occurring at lower doses than 4000 mg/kg in animals could not be excluded. Based on MoA and weight-of-evidence analysis, the Panel concluded that developmental toxicity in animals was attributable to phenylalanine. Phenylalanine at high plasma levels is known to cause developmental toxicity in humans. The Panel concluded that human data on developmental toxicity were more appropriate for the risk assessment. Concentration-response modelling was used to determine the effects of aspartame administration on plasma phenylalanine using human data after phenylalanine administration to normal, PKU heterozygote or PKU homozygote individuals. In normal and PKU heterozygotes, aspartame intakes up to the ADI of 40 mg/kg bw/day, in addition to dietary phenylalanine, would not lead to peak plasma phenylalanine concentrations above the current clinical guideline for the prevention of adverse effects in fetuses. The Panel concluded that aspartame was not of safety concern at the current aspartame exposure estimates or at the ADI of 40 mg/kg bw/day. Therefore, there was no reason to revise the ADI of aspartame. Current exposures to aspartame - and its degradation product DKP - were below their respective ADIs. The ADI is not applicable to PKU patients.

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# Aspartam: Sicherheit



Das ANS-Panel sah keine  
Veranlassung, den bisherigen  
ADI von 40 mg/kg  
Körpergewicht zu ändern.



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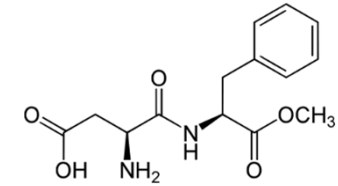
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# Aspartam: Sicherheit



European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

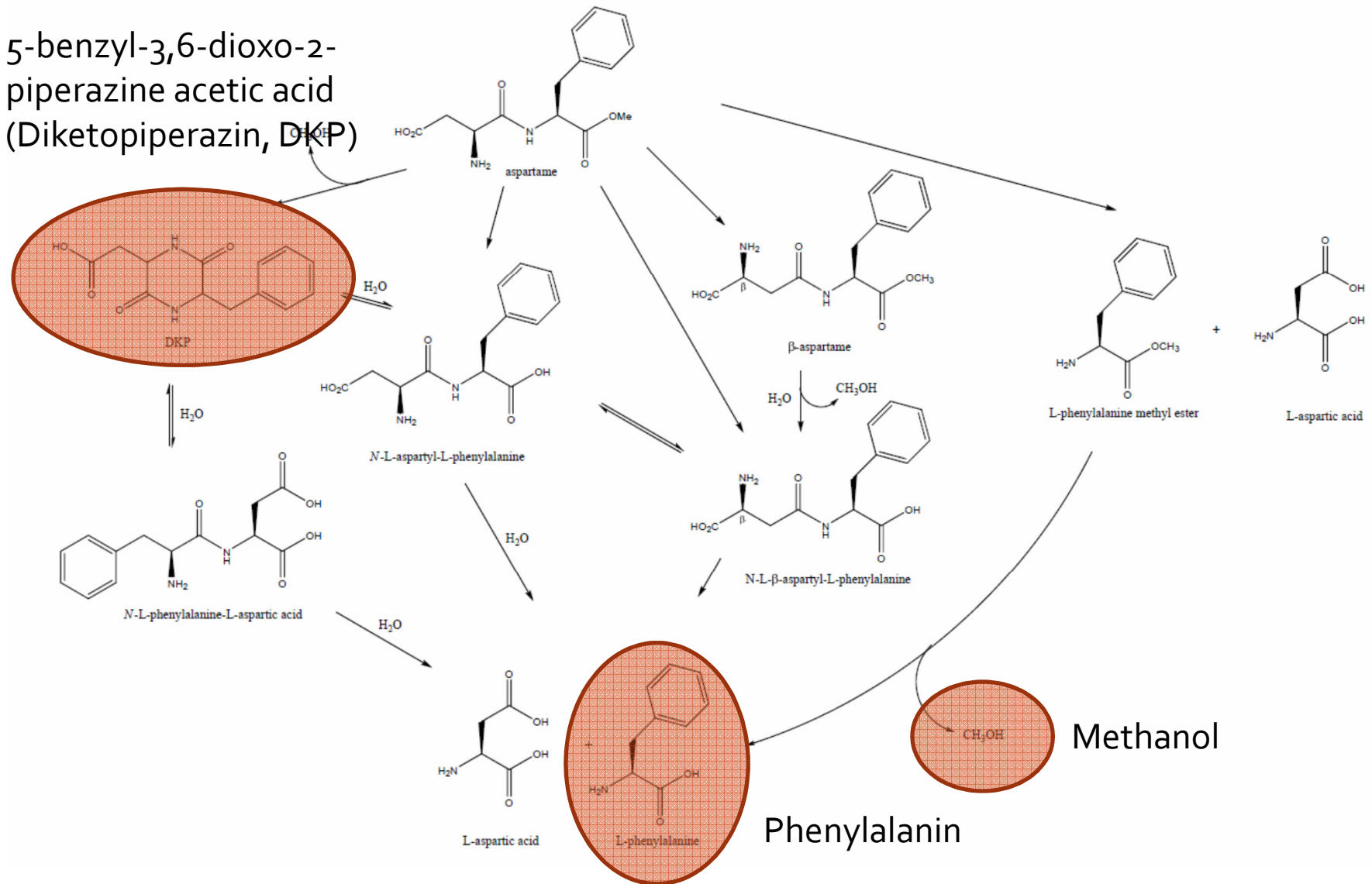
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# Aspartam: Metabolismus

5-benzyl-3,6-dioxo-2-piperazine acetic acid  
(Diketopiperazin, DKP)



# Aspartam: Sicherheit



## Results of Long-Term Carcinogenicity Bioassay on Sprague-Dawley Rats Exposed to Aspartame Administered in Feed

FIGURE 1. BELPOGGI, MORANDO SOFFRITTI, MICHELA PADOVANI,  
DAVIDE DEGLI ESPOSTI, MICHELINA LAURIOLA  
AND

*Ces*  
*and* The ANS Panel (EFSA ANS Panel, 2011) and EFSA (EFSA, 2011a) concluded that the hepatic and pulmonary tumour incidences reported by Soffritti et al. (2010) all fall within their own historical control ranges for spontaneous tumours. It was also noted that Swiss mice are known to have a high background incidence of spontaneous hepatic and pulmonary tumours (Prejean et al., 1973; Fox et al., 2006).

Based on these data, the Panel concluded that the results of the studies performed by Soffritti et al. (2010) do not provide evidence for a carcinogenic effect of aspartame in mice.

## Aspartame Administered in Feed, Beginning Prenatally Through Life Span, Induces Cancers of the Liver and Lung in Male Swiss Mice

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Morando Soffritti, MD,\* Fiorella Belpoggi, DBS, Marco Manservigi, DBS,  
Eva Tibaldi, DBS, Michelina Lauriola, PhD, Laura Falcioni, DVM, and Luciano Bua, MD

# Aspartam: Sicherheit



Istituto Ramazzini

## Results of Long-Term Carcinogenicity

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*Cesare Maltoni Cancer Research Center, European Foundation of Oncology and Envir*

AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 57:383–397 (2014)

OF INDUSTRIAL MEDICINE 53:1197–1206 (2010)

### Commentary

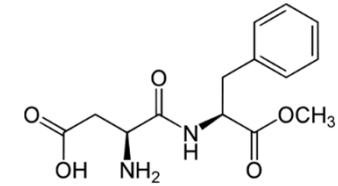
## The Carcinogenic Effects of Aspartame: The Urgent Need for Regulatory Re-Evaluation

Morando Soffritti, MD,\* Michela Padovani, MPH, Eva Tibaldi, PhD, Laura Falcioni, DMV, Fabiana Manservigi, PhD, and Fiorella Belpoggi, PhD

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# Aspartam: Sicherheit



## Methanol:

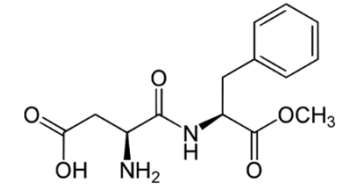
In a weight-of-evidence approach, the Panel concluded that the data set was limited but that the available reliable *in vitro* and *in vivo* data did not indicate a genotoxic concern for methanol.

The Panel noted that for average consumers of aspartame, the contribution to the overall exposure to methanol ranged from 1% up to 10% across the EU general population. In this estimate, the Panel also noted that exposure to methanol from natural sources is a minor contributing source compared to exposure from endogenous pathways (less than 10%).

The Panel noted that the exposure from aspartame-derived methanol is similar to methanol exposure from natural sources.

The Panel concluded that there is no safety concern from the levels of methanol released from aspartame under the current uses and permitted use levels.

# Aspartam: Sicherheit

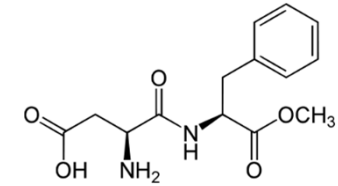


DKP:

Overall, the Panel concluded that available data do not indicate a genotoxic concern for DKP.

DKP administration to mice for 110 weeks in the diet at dose levels up to 1000 mg/kg bw/day indicated neither a carcinogenic effect nor a treatment-related increase in non-neoplastic lesions at the doses tested. The Panel considered that the NOAEL was 1000 mg DKP/kg bw/day, the highest dose level tested.

# Aspartam: Sicherheit

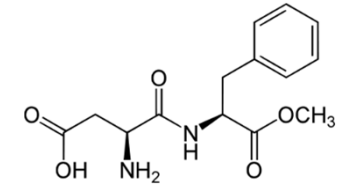


## Phenylalanin:

The Panel considered the following:

- the conservative assumptions used in the modelling, which would all overestimate peak plasma concentrations,
- the available information on adverse effects in development in humans with PKU,
- comparison with a concentration of 240  $\mu\text{M}$  to allow for simultaneous ingestion of phenylalanine from other components of the diet in order to not exceed the current clinical guideline of 360  $\mu\text{M}$
- results of the modelling
- data from repeated oral administration of aspartame in humans
- bolus intakes based on consumption of one litre of soft drink containing aspartame at the MPL of 600 mg/L by a child of 20-30 kg are unlikely to exceed 30 to 20 mg/kg bw, respectively.

# Aspartam: Sicherheit



## Phenylalanin:

Based on these considerations and evaluations, the Panel concluded that under realistic conditions, phenylalanine plasma levels would not exceed 240  $\mu\text{M}$  in normal or PKU heterozygous individuals.

The Panel noted that this was considerably below the concentrations at which adverse effects in the fetus were reported and was also below the current clinical guideline (360  $\mu\text{M}$ ) for prevention of effects in the fetuses of pregnant PKU patients. The Panel noted that in young children who did not suffer from PKU, plasma levels of phenylalanine resulting from aspartame ingestion at or below the ADI (as either a bolus or other aspartame consumption patterns) were likely to remain below 240  $\mu\text{M}$ .

For pregnant women, the Panel noted that there was no risk to the fetus from phenylalanine derived from aspartame at the current ADI (40 mg/kg bw/day) in normal or PKU heterozygous individuals.

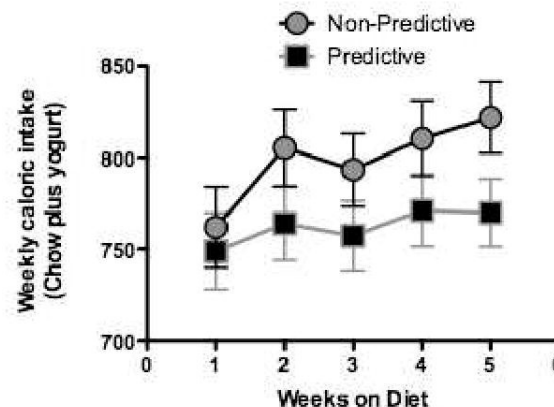
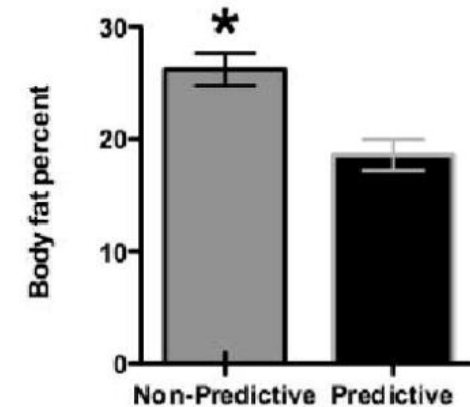
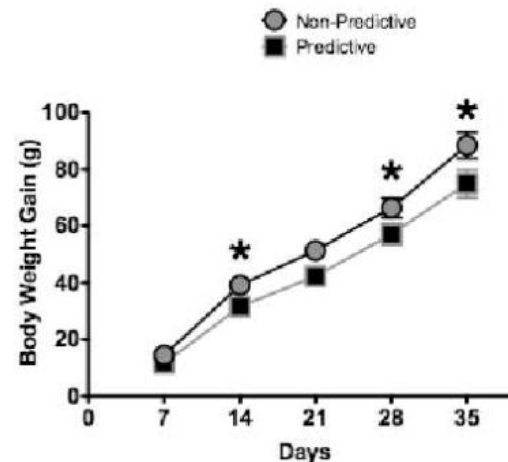


# AUSWIRKUNG VON HIGH- INTENSITY SWEETENERS AUF DAS ÜBERGEWICHT



# High intensity sweeteners

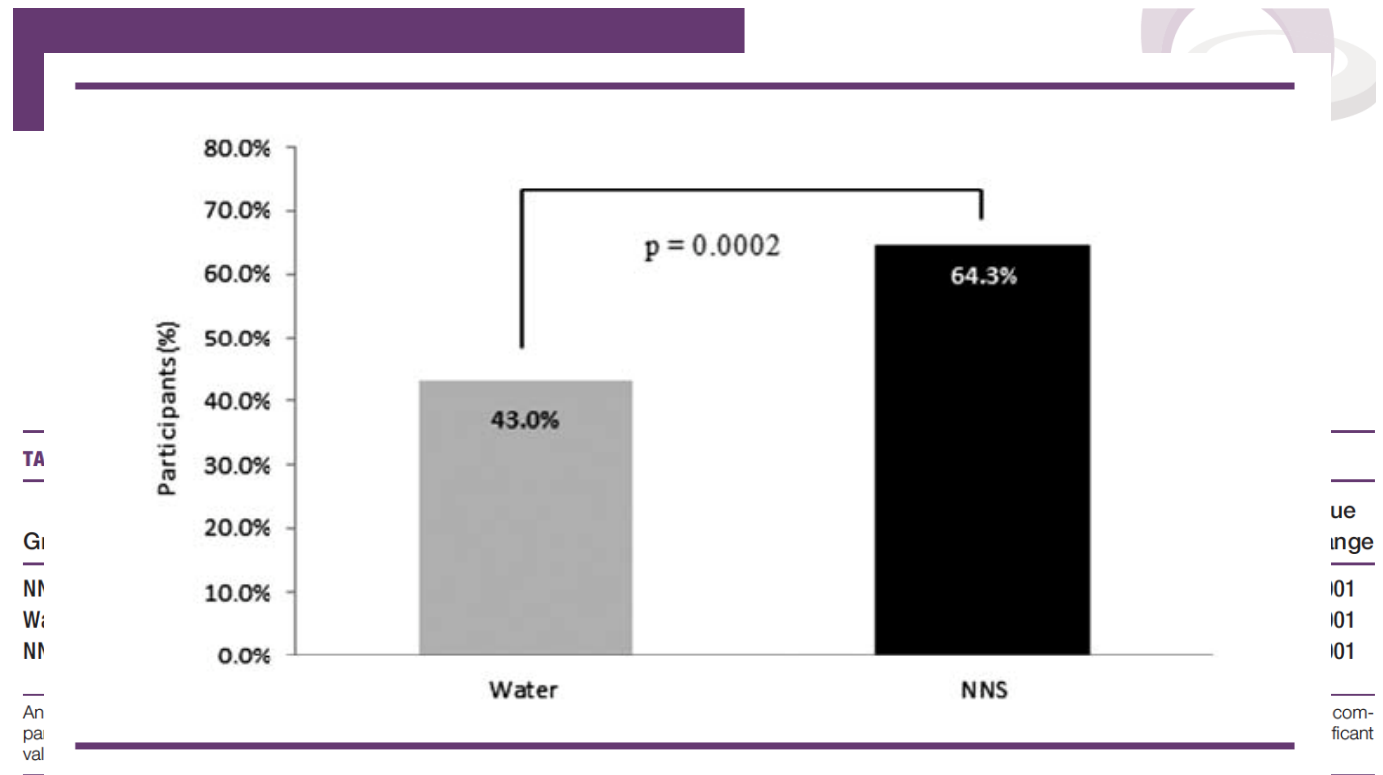
Hypothese: Der Gewöhnung an einen Süßgeschmack von Lebensmitteln ohne eine nachfolgende physiologische Reaktion (z.B. Blutglucosespiegel) führt zu einer Entkopplung des Triggers süß von Regulationsmechanismen der Energiebalance.



Swithers SE, Davidson TL. A role for sweet taste: calorie predictive relations in energy regulation by rats. Behav Neurosci. 2008 Feb;122(1):161-73.

# High intensity sweeteners

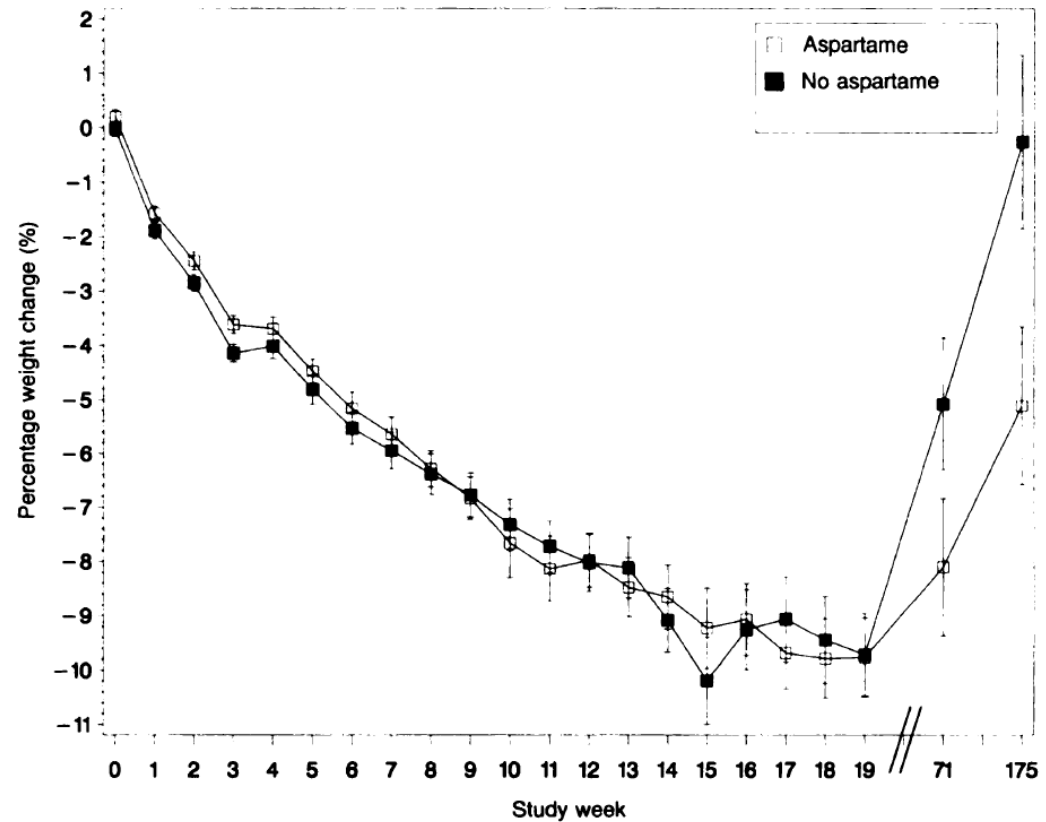
Künstlich  
gesüsste  
Getränke  
tragen besser  
zum  
Gewichts-  
management  
bei als  
Trinkwasser



**FIGURE 2** Percent participants who achieved at least 5% weight loss. Results based on Chi-square analysis. Analysis includes those participants who dropped out of the study in the analysis, using the baseline observation carried forward. This analysis mimics the clinical setting. Difference = 0.2133 or 21.33% difference between groups with 90% CI (0.1212–0.3054).  $n = 154$  for NNS,  $n = 149$  for Water.

# High intensity sweeteners

High intensity sweeteners leisten einen Beitrag zur Reduktion der Energiezufuhr



Blackburn GL, Kanders BS, Lavin PT, Keller SD and Whatley J. The effect of aspartame as part of a multidisciplinary weight-control program on short- and long-term control of body weight. American Journal of Clinical Nutrition, Vol 65, 409-418

# High intensity sweeteners

High intensity sweeteners leisten einen Beitrag zur Reduktion der Energiezufuhr



FROM THE ACADEMY

Position Paper

## Position of the Academy of Nutrition and Dietetics: Use of Nutritive and Nonnutritive Sweeteners

### ABSTRACT

It is the position of the Academy of Nutrition and Dietetics that consumers can safely enjoy a range of nutritive sweeteners and nonnutritive sweeteners (NNS) when consumed within an eating plan that is guided by current federal nutrition recommendations, such as the Dietary Guidelines for Americans and the Dietary Reference Intakes, as well as individual health goals and personal preference. A preference for sweet taste is innate and sweeteners can increase the pleasure of eating. Nutritive sweeteners contain carbohydrate and provide energy. They occur naturally in foods or may be added in food processing or by consumers before consumption. Higher intake of added sugars is associated with higher energy intake and lower diet quality, which can increase the risk for obesity, prediabetes, type 2 diabetes, and cardiovascular disease. On average, adults in the United States consume 14.6% of energy from added sugars. Polyols (also referred to as sugar alcohols) add sweetness with less energy and may reduce risk for dental caries. Foods containing polyols and/or no added sugars can, within food labeling guidelines, be labeled as sugar-free. NNS are those that sweeten with minimal or no carbohydrate or energy. They are regulated by the Food and Drug Administration as food additives or generally recognized as safe. The Food and Drug Administration approval process includes determination of probable intake, cumulative effect from all uses, and toxicology studies in animals. Seven NNS are approved for use in the United States: acesulfame K, aspartame, Luo Han Guo fruit extract, neotame, saccharin, stevia, and sucralose. They have different functional properties that may affect perceived taste or use in different food applications. All NNS approved for use in the United States are determined to be safe.

J Acad Nutr Diet. 2012;112:739-758.

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**Aspartame.** *In adults, does using foods or beverages with aspartame in an energy-restricted or ad libitum diet affect energy balance (weight)?*

**Conclusion Statement.** Use of aspartame and aspartame-sweetened products as part of a comprehensive weight loss or maintenance program by individuals may be associated with greater weight loss and may assist individuals with weight maintenance over time.  
**Grade I=Good.**



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*In adults, does using foods or beverages with aspartame affect appetite or food intake?*

**Conclusion Statement.** There is good evidence that aspartame does not affect appetite or food intake. **Grade I=Good.**

*In children, does using foods or beverages with aspartame affect appetite or food intake?*



WAS NUN?  
PRAKTISCHE RELEVANZ



# Ein Weg hinein oder hinaus?

Die Evidenz für einen Beitrag von High-intensity sweeteners zur Adipositas ist gering, während deren Verwendung im Rahmen einer Reduktionsdiät durchaus hilfreich sein können.

Die Evidenz für einen Beitrag von Fructose zur Adipositas ist fraglich, auch wenn es biochemische Zusammenhänge gibt. Die praktische Relevanz dieser Mechanismen ist allerdings gering.

Insgesamt besteht also kein Grund, auf andere Süßungsmöglichkeiten als Saccharose zu verzichten, langfristig wird aber nur eine dauerhaft wirksame Erhöhung der Ernährungskompetenz gemeinsam mit Optimierung im Bereich der Bewegung zum Ziel führen.







# DANKE FÜR IHRE AUFMERKSAMKEIT!

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