

**COMMISSION REGULATION (EU) No 497/2014****of 14 May 2014****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Advantame as a sweetener****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(1)</sup>, and in particular Articles 10(3) and 14 thereof,Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings <sup>(2)</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 <sup>(3)</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) An application for authorisation of the use of Advantame as a sweetener in several food categories was submitted in May 2010. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) There is a technological need for the use of Advantame as a high-intensity sweetener in various food and tabletop products in order to replace caloric sugars (sucrose, glucose, fructose, etc.) thus allowing for a reduction of the caloric content of those foodstuffs. The addition of Advantame as a sweetener to the categories of foods in which high-intensity sweeteners are authorised according to Annex II to Regulation (EC) No 1333/2008 will provide manufacturers with greater flexibility in formulating energy-reduced foods with a similar taste profile as the full-caloric equivalent. The flavour and sweetness qualities of Advantame, coupled with good stability characteristics, mean that Advantame provides an alternative to already approved high-intensity sweeteners, offering consumers and the food industry the option to choose from a wider selection of sweeteners, thus reducing the intake of each individual sweetener.
- (6) The European Food Safety Authority ('the Authority') evaluated the safety of Advantame when used as a food additive and expressed its opinion on 31 July 2013 <sup>(4)</sup>. The Authority established an Acceptable Daily Intake (ADI) for Advantame of 5 mg/kg bw/day. Conservative estimates of advantame exposure for high level adults and children consumers were below the ADI for the proposed use levels. After considering all the data on stability, degradation products, toxicology and exposure, the Authority concluded that Advantame would not be of safety concern at the proposed uses and use levels as a sweetener.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

<sup>(4)</sup> EFSA Journal 2013; 11(7):3301.

- (7) Therefore, it is appropriate to authorise the use of Advantame as a sweetener in the food categories specified in Annex I to this Regulation and to assign E 969 as an E-number to that food additive.
- (8) The specifications for Advantame should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

*Article 2*

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

*Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 May 2014.

*For the Commission*  
*The President*  
José Manuel BARROSO

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Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, in Table 2 'Sweeteners', the following new entry is inserted after the entry for food additive E 968 Erythritol:

E 969	Advantame
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(2) In Part E, the following entries for E 969 are inserted in numerical order in the food categories referred to:

PART E: AUTHORISED FOOD ADDITIVES AND CONDITIONS OF USE IN FOOD CATEGORIES

Category number	E -Number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	restrictions/exception
<b>01.4</b>	<b>Flavoured fermented milk products including heat-treated products</b>				
	E 969	Advantame	10		only energy-reduced products or with no added sugar'
<b>03</b>	<b>Edible ices</b>				
	E 969	Advantame	10		only energy-reduced or with no added sugar'
<b>04.2.2</b>	<b>Fruit and vegetables in vinegar, oil, or brine</b>				
	E 969	Advantame	3		only sweet-sour preserves of fruit and vegetables'
<b>04.2.3</b>	<b>Canned or bottled fruit and vegetables</b>				
	E 969	Advantame	10		only fruit energy-reduced or with no added sugar'
<b>04.2.4.1</b>	<b>Fruit and vegetable preparations excluding compote</b>				
	E 969	Advantame	10		only energy-reduced'
<b>04.2.5.1</b>	<b>Extra jam and extra jelly as defined by Directive 2001/113/EC</b>				
	E 969	Advantame	10		only energy-reduced jams jellies and marmalades'
<b>04.2.5.2</b>	<b>Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC</b>				
	E 969	Advantame	10		only energy-reduced jams, jellies and marmalades'

Category number	E -Number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	restrictions/exception
<b>04.2.5.3</b>	<b>Other similar fruit or vegetable spreads</b>				
	'E 969	Advantame	10		only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar'
<b>05.1</b>	<b>Cocoa and Chocolate products as covered by Directive 2000/36/EC</b>				
	'E 969	Advantame	20		only energy-reduced or with no added sugars'
<b>05.2</b>	<b>Other confectionery including breath refreshing microsweets</b>				
	'E 969	Advantame	20		only cocoa or dried fruit based, energy reduced or with no added sugar
	E 969	Advantame	10		only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar
	E 969	Advantame	20		only starch based confectionary energy reduced or with no added sugar
	E 969	Advantame	10		only confectionary with no added sugar
	E 969	Advantame	60		only breath-freshening micro-sweets, with no added sugar
	E 969	Advantame	20		only strongly flavoured freshening throat pastilles with no added sugar'
<b>05.3</b>	<b>Chewing gum</b>				
	'E 969	Advantame	200		only with added sugars or polyols, as flavour enhancer
	E 969	Advantame	400		only with no added sugar'
<b>05.4</b>	<b>Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4</b>				
	'E 969	Advantame	20		only starch based confectionary energy reduced or with no added sugar
	E 969	Advantame	10		only confectionary with no added sugar
	E 969	Advantame	20		only cocoa or dried fruit based, energy reduced or with no added sugar
	E 969	Advantame	4		only sauces'

Category number	E -Number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	restrictions/exception
<b>06.3</b>	<b>Breakfast cereals</b>				
	'E 969	Advantame	10		only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy reduced or with no added sugar'
<b>07.2</b>	<b>Fine bakery wares</b>				
	'E 969	Advantame	10		only essoblaten — wafer paper
	E 969	Advantame	17		only fine bakery products for special nutritional uses'
<b>09.2.</b>	<b>Processed fish and fishery products including mollusks and crustaceans</b>				
	'E 969	Advantame	3		only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs'
<b>11.4.1</b>	<b>Table Top Sweeteners in liquid form</b>				
	'E 969	Advantame	<i>quantum satis</i> '		
<b>11.4.2</b>	<b>Table Top Sweeteners in powder form</b>				
	'E 969	Advantame	<i>quantum satis</i> "		
<b>11.4.3</b>	<b>Table Top Sweeteners in tablets</b>				
	'E 969	Advantame	<i>quantum satis</i> '		
<b>12.4</b>	<b>Mustard</b>				
	'E 969	Advantame	4'		
<b>12.5</b>	<b>Soups and broths</b>				
	'E 969	Advantame	2		only energy-reduced soups'
<b>12.6</b>	<b>Sauces</b>				
	'E 969	Advantame	4'		

Category number	E -Number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	restrictions/exception
<b>12.7</b>	<b>Salads and savoury based sandwich spreads</b>				
	'E 969	Advantame	4		only <i>Feinkostsalat</i> '
<b>13.2</b>	<b>Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)</b>				
	'E 960	Advantame	10'		
<b>13.3</b>	<b>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)</b>				
	'E 960	Advantame	8'		
<b>14.1.3</b>	<b>Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products</b>				
	'E 969	Advantame	6		only energy-reduced or with no added sugar'
<b>14.1.4</b>	<b>Flavoured drinks</b>				
	'E 969	Advantame	6		only energy reduced or with no added sugar'
<b>14.2.1</b>	<b>Beer and malt beverages</b>				
	'E 969	Advantame	6		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 "Obergäriges Einfachbier"; Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH; Brown beers of the "oud bruin" type
	E 969	Advantame	0,5		only energy-reduced beer'
<b>14.2.3</b>	<b>Cider and perry</b>				
	'E 969	Advantame	6'		
<b>14.2.8</b>	<b>Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks</b>				
	'E 969	Advantame	6'		
<b>15.1</b>	<b>Potato-, cereal-, flour- or starch-based snacks</b>				
	'E 969	Advantame	5'		

Category number	E -Number	Name	Maximum level (mg/l or mg/kg as appropriate)	Footnotes	restrictions/exception
<b>15.2</b>	<b>Processed nuts</b>				
	'E 969	Advantame	5'		
<b>16.</b>	<b>Desserts excluding products covered in category 1, 3 and 4</b>				
	'E 969	Advantame	10		only energy-reduced or with no added sugar'
<b>17.1</b>	<b>Food supplements supplied in a solid form including capsules and tablets and similar forms</b>				
	'E 969	Advantame	20'		
<b>17.2</b>	<b>Food supplements supplied in a liquid form</b>				
	'E 969	Advantame	6'		
<b>17.3</b>	<b>Food supplements supplied in a syrup-type or chewable form</b>				
	'E 969	Advantame	55'		

## ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for food additive E 968:

**E 969 ADVANTAME****Synonyms****Definition**

Advantame (ANS9801) is produced by chemical synthesis in a three-step process; production of the principal manufacturing intermediate, 3-hydroxy-4-methoxycinnamaldehyde (HMCA), followed by hydrogenation to form 3-(3-hydroxy-4-methoxyphenyl) propionaldehyde (HMPA). In the final step, the HMPA methanol solution (filtrate) is combined with aspartame to give the imine that under selective hydrogenation forms advantame. The solution is allowed to crystallise and crude crystals are washed. The product is re-crystallised and crystals are separated, washed and dried.

CAS No.

714229-20-6

Chemical name

N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl]-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (IUPAC);  
L-phenylalanine, N-[3-(3-hydroxy-4-methoxyphenyl)propyl]-L-α-aspartyl-, 2-methyl ester, monohydrate (CA)

Molecular formula

C<sub>24</sub>H<sub>30</sub>N<sub>2</sub>O<sub>7</sub>·H<sub>2</sub>O

Molecular weight

476,52 g/mol (monohydrate)

Assay

Not less than 97,0 % and not more than 102,0 % on an anhydrous basis

**Description**

White to yellow powder

**Identification**

Melting Point

101,5 °C

**Purity**

N-[N-[3-(3-hydroxy-4-methoxyphenyl)propyl-α-aspartyl]-L-phenylalanine (ANS9801-acid)

Not more than 1,0 %

Total other related substances

Not more than 1,5 %

Residual Solvents

Isopropyl acetate: Not more than 2 000 mg/kg  
Methyl acetate: Not more than 500 mg/kg  
Methanol: Not more than 500 mg/kg  
2-Propanol: Not more than 500 mg/kg

Water content

Not more than 5,0 % (Karl Fischer method)

Residue on ignition

Not more than 0,2 %

Arsenic

Not more than 2 mg/kg

Lead

Not more than 1 mg/kg

Palladium

Not more than 5,3 mg/kg

Platinum

Not more than 1,7 mg/kg'