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From:	European Commission
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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Subject:	ANNEXES [...] to the COMMISSION REGULATION (EU) No .../. 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

Delegations will find attached document D031989/02 - Annexes.

Encl.: D031989/02 - Annexes



Brussels, **XXX**
SANC/10090/2014 Rev. 1 ANNEX
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[...] (2014) **XXX** draft

ANNEXES

[...]

to the

COMMISSION REGULATION (EU) No .../..

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

ANNEX I

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:

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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
01.4	Flavoured fermented milk products including heat-treated products				
	E 969	Advantame	10		only energy-reduced products or with no added sugar
03	Edible ices				
	E 969	Advantame	10		only energy-reduced or with no added sugar
04.2.2	Fruit and vegetables in vinegar, oil, or brine				
	E 969	Advantame	3		only sweet-sour preserves of fruit and vegetables
04.2.3	Canned or bottled fruit and vegetables				
	E 969	Advantame	10		only fruit energy-reduced or with no added sugar
4.2.4.1	Fruit and vegetable preparations excluding compote				
	E 969	Advantame	10		only energy-reduced
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC				
	E 969	Advantame	10		only energy-reduced jams, jellies and marmalades
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC				
	E 969	Advantame	10		only energy-reduced jams, jellies and marmalades
04.2.5.3	Other similar fruit or vegetable spreads				
	E 969	Advantame	10		only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC				
	E 969	Advantame	20		only energy-reduced or with no added sugars

05.2	Other confectionery including breath refreshing microsweets			
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
05.3	Chewing gum			
E 969	Advantame	200		only with added sugars or polyols, as flavour enhancer
E 969	Advantame	400		only with no added sugar
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4			
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
06.3	Breakfast cereals			
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
07.2	Fine bakery wares			
E 969	Advantame	10		only essoblaten - wafer paper
E 969	Advantame	17		only fine bakery products for special nutritional uses

09.2.	Processed fish and fishery products including mollusks and crustaceans						only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs
	E 969	Advantame	3				
11.4.1	Table Top Sweeteners in liquid form						
	E 969	Advantame	<i>quantum satis</i>				
11.4.2	Table Top Sweeteners in powder form						
	E 969	Advantame	<i>quantum satis</i>				
11.4.3	Table Top Sweeteners in tablets						
	E 969	Advantame	<i>quantum satis</i>				
12.4	Mustard						
	E 969	Advantame	4				
12.5	Soups and broths						
	E 969	Advantame	2				only energy-reduced soups
12.6	Sauces						
	E 969	Advantame	4				
12.7	Salads and savoury based sandwich spreads						
	E 969	Advantame	4				only <i>Feinkostsalat</i>
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)						
	E 960	Advantame	10				
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)						
	E 960	Advantame	8				
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products						
	E 969	Advantame	6				only energy-reduced or with no added sugar
14.1.4	Flavoured drinks						
	E 969	Advantame	6				only energy reduced or with no added sugar

14.2.1	Beer and malt beverages				
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
14.2.3	Cider and perry				
E 969	Advantame		6		
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks				
E 969	Advantame		6		
15.1	Potato-, cereal-, flour- or starch-based snacks				
E 969	Advantame		5		
15.2	Processed nuts				
E 969	Advantame		5		
16.	Desserts excluding products covered in category 1, 3 and 4				
E 969	Advantame		10		only energy-reduced or with no added sugar
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms				
E 969	Advantame		20		
17.2	Food supplements supplied in a liquid form				
E 969	Advantame		6		
17.3	Food supplements supplied in a syrup-type or chewable form				
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-alpha-aspartyl-, 2-methyl ester, monohydrate (CA)
Molecular formula	C ₂₄ H ₃₀ N ₂ O ₇ ·H ₂ 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

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