

**COMMISSION REGULATION (EU) 2023/447****of 1 March 2023****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 glycosylated steviol glycosides as 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 Article 10(3) and Article 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) In January 2019, an application was submitted for the authorisation of glycosylated steviol glycosides as a new food additive for use as a sweetener. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Glycosylated steviol glycosides are produced via enzymatic bioconversion using a cyclomaltodextrin glucanotransferase that catalyses the transfer of glucose from starch to mixtures enriched in one or more individual steviol glycosides from purified *Stevia Rebaudiana* leaf extracts. They consist of a mixture of glycosylated steviol glycosides, containing 1–20 additional glucose units bound to the parent steviol glycosides. They have an improved sweetness profile as compared to the other authorised sweeteners including steviol glycosides from *Stevia* (E 960a).
- (6) The European Food Safety Authority ('the Authority') evaluated the safety of glycosylated steviol glycosides and expressed its opinion on 15 December 2021 <sup>(4)</sup>. The Authority considered that the metabolism of glycosylated steviol glycosides is sufficiently similar to the already authorised steviol glycosides, and thus the toxicological data previously assessed by the Authority for steviol glycosides (E 960a) were considered to support their safety as a food additive. The enzyme cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-genetically modified strain of *Anoxybacillus caldiproteolyticus* and intended to be used in the manufacture of modified steviol glycosides does not give rise to safety concerns under the intended conditions of use based on the data provided to the Authority <sup>(5)</sup>. The Authority concluded that there is no safety concern for the use of glycosylated steviol glycosides as a food additive for the same proposed uses and use levels as steviol glycosides (E 960a–960c) used as sweeteners.

<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 2022;20(2):7066.

<sup>(5)</sup> EFSA Journal 2022;20(1):7004.

- (7) Therefore, it is appropriate to authorise the food additive 'glucosylated steviol glycosides' (E 960d) as a sweetener in the food categories where steviol glycosides (E 960a–960c) are currently authorised and at the same the maximum levels.
- (8) The specifications for the food additive glucosylated steviol glycosides should be included in Regulation (EU) No 231/2012 as 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 on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The 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, 1 March 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX I

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

(a) In Part B, 2. Sweeteners, the following entry is inserted after the entry for E 960c:

E 960d	Glucosylated steviol glycosides';
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(b) In Part C, (5) Other additives that may be regulated combined, point (v) is replaced by the following:

'(v) E 960a – 960d: Steviol glycosides

E-number	Name
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides
E 960d	Glucosylated steviol glycosides';

(c) Part E is amended as follows:

(1) In category 01.4 (Flavoured fermented milk products including heat-treated products), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar';
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(2) In category 03 (Edible ices), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar';
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(3) In category 04.2.2 (Fruit and vegetables in vinegar, oil, or brine), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit and vegetables';
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(4) In category 04.2.4.1 (Fruit and vegetable preparations excluding compote), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced';
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(5) In category 04.2.5.1 (Extra jam and extra jelly as defined by Directive 2001/113/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades';
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- (6) In category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades’;
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- (7) In category 04.2.5.3 (Other similar fruit or vegetable spreads), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar’;
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- (8) In category 05.1 (Cocoa and Chocolate products as covered by Directive 2000/36/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugars’;
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- (9) In category 05.2 (Other confectionery including breath freshening microsweets), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar
	E 960a – 960d	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar
	E 960a – 960d	Steviol glycosides	350	(1) (60)	only confectionery with no added sugars only energy-reduced hard confectionery (candies and lollies) only energy-reduced soft confectionery (chewy candies, fruit gums and foam sugar products/marshmallows) only energy-reduced liquorice only energy-reduced nougat only energy-reduced marzipan
	E 960a – 960d	Steviol glycosides	2 000	(1) (60)	only breath-freshening micro-sweets, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	670	(1) (60)	only strongly flavoured freshening throat pastilles, energy-reduced or with no added sugars’;

- (10) In category 05.3 (Chewing gum), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	3300	(1) (60)	only with no added sugar';
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- (11) In category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only confectionary with no added sugar
	E 960a – 960d	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar';

- (12) In category 06.3 (Breakfast cereals), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy reduced or with no added sugar';
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- (13) In category 07.2 (Fine bakery wares), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only essoblaten – wafer paper';
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- (14) In category 09.2 (Processed fish and fishery products including molluscs and crustaceans), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	200	(1) (60)	only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs';
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- (15) In category 11.4.1 (Table-top sweeteners in liquid form), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (16) In category 11.4.2 (Table-top sweeteners in powder form), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (17) In category 11.4.3 (Table-top sweeteners in tablets), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (18) In category 12.4 (Mustard), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	120	(1) (60);	
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- (19) In category 12.5 (Soups and broths), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	40	(1) (60)	only energy-reduced soups;
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- (20) In category 12.6 (Sauces), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)
	E 960a – 960d	Steviol glycosides	175	(1) (60)	Only soy-bean sauce (fermented and non-fermented);

- (21) In category 13.2 (Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60);	
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- (22) In category 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), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	270	(1) (60);	
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- (23) In category 14.1.3 (Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar;
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- (24) In category 14.1.4 (Flavoured drinks), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	80	(1) (60)	only energy-reduced or with no added sugar;
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- (25) In category 14.1.5.2 (Other), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	30	(1) (60) (93)	only coffee, tea and herbal infusion beverages, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	30	(1) (60) (93)	only flavoured instant coffee and instant cappuccino products, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	20	(1) (60) (93)	only malt-based and chocolate/ cappuccino flavoured drinks, energy-reduced or with no added sugars';

- (26) In category 14.2.1 (Beer and malt beverages), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	70	(1) (60)	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';
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- (27) In category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	150	(1)(60);	
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- (28) In category 15.1 (Potato-, cereal-, flour- or starch-based snacks), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	20	(1) (60);	
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- (29) In category 15.2 (Processed nuts), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	20	(1) (60);	
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- (30) In category 16 (Desserts excluding products covered in categories 1, 3 and 4), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar';
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- (31) In category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	670	(1) (60)	
	E 960a – 960d	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form';

- (32) In category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	
	E 960a – 960d	Steviol glycosides	1800	(1) (60)	only food supplements in syrup form'.



## ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry is inserted after the entry for food additive E 960c(iv):

## E 960d GLUCOSYLATED STEVIOL GLYCOSIDES

<b>Synonyms</b>	
<b>Definition</b>	Mixture of larger glycosides of steviol derived by glucosylation of steviol glycosides extracted from leaves of <i>Stevia rebaudiana</i> Bertoni plant. The mixture is composed of glucosylated steviol glycosides and residual parent steviol glycosides from Stevia leaf. Glucosylated steviol glycosides are produced by treating the steviol glycosides, extracted from Stevia leaf, and starch suitable for human consumption with Cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-GMO strain of <i>Anoxybacillus caldiproteolyticus</i> St-88. The enzyme transfers glucose units from the starch to the steviol glycosides. The resulting material is heated and treated with activated carbon to remove the enzyme, then passed through adsorption/desorption resin to remove residual hydrolysed starch (dextrin), followed by purification and preparation of the final product using processes that may include decolourisation, concentration and spray drying.
<b>Chemical name</b>	<p>Steviolbioside: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid</p> <p>Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Dulcoside A: 13-[(2-O-α-L-rhamnopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Stevioside: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside B: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid</p> <p>Rebaudioside C: 13-[(2-O-α-L-rhamnopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester</p> <p>Rebaudioside E: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester</p> <p>Rebaudioside F: 13-[(2-O-β-D-xylofuranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester</p> <p>And their glucosylated derivatives (1-20 added glucose units)</p>

Molecular formula	Trivial name	Formula	Conversion factor
	n-Glucosylated Steviolbioside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Rubusoside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Dulcoside A	$C_{(38+n*6)}H_{(60+n*10)}O_{(17+n*5)}$	
	n-Glucosylated Stevioside	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside A	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside B	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside C	$C_{(44+n*6)}H_{(70+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside D	$C_{(50+n*6)}H_{(80+n*10)}O_{(28+n*5)}$	
	n-Glucosylated Rebaudioside E	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside F	$C_{(43+n*6)}H_{(68+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside M	$C_{(56+n*6)}H_{(90+n*10)}O_{(33+n*5)}$	
	n: number of glucose units enzymatically added to the parent steviol glycoside (n = 1-20) Typical conversion factor for glucosylated steviol glycosides mixtures = 0,20 (on the dried, dextrin-free, basis)		
	Steviol	$C_{20}H_{30}O_3$	1,00
	Steviolbioside	$C_{32}H_{50}O_{13}$	0,50
	Rubusoside	$C_{32}H_{50}O_{13}$	0,50
	Dulcoside A	$C_{38}H_{60}O_{17}$	0,40
	Stevioside	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside B	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside C	$C_{44}H_{70}O_{22}$	0,34
	Rebaudioside D	$C_{50}H_{80}O_{28}$	0,29
	Rebaudioside E	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside F	$C_{43}H_{68}O_{22}$	0,34
	Rebaudioside M	$C_{56}H_{90}O_{33}$	0,25

Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	n-Glucosylated Steviolbioside	Not available	642,73+n*162,15
	n-Glucosylated Rubusoside	Not available	642,73+n*162,15
	n-Glucosylated Dulcoside A	Not available	788,87+n*162,15
	n-Glucosylated Stevioside	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside A	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside B	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside C	Not available	951,02+n*162,15
	n-Glucosylated Rebaudioside D	Not available	1 129,15+n*162,15
	n-Glucosylated Rebaudioside E	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside F	Not available	936,99+n*162,15
	n-Glucosylated Rebaudioside M	Not available	1 291,30+n*162,15
	Steviol		318,46
	Steviolbioside	41093-60-1	642,73
	Rubusoside	64849-39-4	642,73
	Dulcoside A	64432-06-0	788,87
	Stevioside	57817-89-7	804,88
	Rebaudioside A	58543-16-1	967,01
	Rebaudioside B	58543-17-2	804,88
	Rebaudioside C	63550-99-2	951,02
	Rebaudioside D	63279-13-0	1 129,15
	Rebaudioside E	63279-14-1	967,01
	Rebaudioside F	438045-89-7	936,99
	Rebaudioside M	1220616-44-3	1 291,30
Assay	Not less than 95 % of total steviol glycosides, comprised of above mentioned steviol glycosides along with their glucosylated derivatives (1-20 added glucose units), on the dried, dextrin-free, basis.		
<b>Description</b>	White to light yellow powder, approximately between 100 and 200 times sweeter than sucrose (at 5 % sucrose equivalency).		

<b>Identification</b>	
Solubility	Soluble in water
pH	Between 4,5 and 7,0 (1 in 100 solution)
<b>Purity</b>	
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2 h)
Residual solvent	Not more than 200 mg/kg methanol Not more than 3 000 mg/kg ethanol
Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
<b>Microbiological criteria</b>	
Total (aerobic) plate count	Not more than 1 000 CFU/g
Yeast and moulds	Not more than 200 CFU/g
<i>E. coli</i>	Negative in 1 g
<i>Salmonella</i>	Negative in 25 g'