

COMMISSION DIRECTIVE 2006/128/EC**of 8 December 2006****amending and correcting Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽¹⁾, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority (EFSA),

Whereas:

(1) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽²⁾, lists those substances which may be used as sweeteners in foodstuffs.

(2) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽³⁾, sets out the purity criteria for the sweeteners listed in Directive 94/35/EC.

(3) It is necessary to adopt specific criteria for E 968 erythritol, a new food additive authorised by Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs.

(4) A number of language versions of Directive 95/31/EC contain some errors regarding the following substances: E 954 saccharin and its Na, K and Ca salts, E 955 sucralose, E 962 salt of aspartame-acesulfame, E 965 (i) maltitol, E 966 lactitol. Those errors need to be corrected. In addition it is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted

by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In particular where appropriate, the specific purity criteria have been adapted to reflect the limits for individual heavy metals of interest. For reasons of clarity the whole text concerning those substances should be replaced.

(5) EFSA in its scientific opinion of 19 April 2006 concluded that the composition of maltitol syrup based on a new production method will be similar to that of the existing product and will be in accordance with the existing specification. It is therefore necessary to amend the definition of E 965 (ii) maltitol syrup set out in Directive 95/31/EC for E 965 by including that new production method.

(6) Directive 95/31/EC should therefore be amended and corrected accordingly.

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 95/31/EC is amended and corrected in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 February 2008 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2006/52/EC (OJ L 204, 26.7.2006, p. 10).

⁽³⁾ OJ L 178, 28.7.1995, p. 1. Directive as last amended by Directive 2004/46/EC (OJ L 114, 21.4.2004, p. 15).

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

The Annex to Directive 95/31/EC is amended and corrected as follows:

1. The following text concerning E 968 erythritol is inserted after E 967 xylitol:

‘E 968 ERYTHRITOL**Synonyms**

Meso-erythritol, tetrahydroxybutane, erythrite

Definition

Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Trichosporonoides megachilensis*, followed by purification and drying

Chemical name

1,2,3,4-Butanetetrol

Einecs

205-737-3

Chemical formula

C₄H₁₀O₄

Molecular weight

122,12

Assay

Not less than 99 % after drying

Description

White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.

Identification

A. Solubility

Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.

B. Melting range

119-123 °C

Purity

Loss on drying

Not more than 0,2 % (70 °C, six hours, in a vacuum desiccator)

Sulphated ash

Not more than 0,1 %

Reducing substances

Not more than 0,3 % expressed as D-glucose

Ribitol and glycerol

Not more than 0,1 %

Lead

Not more than 0,5 mg/kg'

2. The text concerning E 954 saccharin and its Na, K and Ca salts is replaced by the following:

‘E 954 SACCHARIN AND ITS Na, K AND Ca SALTS**(I) SACCHARIN****Definition**

Chemical name

3-Oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide

Einecs

201-321-0

Chemical formula

C₇H₅NO₃S

Relative molecular mass

183,18

Assay

Not less than 99 % and not more than 101 % of C₇H₅NO₃S on the anhydrous basis

Description

White crystals or a white crystalline powder, odourless or with a faint, aromatic odour, having a sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose

Identification

Solubility

Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol

Purity

Loss on drying

Not more than 1 % (105 °C, two hours)

Melting range

226-230 °C

Sulphated ash

Not more than 0,2 % expressed on dry weight basis

Benzoic and salicylic acid

To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

o-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

p-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

Benzoic acid p-sulfonamide

Not more than 25 mg/kg expressed on dry weight basis

Readily carbonisable substances

Absent

Arsenic

Not more than 3 mg/kg expressed on dry weight basis

Selenium

Not more than 30 mg/kg expressed on dry weight basis

Lead

Not more than 1 mg/kg expressed on dry weight basis.

(II) SODIUM SACCHARIN**Synonyms**

Saccharin, sodium salt of saccharin

Definition

Chemical name

Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulphonazole, oxobenzisulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide sodium salt dihydrate

Einecs

204-886-1

Chemical formula

 $C_7H_4NNaO_3S \cdot 2H_2O$

Relative molecular mass

241,19

Assay

Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis**Description**

White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions

Identification

Solubility

Freely soluble in water, sparingly soluble in ethanol

Purity

Loss on drying

Not more than 15 % (120 °C, four hours)

Benzoic and salicylic acid

To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

o-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

p-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

(III) CALCIUM SACCHARIN**Synonyms**

Saccharin, calcium salt of saccharin

Definition

Chemical name	Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisoxazolone, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-9
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$
Relative molecular mass	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis

Description

White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions

Identification

Solubility	Freely soluble in water, soluble in ethanol
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Purity

Loss on drying	Not more than 13,5 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

(IV) POTASSIUM SACCHARIN**Synonyms**

Saccharin, potassium salt of saccharin

Definition

Chemical name	Potassium o-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisoxazolone, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
Einecs	
Chemical formula	$C_7H_4KNO_3S \cdot H_2O$

Relative molecular mass	239,77
Assay	Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 8 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis'

3. The text concerning E 955 sucralose is replaced by the following:

'E 955 SUCRALOSE

Synonyms	4,1',6'-Trichlorogalactosucrose
Definition	
Chemical name	1,6-Dichloro-1,6-dideoxy- β -D-fructofuranosyl-4-chloro-4-deoxy- α -D-galactopyranoside
Einecs	259-952-2
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % of $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.
Description	White to off-white, practically odourless crystalline powder.
Identification	
A. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate

B. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard
C. Thin layer chromatography	The main spot in the test solution has the same R _f value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol
D. Specific rotation	$[\alpha]_{\text{D}}^{20} = + 84,0^{\circ}$ to $+ 87,5^{\circ}$ calculated on the anhydrous basis (10 % w/v solution)
Purity	
Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %
Lead	Not more than 1 mg/kg'

4. The text concerning E 962 salt of aspartame-acesulfame is replaced by the following:

'E 962 SALT OF ASPARTAME-ACESULFAME

Synonyms	Aspartame-acesulfame, aspartame-acesulfame salt
Definition	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone
Chemical name	6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L- α -aspartic acid
Chemical formula	$\text{C}_{18}\text{H}_{23}\text{O}_9\text{N}_3\text{S}$
Molecular weight	457,46
Assay	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37 % acesulfame (acid form on a dry basis)
Description	A white, odourless, crystalline powder
Identification	
A. Solubility	Sparingly soluble in water, slightly soluble in ethanol
B. Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022
C. Specific rotation	$[\alpha]_{\text{D}}^{20} = + 14,5^{\circ}$ to $+ 16,5^{\circ}$ Determine at concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame

Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg'

5. The text concerning E 965 (i) maltitol is replaced by the following:

'E 965 (i) MALTITOL

Synonyms	D-Maltitol, hydrogenated maltose
Definition	
Chemical name	(α)-D-Glucopyranosyl-1,4-D-glucitol
Einecs	209-567-0
Chemical formula	$C_{12}H_{24}O_{11}$
Relative molecular mass	344,31
Assay	Content not less than 98 % of D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis
Description	Sweet tasting, white crystalline powder
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Melting range	148 to 151 °C
C. Specific rotation	$[\alpha]_D^{20} = + 105,5^\circ$ to $+ 108,5^\circ$ (5 % w/v solution)
Purity	
Water	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,1 % expressed as glucose on dry weight basis
Chlorides	Not more than 50 mg/kg expressed on dry weight basis
Sulphates	Not more than 100 mg/kg expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis'

6. The text concerning E 965 (ii) maltitol syrup is replaced by the following:

'E 965 (ii) MALTITOL SYRUP

Synonyms	Hydrogenated high-maltose glucose syrup, hydrogenated glucose syrup
Definition	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis

Description	Colourless and odourless, clear viscous liquids or white crystalline masses
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Thin layer chromatography	Passes test
Purity	
Water	Not more than 31 % (Karl Fischer)
Reducing sugars	Not more than 0,3 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 50 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg'

7. The text concerning E 966 lactitol is replaced by the following:

'E 966 LACTITOL

Synonyms	Lactit, lactositol, lactobiosit
Definition	
Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Einecs	209-566-5
Chemical formula	C ₁₂ H ₂₄ O ₁₁
Relative molecular mass	344,32
Assay	Not less than 95 % on the dry weight basis
Description	Sweet-tasting crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms
Identification	
A. Solubility	Very soluble in water
B. Specific rotation	[α] _D ²⁰ = + 13° to + 16° calculated on the anhydrous basis (10 % w/v aqueous solution)
Purity	
Water	Crystalline products; not more than 10,5 % (Karl Fischer method)
Other polyols	Not more than 2,5 % on the anhydrous basis
Reducing sugars	Not more than 0,2 % expressed as glucose on dry weight basis
Chlorides	Not more than 100 mg/kg expressed on dry weight basis
Sulphates	Not more than 200 mg/kg expressed on dry weight basis
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis'