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,


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

Whereas:


(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.

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
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**: C$_4$H$_{10}$O$_4$
- **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**: C$_7$H$_5$NO$_3$S
- **Relative molecular mass**: 183,18
- **Assay**: Not less than 99 % and not more than 101 % of C$_7$H$_5$NO$_3$S 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 300 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-oxobenzisosulphonazole, oxobenzisosulphonazole, 1,2-benzi-sothiazolin-3-one-1,1-dioxide sodium salt dihydrate

Einecs
204-886-1

Chemical formula
C₇H₄NNaO₃S·2H₂O

Relative molecular mass
241.19

Assay
Not less than 99 % and not more than 101 % of C₇H₄NNaO₃S 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-oxobenzisosulfonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs 229-349-9
Chemical formula C_{14}H_{8}CaN_{2}O_{6}S_{2}·\frac{3}{2}H_{2}O
Relative molecular mass 467.48
Assay Not less than 95 % of C_{14}H_{8}CaN_{2}O_{6}S_{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
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-oxobenzisosulphonazole, potassium salt of 1,2-benzothiazolin-3-one-1,1-dioxide monohydrate
Einecs
Chemical formula C_{7}H_{4}KNO_{3}S·H_{2}O
Relative molecular mass 239.77
Assay Not less than 99 % and not more than 101 % of C₇H₄KNO₃S 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
$\alpha$-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis
$\beta$-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid $\beta$-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-$\beta$-D-fructofuranosyl-4-chloro-4-deoxy-$\alpha$-D-galactopyranoside
Einecs 259-952-2
Chemical formula C₁₂H₁₉Cl₃O₈
Molecular weight 397.64
Assay Content not less than 98 % and not more than 102 % of C₁₂H₁₉Cl₃O₈ 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 Rf 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

\[ [\alpha]_D^{20} = +84.0^\circ \text{ to } +87.5^\circ \] calculated on the anhydrous basis (10 % w/v solution)

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 2.0 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.7 %</td>
</tr>
<tr>
<td>Other chlorinated disaccharides</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Chlorinated monosaccharides</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Triphenylphosphine oxide</td>
<td>Not more than 150 mg/kg</td>
</tr>
<tr>
<td>Methanol</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

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-phenylalanine-2-methyl-L-β-aspartic acid

**Chemical formula**

C₁₈H₂₃O₉N₃S

**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

\[ [\alpha]_D^{20} = +14.5^\circ \text{ to } +16.5^\circ \]

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-piperazinacetic 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
Einces 209-567-0
Chemical formula
C₁₂H₂₄O₁₁
Relative molecular mass
344.31
Assay
Content not less than 98 % of D-maltitol
C₁₂H₂₄O₁₁ 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
\([\alpha]_D^{20} = +105.5°\) to \(+108.5°\) (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**

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 31% (Karl Fischer)</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3% (as glucose)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1%</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 100 mg/kg</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

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 C₁₂H₂₄O₁₁
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]D₂₀ = +13° to +16° calculated on the anhydrous basis (10% w/v aqueous solution)

**Purity**

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Crystalline products; not more than 10.5% (Karl Fischer method)</td>
</tr>
<tr>
<td>Other polyols</td>
<td>Not more than 2.5% on the anhydrous basis</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.2% expressed as glucose on dry weight basis</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 100 mg/kg expressed on dry weight basis</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 200 mg/kg expressed on dry weight basis</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1% expressed on dry weight basis</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg expressed on dry weight basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg expressed on dry weight basis</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg expressed on dry weight basis</td>
</tr>
</tbody>
</table>