DIRECTIVES

COMMISSION DIRECTIVE 2008/60/EC
of 17 June 2008
laying down specific purity criteria concerning sweeteners for use in foodstuffs
(Text with EEA relevance)
(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,


Whereas:

(1) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs (2) has been substantially amended several times (3). In the interest of clarity and rationality the said Directive should be codified.


(3) It is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(4) Food additives prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food or different from those mentioned in this Directive should be submitted for safety evaluation by the European Food Safety Authority with emphasis on the purity criteria.

(5) The measures provided for in this Directive are in line with the opinion of the Standing Committee on the Food Chain and Animal Health.

(6) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3(3)(a) of Directive 89/107/EC for sweeteners mentioned in Directive 94/35/EC are set out in Annex I to this Directive.

Article 2

Directive 95/31/EC, as amended by the Directives listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

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(3) See Annex II, Part A.
Article 3
This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 4
This Directive is addressed to the Member States.

Done at Brussels, 17 June 2008.

For the Commission
The President
José Manuel BARROSO
E 420 (i) — SORBITOL

Synonyms
D-glucitol, D-sorbitol

Definition

Chemical name
D-glucitol

Einecs
200-061-5

Chemical formula
C$_6$H$_{14}$O$_6$

Relative molecular mass
182,17

Assay
Content not less than 97 % of total glycitols and not less than 91 % of D-sorbitol on dry weight basis.

Glycitols are compounds with the structural formula CH$_2$OH-(CHOH)$_n$-CH$_2$OH, where ‘$n$’ is an integer

Description
White hygroscopic powder, crystalline powder, flakes or granules having a sweet taste

Identification

A. Solubility
Very soluble in water, slightly soluble in ethanol

B. Melting range
88 to 102 °C

C. Sorbitol monobenzylidene derivative
To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

Purity

Water content
Not more than 1 % (Karl Fischer method)

Sulphated ash
Not more than 0,1 % expressed on dry weight basis

Reducing sugars
Not more than 0,3 % expressed as glucose on dry weight basis

Total sugars
Not more than 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

Heavy metals
Not more than 10 mg/kg expressed as Pb on dry weight basis
E 420 (ii) — SORBITOL SYRUP

Synonyms
D-glucitol syrup

Definition

Chemical name
Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides.

The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where \( n \leq 4 \) may be present. Glycitols are compounds with the structural formula \( \text{CH}_2\text{OH}-(\text{CHOH})_n-\text{CH}_2\text{OH} \), where \( n \) is an integer.

Einecs
270-337-8

Assay
Content not less than 69 % total solids and not less than 50 % of D-sorbitol on the anhydrous basis

Description
Clear colourless and sweet-tasting aqueous solution

Identification

A. Solubility
Miscible with water, with glycerol, and with propane-1,2-diol

B. Melting range
To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

Purity

Water content
Not more than 31 % (Karl Fischer method)

Sulphated ash
Not more than 0,1 % expressed on dry weight basis

Reducing sugars
Not more than 0,3 % 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

Heavy metals
Not more than 10 mg/kg expressed as Pb on dry weight basis

E 421 — MANNITOL

(I) MANNITOL

Synonyms
D-mannitol
**Definition**

Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose

- **Chemical name**: D-mannitol
- **Enec**: 200-711-8
- **Chemical formula**: \( C_6H_{14}O_6 \)
- **Molecular weight**: 182.2
- **Assay**: Content not less than 96.0 % D-mannitol and not more than 102 % on the dried basis

**Description**

White, odourless, crystalline powder

**Identification**

- **A. Solubility**: Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
- **B. Melting range**: Between 164 and 169 °C
- **C. Thin layer chromatography**: Passes test
- **D. Specific rotation**: \([\alpha]_{20}^D + 23^\circ \) to + 25° (borate solution)
- **E. pH**: Between 5 and 8
  
  Add 0.5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

**Purity**

- **Loss on drying**: Not more than 0.3 % (105 °C, four hours)
- **Reducing sugars**: Not more than 0.3 % (as glucose)
- **Total sugars**: Not more than 1 % (as glucose)
- **Sulphated ash**: Not more than 0.1 %
- **Chlorides**: Not more than 70 mg/kg
- **Sulphate**: Not more than 100 mg/kg
- **Nickel**: Not more than 2 mg/kg
- **Lead**: Not more than 1 mg/kg

(II) MANNITOL MANUFACTURED BY FERMENTATION

**Synonyms**

D-mannitol

**Definition**

Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii*

- **Chemical name**: D-mannitol
Einecs 200-711-8
Chemical formula C\textsubscript{6}H\textsubscript{14}O\textsubscript{6}
Molecular weight 182.2
Assay Not less than 99 % on the dried basis

**Description**
White, odourless crystalline powder

**Identification**

A. Solubility Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range Between 164 and 169 °C
C. Thin layer chromatography Passes test
D. Specific rotation \( [\alpha]^{20}_D: + 23^\circ \text{ to } + 25^\circ \) (borate solution)
E. pH Between 5 and 8
\textit{Add 0.5 ml of a saturated solution of potassium chloride to 10 ml of a 10 \% w/v solution of the sample, then measure the pH}

**Purity**

Arabitol Not more than 0.3 %
Loss on drying Not more than 0.3 % (105 °C, four hours)
Reducing sugars Not more than 0.3 % (as glucose)
Total sugars Not more than 1 % (as glucose)
Sulphated ash Not more than 0.1 %
Chlorides Not more than 70 mg/kg
Sulphate Not more than 100 mg/kg
Lead Not more than 1 mg/kg
Aerobic mesophilic bacteria Not more than \( 10^3 \text{g} \)
Coliforms Absent in 10 g
Salmonella Absent in 10 g
E. Coli Absent in 10 g
Staphylococcus aureus Absent in 10 g
\textit{Pseudomonas aeruginosa}
Moulds Not more than 100/g
Yeasts Not more than 100/g
## E 950 — ACESULFAME K

### Synonyms
Acesulfame potassium, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one,2,2-dioxide

### Definition
- **Chemical name**: 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
- **Einecs**: 259-715-3
- **Chemical formula**: C₄H₄KNO₄S
- **Molecular weight**: 201.24
- **Assay**: Content not less than 99 % of C₄H₄KNO₄S on the anhydrous basis

### Description
Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose

### Identification
- **A. Solubility**: Very soluble in water, very slightly soluble in ethanol
- **B. Ultraviolet absorption**: Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
- **C. Positive test for potassium**: Passes test (test the residue obtained by igniting 2 g of the sample)
- **D. Precipitation test**: Add a few drops of a 10 % solution of sodium cobalt nitrite to a solution of 0.2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced

### Purity
- **Loss on drying**: Not more than 1 % (105 °C, two hours)
- **Organic impurities**: Passes test for 20 mg/kg of UV active components
- **Fluoride**: Not more than 3 mg/kg
- **Lead**: Not more than 1 mg/kg

## E 951 — ASPARTAME

### Synonyms
Aspartyl phenylalanine methyl ester

### Definition
- **Chemical name**: N-L-α-(Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carboxymethoxy-phenethyl)-succinamic acid-N-methyl ester
- **Einecs**: 245-261-3
- **Chemical formula**: C₁₄H₁₈N₂O₅
- **Relative molecular mass**: 294.31
- **Assay**: Not less than 98 % and not more than 102 % of C₁₄H₁₈N₂O₅ on the anhydrous basis
### Description
White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose.

### Identification
#### Solubility
Slightly soluble in water and in ethanol

### Purity
- **Loss on drying**: Not more than 4.5% (105 °C, four hours)
- **Sulphated ash**: Not more than 0.2% expressed on dry weight basis
- **pH**: Between 4.5 and 6.0 (1 in 125 solution)
- **Transmittance**: The transmittance of a 1% solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0.95, equivalent to an absorbance of not more than approximately 0.022
- **Specific rotation**: $\alpha_D^{20} + 14.5$ to $+16.5°$
  - Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution
- **Arsenic**: Not more than 3 mg/kg expressed on dry weight basis
- **Lead**: Not more than 1 mg/kg expressed on dry weight basis
- **Heavy metals**: Not more than 10 mg/kg expressed as Pb on dry weight basis
- **5-Benzyl-3,6-dioxo-2-piperazineacetic acid**: Not more than 1.5% expressed on dry weight basis

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### E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS

#### (I) CYCLAMIC ACID

#### Synonyms
Cyclohexylsulphamic acid, cyclamate

#### Definition
- **Chemical name**: Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid
- **Einecs**: 202-898-1
- **Chemical formula**: $C_6H_{13}NO_3S$
- **Relative molecular mass**: 179.24
- **Assay**: Cyclohexylsulphamic acid contains not less than 98% and not more than the equivalent of 102% of $C_6H_{13}NO_3S$, calculated on the anhydrous basis

#### Description
A practically colourless, white crystalline powder with a sweet-sour taste. Approximately 40 times as sweet as sucrose.

#### Identification
- **A. Solubility**: Soluble in water and in ethanol
B. Precipitation test

Acidify a 2% solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10% solution of sodium nitrite. A white precipitate forms.

Purity

**Loss on drying**

Not more than 1% (105 °C, one hour)

**Selenium**

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

**Lead**

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

**Heavy metals**

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

**Arsenic**

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

**Cyclohexylamine**

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

**Dicyclohexylamine**

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

**Aniline**

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

(II) SODIUM CYCLAMATE

**Synonyms**

Cyclamate, sodium salt of cyclamic acid

**Definition**

Chemical name: Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate

Einecs: 205-348-9

Chemical formula: C₆H₁₂NNaO₃S and the dihydrate form C₆H₁₂NNaO₃S·2H₂O

Relative molecular mass: 201.22 calculated on the anhydrous form

237.22 calculated on the hydrated form

**Assay**

Not less than 98% and not more than 102% on the dried basis

Dihydrate form: not less than 84% on the dried basis

**Description**

White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose

**Identification**

Solubility

Soluble in water, practically insoluble in ethanol

**Purity**

**Loss on drying**

Not more than 1% (105 °C, one hour)

Not more than 15.2% (105 °C, two hours) for the dihydrate form

**Selenium**

Not more than 30 mg/kg expressed as selenium 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

**Heavy metals**

Not more than 10 mg/kg expressed as Pb on dry weight basis
Cyclohexylamine  Not more than 10 mg/kg expressed on dry weight basis
Dicyclohexylamine  Not more than 1 mg/kg expressed on dry weight basis
Aniline  Not more than 1 mg/kg expressed on dry weight basis

(III) CALCIUM CYCLAMATE

Synonyms  Cyclamate, calcium salt of cyclamic acid
Definition
Chemical name  Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate
Einecs  205-349-4
Chemical formula  \( \text{C}_{12}\text{H}_{24}\text{CaN}_{2}\text{O}_{6}\text{S}_{2} \cdot 2\text{H}_{2}\text{O} \)
Relative molecular mass  432,57
Assay  Not less than 98 % and not more than 101 % on the dried basis
Description  White, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose
Identification
Solubility  Soluble in water, sparingly soluble in ethanol
Purity
Loss on drying  Not more than 1 % (105 °C, one hour)
Not more than 8,5 % (140 °C, four hours) for the dihydrate form
Selenium  Not more than 30 mg/kg expressed as selenium 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
Heavy metals  Not more than 10 mg/kg expressed as Pb on dry weight basis
Cyclohexylamine  Not more than 10 mg/kg expressed on dry weight basis
Dicyclohexylamine  Not more than 1 mg/kg expressed on dry weight basis
Aniline  Not more than 1 mg/kg expressed on dry weight basis

E 953 — ISOMALT

Synonyms  Hydrogenated isomaltulose, hydrogenated palatinose.
## Definition

**Chemical name** Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides: 6-O-\(\alpha\)-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-\(\alpha\)-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM).

**Chemical formula**
- 6-O-\(\alpha\)-D-Glucopyranosyl-D-sorbitol: \(\text{C}_{12}\text{H}_{24}\text{O}_{11}\)
- 1-O-\(\alpha\)-D-Glucopyranosyl-D-mannitol dihydrate: \(\text{C}_{12}\text{H}_{24}\text{O}_{11} \cdot 2\text{H}_{2}\text{O}\)

**Relative molecular mass**
- 6-O-\(\alpha\)-D-Glucopyranosyl-D-sorbitol: 344.32
- 1-O-\(\alpha\)-D-Glucopyranosyl-D-mannitol dihydrate: 380.32

**Assay**
Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O-\(\alpha\)-D-Glucopyranosyl-D-sorbitol and 1-O-\(\alpha\)-D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis.

### Description
Odourless, white, slightly hygroscopic, crystalline mass.

### Identification

**A. Solubility**
Soluble in water, very slightly soluble in ethanol.

**B. Thin layer chromatography**
Examine by thin layer chromatography using a plate coated with an approximately 0.2 mm layer of chromatographic silica gel. The principal spots in the chromatogram are those of 1,1-GPM and 1,6-GPS.

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 7 % (Karl Fischer Method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.05 % expressed on dry weight basis</td>
</tr>
<tr>
<td>D-Mannitol</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>D-Sorbitol</td>
<td>Not more than 6 %</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3 % expressed as glucose 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>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 10 mg/kg expressed on dry weight basis</td>
</tr>
</tbody>
</table>

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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 $C_7H_5NO_3S$

Relative molecular mass 183.18

Assay Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ 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 to 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

$\alpha$-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

(II) SODIUM SACCHARIN

Synonyms Saccharin, sodium salt of saccharin

Definition

Chemical name Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisoulsulphonazole, oxobenzisoulsulphonazole, 1,2-benzoisothiazolin-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 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-oxobenzisulphonazole, 1,2-benzothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)

**Einecs**

229-349-9

**Chemical formula**

C₁₄H₈CaN₂O₆S₂·3½H₂O

**Relative molecular mass**

467.48

**Assay**

Not less than 95% of C₁₄H₈CaN₂O₆S₂ 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-oxobenzisulphonazole, potassium salt of 1,2-benzothiazolin-3-one-1,1-dioxide monohydrate

Einecs

Chemical formula
C_7H_4KNO_3S.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

**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  \( C_{12}H_{19}Cl_{3}O_{8} \)

Molecular weight  397.64

Assay  Content not less than 98 % and not more than 102 % \( C_{12}H_{19}Cl_{3}O_{8} \) 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 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  \([\alpha]^{20}_{D} + 84.0° \text{ to } + 87.5° \text{ calculated on the anhydrous basis (10 % w/v solution)}\)
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

E 957 — THAUMATIN

Synonyms

Chemical name Thaumatin is obtained by aqueous extraction (pH 2.5 to 4) of the arils of the fruit of the natural strain of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material

Einecs 258-822-2

Chemical formula Polypeptide of 207 amino acids

Relative molecular mass Thaumatin I 22209

Thaumatin II 22293

Assay Not less than 16 % nitrogen on the dried basis equivalent to not less than 94 % proteins (N × 5,8)

Description Odourless, cream-coloured powder with an intensely sweet taste. Approximately 2 000 to 3 000 times as sweet as sucrose

Identification

Solubility Very soluble in water, insoluble in acetone

Purity

Loss on drying Not more than 9 % (105 °C to constant weight)

Carbohydrates Not more than 3 % expressed on dry weight basis

Sulphated ash Not more than 2 % expressed on dry weight basis
Aluminium  Not more than 100 mg/kg expressed on dry weight basis
Arsenic  Not more than 3 mg/kg expressed on dry weight basis
Lead  3 mg/kg expressed on dry weight basis
Microbiological criteria  Total aerobic microbial count: Max 1 000/g E. Coli: absent in 1 g

E 959 — NEOHESPERIDINE DIHYDROCHALCONE

Synonyms  Neohesperidin dihydrochalcone, NHDC, hesperetin dihydrochalcone-4′-β-neohesperidoside, neohesperidin DC

Definition  Chemical name 2-O-α-L-rhamnopyranosyl-4′-β-D-glucopyranosyl hesperetin dihydrochalcone; obtained by catalytic hydrogenation of neohesperidin

EINECS  243-978-6

Chemical formula  C_{28}H_{36}O_{15}

Relative molecular mass  612.6

Assay  Content not less than 96 % on the dried basis

Description  Off-white, odourless, crystalline powder having a characteristic, intensive sweet taste. Approximately between 1 000 and 1 800 times as sweet as sucrose

Identification
A. Solubility  Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene
B. Ultraviolet absorption maximum  282 to 283 nm for a solution of 2 mg in 100 ml methanol
C. Neu's test  Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1 % 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced

Purity
Loss on drying  Not more than 11 % (105 °C, three hours)
Sulphated ash  Not more than 0.2 % expressed on dry weight basis
Arsenic  Not more than 3 mg/kg expressed on dry weight basis
Lead  Not more than 2 mg/kg expressed on dry weight basis
Heavy metals  Not more than 10 mg/kg expressed as Pb on dry weight basis
**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**
C$_{18}$H$_{23}$O$_{9}$N$_{3}$S

**Molecular weight**
457.46

**Assay**
63.0 % to 66.0 % aspartame (dry basis) and 34.0 % to 37.0 % acesulfame (acid form on a dry basis)

**Description**
A white, odourless, crystalline powder.

**Identification**

A. **Solubility**
Sparingly soluble 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° to + 16.5°
Determine at a 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

---

**E 965 (i) — MALTITOL**

**Synonyms**
D-Maltitol, hydrogenated maltose

**Definition**

Chemical name
\((\alpha\)-D-Glucopyranosyl-1,4-D-glucitol

Einecs
209-567-0

Chemical formula
C$_{12}$H$_{24}$O$_{11}$
<table>
<thead>
<tr>
<th>Relative molecular mass</th>
<th>344.31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay</td>
<td>Content not less than 98 % D-maltitol (\text{C}<em>{12}\text{H}</em>{22}\text{O}_{11}) on the anhydrous basis</td>
</tr>
</tbody>
</table>

**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

\([\alpha]_D^{20} = + 105.5^\circ \text{ to } +108.5^\circ \) (5 % w/v solution)

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
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<tbody>
<tr>
<td>Water content</td>
<td>Not more than 1 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 % expressed on dry weight basis</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.1 % expressed as glucose on dry weight basis</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 50 mg/kg expressed on dry weight basis</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 100 mg/kg 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>

**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>Component</th>
<th>Specification</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>Sulphate</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>

### 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**: \([\alpha]_{D}^{20} = +13^\circ\) to \(+16^\circ\) calculated on the anhydrous basis (10% w/v aqueous solution)

#### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Crystalline products; not more than 10.5% (Karl Fischer)</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>
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</tbody>
</table>
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

**E 967 — XYLITOL**

**Synonyms**
Xylitol

**Definition**
- Chemical name: D-xylitol
- EINECS: 201-788-0
- Chemical formula: C$_5$H$_{12}$O$_5$
- Relative molecular mass: 152.15
- Assay: Not less than 98.5 % as xylitol on the anhydrous basis

**Description**
White, crystalline powder, practically odourless with a very sweet taste

**Identification**
- A. Solubility: Very soluble in water, sparingly soluble in ethanol
- B. Melting range: 92 to 96 °C
- C. pH: 5 to 7 (10 % w/v aqueous solution)

**Purity**
- Loss on drying: Not more than 0.5 %. Dry 0.5 g of sample in a vacuum over phosphorus at 60 °C for four hours
- Sulphated ash: Not more than 0.1 % expressed on dry weight basis
- Reducing sugars: Not more than 0.2 % expressed as glucose on dry weight basis
- Other polyhydric alcohols: Not more than 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
- Heavy metals: Not more than 10 mg/kg expressed as Pb 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
<table>
<thead>
<tr>
<th><strong>E 968 — ERYTHRITOL</strong></th>
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<tbody>
<tr>
<td><strong>Synonyms</strong></td>
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<tr>
<td><strong>Definition</strong></td>
</tr>
<tr>
<td>Chemical name</td>
</tr>
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<td>Einecs</td>
</tr>
<tr>
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<td><strong>Assay</strong></td>
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<td><strong>Description</strong></td>
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<tr>
<td><strong>Identification</strong></td>
</tr>
<tr>
<td>A. Solubility</td>
</tr>
<tr>
<td>B. Melting range</td>
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<tr>
<td><strong>Purity</strong></td>
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<tr>
<td>Loss on drying</td>
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<tr>
<td>Sulphated ash</td>
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<tr>
<td>Reducing substances</td>
</tr>
<tr>
<td>Ribitol and glycerol</td>
</tr>
<tr>
<td>Lead</td>
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</tbody>
</table>
ANNEX II

PART A

Repealed Directive with list of its successive amendments
(referred to in Article 2)


PART B

List of time-limits for transposition into national law
(referred to in Article 2)

<table>
<thead>
<tr>
<th>Directive</th>
<th>Time-limit for transposition</th>
</tr>
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<tbody>
<tr>
<td>95/31/EC</td>
<td>1 July 1996 (1)</td>
</tr>
<tr>
<td>98/66/EC</td>
<td>1 July 1999</td>
</tr>
<tr>
<td>2000/51/EC</td>
<td>30 June 2001</td>
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<td>2001/52/EC</td>
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<td>2004/46/EC</td>
<td>1 April 2005</td>
</tr>
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<td>2006/128/EC</td>
<td>15 February 2008</td>
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</table>

(1) According to Article 2(2) of Directive 95/31/EC, products put on the market or labelled before 1 July 1996 which do not comply with this Directive may be marketed until stocks are exhausted.
### ANNEX III

**Correlation table**

<table>
<thead>
<tr>
<th>Directive 95/31/EC</th>
<th>This Directive</th>
</tr>
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<tbody>
<tr>
<td>Article 1(1)</td>
<td>Article 1</td>
</tr>
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<td>Article 1(2)</td>
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</tr>
<tr>
<td>Article 2</td>
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<td>Annex III</td>
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