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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)

(OJ L 158, 18.6.2008, p. 17)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Directive 2010/37/EU of 17 June 2010	L 152	12	18.6.2010

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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,

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 authorized for use in foodstuffs intended for human consumption ([1]), and in particular Article 3(3)(a) thereof,

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.

(2) It is necessary to establish purity criteria for all sweeteners mentioned in European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs ([4]).

(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,

([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 178, 28.7.1995, p. 1. Directive as last amended by Directive 2006/128/EC (OJ L 346, 9.12.2006, p. 6).
([3]) See Annex II, Part A.
([4]) 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).

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HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3(3)(a) of Directive 89/107/EEC 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.

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.

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ANNEX I

E 420 (i) — SORBITOL

Synonyms	D-glucitol, D-sorbitol
Definition	
Chemical name	D-glucitol
Einecs	200-061-5
Chemical formula	$C_6H_{14}O_6$
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 $CH_2OH\text{-}(CHOH)_n\text{-}CH_2OH$, 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

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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 $CH_2OH\text{-}(CHOH)_n\text{-}CH_2OH$, 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

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Definition	Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose
Chemical name	D-mannitol
Einecs	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 ° 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

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Einecs	200-711-8
Chemical formula	$C_6H_{14}O_6$
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 ° 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	
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/g
Coliforms	Absent in 10 g
Salmonella	Absent in 10 g
E. Coli	Absent in 10 g
Staphylococcus aureus	Absent in 10 g
Pseudomonas aeruginosa	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g

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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	$C_4H_4KNO_4S$
Molecular weight	201,24
Assay	Content not less than 99 % of $C_4H_4KNO_4S$ 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-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester
Einecs	245-261-3
Chemical formula	$C_{14}H_{18}N_2O_5$
Relative molecular mass	294,31
Assay	Not less than 98 % and not more than 102 % of $C_{14}H_{18}N_2O_5$ on the anhydrous basis

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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

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

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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	$C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S \cdot 2H_2O$
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

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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	$C_{12}H_{24}CaN_2O_6S_2 \cdot 2H_2O$
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.

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Definition	
Chemical name	Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides: 6-O-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)
Chemical formula	6-O-α-D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$ 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11}.2H_2O$
Relative molecular mass	6-O-α-D-Glucopyranosyl-D-sorbitol: 344,32 1-O-α-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-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-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	
Water content	Not more than 7 % (Karl Fischer Method)
Sulphated ash	Not more than 0,05 % expressed on dry weight basis
D-Mannitol	Not more than 3 %
D-Sorbitol	Not more than 6 %
Reducing sugars	Not more than 0,3 % expressed as glucose 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 (as Pb)	Not more than 10 mg/kg expressed on dry weight basis.

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

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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
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

(II) SODIUM SACCHARIN

Synonyms	Saccharin, sodium salt of saccharin
Definition	
Chemical name	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisosulphonazole, oxobenziso-sulphonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate
Einecs	204-886-1
Chemical formula	$C_7H_4NNaO_3S{\cdot}2H_2O$

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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-oxobenzisosulphonazole, 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

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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-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)

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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	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ 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 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 1,0g of sucralose reference standard in 10 ml of methanol.
D. Specific rotation	$[\alpha]\ ^{20}_{D}$ + 84,0 ° to + 87,5 ° calculated on the anhydrous basis (10 % w/v solution)

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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	
Definition	
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

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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

▼M1

E 961 — NEOTAME

Synonyms	N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester, N(3,3-dimethylbutyl)-L-aspartyl-L-phenylalanine methyl ester
Definition	Neotame is manufactured by reaction under hydrogen pressure of aspartame with 3,3,-dimethylbutyraldehyde in methanol in presence of a palladium/carbon catalyst. It is isolated and purified by filtration, where diatomaceous earth may be used. After solvent removal via distillation, neotame is washed with water, isolated by centrifugation and finally vacuum dried
CAS No	165450-17-9
Chemical name	N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester
Chemical formula	$C_{20}H_{30}N_2O_5$
Molecular weight	378,47
Description	white to off-white powder
Assay	Not less than 97,0 % on the dried basis
Identification	
Solubility	4,75 % (w/w) at 60 °C in water, soluble in ethanol and ethyl acetate
Purity	
Water content	Not more than 5 % (Karl Fischer, sample size 25 ± 5 mg)
pH	5,0 – 7,0 (0,5 % aqueous solution)
Melting range	81 °C to 84 °C
N-[(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine	Not more than 1,5 %
Lead	Not more than 1 mg/kg

▼B

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.

▼B

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	$C_{18}H_{23}O_9N_3S$
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	$[\alpha]\ ^{20}_{D}$ + 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	(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 % 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 ° to + 108,5 ° (5 % w/v solution)

▼B

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 0,1 % 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

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

▼B

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	$[\alpha]_D^{20}$ = + 13 ° to + 16 ° calculated on the anhydrous basis (10 % w/v aqueous solution)
Purity	
Water content	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

E 967 — XYLITOL

Synonyms	Xylitol
Definition	
Chemical name	D-xylitol
Einecs	201-788-0
Chemical formula	$C_5H_{12}O_5$
Relative molecular mass	152,15

▼B

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

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	$C_4H_{10}O_4$
Molecular weight	122,12
Assay	Not less than 99 % after drying

▼B

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

▼B

ANNEX II

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 2)

Commission Directive 95/31/EC	(OJ L 178, 28.7.1995, p. 1)
Commission Directive 98/66/EC	(OJ L 257, 19.9.1998, p. 35)
Commission Directive 2000/51/EC	(OJ L 198, 4.8.2000, p. 41)
Commission Directive 2001/52/EC	(OJ L 190, 12.7.2001, p. 18)
Commission Directive 2004/46/EC	(OJ L 114, 21.4.2004, p. 15)
Commission Directive 2006/128/EC	(OJ L 346, 9.12.2006, p. 6)

PART B

List of time-limits for transposition into national law

(referred to in Article 2)

Directive	Time-limit for transposition
95/31/EC	1 July 1996 ([1])
98/66/EC	1 July 1999
2000/51/EC	30 June 2001
2001/52/EC	30 June 2002
2004/46/EC	1 April 2005
2006/128/EC	15 February 2008

([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.

▼B

ANNEX III

Correlation table

Directive 95/31/EC	This Directive
Article 1(1)	Article 1
Article 1(2)	—
Article 2	—
—	Article 2
Article 3	Article 3
Article 4	Article 4
Annex	Annex I
—	Annex II
—	Annex III