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COMMISSION DIRECTIVE 95/31/EC

of 5 July 1995

laying down specific criteria of purity concerning sweeteners for use in foodstuffs

(Text with EEA relevance)

(OJ L 178, 28.7.1995, p. 1)

Amended by:

	Official Journal		
	No	page	date
► <u>M1</u> Commission Directive 98/66/EC of 4 September 1998	L 257	35	19.9.1998
► <u>M2</u> Commission Directive 2000/51/EC of 26 July 2000	L 198	41	4.8.2000
► <u>M3</u> Commission Directive 2001/52/EC of 3 July 2001	L 190	18	12.7.2001
► <u>M4</u> Commission Directive 2004/46/EC of 16 April 2004	L 114	15	21.4.2004

▼B**COMMISSION DIRECTIVE 95/31/EC****of 5 July 1995****laying down specific criteria of purity concerning sweeteners for use in foodstuffs****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption ⁽¹⁾, as amended by Directive 94/34/EC ⁽²⁾, and in particular Article 3 (3) (a) thereof,

After consultation of the Scientific Committee on Food,

Whereas 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 ⁽³⁾;

Whereas it is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the *Codex Alimentarius* and the Joint FAO/WHO Expert Committee on Food Additives (Jecfa);

Whereas food additives, prepared by production methods or starting materials significantly different from those included in the evaluation of the Scientific Committee for Food, or different from those mentioned in this Directive, should be submitted for evaluation by the Scientific Committee for Food with a view to full evaluation with emphasis on the purity criteria;

Whereas the measures provided for in this Directive are in line with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Purity criteria mentioned under Article 3 (3) (a) of Directive 89/107/EEC for sweeteners mentioned in Directive 94/35/EC are set out in the Annex.
2. The purity criteria for E 420 (i), E 420 (ii) and E 421 mentioned in the Annex to this Directive supersede the purity criteria for the said substances mentioned in the Annex to Council Directive 78/663/EEC ⁽⁴⁾.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1996. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

⁽¹⁾ OJ No L 40, 11. 2. 1989, p. 27.

⁽²⁾ OJ No L 237, 10. 9. 1994, p. 1.

⁽³⁾ OJ No L 237, 10. 9. 1994, p. 3.

⁽⁴⁾ OJ No L 223, 14. 8. 1978, p. 7.

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Article 3

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

Article 4

This Directive is addressed to the Member States.

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ANNEX

E 420 (i) — SORBITOL

Synonyms	D-glucitol, D-sorbitol
Definition	
Chemical name	D-glucitol
Einecs	200-061-5
E number	E 420 (i)
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 the dry weight basis. Glycitols are compounds with the structural formula $CH_2OH-(CHOH)_n-CH_2OH$, 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

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-crystallizing) or mannitol. Minor quantities of glycitols where

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<p>Einecs</p> <p>E number</p> <p>Assay</p> <p>Description</p> <p>Identification</p> <p>A. Solubility</p> <p>B. Sorbitol monobenzylidene derivative</p> <p>Purity</p> <p>Water content</p> <p>Sulphated ash</p> <p>Reducing sugars</p> <p>Chlorides</p> <p>Sulphates</p> <p>Nickel</p> <p>Arsenic</p> <p>Lead</p> <p>Heavy metals</p>	<p>$n \leq 4$ may be present. Glycitol is a compound with the structural formula $\text{CH}_2\text{OH}-(\text{CHOH})_n-\text{CH}_2\text{OH}$, where 'n' is an integer</p> <p>270-337-8</p> <p>E 420 (ii)</p> <p>Content not less than 69 % total solids and not less than 50 % of D-sorbitol on the anhydrous basis</p> <p>Clear colourless and sweet tasting aqueous solution</p> <p>Miscible with water, with glycerol, and with propane-1,2-diol</p> <p>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</p> <p>Not more than 31 % (Karl Fischer method)</p> <p>Not more than 0,1 % expressed on dry weight basis</p> <p>Not more than 0,3 % expressed as glucose on dry weight basis</p> <p>Not more than 50 mg/kg expressed on dry weight basis</p> <p>Not more than 100 mg/kg expressed on dry weight basis</p> <p>Not more than 2 mg/kg expressed on dry weight basis</p> <p>Not more than 3 mg/kg expressed on dry weight basis</p> <p>Not more than 1 mg/kg expressed on dry weight basis</p> <p>Not more than 10 mg/kg expressed as Pb on dry weight basis</p>
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▼ **M3****E 421 MANNITOL****1. Mannitol****Synonyms**

D-mannitol

Definition

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

Chemical name

D-mannitol

Einecs

200-711-8

Chemical formula

 $\text{C}_6\text{H}_{14}\text{O}_6$

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

[α]_D²⁰; + 23° to + 25° (borate solution)

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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
2 . Mannitol manufactured by fermentation	
Synonyms	
D-mannitol	
Definition	
Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast <i>Zygosaccharomyces rouxii</i>	
Chemical name	D-mannitol
Einesc	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	$[\alpha]_D^{20}$: + 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
<i>Salmonella</i>	Absent in 10 g
<i>E. coli</i>	Absent in 10 g

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<i>Staphylococcus aureus</i>	Absent in 10 g
<i>Pseudomonas aeruginosa</i>	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g

▼ **M1****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- 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: $C_{12}H_{24}O_{11} \cdot 2H_2O$ *Relative molecular mass*6-O- α -D-Glucopyranosyl-D-sorbitol: 344,321-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 the 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 the dry weight basis

Nickel

Not more than 2 mg/kg expressed on the dry weight basis

Arsenic

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

Lead

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

Heavy metals (as Pb)

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

▼ **B****E 965 (i) — MALTITOL**

Synonyms	D-maltitol, hydrogenated maltose
Definition	
Chemical name	(α)-D-glucopyranosyl-1,4-D-glucitol
Einecs	209-567-0
E number	E 965 (i)
Chemical formula	$C_{12}H_{24}O_{11}$
Relative molecular mass	344,31
Assay	Content not less than 98 % D-mannitol $C_{12}H_{24}O_{11}$ 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	(α) _D ²⁰ = + 105,5 to + 105,5° (5 % w/v solution)
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
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis

▼ **M2****E 965 (ii) SYRUP MALTITOL**

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. 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 %

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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
E number	E 966
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 $+ 16^\circ$ 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
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 967 — XYLITOL**Synonyms**

Xylitol

Definition

Chemical name	D-xylitol
Einecs	201-788-0
E number	E 967
Chemical formula	$C_5H_{12}O_5$
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

▼B**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

▼M3**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. Ultra violet 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 cobaltnitrite 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

▼ **B****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
Einesc	245-261-3
E number	E 951
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
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(1) *CYCLAMIC ACID*

Synonyms	Cyclohexylsulphamic acid, cyclamate
Definition	
Chemical name	Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid
Einesc	202-898-1
E number	E 952
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	

▼ **B**

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) <i>SODIUM CYCLAMATE</i>	
Synonyms	Cyclamate, sodium salt of cyclamic acid
Definition	
Chemical name	Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate
Einecs	205-348-9
E number	E 952
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
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

▼ **B**(III) *CALCIUM CYCLAMATE***Synonyms**

Cyclamate, calcium salt of cyclamic acid

Definition

Chemical name

Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate

Einecs

205-349-4

E number

E 952

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 10 % 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 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

E number

E 954

Chemical formula

 $C_7H_5NO_3S$

Relative molecular mass

183,18

Assay

Not less than 99 % and not more than 101,0 % 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

▼**B**

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
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis
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 carbonizable substances	Absent
(II) SODIUM SACCHARIN	
Synonyms	Saccharin, sodium salt of saccharin
Definition	
Chemical name	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulfonazole, oxobenzisulfonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate
Einecs	204-886-1
E number	E 954
Chemical formula	$C_7H_4NNaO_3S \cdot 2H_2O$
Relative molecular mass	241,19
Assay	Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline efflorescent powder, odourless or with a faint, odour, hving 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)
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
Heavy metals	Not more than 10 mg/kg expressed as Pb 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 carbonizable substances	Absent
(III) CALCIUM SACCHARIN	
Synonyms	Saccharin, calcium salt of saccharin

▼B

Definition	
Chemical name	Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-0
E number	E 954
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$
Relative molecular mass	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, soluble in ethanol
Purity	
Loss on drying	Not more than 13,5 % (120 °C, four hours)
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
Heavy metals	Not more than 10 mg/kg expressed as Pb 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 carbonizable substances	Absent
(IV) <i>POTASSIUM SACCHARIN</i>	
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-benzisothiazolin-3-one-1,1-dioxide monohydrate
Einecs	
E number	E 954
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

▼ **B****Purity**

Loss on drying	Not more than 8 % (120 °C, four hours)
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
Heavy metals	Not more than 10 mg/kg expressed as Pb 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 carbonizable substances	Absent

▼ **M4****E 955 — SUCRALOSE****Synonyms**

4,1',6'-trichlorogalactosucrose

Definition

Chemical name

1,6-Dichloro-1,6-dideoxy-b-D-fructofuranosyl-4-chloro-4-deoxy-a-D-galactopyranoside

Eines

259-952-2

Chemical formula

 $C_{12}H_{19}Cl_3O_8$

Molecular weight

397,64

AssayContent 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. pH of a 10 % solution

Not less than 5,0 and not more than 7,0

B. Solubility

Freely soluble in water, methanol and ethanol

Slightly soluble in ethyl acetate

C. 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.

D. Thin-layer chromatography

The main spot in the test solution has the same R_f value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol.

E. Specific rotation

[α]²⁰_D: + 84,0° to + 87,5° 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 %

Lead

Not more than 1 mg/kg

Other chlorinated disaccharides

Not more than 0,5 %

Chlorinated monosaccharides

Not more than 0,1 %

Triphenylphosphine oxide

Not more than 150 mg/kg

▼ **M4**

Methanol	Not more than 0,1 %
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▼ **B****E 957 — THAUMATIN****Synonyms****Definition**

Chemical name	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
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Einecs	258-822-2
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E number	E 957
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Chemical formula	Polypeptide of 207 aminoacids
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Relative molecular mass	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
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Assay	Not less than 16 % nitrogen on the dried basis equivalent to not less than 94 % proteins (N × 5,8)
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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
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Purity

Loss on drying	Not more than 9 % (105 °C to constant weight)
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Carbohydrates	Not more than 3 % expressed on dry weight basis
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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
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Arsenic	Not more than 3 mg/kg expressed on dry weight basis
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Lead	3 mg/kg expressed on dry weight basis
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Microbiological criteria	Total aerobic microbial count: Max 1 000/g <i>E. Coli</i> : absent in 1 g
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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
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Einecs	243-978-6
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E number	E 959
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Chemical formula	C ₂₈ H ₃₆ O ₁₅
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Relative molecular mass	612,6
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Assay	Content not less than 96 % on the dried basis
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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
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▼B

B. Ultraviolet absorption maximum	water, practically insoluble in ether and benzene 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

▼M4**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-a-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 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	[α] 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, 4 h)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg