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(Acts whose publication is obligatory)

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.

⁽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.

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.

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.

Done at Brussels, 5 July 1995.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

E 420 (i) — SORBITOL

Synonyms	D-glucitol, D-sorbitol
Definition	
<i>Chemical name</i>	D-glucitol
<i>Einecs</i>	200-061-5
<i>E number</i>	E 420 (i)
<i>Chemical formula</i>	$C_6H_{14}O_6$
<i>Relative molecular mass</i>	182,17
<i>Assay</i>	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. <i>Solubility</i>	Very soluble in water, slightly soluble in ethanol
B. <i>Melting range</i>	88 to 102 °C
C. <i>Sorbitol monobenzylidene derivative</i>	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	
<i>Water content</i>	Not more than 1% (Karl Fischer method)
<i>Sulphated ash</i>	Not more than 0,1% expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,3% expressed as glucose on dry weight basis
<i>Total sugars</i>	Not more than 1% expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 50 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis

<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
E 420 (ii) — SORBITOL SYRUP	
Synonyms	D-clucitol syrup
Definition	
<i>Chemical name</i>	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 $n \leq 4$ 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
<i>Einecs</i>	270-337-8
<i>E number</i>	E 420 (ii)
<i>Assay</i>	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	
<i>A. Solubility</i>	Miscible with water, with glycerol, and with propane-1,2-diol
<i>B. Sorbitol monobenzylidene derivative</i>	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	
<i>Water content</i>	Not more than 31 % (Karl Fischer method)
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,3 % expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 50 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 421 — MANNITOL

Synonyms	D-mannitol
Definition	
<i>Chemical name</i>	D-mannitol
<i>Einecs</i>	200-711-8
<i>E number</i>	E 421
<i>Chemical formula</i>	C ₆ H ₁₄ O ₆
<i>Relative molecular mass</i>	182,2
<i>Assay</i>	Content not less than 96 % D-mannitol on the dried basis
Description	Sweet tasting, white, odourless, crystalline powder
Identification	
<i>A. Solubility</i>	Soluble
Purity	
<i>Loss on drying</i>	Not more than 0,3 % (105 °C, four hours)
<i>pH</i>	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
<i>Specific rotation</i>	$(\alpha)_{\text{D}}^{20}$ Specific rotation in a borated solution calculated with reference to the anhydrous substance is between + 23 and + 25°
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,3 % expressed as glucose on dry weight basis
<i>Total sugars</i>	Not more than 1 % expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 70 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 953 — ISOMALT

Synonyms	Hydrogenated isomaltulose, hydrogenated palatinose
Definition	
<i>Chemical name</i>	Isomalt is a mixture of: D-glucopyranosyl-1,6-D-glucitol and D-glucopyranosyl-1,1-D-mannitol dihydrate
<i>Einecs</i>	
<i>E number</i>	E 953
<i>Chemical formula</i>	D-glucopyranosyl-1,6-D-glucitol: $C_{12}H_{24}O_{11}$ D-glucopyranosyl-1,1-D-mannitol dihydrate: $C_{12}H_{24}O_{11} \cdot 2H_2O$
<i>Relative molecular mass</i>	D-glucopyranosyl-1,6-D-glucitol: 344,32 D-glucopyranosyl-1,1-D-mannitol dihydrate: 380,32
<i>Assay</i>	Content not less than 95 % of the mixture of D-glucopyranosyl-1,6-D-glucitol and D-glucopyranosyl-1,1-D-mannitol dihydrate determined on the anhydrous basis
Description	Odourless, white, sweet tasting, crystalline slightly hygroscopic substance
Identification	
A. <i>Solubility</i>	Slightly soluble in water, insoluble in ethanol
B. <i>Specific rotation</i>	$(\alpha)_D^{20}$: between + 90 and + 92° (4 % w/v solution)
C. <i>Melting range</i>	145 to 150 °C
Tests	
<i>Water content</i>	Not more than 7 % (Karl Fischer method)
<i>Sulphated ash</i>	Not more than 0,05 expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 1,5 % expressed as glucose on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed on dry weight basis

E 965 (i) — MALTITOL

Synonyms	D-maltitol, hydrogenated maltose
Definition	
<i>Chemical name</i>	(α)-D-glucopyranosyl-1,4-D-glucitol

<i>Einecs</i>	209-567-0
<i>E number</i>	E 965 (i)
<i>Chemical formula</i>	$C_{12}H_{24}O_{11}$
<i>Relative molecular mass</i>	344,31
<i>Assay</i>	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. <i>Solubility</i>	Very soluble in water, slightly soluble in ethanol
B. <i>Melting range</i>	148 to 151 °C
C. <i>Specific rotation</i>	$(\alpha)_D^{20} = + 105,5$ to $+ 105,5^\circ$ (5 % w/v solution)
Purity	
<i>Water content</i>	Not more than 1 % (Karl Fischer method)
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,1 % expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 50 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 965 (ii) — MALTITOL SYRUP

Synonyms	Hydrogenated high maltose-glucose syrup, hydrogenated glucose syrup
Definition	
<i>Chemical name</i>	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
<i>Einecs</i>	270-337-8

<i>E number</i>	E 965 (ii)
<i>Assay</i>	The following ranges apply on the anhydrous basis: Maltitol not less than 50 % Sorbitol not more than 8 % Maltotriitol not more than 25 % Hydrogenated polysaccharides containing more than three glucose or glucitol units not more than 30 %
Description	Sweet-tasting, colourless and odourless, clear viscous liquids or sweet-tasting white crystalline masses
Identification	
<i>A. Solubility</i>	Very soluble in water, slightly soluble in ethanol
<i>B. Thin layer chromatography</i>	Examine by the thin layer chromatography using a plate coated with a 0,25 mm layer of chromatographic silica gel
Purity	
<i>Water content</i>	Not more than 31 % (Karl Fischer method)
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,3 % expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 50 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 966 — LACTITOL

Synonyms	Lactit, lactositol, lactobiosit
Definition	
<i>Chemical name</i>	4-O-β-D-galactopyranosyl-D-glucitol
<i>Einecs</i>	209-566-5
<i>E number</i>	E 966
<i>Chemical formula</i>	C ₁₂ H ₂₄ O ₁₁
<i>Relative molecular mass</i>	344,32
<i>Assay</i>	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. <i>Solubility</i>	Very soluble in water
B. <i>Specific rotation</i>	$(\alpha)_D^{20} = + 13$ to $+ 16^\circ$ calculated on the anhydrous basis (10 % w/v aqueous solution)
Purity	
<i>Water content</i>	Crystalline products; not more than 10,5 % (Karl Fischer method)
<i>Other polyols</i>	Not more than 2,5 % on the anhydrous basis
<i>Reducing sugars</i>	Not more than 0,2 % expressed as glucose on dry weight basis
<i>Chlorides</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 200 mg/kg expressed on dry weight basis
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 967 — XYLITOL

Synonyms	Xylitol
Definition	
<i>Chemical name</i>	D-xylitol
<i>Einecs</i>	201-788-0
<i>E number</i>	E 967
<i>Chemical formula</i>	$C_5H_{12}O_5$
<i>Relative molecular mass</i>	152,15
<i>Assay</i>	Not less than 98,5 % as xylitol on the anhydrous basis
Description	White, crystalline powder, practically odourless with a very sweet taste
Identification	
A. <i>Solubility</i>	Very soluble in water, sparingly soluble in ethanol
B. <i>Melting range</i>	92 to 96 °C
C. <i>pH</i>	5 to 7 (10 % w/v aqueous solution)

Purity	
<i>Loss on drying</i>	Not more than 0,5 %. Dry 0,5 g of sample in a vacuum over phosphorus at 60 °C for four hours
<i>Sulphated ash</i>	Not more than 0,1 % expressed on dry weight basis
<i>Reducing sugars</i>	Not more than 0,2 % expressed as glucose on dry weight basis
<i>Other polyhydric alcohols</i>	Not more than 1 % expressed on dry weight basis
<i>Nickel</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Chlorides</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Sulphates</i>	Not more than 200 mg/kg expressed on dry weight basis

E 950 — ACESULFAME K

Synonyms	Acesulfame potassium, acesulfam, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide
Definition	
<i>Chemical name</i>	6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
<i>Einecs</i>	259-715-3
<i>E number</i>	E 950
<i>Chemical formula</i>	$C_4H_4NO_4SK$
<i>Relative molecular mass</i>	201,24
<i>Assay</i>	Not less than 99 % of $C_4H_4NO_4SK$ on the anhydrous basis
Description	Odourless, white, crystalline powder having an intensively sweet taste. Approximately 200 times as sweet as sucrose
Identification	
A. <i>Solubility</i>	Very soluble in water, very slightly soluble in ethanol
B. <i>Ultra-violet absorption</i>	Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
Purity	
<i>Loss on drying</i>	Not more than 1 % (105 °C, two hours)

<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Selenium</i>	Not more than 30 mg/kg expressed on dry weight basis
<i>Fluoride</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
E 951 — ASPARTAME	
Synonyms	Aspartyl phenylalanine methyl ester
Definition	
<i>Chemical name</i>	N-L- α -(Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α -carbomethoxy-phenethyl)-succinamic acid-N-methyl ester
<i>Einecs</i>	245-261-3
<i>E number</i>	E 951
<i>Chemical formula</i>	$C_{14}H_{18}N_2O_5$
<i>Relative molecular mass</i>	294,31
<i>Assay</i>	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	
<i>Solubility</i>	Slightly soluble in water and in ethanol
Purity	
<i>Loss on drying</i>	Not more than 4,5 % (105 °C, four hours)
<i>Sulphated ash</i>	Not more than 0,2 % expressed on dry weight basis
<i>pH</i>	Between 4,5 and 6,0 (1 in 125 solution)
<i>Transmittance</i>	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
<i>Specific rotation</i>	$(\alpha)_D^{20}$: +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
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis

<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>5-Benzyl-3,6-dioxo-2-piperazineacetic acid</i>	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	
<i>Chemical name</i>	Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid
<i>Einecs</i>	202-898-1
<i>E number</i>	E 952
<i>Chemical formula</i>	$C_6H_{13}NO_3S$
<i>Relative molecular mass</i>	179,24
<i>Assay</i>	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. <i>Solubility</i>	Soluble in water and in ethanol
B. <i>Precipitation test</i>	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	
<i>Loss on drying</i>	Not more than 1% (105 °C, one hour)
<i>Selenium</i>	Not more than 30 mg/kg expressed as selenium on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Cyclohexylamine</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Dicyclohexylamine</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Aniline</i>	Not more than 1 mg/kg expressed on dry weight basis

(II) SODIUM CYCLAMATE

Synonyms	Cyclamate, sodium salt of cyclamic acid
Definition	
<i>Chemical name</i>	Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate
<i>Einecs</i>	205-348-9
<i>E number</i>	E 952
<i>Chemical formula</i>	$C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S \cdot 2H_2O$
<i>Relative molecular mass</i>	201,22 calculated on the anhydrous form 237,22 calculated on the hydrated form
<i>Assay</i>	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	
<i>Solubility</i>	Soluble in water, practically insoluble in ethanol
Purity	
<i>Loss on drying</i>	Not more than 1 % (105 °C, one hour) Not more than 15,2 % (105 °C, two hours) for the dihydrate form
<i>Selenium</i>	Not more than 30 mg/kg expressed as selenium on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Cyclohexylamine</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Dicyclohexylamine</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Aniline</i>	Not more than 1 mg/kg expressed on dry weight basis

(III) CALCIUM CYCLAMATE

Synonyms	Cyclamate, calcium salt of cyclamic acid
Definition	
<i>Chemical name</i>	Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate
<i>Einecs</i>	205-349-4
<i>E number</i>	E 952
<i>Chemical formula</i>	$C_{12}H_{24}CaN_2O_6S_2 \cdot 2H_2O$

<i>Relative molecular mass</i>	432,57
<i>Assay</i>	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	
<i>Solubility</i>	Soluble in water, sparingly soluble in ethanol
Purity	
<i>Loss on drying</i>	Not more than 1 % (105 °C, one hour) Not more than 8,5 % (140 °C, four hours) for the dihydrate form
<i>Selenium</i>	Not more than 30 mg/kg expressed as selenium on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Cyclohexylamine</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Dicyclohexylamine</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Aniline</i>	Not more than 1 mg/kg expressed on dry weight basis

E 954 — SACCHARIN AND ITS Na. K AND Ca SALTS

(I) SACCHARIN

Definition

<i>Chemical name</i>	3-oxo-2,3dihydrobenzo(d)isothiazol-1,1-dioxide
<i>Einecs</i>	201-321-0
<i>E number</i>	E 954
<i>Chemical formula</i>	$C_7H_5NO_3S$
<i>Relative molecular mass</i>	183,18
<i>Assay</i>	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	
<i>Solubility</i>	Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol

Purity	
<i>Loss on drying</i>	Not more than 1% (105 °C, two hours)
<i>Melting range</i>	226 to 230 °C
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Selenium</i>	Not more than 30 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Sulphated ash</i>	Not more than 0,2% expressed on dry weight basis
<i>Benzoic and salicylic acid</i>	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
<i>o-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>p-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Benzoic acid p-sulfonamide</i>	Not more than 25 mg/kg expressed on dry weight basis
<i>Readily carbonizable substances</i>	Absent
(II) SODIUM SACCHARIN	
Synonyms	Saccharin, sodium salt of saccharin
Definition	
<i>Chemical name</i>	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulfonazole, oxobenzisulfonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate
<i>Einecs</i>	204-886-1
<i>E number</i>	E 954
<i>Chemical formula</i>	$C_7H_4NNaO_3S \cdot 2H_2O$
<i>Relative molecular mass</i>	241,19
<i>Assay</i>	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	
<i>Solubility</i>	Freely soluble in water, sparingly soluble in ethanol
Purity	
<i>Loss on drying</i>	Not more than 15% (120 °C, four hours)

<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Selenium</i>	Not more than 30 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Benzoic and salicylic acid</i>	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
<i>o-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>p-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Benzoic acid p-sulfonamide</i>	Not more than 25 mg/kg expressed on dry weight basis
<i>Readily carbonizable substances</i>	Absent
(III) CALCIUM SACCHARIN	
Synonyms	Saccharin, calcium salt of saccharin
Definition	
<i>Chemical name</i>	Calcium o-benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzisulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
<i>Einecs</i>	229-349-0
<i>E number</i>	E 954
<i>Chemical formula</i>	$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$
<i>Relative molecular mass</i>	467,48
<i>Assay</i>	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	
<i>Solubility</i>	Freely soluble in water, soluble in ethanol
Purity	
<i>Loss on drying</i>	Not more than 13,5 % (120 °C, four hours)
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Selenium</i>	Not more than 30 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis

<i>Benzoic and salicylic acid</i>	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
<i>o-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>p-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>Benzoic acid p-sulfonamide</i>	Not more than 25 mg/kg expressed on dry weight basis
<i>Readily carbonizable substances</i>	Absent
(IV) POTASSIUM SACCHARIN	
Synonyms	Saccharin, potassium salt of saccharin
Definition	
<i>Chemical name</i>	Potassium o-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
<i>Einecs</i>	
<i>E number</i>	E 954
<i>Chemical formula</i>	$C_7H_4KNO_3S \cdot H_2O$
<i>Relative molecular mass</i>	239,77
<i>Assay</i>	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	
<i>Solubility</i>	Freely soluble in water, sparingly soluble in ethanol
Purity	
<i>Loss on drying</i>	Not more than 8 % (120 °C, four hours)
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Selenium</i>	Not more than 30 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 1 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis
<i>Benzoic and salicylic acid</i>	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
<i>o-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis
<i>p-Toluenesulphonamide</i>	Not more than 10 mg/kg expressed on dry weight basis

<i>Benzoic acid p-sulfonamide</i>	Not more than 25 mg/kg expressed on dry weight basis
<i>Readily carbonizable substances</i>	Absent

E 957 — THAUMATIN

Synonyms	
Definition	
<i>Chemical name</i>	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
<i>Einecs</i>	258-822-2
<i>E number</i>	E 957
<i>Chemical formula</i>	Polypeptide of 207 aminoacids
<i>Relative molecular mass</i>	Thaumatococcus I 22209 Thaumatococcus II 22293
<i>Assay</i>	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	
<i>Solubility</i>	Very soluble in water, insoluble in acetone
Purity	
<i>Loss on drying</i>	Not more than 9 % (105 °C to constant weight)
<i>Carbohydrates</i>	Not more than 3 % expressed on dry weight basis
<i>Sulphated ash</i>	Not more than 2 % expressed on dry weight basis
<i>Aluminium</i>	Not more than 100 mg/kg expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	3 mg/kg expressed on dry weight basis
<i>Microbiological criteria</i>	Total aerobic microbial count: Max 1 000/g <i>E. Coli</i> : absent in 1 g

E 959 — NEOHESPERIDINE DIHYDROCHALCONE

Synonyms	Neohesperidin dihydrochalcone, NHDC, hesperetin dihydrochalcone-4'- β -neohesperidoside, neohesperidin DC
Definition	
<i>Chemical name</i>	2-O- α -L-rhamnopyranosyl-4'- β -D-glucopyranosyl hesperetin dihydrochalcone; obtained by catalytic hydrogenation of neohesperidin

<i>Einecs</i>	243-978-6
<i>E number</i>	E 959
<i>Chemical formula</i>	$C_{28}H_{36}O_{15}$
<i>Relative molecular mass</i>	612,6
<i>Assay</i>	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	
<i>A. Solubility</i>	Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene
<i>B. Ultraviolet absorption maximum</i>	282 to 283 nm for a solution of 2 mg in 100 ml methanol
<i>C. Neu's test</i>	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	
<i>Loss on drying</i>	Not more than 11 % (105 °C, three hours)
<i>Sulphated ash</i>	Not more than 0,2 % expressed on dry weight basis
<i>Arsenic</i>	Not more than 3 mg/kg expressed on dry weight basis
<i>Lead</i>	Not more than 2 mg/kg expressed on dry weight basis
<i>Heavy metals</i>	Not more than 10 mg/kg expressed as Pb on dry weight basis