DIRECTIVES

COMMISSION DIRECTIVE 2008/128/EC

of 22 December 2008

laying down specific purity criteria concerning colours for use in foodstuffs

(Codified version)

(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), and in particular Article 3(3)(a) thereof,

Whereas:

- (1) Commission Directive 95/45/EC of 26 July 1995 laying down specific criteria concerning colours for use in food-stuffs (²) has been substantially amended several times (³). In the interests of clarity and rationality the said Directive should be codified.
- (2) It is necessary to establish purity criteria for all colours mentioned in European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in food-stuffs (4).
- (3) It is necessary to take into account the specifications and analytical techniques for colours 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 accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3(3)(a) of Directive 89/107/EEC for colours mentioned in Directive 94/36/EC are set out in Annex I hereto.

Article 2

Directive 95/45/EC, as amended by the Directives listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex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References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.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 20th day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2008.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²) OJ L 226, 22.9.1995, p. 1.

⁽³⁾ See Annex II, Part A.

⁽⁴⁾ OJ L 237, 10.9.1994, p. 13.

ANNEX I

A. GENERAL SPECIFICATIONS FOR ALUMINIUM LAKES OF COLOURS

Definition Aluminium lakes are prepared by reacting colours complying with the purity

criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulfate or chloride with sodium or calcium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted alumina may also be present in

the finished product.

HCl insoluble matter Not more than 0,5 %

Ether extractable matter Not more than 0,2 % (under neutral conditions)

Specific purity criteria for the corresponding colours are applicable.

B. SPECIFIC CRITERIA OF PURITY

E 100 CURCUMIN

CI Natural Yellow 3, Turmeric Yellow, Diferoyl Methane **Synonyms**

Definition Curcumin is obtained by solvent extraction of turmeric i.e. the ground rhizomes of natural strains of Curcuma longa L. In order to obtain a concentrated curcumin

powder, the extract is purified by crystallisation. The product consists essentially of curcumins; i.e. the colouring principle (1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-dien-3,5-dione) and its two desmethoxy derivatives in varying proportions. Minor amounts of oils and resins naturally occuring in turmeric

may be present.

Only the following solvents may be used in the extraction: ethylacetate, acetone, carbon dioxide, dichloromethane, n-butanol, methanol, ethanol, hexane.

Class

Dicinnamoylmethane

Colour Index No 75300

207-280-5 Einecs

Chemical names I 1,7-Bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione

II 1-(4-Hydroxyphenyl)-7-(4-hydroxy-3-methoxy-phenyl-)hepta-1,6-diene-3,5-

III 1,7-Bis(4-hydroxyphenyl)hepta-1,6-diene-3,5-dione

Chemical formula I C₂₁H₂₀O₆

II C₂₀H₁₈O₅

III C19H16O4

Molecular weight I. 368,39 II. 338,39 III. 308,39

Assay Content not less than 90 % total colouring matters

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 1 607 at ca 426 nm in ethanol

Description Orange-yellow crystalline powder

Identification

A. Spectrometry Maximum in ethanol at ca 426 nm

179 °C-182 °C B. Melting Range

Purity	
Solvent residues	Ethylacetate
	Acetone
	n-butanol Not more than 50 mg/kg
	Methanol singly or in combination
	Ethanol
	Hexane
	Dichloromethane: not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Heavy metals (as Pb)	Not more than 40 mg/kg
E 101 (i) RIBOFLAVIN	
Synonyms	Lactoflavin
Class	Isoalloxazine
Einecs	201-507-1
Chemical names	7,8-Dimethyl-10-(D-ribo-2,3,4,5-tetrahydroxypentyl)benzo(g)pteridine-2,4 (3H,10H)-dione
	7,8-dimethyl-10-(1'-D-ribityl)isoalloxazine
Chemical formula	$C_{17}H_{20}N_4O_6$
Molecular weight	376,37
Assay	Content not less than 98 % on the anhydrous basis
	$E_{1~cm}^{1~\%}$ 328 at ca 444 nm in aqueous solution
Description	Yellow to orange-yellow crystalline powder, with slight odour
Identification	
A. Spectrometry	The ratio A_{375}/A_{267} is between 0,31 and 0,33
	The ratio A_{444}/A_{267} is between 0,36 and 0,39 in aqueous solution
	Maximum in water at ca 444 nm
B. Specific rotation	$[\alpha]D^{20}$ between -115° and -140° in a 0,05 N sodium hydroxide solution
Purity	
Loss on drying	Not more than 1,5 % after drying at 105 °C for 4 hrs
Sulfated ash	Not more than 0,1 %
Primary aromatic amines	Not more than 100 mg/kg (calculated as aniline)
A	Not more than 2 malles

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 101 (ii) RIBOFLAVIN-5'-PHOSPHATE

Synonyms

 $Riboflavin\hbox{-}5'\hbox{-}phosphate\ sodium$

Definition

These specifications apply to riboflavin 5'-phosphate together with minor amounts of free riboflavin and riboflavin diphosphate

Class Isoalloxazine
Einecs 204-988-6
Chemical names Monosodium

 $(2R,3R,4S)-5-(3')10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl)-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzo[\gamma]pteridinyl-10'-dihydro-7'-di-10'-d$

2,3,4-trihydroxypentyl phosphate;

monosodium salt of 5'-monophosphate ester of riboflavin

Chemical formula For the dihydrate form: C₁₇H₂₀N₄NaO₉P·2H₂O

For the anhydrous form: $C_{17}H_{20}N_4NaO_9P$

Molecular weight 541,36

Assay Content not less than 95 % total colouring matters calculated as

 $C_{17}H_{20}N_4NaO_9P\cdot 2H_2O$

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 250 at ca 375 nm in aqueous solution

Description Yellow to orange crystalline hygroscopic powder, with slight odour and a bitter

aste

Identification

A. Spectrometry The ratio A_{375}/A_{267} is between 0,30 and 0,34

in aqueous solution

The ratio A_{444}/A_{267} is between 0,35 and 0,40

Maximum in water at ca 444 nm

B. Specific rotation $[a]D_{20}$ between + 38° and + 42° in a 5 molar HCl solution

Purity

Loss on drying Not more than 8% (100 °C, 5 hrs in vacuum over P_2O_5) for the dihydrate form

Sulfated ash Not more than 25 %

Inorganic phosphate Not more than 1,0 % (calculated as PO₄ on the anhydrous basis)

Subsidiary colouring matters Riboflavin (free): Not more than 6 %

Riboflavine diphosphate: Not more than 6 %

Primary aromatic amines Not more than 70 mg/kg (calculated as aniline)

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 102 TARTRAZINE

Synonyms CI Food Yellow 4

DefinitionTartrazine consists essentially of trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-(4-

sulfonatophenylazo)-H-pyrazole-3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured

components.

Tartrazine is described as the sodium salt. The calcium and the potassium salt are

also permitted.

Class Monoazo
Colour Index No 19140
Einecs 217-699-5

Chemical names Trisodium-5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-

pyrazole-3-carboxylate

Chemical formula $C_{16}H_9N_4Na_3O_9S_2$

534,37 Molecular weight

Content not less than $85\,\%$ total colouring matters calculated as the sodium salt Assay

E_{1 cm}^{1 %} 530 at ca 426 nm in aqueous solution

Description Light orange powder or granules

Identification

A. Spectrometry Maximum in water at ca 426 nm

B. Yellow solution in water

Purity

Water insoluble matter Not more than 0,2 % Subsidiary colouring matters Not more than 1.0 %

Organic compounds other than colouring matters:

4-hydrazinobenzene sulfonic acid

4-aminobenzene-1-sulfonic acid

5-oxo-1-(4-sulfophenyl)-2pyrazoline-3-carboxylic acid

4,4'-diazoaminodi(benzene sulfonic acid)

Tetrahydroxysuccinic acid

Unsulfonated primary aromatic

amines

Ether extractable matter Not more than 0,2 % under neutral conditions

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Not more than 1 mg/kg Mercury Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 104 QUINOLINE YELLOW

Synonyms CI Food Yellow 13

Definition Quinoline Yellow is prepared by sulfonating 2-(2-quinolyl) indan-1,3-dione.

Total not more than 0,5 %

Not more than 0,01 % (calculated as aniline)

Quinoline Yellow consists essentially of sodium salts of a mixture of disulfonates (principally), monosulfonates and trisulfonates of the above compound and subsidiary colouring matters together with sodium chloride and/or sodium

sulfate as the principal uncoloured components.

Quinoline Yellow is described as the sodium salt. The calcium and the potassium

salt are also permitted.

Class Chinophthalone

Colour Index No 47005 Einecs 305-897-5

Chemical name The disodium salts of the disulfonates of 2-(2-quinolyl) indan-1,3-dione

(principal component)

 $C_{18}H_9N\ Na_2O_8S_2$ (principal component) Chemical formula

Molecular weight 477,38 (principal component)

Α	S	S	а	v	

Content not less than 70 % total colouring matters calculated as the sodium salt

Quinoline Yellow shall have the following composition:

Of the total colouring matters present:

- not less than 80 % shall be disodium 2-(2-quinolyl) indan-1,3-dione-disulfonates
- not more than 15 % shall be sodium 2-(2-quinolyl) indan-1,3-dione-monosulfonates
- not more than 7,0 % shall be trisodium 2-(2-quinolyl) indan-1,3-dione-trisulfonate

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 865 (principal component) at ca 411 nm in aqueous acetic acid solution

Yellow powder or granules

Not more than 0,2 %

Not more than 4,0 %

Description

Identification

A. Spectrometry

B. Yellow solution in water

Maximum in aqueous acetic acid solution of pH 5 at ca 411 nm

Purity

Water insoluble matter

Subsidiary colouring matters

Organic compounds other than colouring matters:

2-methylquinoline

2-methylquinoline-sulfonic

Phthalic acid

2,6-dimethyl quinoline

2,6-dimethyl quinoline sulfonic acid

2-(2-quinolyl)indan-1,3-dione

Unsulfonated primary aromatic amines

Ether extractable matter

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg

Total not more than 0.5 %

Not more than 4 mg/kg

Not more than 0,01 % (calculated as aniline)

Not more than 0,2 % under neutral conditions

Not more than 40 mg/kg

E 110 SUNSET YELLOW FCF

Heavy metals (as Pb)

Synonyms

CI Food Yellow 3, Orange Yellow S

Definition

Sunset Yellow FCF consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.

Sunset Yellow FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.

Class Monoazo Colour Index No 15985 Einecs 220-491-7

Chemical names

Disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate

- 16	H_1	10	V ₂	Na	$_{2}C$) ₇	S
	- 16	$C_{16}H$	$C_{16}H_{10}N$	$C_{16}H_{10}N_2$	C ₁₆ H ₁₀ N ₂ Na	$C_{16}H_{10}N_2Na_2C_1$	C ₁₆ H ₁₀ N ₂ Na ₂ O ₇ S

452.37 Molecular weight

Content not less than 85 % total colouring matters calculated as the sodium salt Assay

 $E_{1 \text{ cm}}^{1 \text{ %}}$ 555 at ca 485 nm in aqueous solution at pH 7

Description

Identification

A. Spectrometry

Maximum in water at ca 485 nm at pH 7

Orange-red powder or granules

B. Orange solution in water

Purity

Subsidiary colouring matters

1-(Phenylazo)-2-naphthalenol (Sudan I)

Organic compounds other than colouring matters:

4-aminobenzene-1-sulfonic acid

3-hydroxynaphthalene-2,7disulfonic acid

6-hydroxynaphthalene-2sulfonic acid

7-hydroxynaphthalene-1,3disulfonic acid

4,4'-diazoaminodi(benzene sulfonic acid)

6,6'-oxydi(naphthalene-2sulfonic acid)

Unsulfonated primary aromatic

Ether extractable matter

Arsenic Not more than 3 mg/kg Lead Not more than 2 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg

E 120 COCHINEAL, CARMINIC ACID, CARMINES

Water insoluble matter

Not more than 0,2 %

Not more than 5,0 %

Not more than 0,5 mg/kg

Total not more than 0,5 %

Not more than 0,01 % (calculated as aniline)

Not more than 0,2 % under neutral conditions

Definition

Carmines and carminic acid are obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect Dactylopius coccus Costa.

The colouring principle is carminic acid.

Aluminium lakes of carminic acid (carmines) can be formed in which aluminium and carminic acid are thought to be present in the molar ratio 1:2.

In commercial products the colouring principle is present in association with ammonium, calcium, potassium or sodium cations, singly or in combination, and these cations may also be present in excess.

Commercial products may also contain proteinaceous material derived from the source insect, and may also contain free carminate or a small residue of unbound aluminium cations.

Class Anthraquinone

Colour Index No

Einecs Cochineal: 215-680-6; carminic acid: 215-023-3; carmines: 215-724-4 Chemical names 7-β-D-glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxoanthracene-2-

carboxylic acid (carminic acid); carmine is the hydrated aluminium chelate of this

Chemical formula C₂₂H₂₀O₁₃ (carminic acid) Molecular weight 492,39 (carminic acid)

Content not less than 2,0 % carminic acid in the extracts containing carminic Assay

acid; not less than 50 % carminic acid in the chelates.

Description Red to dark red, friable, solid or powder. Cochineal extract is generally a dark red

liquid but can also be dried as a powder.

Identification

Spectrometry Maximum in aqueous ammonia solution at ca 518 nm

Maximum in dilute hydrochloric solution at ca 494 nm for carminic acid

Purity

Definition

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 122 AZORUBINE. CARMOISINE

Synonyms

CI Food Red 3

Azorubine consists essentially of disodium 4-hydroxy-3-(4-sulfonato-1naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured

Azorubine is described as the sodium salt. The calcium and the potassium salt

are also permitted.

Class Monoazo Colour Index No 14720 Einecs 222-657-4

Chemical name Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate

Chemical formula $C_{20}H_{12}N_2Na_2O_7S_2$

Molecular weight 502.44

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt

E_{1 cm} 1 % 510 at ca 516 nm in aqueous solution

Description Red to maroon powder or granules

Identification

A. Spectrometry Maximum in water at ca 516 nm

B. Red solution in water

Purity

Water insoluble matter Not more than 0,2 % Subsidiary colouring matters Not more than 2,0 %

Organic compounds other than colouring matters:

4-aminonaphthalene-1sulfonic acid

4-hydroxynaphthalene-1sulfonic acid

Total not more than 0,5 %

Unsulfonated primary aromatic

Ether extractable matter

amines

Not more than 0,2 % under neutral conditions

Not more than 0,01 % (calculated as aniline)

Arsenic Not more than 3 mg/kg Not more than 10 mg/kg Lead Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 123 AMARANTH

Synonyms

CI Food Red 9 Definition Amaranth consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-

naphthylazo) naphthalene-3,6-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured

components.

Amaranth is described as the sodium salt. The calcium and the potassium salt are

also permitted.

Class Monoazo 16185 Colour Index No Einecs 213-022-2

Chemical name Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate

Chemical formula $C_{20}H_{11}N_2Na_3O_{10}S_3$

Molecular weight 604,48

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 440 at ca 520 nm in aqueous solution

Description Reddish-brown powder or granules

Identification

A. Spectrometry Maximum in water at ca 520 nm

B. Red solution in water

Purity

Water insoluble matter Not more than 0,2 %

Subsidiary colouring matters Organic compounds other than colouring matters:

4-aminonaphthalene-1sulfonic acid

3-hydroxynaphthalene-2,7disulfonic acid

6-hydroxynaphthalene-2sulfonic acid

7-hydroxynaphthalene-1,3disulfonic acid

7-hydroxynaphthalene-1,3-6-trisulfonic acid

Unsulfonated primary aromatic

amines

Not more than 0,01 % (calculated as aniline)

Ether extractable matter Not more than 0,2 % under neutral conditions

Arsenic Not more than 3 mg/kg

Total not more than 0,5 %

Not more than 3,0 %

Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 124 PONCEAU 4R, COCHINEAL RED A

Definition Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-

naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured

components.

Ponceau 4R is described as the sodium salt. The calcium and the potassium salt

are also permitted.

Class Monoazo

Colour Index No 16255

220-036-2 Einecs

 $Trisodium \ \ 2-hydroxy-1-(4-sulfonato-1-naphthylazo) \ \ naphthalene-6, 8-disulfonate$ Chemical name

Chemical formula $C_{20}H_{11}N_2Na_3O_{10}S_3$

Molecular weight 604,48

Content not less than 80 % total colouring matters, calculated as the sodium salt. Assay

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 430 at ca 505 nm in aqueous solution

Description Reddish powder or granules

Identification

A. Spectrometry Maximum in water at ca 505 nm

B. Red solution in water

Purity

Water insoluble matter Not more than 0,2 %

Organic compounds other than

colouring matters:

4-aminonaphthalene-1sulfonic acid

Subsidiary colouring matters

7-hydroxynaphthalene-1,3disulfonic acid

3-hydroxynaphthalene-2,7disulfonic acid

6-hydroxynaphthalene-2sulfonic acid

7-hydroxynaphthalene-1,3-6-trisulfonic acid

Unsulfonated primary aromatic

amines

Not more than 0,01 % (calculated as aniline)

Ether extractable matter Not more than 0,2 % under neutral conditions

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg

Total not more than 0,5 %

Not more than 1,0 %

Mercury

Cadmium

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

E 127 ERYTHROSINE

Synonyms CI Food Red 14

Definition Erythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxox-

anthen-9-yl) benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulfate as the principal uncoloured

components

Erythrosine is described as the sodium salt. The calcium and the potassium salt

are also permitted.

Class Xanthen
Colour Index No 45430

Einecs 240-474-8

Chemical name Disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl)benzoate monohydrate

Chemical formula $C_{20}H_6I_4Na_2O_5.H_2O$

Molecular weight 897,88

Assay Content not less than 87 % total colouring matters, calculated as the anhydrous

sodium salt

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 1 100 at ca 526 nm in aqueous solution at pH 7

Description Red powder or granules.

Identification

A. Spectrometry Maximum in water at ca 526 nm at pH 7

B. Red solution in water

Purity

Inorganic iodides calculated as Not more than 0,1 %

sodium iodide

Fluorescein

Water insoluble matter Not more than 0,2 %

Subsidiary colouring matters

(except fluorescein)

Not more than 4,0 %

Not more than 20 mg/kg

Organic compounds other than

colouring matters:

Tri-iodoresorcinol Not more than 0,2 % 2-(2,4-dihydroxy-3,5-diodobenzoyl) benzoic acid Not more than 0,2 %

Ether extractable matter

From a solution of pH from 7 through 8, not more than 0,2 %

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg
Heavy metals (as Pb) Not more than 40 mg/kg

The more than to mg/ng

Aluminium Lakes The hydrochloric acid insoluble matter method is not applicable. It is replaced by

a sodium hydroxide insoluble matter, at not more than 0,5 %, for this colour

only.

E 128 RED 2G

Synonyms CI Food Red 10, Azogeranine

Definition Red 2G consists essentially of disodium 8-acetamido-1-hydroxy-2-phenylazo-

naphthalene-3,6-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.

Red 2G is described as the sodium salt. The calcium and the potassium salt are

also permitted.

Class Monoazo
Colour Index No 18050

Einecs 223-098-9

Chemical name Disodium 8-acetamido-1-hydroxy-2-phenylazo-naphthalene-3,6-disulfonate

Chemical formula $C_{18}H_{13}N_3Na_2O_8S_2$

Molecular weight 509,43

Assay Content not less than 80 % total colouring matters, calculated as the sodium salt

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 620 at ca 532 nm in aqueous solution

Description Red powder or granules

Identification

A. Spectrometry Maximum in water at ca 532 nm

B. Red solution in water

Purity

Water insoluble matter

Not more than 0,2 %

Subsidiary colouring matters

Not more than 2,0 %

Organic compounds other than colouring matters:

5-acetamido-4-hydroxynaphthalene-2,7-disulfonic acid

5-amino-4-hydroxynaphthalene-2,7-disulfonic acid

Unsulfonated primary aromatic

Ether extractable matter

amines

S

Total not more than 0,5 %

Not more than 0,01 % (calculated as aniline)

Not more than 0,2 % under neutral conditions

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

E 129 ALLURA RED AC

Synonyms CI Food Red 17

Definition

Allura Red AC consists essentially of disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate and subsidiary

colouring matters together with sodium chloride and/or sodium sulfate as the

principal uncoloured components.

Allura Red AC is described as the sodium salt. The calcium and the potassium

salt are also permitted.

Class Monoazo
Colour Index No 16035

Einecs 247-368-0

Chemical name Disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo)

naphthalene-6-sulfonate

Chemical formula $C_{18}H_{14}N_2Na_2O_8S_2$

Molecular weight 496,42

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 540 at ca 504 nm in aqueous solution at pH 7

Description Dark red powder or granules

Identification

A. Spectrometry Maximum in water at ca 504 nm

B. Red solution in water

Purity

Water insoluble matter

Not more than 0,2 %

Subsidiary colouring matters

Not more than 3,0 %

Organic compounds other than colouring matters:

6-hydroxy-2-naphthalene sulfonic acid, sodium salt

Not more than 0,3 %

4-amino-5-methoxy-2methylbenezene sulfonic acid

Not more than 0,2 %

6,6-oxybis (2-naphthalene sulfonic acid) disodium salt

Not more than 1,0 %

Unsulfonated primary aromatic

amines

Not more than 0,01 % (calculated as aniline)

Ether extractable matter From a solution of pH 7, not more than 0,2 %

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 131 PATENT BLUE V

Synonyms CI Food Blue 5

Definition Patent Blue V consists essentially of the calcium or sodium compound of [4-(α-

(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene)2,5-cyclo-hexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with sodium chloride and/or sodium sulfate and/or calcium sulfate as the principal uncoloured components.

The potassium salt is also permitted.

Class Triarylmethane

Colour Index No 42051
Einecs 222-573-8

Chemical names The calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-

2,4-disulfophenyl-methylidene) 2,5-cyclohexadien-1-ylidene] diethyl-ammonium

hydroxide inner salt

Chemical formula Calcium compound: C₂₇H₃₁N₂O₇S₂Ca_{1/2}

Sodium compound: C₂₇H₃₁N₂O₇S₂Na

Molecular weight Calcium compound: 579,72

Sodium compound: 582,67

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt

Total not more than 0,5 %

Not more than 0,01 % (calculated as aniline)

Not more than 4,0 %

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 2 000 at ca 638 nm in aqueous solution at pH 5

Description Dark-blue powder or granules

Identification

A. Spectrometry Maximum in water at 638 nm at pH 5

B. Blue solution in water

Purity

Water insoluble matter $\,$ Not more than 0,2 % Subsidiary colouring matters $\,$ Not more than 2,0 %

Organic compounds other than colouring matters:

3-hydroxy benzaldehyde

3-hydroxy benzoic acid

3-hydroxy-4-sulfobenzoic

acid

N,N-diethylamino benzene sulfonic acid

Leuco base

Unsulfonated primary aromatic

amines

Ether extractable matter From a solution of pH 5 not more than 0,2 %

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 132 INDIGOTINE, INDIGO CARMINE

Synonyms

CI Food Blue 1

Definition

Indigotine consists essentially of a mixture of disodium 3,3'dioxo-2,2'-bi-indo-lylidene-5,5'-disulfonate, and disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,7'-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.

Indigotine is described as the sodium salt. The calcium and the potassium salt are also permitted.

Class Indigoid
Colour Index No 73015
Einecs 212-728-8

Chemical names Disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,5'-disulfonate

Chemical formula $C_{16}H_8N_2Na_2O_8S_2$

Molecular weight 466,36

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt;

disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,7'-disulfonate: not more than 18 %

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 480 at ca 610 nm in aqueous solution

	•	. •	
Desc	rip	tion	
Desc	TIP	шоп	

Identification

Dark-blue powder or granules

Maximum in water at ca 610 nm

A. Spectrometry

B. Blue solution in water

Purity

Water insoluble matter

Not more than 0,2 %

Subsidiary colouring matters

Excluding disodium 3,3'-dioxo-2,2'-bi-indolylidene-5,7'-disulfonate: not more

Organic compounds other than colouring matters:

Isatin-5-sulfonic acid

5-sulfoanthranilic acid

Anthranilic acid

Unsulfonated primary aromatic

Ether extractable matter

Arsenic

Lead Mercury

Cadmium

Heavy metals (as Pb)

than 1,0 %

Total not more than 0,5 %

Not more than 0,01 % (calculated as aniline)

Not more than 0,2 % under neutral conditions

Not more than 3 mg/kg

Not more than 10 mg/kg

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

E 133 BRILLIANT BLUE FCF

Synonyms

CI Food Blue 2

Definition

Brilliant Blue FCF consists essentially of disodium α -(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate and its isomers and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.

Brilliant Blue FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.

Class Triarylmethane

Colour Index No 42090

223-339-8 Einecs

Chemical names Disodium α -(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)- α -(4-N-ethyl-3-sulfona-

tobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate

Chemical formula $\mathrm{C_{37}H_{34}N_2Na_2O_9S_3}$

792,84 Molecular weight

Assay Content not less than 85 % total colouring matters, calculated as the sodium salt

Reddish-blue powder or granules

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 1 630 at ca 630 nm in aqueous solution

Description

Identification

A. Spectrometry Maximum in water at ca 630 nm

B. Blue solution in water

Purity

Water insoluble matter Not more than 0,2 % Subsidiary colouring matters Not more than 6,0 % Organic compounds other than colouring matters:

Sum of 2-, 3- and 4-formyl

benzene sulfonic acids

3-((ethyl)(4-sulfophenyl)

amino) methyl benzene sulfonic acid

Not more than 1,5 %

Not more than 0,3 %

Leuco base Not more than 5,0 %

Unsulfonated primary aromatic

Not more than 0,01 % (calculated as aniline)

Ether extractable matter Not more than 0,2 % at pH 7

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Not more than 40 mg/kg Heavy metals (as Pb)

E 140 (i) CHLOROPHYLLS

Synonyms

CI Natural Green 3, Magnesium Chlorophyll, Magnesium Phaeophytin

Definition

Chlorophylls are obtained by solvent extraction of natural strains of edible plant material, grass, lucerne and nettle. During the subsequent removal of solvent, the naturally present co-ordinated magnesium may be wholly or partly removed from the chlorophylls to give the corresponding phaeophytins. The principal colouring matters are the phaeophytins and magnesium chlorophylls. The extracted product, from which the solvent has been removed, contains other pigments such as carotenoids as well as oils, fats and waxes derived from the source material. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

Class Porphyrin 75810 Colour Index No

Einecs Chlorophylls: 215-800-7, chlorophyll a: 207-536-6, Chlorophyll b: 208-272-4

Chemical names The major colouring principles are:

> Phytyl (13²R.17<u>S</u>,18<u>S</u>)-3-(8-ethyl-13²-methoxycarbonyl-2,7,12,18-tetramethyl-13'-oxo-3-vinyl-13¹-13²-17,18-tetrahydrocyclopenta [at]-porphyrin-17-yl)propionate, (Pheophytin a), or as the magnesium complex (Chlorophyll a)

Phytyl (13 2 <u>R</u>,17 \underline{S} ,18 \underline{S})-3-(8-ethyl-7-formyl-13 2 -methoxycarbonyl-2,12,18-trimethyl-13'-oxo-3-vinyl-13 1 -13 2 -17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)propionate, (Pheophytin b), or as the magnesium complex (Chlorophyll b)

Chemical formula Chlorophyll a (magnesium complex): C₅₅H₇₂MgN₄O₅

Chlorophyll a: C55H74N4O5

Chlorophyll b (magnesium complex): C55H70MgN4O6

Chlorophyll b: C55H72N4O6

Molecular weight Chlorophyll a (magnesium complex): 893,51

Chlorophyll a: 871,22

Chlorophyll b (magnesium complex): 907,49

Chlorophyll b: 885,20

Content of total combined Chlorophylls and their magnesium complexes is not Assay

less than 10 %

 $E_{1~cm}^{1~\%}$ 700 at ca 409 nm in chloroform

DescriptionWaxy solid ranging in colour from olive green to dark green depending on the content of co-ordinated magnesium

Identification

Spectrometry Maximum in chloroform at ca 409 nm

Purity

Solvent residues Acetone

Methyl Ethyl ketone

Methanol Ethanol Propan-2-ol

Hexane

Dichloromethane: Not more than 10 mg/kg

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

Not more than 50 mg/kg, singly or in combination

E 140 (ii) CHLOROPHYLLINS

Synonyms

CI Natural Green 5, Sodium Chlorophyllin, Potassium Chlorophyllin

Definition

The alkali salts of chlorophyllins are obtained by the saponification of a solvent extract of natural strains of edible plant material, grass, lucerne and nettle. The saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. The acid groups are neutralized to form the salts of potassium and/or sodium.

Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

Class Porphyrin
Colour Index No 75815
Einecs 287-483-3

— 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin a)

and

— 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl)propionate (chlorophyllin b)

Depending on the degree of hydrolysis the cyclopentenyl ring may be cleaved with the resultant production of a third carboxyl function.

Magnesium complexes may also be present.

Chemical formula Chlorophyllin a (acid form): C₃₄H₃₄N₄O₅

Chlorophyllin b (acid form): C₃₄H₃₂N₄O₆

Molecular weight Chlorophyllin a: 578,68

Chlorophyllin b: 592,66

Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved.

Not more than 50 mg/kg, singly

or in combination

Assay Content of total chlorophyllins is not less than 95 % of the sample dried at ca

100 °C for 1 hour.

 $E_{1~cm}^{-1~\%}$ 700 at ca 405 nm in aqueous solution at pH 9

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 140 at ca 653 nm in aqueous solution at pH 9

Description Dark green to blue/black powder

Identification

Spectrometry Maximum in aqueous phosphate buffer at pH 9 at ca 405 nm and at ca 653 nm

Purity

Solvent residues Acetone

Methyl ethyl ketone

Methanol Ethanol

Propan-2-ol

Hexane

Dichloromethane: not more than 10 mg/kg

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS

Synonyms CI Natural Green 3, Copper Chlorophyll, Copper Phaeophytin

Definition

Copper chlorophylls are obtained by addition of a salt of copper to the substance obtained by solvent extraction of natural strains of edible plant material, grass, lucerne, and nettle. The product, from which the solvent has been removed, contains other pigments such as carotenoids as well as fats and waxes derived from the source material. The principal colouring matters are the copper phaeophytins. Only the following solvents may be used for the

extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

Class Porphyrin
Colour Index No 75815

Einecs Copper chlorophyll a: 239-830-5; copper chlorophyll b: 246-020-5

Chemical names [Phytyl (13²R,17<u>S</u>,18<u>S</u>)-3-(8-ethyl-13²-methoxycarbonyl-2,7,12,18-tetramethyl-

13'-oxo-3-vinyl-13¹-13²-17,18-tetrahydrocyclopenta[at]-porphyrin-17-yl)pro-

pionate] copper (II) (Copper Chlorophyll a)

[Phytyl $(13^2\underline{R},17\underline{S},18\underline{S})$ -3-(8-ethyl-7-formyl- 13^2 -methoxycarbonyl-2,12,18-trimethyl-13'-oxo-3-vinyl- 13^1 - 13^2 -17,18-tetrahydrocyclopenta[at]-porphyrin-

17-yl)propionate] copper (II) (Copper chlorophyll b)

Chemical formula Copper chlorophyll a: C₅₅H₇₂Cu N₄O₅

Copper chlorophyll b: C₅₅H₇₀Cu N₄O₆

Molecular weight Copper chlorophyll a: 932,75

Copper chlorophyll b: 946,73

Assay Content of total copper chlorophylls is not less than 10 %.

 $E_{1~cm}^{1\,\%}$ 540 at ca 422 nm in chloroform

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 300 at ca 652 nm in chloroform

Description Waxy solid ranging in colour from blue green to dark green depending on the

source material

Identification

Spectrometry Maximum in chloroform at ca 422 nm and at ca 652 nm

Purity

Solvent residues Acetone

Methyl ethyl ketone

Methanol

Ethanol

Not more than
50 mg/kg, singly
or in combination

Propan-2-ol Hexane

Dichloromethane: not more than 10 mg/kg

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 200 mg/kg

Total copper Not more than 8,0 % of the total copper phaeophytins

E 141 (ii) COPPER COMPLEXES OF CHLOROPHYLLINS

Synonyms Sodium Copper Chlorophyllin, Potassium Copper Chlorophyllin, CI Natural

Green 5

Definition The alkali salts of copper chlorophyllins are obtained by the addition of copper

to the product obtained by the saponification of a solvent extraction of natural strains of edible plant material, grass, lucerne, and nettle; the saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. After addition of copper to the purified chlorophyllins, the acid groups are neutralized to form the salts of potassium and/or sodium.

Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide methanol, ethanol, propan-2-ol

and hexane.

75815

Class Porphyrin

Einecs

Colour Index No

Chemical names

The major colouring principles in their acid forms are:

3-(10-Carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl) pro-10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl) pro-10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-carboxylato-4-ethyl-9-carboxylato-4-ethyl-9-carboxylato-4-ethyl-9-carboxylato-4-ethyl-9-ethyl-

pionate, copper complex (Copper chlorophyllin a)

and

3-(10-Carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl)

propionate, copper complex (Copper chlorophyllin b)

Chemical formula Copper chlorophyllin a (acid form): C₃₄H₃₂Cu N₄O₅

Copper chlorophyllin b (acid form): $C_{34}H_{30}Cu\ N_4O_6$

Molecular weight Copper chlorophyllin a: 640,20

Copper chlorophyllin b: 654,18

Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved.

Assay Content of total copper chlorophyllins is not less than 95 % of the sample dried

at 100 °C for 1 h.

 $E_{1~cm}^{-1\,\%}$ 565 at ca 405 nm in aqueous phosphate buffer at pH 7,5

 $E_{1 \text{ cm}}^{1 \text{ %}}$ 145 at ca 630 nm in aqueous phosphate buffer at pH 7,5

Not more than 50 mg/kg, singly

or in combination

Description Dark green to blue/black powder

Identification

Spectrometry Maximum in aqueous phosphate buffer at pH 7,5 at ca 405 nm and at

ca 630 nm

Purity

Solvent residues Acetone

Methyl ethyl ketone

Methanol
Ethanol

Propan-2-ol

Hexane

Dichloromethane: not more than 10 mg/kg

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 200 mg/kg

Total copper Not more than 8,0 % of the total copper chlorophyllins

E 142 GREEN S

Synonyms CI Food Green 4, Brilliant Green BS

Definition Green S consists essentially of sodium N-[4-(dimethylamino)phenyl] 2-hydroxy-

3,6-disulfo-1-naphthalenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-methanaminium and subsidiary colouring matters together with sodium chloride

and/or sodium sulphate as the principal uncoloured compounds.

Green S is described as the sodium salt. The calcium and the potassium salt are

also permitted.

Class Triarylmethane

Colour Index No 44090 Einecs 221-409-2

Chemical names Sodium N-[4-[[4-(dimethylamino)phenyl](2-hydroxy-3,6-disulfo-1-naphthalenyl)-

methylene]2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium;

Sodium 5-[4-dimethylamino-α-(4-dimethyliminocyclohexa-2,5-dienylidene) benzyl]-6-hydroxy-7-sulfonato-naphthalene-2-sulfonate (alternative chemical

name).

Chemical formula $C_{27}H_{25}N_2NaO_7S_2$

Molecular Weight 576,63

Assay Content not less than 80 % total colouring matters calculated as the sodium salt

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 1 720 at ca 632 nm in aqueous solution

Description Dark blue or dark green powder or granules

Identification

A. Spectrometry Maximum in water at ca 632 nm

B. Blue or green solution in water

Purity

Not more than 0,2 % Water insoluble matter Not more than 1,0 % Subsidiary colouring matters

Organic compounds other than colouring matters:

4,4'-bis(dimethylamino)benzhydryl alcohol

Not more than 0,1 %

4,4'-bis(dimethylamino)benzophenone

Not more than 0,1 %

3-hydroxynaphthalene-2,7-

disulfonic acid

Not more than 0,2 %

Leuco base

Not more than 5,0 %

Unsulfonated primary aromatic

amines

Not more than 0,01 % (calculated as aniline)

Ether extractable matter Not more than 0.2 % under neutral conditions

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 150a PLAIN CARAMEL

Definition Plain caramel is prepared by the controlled heat treatment of carbohydrates

(commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose). To promote caramelization, acids, alkalis and salts may be employed, with the exception of ammonium

compounds and sulphites.

Einecs 232-435-9

Description Dark brown to black liquids or solids

Purity

Colour bound by DEAE

Not more than 50 %

cellulose

Colour bound by phosphoryl

cellulose

Not more than 50 %

Colour intensity (1)

0,01-0,12 Not more than 0,1 %

Total nitrogen Total sulphur Not more than 0,2 % Arsenic Not more than 1 mg/kg Lead Not more than 2 mg/kg Not more than 1 mg/kg Mercury Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 25 mg/kg

⁽¹⁾ Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

E 150b CAUSTIC SULPHITE CARAMEL

Definition

Caustic sulphite caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of sulphite compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite and sodium bisulphite); no ammonium compounds are used.

Einecs 232-435-9

Description Dark brown to black liquids or solids

Purity

Colour bound by DEAE More than 50 %

cellulose

0,05-0,13 Colour intensity (1)

Total nitrogen Not more than 0,3 % (2) Sulphur dioxide Not more than 0,2 % (2)

Total sulphur 0,3-3,5% (2)

Sulphur bound by DEAE cellulose

Absorbance ratio of colour

bound by DEAE cellulose

19-34

More than 40 %

Greater than 50 Absorbance ratio

(A 280/560)

Arsenic Not more than 1 mg/kg Lead Not more than 2 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Heavy metals (as Pb) Not more than 25 mg/kg

E 150c AMMONIA CARAMEL

Definition

Ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/ or invert syrups, and dextrose) with or without acids or alkalis, in the presence of ammonium compounds (ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate and ammonium phosphate); no sulphite

compounds are used.

Einecs 232-435-9

Description Dark brown to black liquids or solids

Purity

Colour bound by DEAE Not more than 50 %

cellulose

Colour bound by phosphoryl

More than 50 %

Colour intensity (1) 0,08-0,36

Not more than 0,3 % (2) Ammoniacal nitrogen

4-methylimidazole Not more than 250 mg/kg (2) 2-acetyl-4-tetrahydroxy-butyli-

midazole

Not more than 10 mg/kg (2)

⁽¹⁾ Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

⁽²⁾ Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

Total sulphur Not more than 0,2 % (1)

Total nitrogen 0,7-3,3% (1)

Absorbance ratio of colour

bound by phosphoryl cellulose

Arsenic Not more than 1 mg/kg

13-35

Lead Not more than 2 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 25 mg/kg

E 150d SULPHITE AMMONIA CARAMEL

Sulphite ammonia caramel is prepared by the controlled heat treatment of Definition

carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof (e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis in the presence of both sulphite and ammonium compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite, sodium bisulphite, ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate, ammonium phosphate, ammonium sulphate, ammonium sulphite and

ammonium hydrogen sulphite).

232-435-9 Einecs

Dark brown to black liquids or solids Description

Purity

Colour bound by DEAE More than 50 %

cellulose

Colour intensity (2) 0,10-0,60

Ammoniacal nitrogen Not more than 0,6 % (1)

Not more than 0,2 % (1) Sulphur dioxide

4-methylimidazole Not more than 250 mg/kg (1)

Total nitrogen 0,3-1,7% (1)

Total sulphur 0,8-2,5 % (1) 0,7-2,7 Nitrogen/sulphur ratio of

Absorbance ratio of alcohol

precipitate (3)

alcohol precipitate

8-14

Absorbance ratio (A 280/560) Not more than 50

Arsenic Not more than 1 mg/kg Lead Not more than 2 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 25 mg/kg

E 151 BRILLIANT BLACK BN, BLACK PN

CI Food Black 1 Synonyms

⁽¹⁾ Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.

⁽²⁾ Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

⁽³⁾ Absorbance ratio of alcohol precipitate is defined as the absorbance of the precipitate at 280 nm divided by the absorbance at 560 nm (1 cm cell).

Definition

Brilliant Black BN consists essentially of tetrasodium-4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.

Brilliant Black BN is described as the sodium salt. The calcium and the potassium salt are also permitted.

Class Bisazo
Colour Index No 28440

Einecs 219-746-5

Chemical names Tetrasodium 4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-

naphthylazo] naphthalene-1,7-disulfonate

Chemical formula $C_{28}H_{17}N_5Na_4O_{14}S_4$

Molecular weight 867,69

Assay Content not less than 80 % total colouring matters calculated as the sodium salt

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 530 at ca 570 nm in solution

Description

Identification

A. Spectrometry

B. Black-bluish solution in water

Maximum in water at ca 570 nm

Black powder or granules

Purity

Water insoluble matter

Not more than 0.2 %

Subsidiary colouring matters

Not more than 10 % (expressed on the dye content)

Organic compounds other than colouring matters:

4-acetamido-5-hydroxynaphthalene-1,7-disulfonic acid

4-amino-5-hydroxynaphthalene-1,7-disulfonic acid

8-aminonaphthalene-2-sulfonic acid

4,4'-diazoaminodi-(benzenesulfonic acid)

Unsulfonated primary aromatic

Ether extractable matter

amines

Not more than 0,01 % (calculated as aniline)

Total not more than 0,8 %

Not more than 0,2 % under neutral conditions

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 153 VEGETABLE CARBON

Synonyms

Vegetable black

Definition

Vegetable carbon is produced by the carbonization of vegetable material such as wood, cellulose residues, peat and coconut and other shells. The raw material is carbonised at high temperatures. It consists essentially of finely divided carbon. It may contain minor amounts of nitrogen, hydrogen and oxygen. Some moisture may be absorbed on the product after manufacture.

Colour Index No 77266

Einecs 215-609-9

Chemical names Carbon

Chemical formula C

Molecular weight 12,01

Assay Content not less than 95 % of carbon calculated on an anhydrous and ash-free

basis

Description Black powder, odourless and tasteless

Identification

A. Solubility Insoluble in water and organic solvents

B. Burning When heated to redness it burns slowly without a flame

Purity

Ash (Total) Not more than 4,0 % (ignition temperature: 625 °C)

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

Polyaromatic hydrocarbons
The extract obtained by extraction of 1 g of the product with 10 g pure

cyclohexane in a continuous extraction apparatus shall be colourless, and the fluorescence of the extract in ultraviolet light shall not be more intense than that of a solution of 0,100~mg of quinine sulfate in 1~000~ml of 0,01~M sulphuric

acid.

Loss on drying Not more than 12 % (120 °C, 4 hrs)

Alkali soluble matter The filtrate obtained by boiling 2 g of the sample with 20 ml N sodium

hydroxide and filtering shall be colourless

E 154 BROWN FK

Synonyms CI Food Brown 1

Definition Brown FK consists essentially of a mixture of:

I sodium 4-(2,4-diaminophenylazo) benzenesulfonate

II sodium 4-(4,6-diamino-m-tolylazo) benzenesulfonate

III disodium 4,4'-(4,6-diamino-1,3-phenylenebisazo)di (benzenesulfonate)

IV disodium 4,4'-(2,4-diamino-1,3-phenylenebisazo)di (benzenesulfonate)

V disodium 4,4'-(2,4-diamino-5-methyl-1,3-phenylenebisazo)di (benzenesulfonate)

VI trisodium 4,4',4"-(2,4-diaminobenzene-1,3,5-trisazo)tri-(benzenesulfonate)

and subsidiary colouring matters together with water, sodium chloride and/or sodium sulfate as the principal uncoloured components.

Brown FK is described as the sodium salt. The calcium and the potassium salt are also permitted.

Class Azo (a mixture of mono-, bis- and trisazo colours)

Einecs

Chemical names	A mixture of:
	I sodium 4-(2,4-diaminophenylazo) benzenesulfonate
	II sodium 4-(4,6-diamino-m-tolylazo) benzenesulfonate
	III disodium 4,4'-(4,6-diamino-1,3-phenylenebisazo)di (benzenesulfonate)
	IV disodium 4,4'-(2,4-diamino-1,3-phenylenebisazo)di (benzenesulfonate)
	V disodium 4,4'-(2,4-diamino-5-methyl-1,3-phenylenebisazo)di (benzenesul-fonate)
	VI trisodium 4,4',4"-(2,4-diaminobenzene-1,3,5-trisazo)tri-(benzenesulfonate)
Chemical formula	I C ₁₂ H ₁₁ N ₄ NaO ₃ S
	II C ₁₃ H ₁₃ N ₄ NaO ₃ S
	III $C_{18}H_{14}N_6Na_2O_6S_2$
	IV $C_{18}H_{14}N_6Na_2O_6S_2$
	V C ₁₉ H ₁₆ N ₆ Na ₂ O ₆ S ₂
	VI C ₂₄ H ₁₇ N ₈ Na ₃ O ₉ S ₃
Molecular weight	I 314,30
	II 328,33
	III 520,46
	IV 520,46
	V 534,47
	VI 726,59
Assay	Content not less than 70 % total colouring matters
	Of the total colouring matters present the proportions of the components shall not exceed:
	I 26 %
	II 17 %
	III 17 %
	IV 16 %
	V 20 %
	VI 16 %
Description	Red-brown powder or granules
Identification	
Orange to reddish solution	
Purity	
Water insoluble matter	Not more than 0,2 %
Subsidiary colouring matters	Not more than 3,5 %
Organic compounds other than colouring matters:	
4-aminobenzene-1-sulfonic acid	Not more than 0,7 %
m-phenylenediamine and 4- methyl-m-phenylenediamine	Not more than 0,35 %
Unsulfonated primary aromatic amines other than m-phenylene diamine and 4-methyl-m- phenylene diamine	Not more than 0,007 % (calculated as aniline)

Ether extractable matter From a solution of pH 7, not more than 0,2 %

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

E 155 BROWN HT

Synonyms CI Food Brown 3

Definition Brown HT consists essentially of disodium 4,4'-(2,4-dihydroxy-5-hydroxymethyl-

1,3-phenylene bisazo) di (naphthalene-1-sulfonate) and subsidiary colouring matters together with sodium chloride and/or sulfate as the principal uncoloured

components.

Brown HT is described as the sodium salt. The calcium and potassium salt are

also permitted.

Class Bisazo
Colour Index No 20285
Einecs 224-924-0

Chemical names Disodium 4,4'-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo)di

(naphthalene-1-sulfonate)

Chemical formula $C_{27}H_{18}N_4Na_2O_9S_2$

Molecular Weight 652,57

Assay Content not less than 70 % total colouring matters calculated as the sodium salt.

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 403 at ca 460 nm in aqueous solution at pH 7

Description Reddish-brown powder or granules

Identification

A. Spectrometry Maximum in water of pH 7 at ca 460 nm

B. Brown solution in water

Purity

Water insoluble matter Not more than 0,2 %

Subsidiary colouring matters Not more than 10 % (TLC method)

Organic compounds other than colouring matters:

4-aminonaphthalene-1-

sulfonic acid

Not more than 0,7 %

Unsulfonated primary aromatic amines

Not more than 0,01 % (calculated as aniline)

Ether extractable matter Not more than 0,2 % in a solution of pH 7

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 160a (i) MIXED CAROTENES

1. Plant carotenes

Synonyms CI Food Orange 5

Definition

Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (¹), dichloromethane and carbon dioxide.

Class Carotenoid
Colour Index No 75130

Einecs 230-636-6

Chemical formula Beta-carotene: $C_{40}H_{56}$ Molecular weight Beta-carotene: 536,88

Assay Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetables oils: not less than 0,2 % in

edible fats.

 $E_{1~cm}^{-1~\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification

Spectrometry Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm

Purity

Solvent residues Acetone

Methyl ethyl ketone

Methanol Propan-2-ol

Hexane Ethanol

Dichloromethane: Not more than 10 mg/kg

Lead Not more than 5 mg/kg

2. Algal carotenes

Synonyms

CI Food Orange 5

Definition

Mixed carotenes may also be produced from natural strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. Betacarotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29.

50 mg/kg, singly or in combination

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

Class Carotenoid
Colour Index No 75130

Chemical formula Beta-Carotene: $C_{40}H_{56}$ Molecular weight Beta-Carotene: 536,88

Assay Content of carotenes (calculated as beta-carotene) is not less than 20 %

E_{1 cm} 1 % 2 500 at approximately by 440 nm to 457 nm in cyclohexane

Identification

Spectrometry Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm

⁽¹⁾ Benzene not more than 0,05 % v/v.

Purity

Natural tocopherols in edible

oil

Not more than 0,3 %

Lead

Not more than 5 mg/kg

E 160a (ii) BETA-CAROTENE

1. Beta-carotene

Synonyms CI Food Orange 5

Definition Thes

These specifications apply predominantly to all trans isomer of beta-carotene

together with minor amounts of other carotenoids. Diluted and stabilised

preparations may have different trans-cis isomer ratios.

Class Carotenoid

Colour Index No 40800

Einecs 230-636-6

Chemical names Beta-carotene, beta, beta-carotene

Assay Not less than 96 % total colouring matters (expressed as beta-carotene)

E_{1 cm}^{1 %} 2 500 at approximately by 440 nm to 457 nm in cyclohexane

Description Red to brownish-red crystals or crystalline powder

Identification

Spectrometry Maximum in cyclohexane at 453 nm to 456 nm

Purity

Sulfated ash Not more than 0,2 %

Subsidiary colouring matters | Carotenoids other than beta-carotene: not more than 3,0 % of total colouring

matters

Lead Not more than 2 mg/kg

2. Beta-carotene from Blakeslea

trispora

Synonyms CI Food Orange 5

Definition Obtained by a fermentation process using a mixed culture of the two sexual

mating types (+) and (-) of natural strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate, or isobutyl acetate followed by isopropyl alcohol, and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process approximately 3 % of the product consists of mixed carotenoids, which is specific for the product

of the product consists of mixed carotenoids, which is specific for the product.

Class

Carotenoid

Colour Index No 40800
Einecs 230-636-6

Chemical names Beta-carotene, beta,beta-carotene

Assay Not less than 96 % total colouring matters (expressed as beta-carotene)

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Description Red, brownish-red or purple-violet crystals or crystalline powder (colour varies

according to extraction solvent used and conditions of crystallisation)

Identification

Spectrometry Maximum in cyclohexane at 453 nm to 456 nm

Purity

Solvent residues Ethyl acetate

Ethanol

Not more than 0,8 %, singly or in combination

Isobutyl acetate: Not more than 1,0 %

Isopropyl alcohol: Not more than 0,1 %

Sulfated ash Not more than 0,2 %

Subsidiary colouring matters | Carotenoids other than beta-carotene: not more than 3,0 % of total colouring

natters

Lead Not more than 2 mg/kg

Mycotoxins:

Aflatoxin B1 Absent
Trichothecene (T2) Absent
Ochratoxin Absent
Zearalenone Absent

Microbiology:

Moulds Not more than 100/g

Yeasts Not more than 100/g

Salmonella Absent in 25 g
Escherichia coli Absent in 5 g

E 160b ANNATTO, BIXIN, NORBIXIN

Synonyms CI Natural Orange 4

Definition

Class Carotenoid
Colour Index No 75120

Einecs Annatto: 215-735-4, annatto seed extract: 289-561-2; bixin: 230-248-7

Chemical names Bixin: 6'-Methylhydrogen-9'-cis-6,6'-diapocarotene-6,6'-dioate

6'-Methylhydrogen-9'-trans-6,6'-diapocarotene-6,6'-dioate

Norbixin: 9'Cis-6,6'-diapocarotene-6,6'-dioic acid

9'-Trans-6,6'-diapocarotene-6,6'-dioic acid

Chemical formula Bixin: C₂₅H₃₀O₄

Norbixin: C₂₄H₂₈O₄

Molecular weight Bixin: 394,51

Norbixin: 380,48

Description Reddish-brown powder, suspension or solution

Identification

Spectrometry Bixin: maximum in chloroform at ca 502 nm

Norbixin: maximum in dilute KOH solution at ca 482 nm

(i)	Solvent	extracted	bixin	and
	norbixir	1.		

Definition

Bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (Bixa orellana L.) with one or more of the following solvents: acetone, methanol, hexane or dichloromethane, carbon dioxide followed by the removal of the solvent.

Norbixin is prepared by hydrolysis by aqueous alkali of the extracted bixin.

Bixin and norbixin may contain other materials extracted from the annatto seed.

The bixin powder contains several coloured components, the major single one being bixin, which may be present in both cis- and trans- forms. Thermal degradation products of bixin may also be present.

The norbixin powder contains the hydrolysis product of bixin, in the form of the sodium or potassium salts as the major colouring principle. Both cis- and transforms may be present.

Assay

Content of bixin powders not less than 75 % total carotenoids calculated as

Content of norbixin powders not less than 25 % total carotenoids calculated as norbixin

 $E_{1~cm}^{1~\%}$ 2 870 at ca 502 nm in chloroform Bixin:

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 2 870 at ca 482 nm in KOH solution Norbixin:

Purity

Solvent residues Acetone

not more than Methanol 50 mg/kg, singly or in combination

Hexane

Dichloromethane: not more than 10 mg/kg

Arsenic Not more than 3 mg/kg Not more than 10 mg/kg Lead Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

(ii) Alkali extracted annatto

Definition

Water soluble annatto is prepared by extraction with aqueous alkali (sodium or potassium hydroxide) of the outer coating of the seeds of the annatto tree (Bixa orellana L.)

Water soluble annatto contains norbixin, the hydrolysis product of bixin, in the form of the sodium or potassium salts, as the major colouring principle. Both cis- and trans- forms may be present.

Contains not less than 0,1 % of total carotenoids expressed as norbixin Assay

> E_{1 cm} 1 % 2 870 at ca 482 nm in KOH solution Norbixin:

Purity

Not more than 3 mg/kg Arsenic Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg

Heavy metals (as Pb)

Not more than 40 mg/kg

(iii)	Oil	extracted	annatto
-------	-----	-----------	---------

Definition Annatto extracts in oil, as solution or suspension, are prepared by extraction of

the outer coating of the seeds of the annatto tree (Bixa orellana L.) with edible vegetable oil. Annatto extract in oil contains several coloured components, the major single one being bixin, which may be present in both cis- and trans-

forms. Thermal degradation products of bixin may also be present.

Assay Contains not less than 0,1 % of total carotenoids expressed as bixin

Bixin: $E_{1 \text{ cm}}^{1 \text{ \%}}$ 2 870 at ca 502 nm in chloroform

Purity

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg
Heavy metals (as Pb) Not more than 40 mg/kg

E 160c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN

Synonyms Paprika Oleoresin

Definition Paprika extract is obtained by solvent extraction of the natural strains of paprika,

which consists of the ground fruits pods, with or without seeds, of *Capsicum annuum* L., and contains the major colouring principles of this spice. The major colouring principles are capsanthin and capsorubin. A wide variety of other

coloured compounds is known to be present.

Only the following solvents may be used in the extraction: methanol, ethanol,

acetone, hexane, dichloromethane, ethyl acetate and carbon dioxide.

Class Carotenoid

Einecs Capsanthin: 207-364-1, capsorubin: 207-425-2

Chemical names Capsanthin: (3R, 3'S, 5'R)-3,3'-dihydroxy-β,k-carotene-6-one

Capsorubin: (3S, 3'S, 5R, 5R')-3,3'-dihydroxy-k,k-carotene-6,6'-dione

Chemical formula Capsanthin: C₄₀H₅₆O₃

Capsorubin: C40H56O4

Molecular weight Capsanthin: 584,85

Capsorubin: 600,85

Assay Paprika extract: content not less than 7,0 % carotenoids

Capsanthin/capsorubin: not less than 30 % of total carotenoids

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 2 100 at ca 462 nm in acetone

Description Dark-red viscous liquid

Identification

A. Spectrometry Maximum in acetone at ca 462 nm

B. Colour reaction A deep blue colour is produced by adding one drop of sulfuric acid to one drop

of sample in 2-3 drops of chloroform

Purity

Solvent residues Ethyl acetate

Methanol

Ethanol Acetone

Hexane

Dichloromethane: not more than 10 mg/kg

Not more than 50 mg/kg, singly or in combination

Capsaicin

Arsenic

Not more than 250 mg/kg

Not more than 3 mg/kg

Not more than 10 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Not more than 1 mg/kg

Not more than 40 mg/kg

E 160d LYCOPENE

Synonyms Natural Yellow 27

Definition Lycopene is obtained by solvent extraction of the natural strains of red tomatoes

(Lycopersicon esculentum L.) with subsequent removal of the solvent. Only the following solvents may be used: dichloromethane, carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol, hexane. The major colouring principle of tomatoes is lycopene, minor amounts of other carotenoid pigments may be present. Beside the other colour pigments the product may contain oils,

Not more than 50 mg/kg, singly

or in combination

fats, waxes, and flavour components naturally occurring in tomatoes.

Class Carotenoid

Colour Index No 75125

Chemical names Lycopene, ψ,ψ-carotene

Chemical formula $C_{40}H_{56}$ Molecular weight 536,85

Assay Content not less than 5 % total colouring matters

 $E_{1 \text{ cm}}^{1 \text{ }\%}$ 3 450 at ca 472 nm in hexane

Description Dark red viscous liquid

Identification

Spectrometry Maximum in hexane at ca 472 nm

Purity

Solvent residues Ethyl acetate

Methanol Ethanol

Acetone

Hexane

Propan-2-ol

Dichloromethane: not more than 10 mg/kg

Sulfated ash Not more than 0,1 %

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 160e BETA-APO-8'-CAROTENAL (C30)

Synonyms CI Food Orange 6

Definition These specifications apply to predominantly all trans isomer of β-apo-8'-

carotenal together with minor amounts of other carotenoids. Diluted and stabilized forms are prepared from β -apo-8'-carotenal meeting these specifications and include solutions or suspensions of β -apo-8' carotenal in edible fats or oils, emulsions and water dispersible powders. These preparations may

have different cis/trans isomer ratios.

Class Carotinoid
Colour Index No 40820
Einecs 214-171-6

Chemical names β-apo-8'-carotenal, Trans-β-apo-8'carotene-aldehyde

Chemical formula $C_{30}H_{40}O$ Molecular weight 416,65

Assay Not less than 96 % of total colouring matters

 $E_{1 \text{ cm}}^{1 \text{ \%}}$ 2 640 at ca 460-462 nm in cyclohexane

Description Dark violet crystals with metallic lustre or crystalline powder

Identification

Spectrometry Maximum in cyclohexane at 460-462 nm

Purity

Sulfated ash Not more than 0,1 %

not more than 3,0 % of total colouring matters

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 160f ETHYL ESTER OF BETA-APO-8'-CAROTENOIC ACID (C30)

Synonyms CI Food Orange 7, β-apo-8'-carotenoic ester

Definition These specifications apply to predominantly all trans isomer of β-apo-8'-caro-

tenoic acid ethyl ester together with minor amounts of other carotenoids. Diluted and stabilized forms are prepared from β -apo-8'-carotenoic acid ethyl ester meeting these specifications and include solutions or suspensions of β -apo-8'-carotenoic acid ethyl ester in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer

ratios.

Class Carotenoid
Colour Index No 40825

Einecs 214-173-7

Chemical names β-apo-8'-carotenoic acid ethyl ester, ethyl 8'-apo-β-caroten-8'-oate

Chemical formula $C_{32}H_{44}O_2$ Molecular weight 460,70

Assay Not less than 96 % of total colouring matters

 $E_{1~cm}^{1~\%}$ 2 550 at ca 449 nm in cyclohexane

Description Red to violet-red crystals or crystalline powder

Identification

Spectrometry Maximum in cyclohexane at ca 449 nm

Purity

Sulfated ash Not more than 0,1 %

Subsidiary colouring matters Carotenoids other than β-apo-8'-carotenoic acid ethyl ester: not more than 3,0 %

of total colouring matters

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 161b LUTEIN

Synonyms Mixed Carotenoids, Xanthophylls

Definition Lutein is obtained by solvent extraction of the natural strains of edible fruits and

plants, grass, lucerne (alfalfa) and tagetes erecta. The main colouring principle consists of carotenoids of which lutein and its fatty acid esters account for the major part. Variable amounts of carotenes will also be present. Lutein may contain fats, oils and waxes naturally occurring in the plant material.

Only the following solvents may be used for the extraction: methanol, ethanol, propan-2-ol, hexane acetone methyl ethyl ketone dichloromethane and carbon

propan-2-ol, hexane, acetone, methyl ethyl ketone, dichloromethane and carbon

dioxide

Class Carotenoid
Einecs 204-840-0

Chemical names 3,3'-dihydroxy-d-carotene

Chemical formula $C_{40}H_{56}O_2$ Molecular weight 568,88

Assay Content of total colouring matter not less than 4 % calculated as lutein

 $E_{1~cm}^{1~\%}$ 2 550 at ca 445 nm in chloroform/ethanol (10 + 90) or in hexane/

ethanol/acetone (80 + 10 + 10)

Description Dark, yellowish brown liquid

Identification

Spectrometry Maximum in chloroform/ethanol (10 + 90) at ca 445 nm

Purity

Solvent residues Acetone

Methyl ethyl ketone

Methanol

Ethanol

Propan-2-ol

Hexane

Dichloromethane: not more than 10 mg/kg

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

01 0

Heavy metals (as Pb) Not more than 40 mg/kg

Not more than 50 mg/kg, singly or in combination

E 161g CANTHAXANTHIN

CI Food Orange 8 Synonyms

Definition These specifications apply to predominantly all trans isomers of canthaxanthin

together with minor amounts of other carotenoids. Diluted and stabilized forms are prepared from canthaxanthin meeting these specifications and include solutions or suspensions of canthaxanthin in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans

isomer ratios.

Class Carotinoid

Colour Index No 40850 Einecs 208-187-2

Chemical names β-Carotene-4,4'-dione, canthaxanthin, 4,4'-dioxo-β-carotene

Chemical formula $C_{40}H_{52}O_{2}$ Molecular weight 564,86

Not less than 96 % of total colouring matters (expressed as canthaxanthin) Assay

> $E_{1\ cm}^{1\ \%}\ 2\ 200$ at ca 485 nm in chloroform

> > at 468-472 nm in cyclohexane

at 464-467 nm in petroleum ether

Description Deep violet crystals or crystalline powder

Identification

Maximum in chloroform at ca 485 nm Spectrometry

Maximum in cyclohexane at 468-472 nm

Maximum in petroleum ether at 464-467 nm

Purity

Sulfated ash Not more than 0,1 %

Subsidiary colouring matters Carotenoids other than canthaxanthin: not more than 5,0 % of total colouring

Arsenic Not more than 3 mg/kg Lead Not more than 10 mg/kg Mercury Not more than 1 mg/kg Cadmium Not more than 1 mg/kg Not more than 40 mg/kg

E 162 BEETROOT RED, BETANIN

Heavy metals (as Pb)

Synonyms Beet Red

Definition Beet red is obtained from the roots of natural strains of red beets (Beta vulgaris L.

var. rubra) by pressing crushed beet as press juice or by aqueous extraction of shredded beet roots and subsequent enrichment in the active principle. The colour is composed of different pigments all belonging to the class betalaine. The main colouring principle consists of betacyanins (red) of which betanin accounts for 75-95 %. Minor amounts of betaxanthin (yellow) and degradation

products of betalaines (light brown) may be present.

Besides the colour pigments the juice or extract consists of sugars, salts, and/or proteins naturally occurring in red beets. The solution may be concentrated and some products may be refined in order to remove most of the sugars, salts and

proteins.

Class Betalaine Einecs 231-628-5

Chemical names (S-(R',R')-4-(2-(2-Carboxy-5(β-D-glucopyranosyloxy)-2,3-dihydro-6-hydroxy-1H-

indol-1-yl)ethenyl)-2,3-dihydro-2,6-pyridine-dicarboxylic acid; 1-(2-(2,6-dicarboxy-1,2,3,4-tetrahydro-4-pyridylidene)ethylidene)-5-β-D-glucopyrano-

syloxy)-6-hydroxyindolium-2-carboxylate

Chemical formula Betanin: C₂₄H₂₆N₂O₁₃

Molecular weight 550,48

Assay Content of red colour (expressed as betanine) is not less than 0,4 %

 $E_{1 \text{ cm}}^{1 \text{ %}}$ 1 120 at ca 535 nm in aqueous solution at pH 5

Description Red or dark red liquid, paste, powder or solid

Identification

Spectrometry Maximum in water of pH 5 at ca 535 nm

Purity

Nitrate Not more than 2 g nitrate anion/g of red colour (as calculated from assay).

Arsenic Not more than 3 mg/kg

Lead Not more than 10 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

Heavy metals (as Pb) Not more than 40 mg/kg

E 163 ANTHOCYANINS

DefinitionAnthocyanins are obtained by extraction with sulphited water, acidified water, carbon dioxide, methanol or ethanol from the natural strains of vegetables and adible facility. Anthocyaning contains company to of the source metapid

edible fruits. Anthocyanins contain common components of the source material, namely anthocyanine, organic acids, tannins, sugars, minerals etc., but not neces-

sarily in the same proportions as found in the source material.

Class Anthocyanin

Einecs 208-438-6 (cyanidin); 205-125-6 (peonidin); 208-437-0 (delphinidin); 211-403-

8 (malvidin); 205-127-7 (pelargonidin)

Chemical names 3,3',4',5,7-Pentahydroxy-flavylium chloride (cyanidin)

3,4′,5,7-Tetrahydroxy-3′-methoxyflavylium chloride (peonidin)

3,4',5,7-Tetrahydroxy-3',5'-dimethoxyflavylium chloride (malvidin)

3,5,7-Trihydroxy-2-(3,4,5,trihydroxyphenyl)-1-benzopyrylium chloride

(delphinidin)

3,3'4',5,7-Pentahydroxy-5'-methoxyflavylium chloride (petunidin)

3,5,7-Trihydroxy-2-(4-hydroxyphenyl)-1-benzopyrilium chloride (pelargonidin)

Chemical formula Cyanidin: C₁₅H₁₁O₆Cl

Peonidin: $C_{16}H_{13}O_6Cl$

Malvidin: C₁₇H₁₅O₇Cl

Delphinidin: C₁₅H₁₁O₇Cl

Petunidin: C₁₆H₁₃O₇Cl

Pelargonidin: C₁₅H₁₁O₅Cl

Molecular weight Cyanidin: 322,6

Peonidin: 336,7 Malvidin: 366,7 Delphinidin: 340,6 Petunidin: 352,7 Pelargonidin: 306,7

Assay $E_{1 \text{ cm}}^{1 \text{ %}} 300 \text{ for the pure pigment at } 515-535 \text{ nm at pH } 3,0$

Description Purplish-red liquid, powder or paste, having a slight characteristic odour

Identification

Spectrometry Maximum in methanol with 0,01 % conc. HCl

Cyanidin: 535 nm
Peonidin: 532 nm
Malvidin: 542 nm
Delphinidin: 546 nm
Petunidin: 543 nm
Pelargonidin: 530 nm

Purity

Solvent residues Methanol

Not more than

50 mg/kg, singly
or in combination

Sulfur dioxide Not more than 1 000 mg/kg per percent pigment

Ethanol

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg
Heavy metals (as Pb) Not more than 40 mg/kg

E 170 CALCIUM CARBONATE

Synonyms CI Pigment White 18, Chalk

Definition Calcium carbonate is the product obtained from ground limestone or by the

precipitation of calcium ions with carbonate ions.

Class Inorganic
Colour Index No 77220

Einecs Calcium carbonate: 207-439-9

Limestone: 215-279-6

Chemical names Calcium carbonate

 $\begin{array}{c} \text{Chemical formula} & \text{CaCO}_3 \\ \text{Molecular weight} & 100,1 \end{array}$

Assay Content not less than 98 % on the anhydrous basis

Description White crystalline or amorphous, odourless and tasteless powder

Identification

Solubility Practically insoluble in water and in alcohol. Dissolves with effervescence in

diluted acetic acid, in diluted hydrochloric acid and in diluted nitric acid, and

the resulting solutions, after boiling, give positive tests for calcium.

Purity

Loss on drying

Not more than 2,0 % (200 °C, 4 hours)

Not more than 0,2 %

Not more than 1,5 %

Not more than 50 mg/kg

Acid-insoluble substances

Magnesium and alkali salts

Fluoride

Antimony (as Sb)

Copper (as Cu)

Chromium (as Cr)

Zinc (as Zn)

Barium (as Ba)

Arsenic

Lead Cadmium Not more than 100 mg/kg, singly or in combination

Not more than 3 mg/kg

Not more than 10 mg/kg

Not more than 1 mg/kg

E 171 TITANIUM DIOXIDE

Synonyms

CI Pigment White 6

Definition

Titanium dioxide consists essentially of pure anatase and/or rutile titanium dioxide which may be coated with small amounts of alumina and/or silica to

improve the technological properties of the product.

Class

77891 Colour Index No

Einecs

236-675-5

Inorganic

Chemical names

Titanium dioxide

Chemical formula Molecular weight

TiO₂ 79.88

Assay

Content not less than 99 % on an alumina and silica-free basis

Description

White to slightly coloured powder

Identification

Solubility

Insoluble in water and organic solvents. Dissolves slowly in hydrofluoric acid and in hot concentrated sulfuric acid.

Purity

Loss on drying

Not more than 0,5 % (105 °C, 3 hours)

Loss on ignition

Not more than 1,0 % on a volatile matter free basis (800 °C)

Aluminium oxide and/or

silicon dioxide

Total not more than 2,0 %

Matter soluble in 0,5 N HCl

Not more than 0,5 % on an alumina and silica-free basis and, in addition, for products containing alumina and/or silica, not more than 1,5 % on the basis of

the product as sold.

Water soluble matter

Not more than 0,5 %

Cadmium

Not more than 1 mg/kg

Antimony Arsenic

Not more than 50 mg/kg by total dissolution

Lead

Not more than 3 mg/kg by total dissolution

Mercury Zink

Not more than 10 mg/kg by total dissolution

Not more than 1 mg/kg by total dissolution Not more than 50 mg/kg by total dissolution

E 172 IRON OXIDES AND IRON HYDROXIDES

Synonyms Iron Oxide Yellow: CI Pigment Yellow 42 and 43

Iron Oxide Red: CI Pigment Red 101 and 102

Iron Oxide Black: CI Pigment Black 11

Definition Iron oxides and iron hydroxides are produced synthetically and consist essen-

tially of anhydrous and/or hydrated iron oxides. The range of hues includes yellows, reds, browns and blacks. Food quality iron oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals. This is achieved by the selection and control of the source of the iron and/or by the extent of chemical purification during the manufacturing

process.

Class Inorganic

Colour Index No Iron Oxide Yellow: 77492

Iron Oxide Red: 77491

Iron Oxide Black: 77499

Einecs Iron Oxide Yellow: 257-098-5

Iron Oxide Red: 215-168-2

Iron Oxide Black: 235-442-5

Iron Oxide Red: anhydrous ferric oxide, anhydrous iron (III) oxide

Iron Oxide Black: ferroso ferric oxide, iron (II, III) oxide

Chemical formula Iron Oxide Yellow: FeO(OH)·H₂O

Iron Oxide Red: Fe₂O₃

Iron Oxide Black: FeO·Fe₂O₃

Molecular weight 88,85: FeO(OH)

159,70: Fe₂O₃

231,55: FeO·Fe₂O₃

Assay Yellow not less than 60 %, red and black not less than 68 % total iron, expressed

as iron

Description Powder; yellow, red, brown or black in hue

Identification

Solubility Insoluble in water and in organic solvents

Soluble in concentrated mineral acids

Purity

Water soluble matter Not more than 1,0 %

Arsenic Not more than 5 mg/kg

Barium Not more than 50 mg/kg

Cadmium Not more than 5 mg/kg

Chromium Not more than 100 mg/kg

Copper Not more than 50 mg/kg
Lead Not more than 20 mg/kg
Mercury Not more than 1 mg/kg

Nickel Not more than 200 mg/kg

Zinc Not more than 100 mg/kg

By total dissolution

E 173 ALUMINIUM

Synonyms CI Pigment Metal, Al

Definition Aluminium powder is composed of finely divided particles of aluminium. The

grinding may or may not be carried out in the presence of edible vegetable oils and/or food additive quality fatty acids. It is free from admixture with substances other than edible vegetable oils and/or food additive quality fatty acids.

Colour Index No 77000

Einecs 231-072-3 Chemical names Aluminium

Chemical formula Al
Atomic weight 26,98

Assay Not less than 99 % calculated as Al on an oil-free basis

Description A silvery-grey powder or tiny sheets

Identification

Solubility Insoluble in water and in organic solvents. Soluble in dilute hydrochloric acid.

The resulting solution gives positive tests for aluminium.

Purity

Loss on drying Not more than 0,5 % (105 °C, to constant weight)

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg
Heavy metals (as Pb) Not more than 40 mg/kg

itetais (as 10)

E 174 SILVER

Synonyms Argentum, Ag
Class Inorganic
Colour Index No 77820
Einecs 231-131-3

Chemical names Silver
Chemical formula Ag
Atomic weight 107,87

Assay Content not less than 99,5 % Ag

Description Silver-coloured powder or tiny sheets

E 175 GOLD

Synonyms Pigment Metal 3, Aurum, Au

Class Inorganic
Colour Index No 77480
Einecs 231-165-9
Chemical names Gold
Chemical formula Au
Atomic weight 197,0

Assay Content not less than 90 % Au

Description Gold-coloured powder or tiny sheets

Purity

Silver Not more than 7,0 %
Copper Not more than 4,0 %

After complete dissolution

E 180 LITHOLRUBINE BK

Synonyms CI Pigment Red 57, Rubinpigment, Carmine 6B

DefinitionLithol Rubine BK consists essentially of calcium 3-hydroxy-4-(4-methyl-2-sulfo-

natophenylazo)-2-naphthalenecarboxylate and subsidiary colouring matters together with water, calcium chloride and/or calcium sulfate as the principal

uncoloured components.

Class Monoazo
Colour Index No 15850:1
Einecs 226-109-5

Chemical names Calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalene-

carboxylate

Chemical formula $C_{18}H_{12}CaN_2O_6S$

Molecular weight 424,45

Assay Content not less than 90 % total colouring matters

 $E_{1 \text{ cm}}^{1 \text{ } \%}$ 200 at ca 442 nm in dimethylformamide

Description Red powder

Identification

Spectrometry Maximum in dimethylformamide at ca 442 nm

Not more than 0,2 %

Not more than 0,4 %

Not more than 0,01 % (expressed as aniline)

Purity

Subsidiary colouring matters Not more than 0,5 %

Organic compounds other than colouring matters:

2-Amino-5-methylbenzenesulfonic acid, calcium salt

sulfonic acid, calcium salt

3-hydroxy-2-naphthalenecarboxylic acid, calcium salt

Unsulfonated primary aromatic

amines

Ether extractable matter From a solution of pH 7, not more than 0,2 %

Arsenic Not more than 3 mg/kg
Lead Not more than 10 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg
Heavy metals (as Pb) Not more than 40 mg/kg

ANNEX II

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 2)

Commission Directive 95/45/EC	(OJ L 226, 22.9.1995, p. 1)
Commission Directive 1999/75/EC	(OJ L 206, 5.8.1999, p. 19)
Commission Directive 2001/50/EC	(OJ L 190, 12.7.2001, p. 14)
Commission Directive 2004/47/EC	(OJ L 113, 20.4.2004, p. 24)
Commission Directive 2006/33/EC	(OJ L 82, 21.3.2006, p. 10)

PART B List of time-limits for transposition into national law

(referred to in Article 2)

Directive	Time-limit for transposition
95/45/EC	1 July 1996 (¹)
1999/75/EC	1 July 2000
2001/50/EC	29 June 2002
2004/47/EC	1 April 2005 (²)
2006/33/EC	10 April 2007

According to Article 2(2) of Directive 95/45/EC, products put on the market or labelled before 1 July 1996 which do not comply with that Directive may, however, be marketed until stocks are exhausted.
 According to Article 3 of Directive 2004/47/EC, products on the market or labelled before 1 April 2005 which do not comply with that Directive may be marketed until stocks are exhausted.

ANNEX III

Correlation table

Directive 95/45/EC	This Directive
Article 1, first paragraph	Article 1
Article 1, second paragraph	_
Article 2	_
_	Article 2
Article 3	Article 3
Article 4	Article 4
Annex	Annex I
_	Annex II
_	Annex III