

**EUROPEAN COMMUNITIES (GENERAL PROVISIONS ON THE CONTROL OF  
ADDITIVES,  
AND IN PARTICULAR COLOURS AND SWEETENERS FOR USE IN  
FOODSTUFFS)  
REGULATIONS 1995 -**

The Minister for Health in exercise of the powers conferred on him by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) hereby makes the following Regulations for the purpose of giving effect to:

Council Directive 89/107/EEC(1) on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.

(1)O.J. No. L40, 11.2.89, pp 27-33

European Parliament and Council Directive 94/35/EC(2) on sweeteners for use in foodstuffs.

(2)O.J. No. L237, 10.9.94, pp 3-12

European Parliament and Council Directive 94/36/EC(3) on colours for use in foodstuffs.

(3)O.J. No. L237, 10.9.94, pp 13-29

Commission Directive 95/31/EC(4) laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

(4)O.J. No. L178, 28.7.95, pp 1-19

Commission Directive 95/45/EC(5) laying down specific purity criteria concerning colours for use in foodstuffs.

(5)O.J. No. L226, 22.9.95, pp 1-45

**REG 1**

1. These Regulations may be cited as the European Communities (General Provisions on the Control of Additives, and in particular Colours and Sweeteners for use in Foodstuffs) Regulations, 1995.

**REG 2**

2. These Regulations shall come into force on the 31st day of December, 1995.

**REG 3**

3. In these Regulations words and phrases shall, except where otherwise indicated, be construed as a reference to an article contained in these Regulations or, as may be, to the Schedule thereto; any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article.

**PART I**  
**GENERAL PROVISIONS ON FOOD ADDITIVES**

REG 4

4. (1) Subject to sub-article (3) of this article, these Regulations shall apply to all food additives coming within the various categories of food additives listed in Schedule I and which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff and are still present in the final product, even if in altered form, hereinafter called "food additives".

(2) For the purposes of these Regulations "food additive" means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

(3) These regulations shall not apply to:

- ( a ) processing aids;
- ( b ) substances used in the protection of plants and plant products in conformity with Community rules relating to plant health;
- ( c ) flavourings for use in foodstuffs for human consumption in accordance with EC (Flavourings for use in Foodstuffs for Human Consumption) Regulations, 1992 (S.I. No. 22 of 1992).
- ( d ) substances added to foodstuffs as nutrients (for example, minerals, trace elements or vitamins).

REG 5

5. ( a ) For the purposes of these Regulations, "processing aid" means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, food or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

( b ) The term "quantum satis" when used in the Schedule to these Regulations means that no maximum level is specified. However, the additives in question shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

( c ) For the purposes of these Regulations "unprocessed" means not

having undergone any treatment resulting in a substantial change in the original state of the foodstuffs. However, they may have been, for example, divided, parted, severed, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen, frozen, chilled, milled or husked, packed or unpacked.

( d ) For the purposes of these Regulations:

(i) the word "infant(s)" shall mean a child/ children under the age of twelve months;

(ii) the words "young children" shall mean children aged between one and three years.

( e ) For the purposes of these Regulations the term "import" shall be construed to mean "from any place outside the European Union".

( f ) For the purposes of these Regulations "sell" shall be construed to include possess for sale or offer, expose or advertise for sale, and "sale" shall be construed accordingly.

## REG 6

6. Where the Minister for Health is of the view that the use or intended use in foodstuffs of any food additive, although complying with these Regulations, endangers human health he may take appropriate measures including the temporary suspension or restriction of trade in that food or food additive in order to protect public health.

## REG 7

7. (1) Food additives not intended for sale to the ultimate consumer shall not be marketed, imported, manufactured, sold, distributed, offered or kept for sale, unless their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible;

( a ) (i) in the case of food additives sold singly or mixed with each other, for each additive, the name laid down by any regulation made by the Minister for Health and its EEC number or, in the absence of such regulations, a description of the additive that is sufficiently precise to enable it to be distinguished from additives with which it could be confused, in descending order of the proportion by weight in the total;

(ii) when other substances or materials or food ingredients to facilitate storage, sale, standardisation, dilution or dissolution of a food additive or food additive are incorporated in the additives, the name of the additive in accordance with subarticle (1) (a) (i) and an indication of each component in descending order to the proportion by weight in the total.

( b ) either the statement "for use in food" or the statement "restricted use in food", or a more specific reference to its intended food use;

( c ) if necessary, the special conditions of storage and use;

- ( d ) directions for use, if the omission thereof would preclude appropriate use of the additive;
  - ( e ) a mark identifying the batch or lot;
  - ( f ) the name or business name and address of the manufacturer or packer, or of a seller established within the European Economic Community;
  - ( g ) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any European Economic Community provisions applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;
  - ( h ) the net quantity.
- (2) By way of derogation from paragraph 1, the information required in sub-article (1) (a) (ii) and sub-article (1) (d) to (g), may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication "intended for manufacture of foodstuffs and not for retail sale" appears on a conspicuous part of the packaging or container of the product in question.

#### REG 8

8. Food additives intended for sale to the ultimate consumer shall not be marketed, imported, distributed, manufactured, sold or offered for sale, unless their packaging or containers bear the following information which must be conspicuous, clearly legible and indelible.
- ( a ) the name under which the product is sold (this name shall be constituted by the name laid down by any Regulation made by the Minister for Health in relation to the product in question plus its EEC number or, in the absence of such provisions, by a description of the product that is sufficiently precise to enable it to be distinguished from products with which it could be confused);
  - ( b ) the information required by article 7 (1) (a) to (f) and (h);
  - ( c ) the date of minimum durability within the meaning of the Council Directive 79/112/EEC(1), as amended.
- OJ No. L33, 8.2.1979, page 1

#### REG 9

9. (1) Articles 7 and 8 of these Regulations shall not affect more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures, or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or the transport of such substances.
- (2) The particulars required by articles 7 and 8 shall be given in the Irish or English languages unless other measures have been taken to ensure that the purchaser is informed. The provision shall not

prevent such particulars from also being indicated in various other languages.

#### REG 10

10. (1) A person shall not import, manufacture, sell, distribute, or offer for sale or keep for sale, food additives except in conformance with these Regulations.

(2) However, and where appropriate, Article 20 may be relied upon by way of derogation from sub-article (1) of this Article.

## **PART II**

### **SWEETENERS FOR USE IN FOODSTUFFS**

#### REG 11

11. (1) For the purposes of these Regulations, the term "sweeteners" refers to food additives which are used:

- to impart a sweet taste to foodstuffs
- as table-top sweeteners

These Regulations do not apply to foodstuffs with sweetening properties.

(2) A sweetener listed in Schedule II to these Regulations must satisfy the purity criteria for that sweetener as set out in Schedule III laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

(3) For the purpose of these Regulations, "with no added sugar" and 'energy-reduced' in column III of Schedule II shall be defined as follows:

- 'with no added sugar': without any added mono-or disaccharides or any other foodstuff used for its sweetening properties;
- 'energy-reduced': with an energy value reduced by at least 30% compared with the original foodstuff or a similar product.

#### REG 12

12. (1) Only those sweeteners listed in Schedule II may be placed on the market with a view to:

- sale to the ultimate consumer; or
- use in the manufacture of foodstuffs.

(2) Sweeteners referred to in the second indent of sub-article (1) may only be used in the manufacture of the foodstuffs listed in Schedule II under the conditions specified therein.

(3) Except where specifically provided for, sweeteners may not be used in foods for infants or young children, as specified in the Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991).

(4) The maximum usable doses indicated in Schedule II refer to ready-to-eat foodstuffs prepared according to the instructions for

use.

#### REG 13

13. (1) These Regulations shall apply without prejudice to any other Regulations permitting additives listed in Schedule II to be used for purposes other than sweetening.

(2) These Regulations shall also apply without prejudice to national or Community provisions governing the composition and the description of foodstuffs.

#### REG 14

14. (1) The sale description of a table-top sweetener must include the term 'x based table-top sweetener', where 'x' is the name(s) of the sweetening substances(s) used in its composition.

(2) The labelling of a table-top sweetener containing polyols and/or aspartame must bear the following warnings:

—polyols: 'excessive consumption may induce laxative effects',

—aspartame: 'contains a source of phenylalanine'.

### **PART III**

#### **COLOURS FOR USE IN FOODSTUFFS**

#### REG 15

15. (1) For the purposes of these Regulations, 'colours' are substances which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food.

Preparations obtained from foodstuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of these Regulations.

The following substances shall not be considered colours for the purposes of these Regulations.

(i) foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron.

(ii) colours used for the colouring of the inedible external parts of foodstuffs, such as cheese coatings and sausage casings.

(2) Only the substances listed in Schedule IV, Part A may be used as colours in foodstuffs.

(3) Colours may be used only in the foodstuffs listed in Schedule IV, Part C, D and E and under the conditions specified therein;

colours may be used in those same foodstuffs when they are intended for particular uses in accordance with Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991).

(4) Colours may not be used in the foodstuffs listed in Schedule IV, Part B except where specifically provided for in Schedule IV, Part C, Part D or Part E.

(5) Colours permitted for certain uses only are listed in Schedule IV, Part D.

(6) Colours permitted in general in foodstuffs and the conditions of use therefor are listed in Schedule IV, Part E.

(7) The maximum levels indicated in Schedule IV to these Regulations

(i) relate to ready-to-eat foodstuffs, prepared according to the instructions for use,

(ii) refer to the quantities of colouring principle contained in the colouring preparation.

(8) For the purpose of health marking as provided in Directive 91/497/EEC(1) and other marking required on meat products, only E155 Brown HT, E133 Brilliant Blue FCF or E129 Allura Red AC or an appropriate mixture of E133 Brilliant Blue FCF and E129 Allura Red AC may be used.

(1)OJ No. L268, 24.9.1991, p. 69

(9) Only those colours mentioned in Schedule IV, Part A may be used for the decorative colouring of eggshells or for the stamping of eggshells as provided in Regulations (EEC) No. 1274/91(2).

(2)OJ No. L121, 16.5.1991, p. 11

(10) Only those colours listed in Schedule IV, Part A, except E123, E127, E128, E154, E160b, E161g, E173 and E180 may be sold directly to consumers.

(11) A colour listed in Schedule IV to these Regulations must satisfy the purity criteria for that colour as set out in Schedule V, laying down specific criteria of purity concerning colours for use in foodstuffs.

## REG 16

16. Without prejudice to other European Community provisions, the presence of a colour in a foodstuff is permissible:

(i) in a compound foodstuff other than one mentioned in Schedule IV, Part B to the extent that the colour is permitted in one of the ingredients of the compound foodstuff;

(ii) if the foodstuff is destined to be used solely in the preparation of a compound foodstuff and to such an extent that the compound foodstuff conforms to the provisions of these Regulations.

## **PART IV**

### **FINAL PROVISIONS**

#### REG 17

17. ( a ) These Regulations shall be enforced and executed by each health board, established in accordance with the Health Act 1970 (No. 1 of 1970) in respect of its functional area through its authorised officers and/or the officers of the Minister for Health who are authorised officers for the purposes of these Regulations.

( b ) For the purposes of these Regulations, "authorised officer" means

( a ) an officer of the Minister for Health who is authorised in writing by the Minister for Health to be an authorised officer for the purposes of these Regulations; or

( b ) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.

#### REG 18

18. (1) Where an authorised officer reasonably suspects or believes that a foodstuff or food additive does not comply with these regulations, the authorised officer may seize, remove and/or detain such foodstuffs or food additive as being a foodstuff or food additive which is unfit for human consumption.

(2) With the consent in writing of the owner or person responsible for such foodstuff or food additive, an authorised officer may destroy or otherwise dispose of it so as to prevent its use for human consumption.

(3) An authorised officer who has seized any foodstuff or food additive in pursuance of the provisions of this article may, on giving notice in writing to the owner or person responsible for such foodstuff or food additive apply to a Judge of the District Court for an Order directing that such food or food additive be destroyed or otherwise disposed of as being a foodstuff or food additive which is unfit for human consumption.

(4) A Judge of the District Court to whom the application is made for an Order under sub-article (3) of this article shall, if satisfied that such foodstuff or food additive does not comply with these Regulations, order that it be destroyed or otherwise disposed of after such period, not exceeding fourteen days, as may be specified in such order, as being a foodstuff or food additive



which is unfit for human consumption and an officer shall destroy or dispose of it accordingly.

#### REG 19

19. A person shall give to any authorised officer all reasonable assistance that the officer may require in the performance of his duties under these Regulations and such assistance shall include the giving of information relating to the composition and use of any foodstuff or food additive and the identity of the person from whom or the place from which any such foodstuff or food additive has been obtained and the person to whom and the place to which it has been consigned or the manner in which it has been consigned or the manner in which it has otherwise been disposed of.

#### REG 20

20. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to show that the food in respect of which the offence is alleged to have been committed was intended for export and complied with the domestic food legislation of the importing country relevant to the alleged offence.

#### REG 21

21. (1) Any person who contravenes any Article or Sub Article of these Regulations shall be guilty of an offence.

(2) A person guilty of an offence under the Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or to both.

(3) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, manager, secretary or other officer of the body corporate, the director, manager, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

(4) Notwithstanding section 10 (4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within 12 months from the date of the offence.

## REG 22

22. An offence under these Regulations shall be prosecuted by the Minister for Health or by a health board in whose functional area the offence was committed.

## REG 23

23. The following Regulations are hereby revoked:—  
Health (Colouring Agents in Food) Regulations, 1973 (S.I. No. 149 of 1973),  
Health (Colouring Agents in Food) (Amendment) Regulations, 1978 (S.I. No. 140 of 1978).  
Health (Colouring Agents in Food) (Amendment) Regulations, 1981 (S.I. No. 336 of 1981),  
Health (Colouring Agents in Food) (Amendment) Regulations, 1992 (S.I. No. 68 of 1992),  
Health (Cyclamate in Food) Regulations, 1970 (S.I. No. 49 of 1970),  
Health (Cyclamate in Food) (Amendment) Regulations, 1992 (S.I. No. 73 of 1992), and  
European Communities (Labelling of Additives for use in Foodstuffs) Regulations, 1992 (S.I. No. 23 of 1992).

## SCHEDULES

### SCHEDULE I

Categories of Food Additives

### SCHEDULE II

Sweeteners for use in Foodstuffs

### SCHEDULE III

Specific Criteria of Purity concerning Sweeteners for use in foodstuffs

### SCHEDULE IV

List of Permitted Food Colours

## **SCHEDULE II**

Specific Purity Criteria concerning Colours for use in Foodstuffs

## **SCHEDULE I**

Categories of Food Additives

Colour

Preservative

Anti-oxidant

Emulsifier

Emulsifying salt

Thickener

Gelling agent

Stabilizer(1)  
 Flavour enhancer  
 Acid  
 Acidity regulator(2)  
 Anti-caking agent  
 Modified starch  
 Sweetener  
 Raising agent  
 Anti-foaming agent  
 Glazing agent(3)  
 Flour treatment agent  
 Firming agent  
 Humectant  
 Sequestrant(4)  
 Enzyme(4) (5)  
 Bulking agent  
 Propellant gas and packaging gas

(1) This category also comprises foam stabilizers.

(2) These can act as two-way acidity regulators.

(3) These substances include lubricants.

(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.

(5) Only those used as additives.

## SCHEDULE II

### Sweeteners for use in Foodstuffs

EC No.	Name	Foodstuffs	Maximum usable dose
E 420	Sorbitol	Desserts and similar products	quantum satis
	(i) Sorbitol		
	(ii) Sorbitol syrup		
E 421	Mannitol	Water-based flavoured desserts, energy-reduced or with no added sugar	
E 953	Isomaltulose		
E 965	Maltitol	Milk and milk-derivative-based preparations, energy-reduced or with no added sugar	
	(i) Maltitol		
	(ii) Maltitol syrup		
		Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	
E 966	Lactitol		
E 967	Xylitol	Egg-based desserts, energy-reduced or with no added sugar	
		Cereal-based desserts, energy reduced or with no added sugar	
		Breakfast cereals or cereal-based products, energy reduced or with no added sugar	
		Fat-based desserts, energy-reduced or with no added sugar	
		Edible ices, energy-reduced or with no added sugar	
		Jams, jellies, marmalades and crystallized fruit, energy-reduced or with no added sugar	
		Fruit preparations, energy-reduced or with no added sugar, with the exception of those intended for the manufacture of fruit-juice-based drinks	
		Confectionery—Confectionery with no added sugar	
		Dried-fruit-based confectionery, energy-reduced or with no added sugar	
		Starch-based confectionery, energy-reduced or with no added sugar	

E 420, E 421, E 953, E 965, E 966, E 967 —contd.—Cocoa-based products, energy-reduced or with no added sugar—Cocoa, milk,

dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar—Chewing gum with no added sugar—Sauces—Mustard—Fine bakery products, energy-reduced or with no added sugar—Products intended for particular nutritional uses—Solid food supplements/dietary integrators E 950 Acesulfame K Non-alcoholic drinks—Water-based flavoured drinks, energy-reduced or with no added sugar 350 mg/l—Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar 350 mg/l Desserts and similar products—Water-based flavoured desserts, energy-reduced or with no added sugar 350 mg/kg—Milk and milk-derivative-based preparations, energy-reduced or with no added sugar 350 mg/kg—Fruit and vegetable-based desserts, energy-reduced or with no added sugar 350 mg/kg—Egg-based desserts, energy-reduced or with no added sugar 350 mg/kg—Cereal-based desserts, energy-reduced or with no added sugar 350 mg/kg—Fat-based desserts, energy-reduced or with no added sugar 350 mg/kg—'snacks': certain flavours or ready to eat, prepacked, dry, savoury starch products and coated nuts 350 mg/kg

E 950—contd. Confectionery—Confectionery with no added sugar 500 mg/kg—Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar 500 mg/kg—Starch-based confectionery, energy-reduced or with no added sugar 1 000 mg/kg—Cocoa, milk, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar 1 000 mg/kg—Chewing gum with no added sugar 2 000 mg/kg—Cider and perry 350 mg/l—Alcohol-free beer or with an alcohol content not exceeding 1,2% vol 350 mg/l—'Biere de table/Tafelbier/Table Beer' (original wort content less than 6%) except for 'Obergariges Einfachbier' 350 mg/l—Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH 350 mg/l—Brown beers of the 'oud bruin' type 350 mg/l—Edible ices, energy-reduced or with no added sugar 800 mg/kg—Canned or bottled fruit, energy-reduced or with no added sugar 350 mg/kg—Energy-reduced jams, jellies and marmalades 1 000 mg/kg—Energy-reduced fruit and vegetable preparations 350 mg/kg—Sweet-sour preserves of fruit and vegetables 200 mg/kg—Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs 200 mg/kg—Sauces 350 mg/kg—Mustard 350 mg/kg—Fine bakery products for special nutritional uses 1 000 mg/kg—Complete formulae for weight control intended to replace total daily food intake or an individual meal 450 mg/kg—Complete formulae and nutritional supplements for use under medical supervision 450 mg/kg—Liquid food supplements/dietary integrators 350 mg/l—Solid food supplements/dietary integrators 500 mg/l—Vitamins and dietary preparations 2 000 mg/kg

E 951 Aspartame Non-alcoholic drinks—Water-based flavoured drinks, energy-reduced or with no added sugar 600 mg/l—Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar 600 mg/l Desserts and similar products—Water-based flavoured desserts, energy-reduced or with no added sugar 1 000 mg/kg—Milk and milk-derivative-based preparations, energy-reduced or with no added sugar 1 000 mg/kg—Fruit and vegetable-based desserts,

energy-reduced or with no added sugar 1 000 mg/kg—Egg-based desserts, energy-reduced or with no added sugar 1 000 mg/kg—Cereal-based desserts, energy-reduced or with no added sugar 1 000 mg/kg—Fat-based desserts, energy-reduced or with no added sugar 1 000 mg/kg—'snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts 500 mg/kg Confectionery—Confectionery with no added sugar 1 000 mg/kg—Cocoa or dried-fruit-based confectionery, energy-reduced or with no added sugar 2 000 mg/kg—Starch-based confectionery, energy-reduced or with no added sugar 2 000 mg/kg—Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy reduced or with no added sugar 1 000 mg/kg—Chewing gum with no added sugar 5 500 mg/kg—Cider and perry 600 mg/l—Alcohol-free or with an alcohol content not exceeding 1,2% vol 600 mg/l—'Biere de table/Tafelbier Beer' (original wort content less than 6%) except for 'Obergariges Einfachbier' 600 mg/l—Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH 600 mg/l—Brown Beers of the 'oud bruin' type 600 mg/l

E 951—contd.—Edible ices, energy-reduced or with no added sugar 800 mg/kg—Canned or bottled fruit, energy-reduced or with no added sugar 1 000 mg/kg—Energy-reduced jams, jellies and marmalades 1 000 mg/kg—Energy-reduced fruit and vegetable preparations 1 000 mg/kg—Sweet-sour preserves of fruit and vegetables 300 mg/kg—Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs 300 mg/kg—Sauces 350 mg/kg—Mustard 350 mg/kg—Fine bakery products for special nutritional uses 1 700 mg/kg—Complete formulae for weight control intended to replace total daily food intake or an individual meal 800 mg/kg—Complete formulae and nutritional supplements for use under medical supervision 1 000 mg/kg—Liquid food supplements/dietary integrators 600 mg/kg—Solid food supplements/dietary integrators 2 000 mg/kg Vitamins and dietary preparations 5 500 mg/kg E 952 Cyclamic acid and its Na and Ca salts Non-alcoholic drinks—Water-based flavoured drinks, energy-reduced or with no added sugar 400 mg/l—Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar 400 mg/l Desserts and similar products—Water-based flavoured desserts, energy-reduced or with no added sugar 250 mg/kg—Milk-and milk-derivative-based preparations, energy-reduced or with no sugar added 250 mg/kg—Fruit-and vegetable-based desserts, energy-reduced or with no added sugar 250 mg/kg—Egg-based desserts, energy-reduced or with no added sugar 250 mg/kg—Cereal-based desserts, energy-reduced or with no added sugar 250 mg/kg—Fat-based desserts, energy-reduced or with no added sugar 250 mg/kg

E 952—contd. Confectionery—Confectionery with no added sugar 500 mg/kg—Cocoa or dried-fruit-based confectionery, energy-reduced or with no added sugar 500 mg/kg—Starch-based confectionery, energy-reduced or with no added sugar 500 mg/kg—Cocoa, milk, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar 500 mg/kg—Chewing gum with no added sugar 1 500 mg/kg—Edible ices,

energy-reduced or with no added sugar 250 mg/kg—Canned or bottled fruit, energy-reduced or with no added sugar 1 000 mg/kg—Energy-reduced jams, jellies, and marmalades 1 000 mg/kg—Energy-reduced fruit and vegetable preparations 250 mg/kg—Fine bakery products for special nutritional uses 1 600 mg/kg—Complete formulae for weight control intended to replace total daily food intake or an individual meal 400 mg/kg—Complete formulae and nutritional supplements for use under medical supervision 400 mg/kg—Liquid food supplements/dietary integrators 400 mg/kg—Solid food supplements/dietary integrators 500 mg/kg E 954 Saccharin and its Na, K and Ca salts Non-alcoholic drinks—Water-based flavoured drinks, energy-reduced or with no added sugar 80 mg/l—Milk-and milk-derivative-based or fruit-based drinks, energy-reduced or with no added sugar 80 mg/l—'Gaseosa': non-alcoholic water-based drink with added carbon dioxide, sweeteners and flavourings 100 mg/l

E 954—contd. Desserts and similar products—Water-based flavoured desserts, energy-reduced or with no added sugar 100 mg/kg—Milk-and milk-derivative-based preparations, energy-reduced or with no added sugar 100 mg/kg—Fruit and vegetable-based desserts, energy-reduced or with no added sugar 100 mg/kg—Egg-based desserts, energy-reduced or with no added sugar 100 mg/kg—Cereal-based desserts, energy-reduced or with no added sugar 100 mg/kg—Fat-based desserts, energy-reduced or with no added sugar 100 mg/kg—'snacks': certain flavours of ready to eat, prepacked, dry savoury starch products and coated nuts 100 mg/kg Confectionery—Confectionery with no added sugar 500 mg/kg—Cocoa-or dried-fruit-based confectionery, energy reduced or with no added sugar 500 mg/kg—Starch-based confectionery, energy-reduced or with no added sugar 300 mg/kg—Essoblaten 800 mg/kg—Cocoa-, milk, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar 200 mg/kg—Chewing gum with no added sugar 1 200 mg/kg—Cider and perry 80 mg/l—Alcohol-free beer or with an alcohol content not exceeding 1.2% vol 80 mg/l—'Biere de table/Tafelbier/Table beer' (original wort content less than 6%) except 'Obergariges Einfachbier' 80 mg/l—Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH 80 mg/l—Brown beers of the 'oud bruin' type 80 mg/l—Edible ices, energy-reduced or with no added sugar 100 mg/kg—Canned or bottled fruit, energy-reduced or with no added sugar 200 mg/kg—Energy-reduced jams, jellies and marmalades 200 mg/kg

E 954 — contd.—Energy-reduced fruit and vegetable preparations 200 mg/kg—Sweet-sour preserves of fruit and vegetables 160 mg/kg—Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs 160 mg/kg—Sauces 160 mg/kg—Mustard 320 mg/kg—Fine bakery products for special nutritional uses 170 mg/kg—Complete formulae for weight control intended to replace total daily food intake or an individual meal 240 mg/kg—Complete formulae and nutritional supplements for use under medical supervision 200 mg/kg—Liquid food supplements/dietary integrators 80 mg/kg—Solid food supplements/dietary integrators 500 mg/kg—Vitamins and dietary preparations 1 200 mg/kg E

957Thaumatococcus—Confectionery—Confectionery with no added sugar50 mg/kg—Cocoa-or dried-fruit-based confectionery, energy-reduced or with no added sugar50 mg/kg—Chewing gum with no added sugar50 mg/kg—Vitamins and dietary preparations400 mg/kgE 959Neohesperidine DCNon-alcoholic drinks—Water based flavoured drinks, energy-reduced or with no added sugar30 mg/l—Milk and milk-derivative-based drinks, energy-reduced or with no added sugar50 mg/l—Fruit-juice-based drinks, energy-reduced or with no added sugar30 mg/lDesserts and similar products—Water-based flavoured desserts, energy-reduced or with no added sugar50 mg/kg—Milk-and milk-derivative-based preparations, energy-reduced or with no added sugar50 mg/kg

E959 — contd.—Fruit and vegetable-based desserts, energy-reduced or with no added sugar50 mg/kg—Egg-based desserts, energy-reduced or with no added sugar50 mg/kg—Cereal-based desserts, energy-reduced or with no added sugar50 mg/kg—Fat-based desserts, energy-reduced or with no added sugar50 mg/kgConfectionery—Confectionery with no added sugar100 mg/kg—Cocoa or dried-fruit-based confectionery, energy- reduced or with no added sugar100 mg/kg—Starch-based confectionery, energy-reduced or with no added sugar150 mg/kg—Essoblaten50 mg/kg—Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar50 mg/kg—Chewing gum with no added sugar400 mg/kg—Cider and perry20 mg/l—Alcohol-free beer or with an alcohol content not exceeding 1.2% vol10 mg/l—'Biere de table/Tafelbier/Table beer' (original wort content less than 6%) except 'Obergariges Einfachbier'10 mg/l—Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH10 mg/l—Brown beers of the 'oud bruin' type10 mg/l—Edible ices, energy-reduced or with no added sugar50 mg/kg—Canned or bottled fruit, energy-reduced or with no added sugar50 mg/kg—Energy-reduced jams, jellies and marmalades50 mg/kg—Sweet-sour preserves of fruit and vegetables100 mg/kg—Energy-reduced fruit and vegetable preparations50 mg/kg—Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs30 mg/kg—Sauces50 mg/kg—Mustard50 mg/kg—Fine bakery products for special nutritional uses150 mg/kg—Complete formulae for weight control intended to replace total daily food intake or an individual meal100 mg/kg—Liquid food supplements/dietary integrators50 mg/kg—Solid food supplements/dietary integrators100 mg/kg

### SCHEDULE III

Specific Criteria of Purity concerning Sweeteners for use in foodstuffs

E 420 (i) — SORBITOLD-glucitol, D-sorbitolDefinitionChemical nameD-glucitolEinics200-061-5E numberE 420 (i)Chemical formulaC<sub>6</sub>H<sub>14</sub>O<sub>6</sub>Relative molecular mass182,17AssayContent 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<sub>2</sub>OH(CHOH)<sub>n</sub>CH<sub>2</sub>OH, where "n" is an integer.DescriptionWhite hygroscopic powder, crystalline powder, flakes or granules having a sweet

taste. Identification A. Solubility Very soluble in water, slightly soluble in ethanol B. Melting range 88 to 102°C C. Sorbitol monobenzylidene derivative To 5g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179°C. Purity Water content Not more than 1% (Karl Fischer method) Sulphated ash Not more than 0.1% expressed on dry weight basis Reducing sugars Not more than 0.3% expressed as glucose on dry weight basis Total sugars Not more than 1% expressed as glucose on dry weight basis Chlorides Not more than 50 mg/kg expressed on dry weight basis Sulphates Not more than 100 mg/kg on dry weight basis Nickel Not more than 2 mg/kg expressed on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 420 (ii) SORBITOL SYRUPS  
 Synonyms D-glucitol syrup  
 Definition Chemical name Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides. The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where  $n < 4$  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  
 E number E 420 (ii)  
 Assay Content not less than 69% total solids and not less than 50% of D-sorbitol on the anhydrous basis  
 Description Clear colourless and sweet tasting aqueous solution  
 Identification A. Solubility Miscible with water, with glycerol, and with propane-1,2-diol B. Sorbitol monobenzylidene derivative To 5g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179°C. Purity Water content Not more than 31% (Karl Fischer method) Sulphated ash Not more than 0.1% expressed on dry weight basis Reducing sugars Not more than 0.3% expressed as glucose on dry weight basis Chlorides Not more than 50 mg/kg expressed on dry weight basis Sulphates Not more than 100 mg/kg expressed on dry weight basis Nickel Not more than 2 mg/kg expressed on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 421 — MANNITOL  
 Synonyms D-Mannitol  
 Definition Chemical name D-mannitol  
 E number E 421  
 Chemical formula  $\text{C}_6\text{H}_{14}\text{O}_6$   
 Relative molecular mass 182.2  
 Assay Content not less than 96% D-mannitol on the dried basis  
 Description Sweet tasting, white, odourless, crystalline powder  
 Identification A. Solubility Soluble  
 Purity Loss on drying Not more than



0,3% (105 °C, four hours) pH Between 5 and 8 Add 0,5ml of a saturated solution of potassium chloride to 10ml of a 10% w/v solution of the sample then measure the pH Specific rotation Specific rotation in a borated solution calculated with reference to the anhydrous substance is between + 23 and + 25° Sulphated ash Not more than 0,1% expressed on dry weight basis Reducing sugars Not more than 0,3% expressed as glucose on dry weight basis Total sugars Not more than 1% expressed as glucose on dry weight basis Chlorides Not more than 70 mg/kg expressed on dry weight basis Sulphates Not more than 100 mg/kg expressed on dry weight basis Nickel Not more than 2 mg/kg expressed on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 953 — ISOMALTS Synonyms Hydrogenated isomaltulose, hydrogenated palatinose Definition Chemical name Isomalt is a mixture of: D-glucopyranosyl-1,6-D-glucitol and D-glucopyranosyl-1,1-D-mannitoldihydrate E number E 953 Chemical formula D-glucopyranosyl-1,6-D-glucitol:  $C_{12}H_{24}O_{11}$  D-glucopyranosyl-1,1-D-mannitoldihydrate:  $C_{12}H_{24}O_{11} \cdot 2H_2O$  Relative molecular mass D-glucopyranosyl-1,6-D-glucitol: 344,32 D-glucopyranosyl-1,1-D-mannitoldihydrate: 380,32 Assay 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. Solubility Slightly soluble in water, insoluble in ethanol B. Specific rotation a : between + 90 and + 92° (4% w/v solution) C. Melting range 145 to 150 °C Tests Water content Not more than 7% (Karl Fischer method) Sulphated ash Not more than 0,05% expressed on dry weight basis Reducing sugars Not more than 1,5% expressed as glucose on dry weight basis Nickel Not more than 2 mg/kg expressed on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed on dry weight basis

E 965 (i) — MALTITOLS Synonyms D-maltitol, hydrogenated maltose Definition Chemical name (a)-D-glucopyranosyl-1,4-D-glucitol E number E 965 (i) Chemical formula  $C_{12}H_{24}O_{11}$  Relative molecular mass 344,31 Assay Content not less than 98% D-mannitol  $C_{12}H_{24}O_{11}$  on the anhydrous basis Description Sweet tasting, white crystalline powder Identification A. Solubility Very soluble in water, slightly soluble in ethanol B. Melting range 148 to 151 °C C. Specific rotation (a) = + 105,5 to + 105,5° (5% w/v solution) Purity Water content Not more than 1% (Karl Fischer method) Sulphated ash Not more than 0,1% expressed on dry weight basis Reducing sugars Not more than 0,1% expressed as glucose on dry weight basis Chlorides Not more than 50 mg/kg expressed on dry weight

basis Sulphates Not more than 100 mg/kg expressed on dry weight basis  
Nickel Not more than 2 mg/kg expressed on dry weight basis  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed on dry weight basis

E 965 (ii) — MALTITOL SYRUPS  
Synonyms Hydrogenated high maltose-glucose syrup, hydrogenated glucose syrup  
Definition Chemical name 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  
E inics 270-337-8E  
number E 965 (ii)  
Assay The following ranges apply on the anhydrous basis: Maltitol not less than 50% Sorbitol not more than 8%  
Maltitol 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 Description Identification A. Solubility Very soluble in water, slightly soluble in ethanol B. Thin layer chromatography Examine by the thin layer chromatography using a plate coated with a 0,25 mm layer of chromatographic silica gel  
Purity Water content Not more than 31% (Karl Fischer method)  
Sulphated ash Not more than 0,1% expressed on dry weight basis  
Reducing sugars Not more than 0,3% expressed as glucose on dry weight basis  
Chlorides Not more than 50 mg/kg expressed on dry weight basis  
Sulphates Not more than 100 mg/kg expressed on dry weight basis  
Nickel Not more than 2 mg/kg expressed on dry weight basis  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 966 — LACTITOLS  
Synonyms Lactit, lactositol, lactobiosit  
Definition Chemical name 4-0-β-D-galactopyranosyl-D-glucitol  
E inics 209-566-5E  
number E 966  
Chemical formula C<sub>12</sub>H<sub>24</sub>O<sub>11</sub>  
Relative molecular mass 344,32  
Assay Not less than 95% on the dry weight basis  
Description Sweet-tasting, crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms  
Identification A. Solubility Very soluble in water B. Specific rotation (α) = + 13 to + 16° calculated on the anhydrous basis (10% w/v aqueous solution)  
Purity Water content Crystalline products; not more than 10.5% (Karl Fischer method)  
Other polyols Not more than 2,5% on the anhydrous basis  
Reducing sugars Not more than 0,2% expressed as glucose on dry weight basis  
Chlorides Not more than 100 mg/kg expressed on dry weight basis  
Sulphates Not more than 200 mg/kg expressed on dry weight basis  
Sulphated ash Not more than 0,1% expressed on dry weight basis  
Nickel Not more than 2 mg/kg expressed on dry weight basis  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 967 — XYLITOL  
Synonyms Xylitol  
Definition Chemical name D-xylitol  
E inics 201-788-0  
E number E 967  
Chemical formula  $C_5H_{12}O_5$   
Relative molecular mass 152,15  
Assay Not less than 98,5% as xylitol on the anhydrous basis  
Description White, Crystalline Powder, practically odourless with a very sweet taste  
Identification A. Solubility Very soluble in water, sparingly soluble in ethanol  
B. Melting range 92 to 96 °C  
C. pH 5 to 7 (10 w/v aqueous solution)  
Purity Loss on drying Not more than 0,5%. Dry 0,5 g of sample in a vacuum over phosphorus at 60 °C for four hours  
Sulphated ash Not more than 0,1% expressed on dry weight basis  
Reducing sugars Not more than 0,2% expressed as glucose on dry weight basis  
Other polyhydric alcohols Not more than 1% expressed on dry weight basis  
Nickel Not more than 2 mg/kg expressed on dry weight basis  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis  
Chlorides Not more than 100 mg/kg expressed on dry weight basis  
Sulphates Not more than 200 mg/kg expressed on dry weight basis

E 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 Chemical name 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt  
E inecs 259-715-3  
E number E 950  
Chemical formula  $C_4H_4NO_4SK$   
Relative molecular mass 201,24  
Assay 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. Solubility Very soluble in water, very slightly soluble in ethanol  
B. Ultra-violet absorption Maximum  $227 \pm 2$  nm for a solution of 10 mg in 1,000 ml of water  
Purity Loss on drying Not more than 1% (105 °C, two hours)  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Selenium Not more than 30 mg/kg expressed on dry weight basis  
Fluoride Not more than 3 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis

E 951 — ASPARTAMES  
Synonyms Aspartyl phenylalanine methyl ester  
Definition Chemical name N-L-a -(Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(a-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester  
E inecs 245-261-3  
E number E 951  
Chemical formula  $C_{14}H_{18}N_2O_5$   
Relative molecular mass 294,31  
Assay Not less than 98% and not more than 102% of  $C_{14}H_{18}N_2O_5$  on the anhydrous basis  
Description White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as Sucrose  
Identification Solubility Slightly soluble in water and in ethanol  
Purity Loss on drying Not more than 4,5% (105°C, four hours)  
Sulphated ash Not more than 0,2% expressed on dry weight basis  
pH Between 4,5 and 6,0 (1 in 125 solution)  
Transmittance The transmittance of a 1% solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using

2N hydrochloric acid as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022 Specific rotation( $\alpha$ ) : + 14,5 to + 16,5°

Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed on dry weight basis 5-Benzyl-3,6-dioxo-2-piperazineacetic acid Not more than 1,5% expressed on dry weight basis

E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS(I) CYCLAMIC ACIDS Synonyms Cyclohexylsulphamic acid, cyclamate Definition Chemical name Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid E inecs 202-898-1 E number E 952 Chemical formula  $C_6H_{13}NO_3S$  S Relative molecular mass 179,24 Assay Cyclohexylsulphamic acid contains not less than 98% and not more than the equivalent of 102% of  $C_6H_{13}NO_3S$ , calculated on the anhydrous basis Description A practically colourless, white crystalline powder with a sweet-sour taste. Approximately 40 times as sweet as sucrose Purity Loss on drying Not more than 1% (105°C, one hour)

Not more than 8,5% (140°C, four hours) for the dihydrate form Selenium Not more than 30 mg/kg expressed as selenium on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis Cyclohexylamine Not more than 10 mg/kg expressed on dry weight basis Dicyclohexylamine Not more than 1 mg/kg expressed on dry weight basis Aniline Not more than 1 mg/kg expressed on dry weight basis

E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS—contd.(II) SODIUM CYCLAMATE Synonyms Cyclamate, sodium salt of cyclamic acid Definition Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate Chemical name 205-348-9 E inecs E 952 E number  $C_6H_{12}NNaO_3S$  and the dihydrate form  $C_6H_{12}NNaO_3S \cdot 2H_2O$  Chemical formula 201,22 calculated on the anhydrous form Relative molecular mass 237,22 calculated on the hydrated form Assay Not less than 98% and not more than 102% on the dried basis Dihydrate form: not less than 84% on the dried basis Description White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose Identification Solubility Soluble in water, practically insoluble in ethanol Purity Loss on drying Not more than 1% (105°C, one hour) Not more than 15,2% (105°C, two hours) for the dihydrate form Selenium Not more than 30 mg/kg expressed as selenium on dry weight basis Arsenic Not more than 3 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis Cyclohexylamine Not more than 10 mg/kg expressed on dry weight basis Dicyclohexylamine Not more than 1 mg/kg expressed on dry weight basis Aniline Not more than 1 mg/kg expressed on dry weight basis

E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS — contd.(III)  
CALCIUM CYCLAMATE SynonymsCyclamate, calcium salt of cyclamic acid  
DefinitionChemical nameCalcium cyclohexanesulphamate, calcium cyclohexylsulphamate  
Einecs205-349-4E numberE 952Chemical formulaC<sub>12</sub>H<sub>24</sub>CaN<sub>2</sub>O<sub>6</sub>S<sub>2</sub>·2H<sub>2</sub>O  
Relative molecular mass432,57AssayNot less than 98% and not more than 10% on the dried basis  
DescriptionWhite, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose  
IdentificationSolubilitySoluble in water, sparingly soluble in ethanol  
Purity Not more than 1% (105°C, one hour)Loss on dryingNot more than 8,5% (140°C, four hours) for the dihydrate form  
SeleniumNot more than 30 mg/kg expressed as selenium on dry weight basis  
ArsenicNot more than 3 mg/kg expressed on dry weight basis  
LeadNot more than 1 mg/kg expressed on dry weight basis  
Heavy metalsNot more than 10 mg/kg expressed as Pb on dry weight basis  
CyclohexylamineNot more than 10 mg/kg expressed on dry weight basis  
DicyclohexylamineNot more than 1 mg/kg expressed on dry weight basis  
AnilineNot more than 1 mg/kg expressed on dry weight basis

E 954 — SACCHARIN AND ITS Na. K AND Ca SALTS (I)  
SACCHARINDefinitionChemical name 3-oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide  
Einecs201-321-0E numberE 954  
Chemical formulaC<sub>7</sub>H<sub>5</sub>NO<sub>3</sub>SRelative molecular mass183,18AssayNot less than 99% and not more than 101,0% of C<sub>7</sub>H<sub>5</sub>NO<sub>3</sub>S 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  
IdentificationSolubilitySlightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol  
PurityLoss on drying Not more than 1% (105°C, two hours) Melting range 226 to 230°C  
ArsenicNot more than 3 mg/kg expressed on dry weight basis  
SeleniumNot more than 30 mg/kg expressed on dry weight basis  
LeadNot more than 1 mg/kg expressed on dry weight basis  
Heavy metalsNot more than 10 mg/kg expressed as Pb on dry weight basis  
Sulphated ash Not more than 0,2% expressed on dry weight basis  
Benzoic and salicylic acidTo 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears  
o-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis  
p-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis  
Benzoic acid p-sulfonamideNot more than 25 mg/kg expressed on dry weight basis  
Readily carbonizable substancesAbsent

E 954 — SACCHARIN AND ITS Na. K AND Ca SALTS — contd.(II) SODIUM SACCHARIN  
SynonymsSaccharin, sodium salt of saccharin  
DefinitionChemical name Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulfonazole, oxobenzisulfonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate  
Einecs204-886-1E numberE 954  
Chemical

formula  $C_7H_4NNaO_3S \cdot 2H_2O$  Relative molecular mass 241,19 Assay Not less than 99% and not more than 101% of  $C_7H_4NNaO_3S$  on the anhydrous basis Description White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions Identification Solubility Freely soluble in water, sparingly soluble in ethanol Purity Loss on drying Not more than 15% (120°C, four hours) Arsenic Not more than 3 mg/kg expressed on dry weight basis Selenium Not more than 30 mg/kg expressed on dry weight basis Lead Not more than 1 mg/kg expressed on dry weight basis Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis Benzoic and salicylic acid To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears o-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis p-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis Benzoic acid p-sulfonamide Not more than 25 mg/kg expressed on dry weight basis Readily carbonizable substances Absent

E 954 — SACCHARIN AND ITS Na. K AND Ca SALTS — contd.(III)

CALCIUM SACCHARINS Synonyms Saccharin, calcium salt of saccharin Definition

Chemical name Calcium o-benzosulphimide,

calcium salt of 2,3-dihydro-3-oxobenzisothiazolone,

1,2-benzisothiazolin-3-one-1,1-dioxide

calcium salt hydrate (2:7) EINECS 229-349-0E number E 954 Chemical formula

$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$  Relative molecular mass 467,48 Assay Not less than 95%

of  $C_{14}H_8CaN_2O_6S_2$  on the anhydrous basis Description White crystals or a

white crystalline powder, odourless or with a faint odour, having an

intensely sweet taste, even in very dilute solutions. Approximately

between 300 and 500 times as sweet as sucrose in dilute

solutions Identification Solubility Freely soluble in water, soluble in

ethanol Purity Loss on drying Not more than 13,5% (120°C, four

hours) Arsenic Not more than 3 mg/kg expressed on dry weight

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

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

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

basis Benzoic and salicylic acid To 10 ml of a 1 in 20 solution,

previously acidified with five drops of acetic acid, add three drops

of an approximately molar solution of ferric chloride in water. No

precipitate or violet colour appears o-Toluenesulphonamide Not more than

10 mg/kg expressed on dry weight basis p-Toluenesulphonamide Not more

than 10 mg/kg expressed on dry weight basis Benzoic acid

p-sulfonamide Not more than 25 mg/kg expressed on dry weight

basis Readily carbonizable substances Absent

E 954 — SACCHARIN AND ITS Na. K AND Ca SALTS — contd.(IV)

POTASSIUM SACCHARINS Synonyms Saccharin, potassium salt of

saccharin Definition Chemical name Potassium o-benzosulphimide, potassium

salt of- 2,3-dihydro-3-oxobenzisulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate  
Einecs E number E 954  
Chemical formula  $C_7H_4KNO_3SH_2O$  Relative molecular mass 239,77  
Assay Not less than 99% and not more than 101% of  $C_7H_4KNO_3S_2$  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  
Identification Solubility Freely soluble in water, sparingly soluble in ethanol  
Purity Loss on drying Not more than 8% (120 °C, four hours)  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Selenium Not more than 30 mg/kg expressed on dry weight basis  
Lead Not more than 1 mg/kg expressed on dry weight basis  
Heavy metals Not more than 10 mg/kg expressed as Pb on dry weight basis  
Benzoic and salicylic acid To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears  
o-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis  
p-Toluenesulphonamide Not more than 10 mg/kg expressed on dry weight basis  
Benzoic acid p-sulfonamide Not more than 25 mg/kg expressed on dry weight basis  
Readily carbonizable substances Absent

E 957 — THAUMATINS  
Synonyms Definition Chemical name Thaumatin is obtained by aqueous extraction (pH 2.5 to 4) of the arils of the fruit of the natural strain of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material  
Einecs 258-822-2 E number E 957  
Chemical formula Polypeptide of 207 amino acids  
Relative molecular mass Thaumatin I 22209  
Thaumatin II 22293  
Assay Not less than 16% nitrogen on the dried basis equivalent to not less than 94% proteins (N x 5,8)  
Description Odourless, cream-coloured powder with an intensely sweet taste. Approximately 2 000 to 3 000 times as sweet as sucrose  
Identification Solubility Very soluble in water, insoluble in acetone  
Purity Loss on drying Not more than 9% (105 °C to constant weight)  
Carbohydrates Not more than 3% expressed on dry weight basis  
Sulphated ash Not more than 2% expressed on dry weight basis  
Aluminium Not more than 100 mg/kg expressed on dry weight basis  
Arsenic Not more than 3 mg/kg expressed on dry weight basis  
Lead 3 mg/kg expressed on dry weight basis  
Microbiological criteria Total aerobic microbial count: Max 1,000/g  
E. Coli: absent in 1g

E959 — NEOHESPERIDINE DIHYDROCHALCONES  
Synonyms Neohesperidine dihydrochalcone, NHDC, hesperetin dihydrochalcone-4'- $\beta$ - neohesperidoside, neohesperidin DC  
Definition Chemical name 2-O-a-L-rhamnopyranosyl-4'- $\beta$ -D-glucopyranosyl hesperetin dihydrochalcone; obtained by catalytic hydrogenation of neohesperidin  
Einecs 243-978-6 E number E 959  
Chemical formula  $C_{28}H_{36}O_{15}$  Relative molecular mass 612,6  
Assay Content not less than 96% on the dried basis  
Description Off white, odourless, crystalline powder having a

characteristic, intensive sweet taste. Approximately between 1 000 and 1 800 times as sweet as sucrose  
**Identification**A. SolubilityFreely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene  
**B.** Ultraviolet absorption maximum282 to 283 nm for a solution of 2 mg in 100 ml methanol  
**C.** Neu's testDissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1% 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced  
**Purity** Loss on drying Not more than 11% (105°C, three hours)  
**Sulphated ash** Not more than 0.2% expressed on dry weight basis  
**Arsenic** Not more than 3 mg/kg expressed on dry weight basis  
**Lead** Not more than 2 mg/kg expressed on dry weight basis  
**Heavy metal** Not more than 10 mg/kg expressed as Pb on dry weight basis

## SCHEDULE IV

### PART A

#### List of Permitted Food Colours

Note: Aluminium lakes prepared from colours mentioned in this Part are authorized

EC Number	Common Name	Colour Index Number(1) or description	E100
Curcumin75300			
		(i) Riboflavin (ii)	
Riboflavin-5'-phosphateE102	Tartrazine19140	E104	Quinoline Yellow47005E110
Sunset Yellow FCF15985	Orange Yellow SE120	Cochineal, Carminic acid. Carmines 75470E122	Azorubine, Carmoisine14720E123
Amaranth16185	E124	Ponceau 4R, Cochineal Red A16255	E127
Erythrosine45430	E128	Red 2G18050	E129
Allura Red AC16035	E131	Patent Blue V42051	E132
Indigotine, Indigo carmine 73015	E133	Brilliant Blue FCF 42090	E140
Chlorophylls and 75810	Chlorophyllins75815	(i) Chlorophylls (ii) Chlorophyllins	E141
Copper complexes of chlorophylls and chlorophyllins 75815	(i) Copper complexes of chlorophylls (ii) Copper complexes of chlorophyllins	E 142	Greens S44090
E150a	Plain caramel (2)	E150b	Caustic sulphite caramel
E150c	Ammonia caramel	E150d	Sulphite ammonia caramel
E151	Brilliant Black BN, Black PN28440	E153	Vegetable carbon
E154	Brown FKE155	Brown HT20285	E160a
Carotenes:(i) Mixed carotenes75130	(ii) Beta-carotene40800	E160b	Annatto, bixin, norbixin75120
E160c	Paprika extract, capsanthin, capsorubin	E160d	Lycopene

(1) Colour index numbers are taken from the third edition 1982 of the Colour Index, volumes 1 to 7, 1315. Also amendments 37 to 40 (125), 41 to 44 (127-50), 45 to 48 (130), 49 to 52 (132-50), 53 to 56 (135).

(2) The term caramel relates to products of a more or less intense brown colour which are intended for colouring. It does not correspond to the sugary aromatic product obtained from heating sugars and which is used for flavouring food (e.g. confectionery, pastry, alcoholic drinks).

EC Number	Common Name	Colour Index Number(1) or description
E160e	Beta-apo-8' carotenal (C 30)	40820
E160f	Ethyl ester of beta-apo-8'-carotenic acid	40825(C30)
E161b	Lutein	E161g
Canthaxanthin	E162	Beetroot



Red, betaninE163Anthocyanins Prepared by physical means from fruits  
and vegetablesE170Calcium carbonate77220E171Titanium dioxide77891E172Iron  
oxides and  
hydroxides774917749277499E173AluminiumE174SilverE175GoldE180Litholrubine BK

(1) Colour index numbers are taken from the third edition 1982 of  
the Colour Index, volumes 1 to 7, 1315. Also amendments 37 to 40  
(125), 41 to 44 (127-50), 45 to 48 (130), 49 to 52 (132-50), 53  
to 56 (135).

#### PART B

Foodstuffs which may not Contain Added Colours, Except Where  
Specifically Provided for in Parts, C, D or E

(The designations used in Part B do not prejudice the "carry over"  
principle in cases where products contain ingredients with legitimate  
colouring in their own right).

1. Unprocessed foodstuffs
2. All bottled or packed waters
3. Milk, semi-skimmed and skimmed milk, pasteurised or sterilised  
(including UHT sterilisation) (unflavoured)
4. Chocolate milk
5. Fermented milk (unflavoured)
6. Preserved milks as mentioned in Directive 76/118/EEC
7. Butter-milk (unflavoured)
8. Cream and cream powder (unflavoured)
9. Oils and fats of animal or vegetable origin
10. Eggs and egg products as defined in Article 2 (1) of Directive  
89/437/EEC
11. Flour and other milled products and starches
12. Bread and similar products
13. Pasta and gnocchi
14. Sugar, including all mono- and disaccharides
15. Tomato paste and canned and bottled tomatoes
16. Tomato-based sauces
17. Fruit juice and fruit nectar as mentioned in Directive  
75/726/EEC and vegetable juice
18. Fruit, vegetables (including potatoes) and mushrooms — canned,  
bottled or dried; processed fruit, vegetables (including potatoes) and  
mushrooms)
19. Extra jam, extra jelly, and chestnut puree as mentioned in  
Directive 79/693/EEC, creme de pruneaux
20. Fish, molluscs and crustaceans, meat, poultry and game as well  
as their preparations, but not including prepared meals containing  
these ingredients.
21. Cocoa products and chocolate components in chocolate products as  
mentioned in Directive 73/241/EEC
22. Roasted coffee, tea, chicory, tea and chicory extracts; tea,  
plant, fruit and cereal preparations for infusions, as well as mixes  
and instant mixes of these products
23. Salt, salt substitutes, spices and mixtures of spices
24. Wine and other products defined by Regulation (EEC) No. 822/87
25. Korn, Kornbrand, fruit spirit drinks, Fruit Spirits, Ouzo,

Grappa, Tsikoudia from Crete, Tsipouro from Macedonia, Tsipouro from Thessaly, Tsipouro from Tyrnavos, Eau de vie de marc Marque nationale luxembourgeoise, Eau de vie de seigle Marque nationale luxembourgeoise, London gin, as defined in Regulation (EEC) No. 1576/89

26. Sambuca, Maraschino and Mistra as defined in Regulation (EEC) No. 1180/91

27. Sangria, Clarea and Zurra as mentioned in Regulation (EEC) No. 1601/91

28. Wine vinegar

29. Foods for infants and young children as mentioned in Directive 89/398/EEC including foods for infants and young children not in good health

30. Honey

31. Malt and malt products

32. Ripened and unripened cheese (unflavoured)

33. Butter from sheep and goats' milk

#### PART C

#### Foodstuffs to Which Only Certain Permitted Colours May be Added

Foodstuffs	Permitted colour	Maximum level	Malt Bread	E 150a Plain caramel	quantum satis	E 150b Caustic sulphite caramel	E 150c Ammonia caramel	E 150d Sulphite ammonia caramel								
Beer	E 150a Plain caramel	quantum satis	Cider bouché	E 150b Caustic sulphite caramel	E 150c Ammonia caramel	E 150d Sulphite ammonia caramel	Butter (including reduced fat butter and concentrated butter)	E 160a Carotenes	quantum satis	Margarine, minarine, other fat emulsions, and fats essentially free from water	E 160a Carotenes	quantum satis	E 100 Curcumin	quantum satis	E 160b Annatto, Bixine, 10 mg/kg	Norbixine

Foodstuffs	Permitted colour	Maximum level	Sage Derby cheese	E 140 Chlorophylls	quantum satis	Chlorophyllins	E 141 Copper complexes of chlorophylls and chlorophyllins	Ripened Orange, Yellow and broken- white cheese; unflavoured processed cheese	E 160a Carotenes	E 160c Paprika extract	quantum satis	E 160b Annatto, Bixin, Norbixin	15 mg/kg	Red Leicester cheese	E 160b Annatto, Bixin, Norbixin	50 mg/kg	Mimolette cheese	E 160b Annatto, Bixin, Norbixin	35 mg/kg	Morbier cheese	E 153 Vegetable carbon	quantum satis	Red marbled cheese	E 120 Cochineal, Carminic acid, Carmines	125 mg/kg	E 163 Anthocyanins	quantum satis	Vinegar	E 150a Plain caramel	quantum satis	E 150b Caustic sulphite caramel	E 150c Ammonia caramel	E 150d Sulphite ammonia caramel	Whisky, Whiskey, grain spirit (other than Korn or Kornbrand or Eau de vie de seigle Marque nationale luxembourgeoise), wine spirit, rum. Brandy, Weinbrand, grape marc, grape marc spirit (other than Tsikoudia and Tsipouro and Eau de vie de marc Marque nationale luxembourgeoise), Grappa invecchiata, Bagaceira velha as mentioned in Regulation (EEC) No. 1576/89	E 150a Plain caramel	E 150b Caustic sulphite caramel	E 150c Ammonia caramel
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E 150d Sulphite ammonia caramel quantum satis

Foodstuffs Permitted colour Maximum level Aromatized wine-based drinks (except bitter soda) and aromatized wines as mentioned in Regulation (EEC) No. 1601/91

E 150a Plain caramel  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel quantum satis

Americano  
E 150a Plain caramel quantum satis  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel  
E 163 Anthocyanins  
E 100 Curcumin  
E 101 (i) Riboflavin  
(ii) Riboflavin-5'-phosphate 100 mg/l (individually or in combination)

E 102 Tartrazine  
E 104 Quinoline Yellow  
E 120 Cochineal, Carminic acid, Carmine  
E 122 Azorubine carmoisine  
E 123 Amaranth  
E 124 Ponceau 4R  
Bitter soda, bitter vino as mentioned in Regulation (EEC) No. 1601/91

E 150a Plain caramel quantum satis  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel  
E 100 Curcumin 100 mg/l (individually or in combination)

E 101 (i) Riboflavin  
(ii) Riboflavin-5'-phosphate  
E 102 Tartrazine  
E 104 Quinoline Yellow  
E 110 Sunset Yellow FCF  
E 109 Orange Yellow SE  
E 120 Cochineal, Carminic acid, Carmine  
E 122 Azorubine, Carmoisine  
E 123 Amaranth  
E 124 Ponceau 4R, Cochineal Red AE  
E 129 Allura Red AC

Foodstuffs Permitted colour Maximum level Liqueur wines and quality liqueur wines produced in specified regions

E 150a Plain caramel quantum satis  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel

Vegetables in vinegar, brine or oil (excluding olives)

E 101 (i) Riboflavin  
(ii) Riboflavin-5'-phosphate quantum satis

E 140 Chlorophylls, Chlorophyllins  
E 150a Plain caramel  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel

E 141 Copper complexes of chlorophylls and chlorophyllins  
E 160a Carotenes: (i) Mixed carotenes (ii) Beta-carotene  
E 162 Beetroot Red, betanin  
E 163 Anthocyanins

Extruded, puffed and/or fruit-flavoured breakfast cereals

E 150c Ammonia caramel quantum satis  
E 160a Carotenes quantum satis  
E 160b Annatto, Bixin, Norbixin 25 mg/kg  
E 160c Paprika extract, Capsanthin, Capsorubin quantum satis

Fruit-flavoured breakfast cereals  
E 120 Cochineal, Carminic acid, Carmine 200 mg/kg in E 162 Beetroot Red, betanin (individually or in combination)

Jam, jellies and marmalades as mentioned in Directive 79/693/EEC and other similar fruit preparations including low calorie products

E 100 Curcumin quantum satis  
E 140 Chlorophylls and chlorophyllins  
E 141 Copper complexes of chlorophylls and chlorophyllins  
E 150a Plain caramel  
E 150b Caustic sulphite caramel  
E 150c Ammonia caramel  
E 150d Sulphite ammonia caramel

E 160a Carotenes: (i) Mixed carotenes (ii) Beta-carotene  
E 160c Paprika extract, Capsanthin, Capsorubin

Foodstuffs Permitted colour Maximum level

E 162 Beetroot Red, betanin  
E 163 Anthocyanins  
E 104 Quinoline Yellow 100 mg/kg (individually or in combination)

E 110 Sunset Yellow  
E 120 Cochineal, Carminic acid,

Carmines E 124 Ponceau 4R, Cochineal E 142 Green SE 160d Lycopene E 161b Lutein Sausages, pâtés and terrines E 100 Curcumin 20 mg/kg E 120 Cochineal, Carminic acid, Carmines 100 mg/kg E 150a Plain caramel quantum satis E 150b Caustic sulphite caramel quantum satis E 150c Ammonia caramel quantum satis E 150d Sulphite ammonia caramel quantum satis E 160a Carotenes E 160c Paprika extract, Capsanthin, Capsorubin 20 mg/kg 10 mg/kg E 162 Beetroot Red, betanin quantum satis Luncheon meat E 129 Allura Red 25 mg/kg Breakfast sausages with a minimum cereal content of 6% E 129 Allura Red AC 25 mg/kg Burger meat with a minimum vegetable and/or cereal content of 4% E 120 Cochineal, Carminic acid. Carmines 100 mg/kg E 150a Plain caramel quantum satis E 150b Caustic sulphite caramel quantum satis E 150c Ammonia caramel quantum satis E 150d Sulphite ammonia caramel quantum satis Chorizo sausage E 120 Cochineal Carminic acid, Carmines 200 mg/kg Salchichon E 124 Ponceau 4R, Cochineal Red A 250 mg/kg Sobrasada E 110 Sunset Yellow FCF 135 mg/kg E 124 Ponceau 4R, Cochineal Red A 200 mg/kg

Foodstuffs Permitted colour Maximum level Pasturmas (edible external coating) E 100 Curcumin quantum satis E 101 (i) Riboflavin (ii) Riboflavin-5'-phosphate E 120 Cochineal, Carminic acid, Carmines Dried potato granules and flakes E 100 Curcumin quantum satis Processed mushy and garden peas (canned) E 102 Tartrazine 100 mg/kg E 133 Brilliant Blue 20 mg/kg E 142 Green S 10 mg/kg

#### PART D

##### Colours Permitted for Certain Uses Only

Colour Foodstuff Maximum level E 123 Amaranth Aperitif wines, spirit drinks including products with less than 15% alcohol by volume 30 mg/l Fish roe 30 mg/kg E 127 Erythrosine Cocktail cherries and candied cherries 200 mg/kg Bigarreaux cherries in syrup and in cocktails 150 mg/kg E 128 Red 2G Breakfast sausages with a minimum cereal content of 6% Burger meat with a minimum vegetable and/or cereal content of 4% 20 mg/kg E 154 Brown FK Kippers 20 mg/kg E 161g Canthaxanthin Saucisses de Strasbourg 15 mg/kg E 173 Aluminium External coating of sugar confectionery for the decoration of cakes and pastries quantum satis E 174 Silver External coating of confectionery Decoration of chocolates Liqueurs quantum satis E 175 Gold External coating of confectionery quantum satis Decoration of chocolates Liqueurs E 180 Litholrubine BK Edible cheese rind quantum satis E 160b Annatto, Bixin, Norbixin Margarine, Minarine other fat emulsions, and fats essentially free from water 10 mg/kg Decorations and coatings 20 mg/kg Fine bakery wares 10 mg/kg Edible ices 20 mg/kg Liqueurs, including fortified beverages with less than 15% alcohol by volume 10 mg/l Flavoured processed cheese 15 mg/kg Ripened Orange, Yellow and broken-white cheese 15 mg/kg Unflavoured processed cheese 15 mg/kg Desserts 10 mg/kg Snacks: dry, savoury potato, cereal or starch-based snack products:—Extruded or expanded savoury snack products 20 mg/kg—Other savoury snack products and savoury coated nuts 10 mg/kg Smoked fish 10 mg/kg Edible cheese rind and edible casings 20 mg/kg Red Leicester cheese 50 mg/kg

Mimolette cheese 35 mg/kg Extruded, puffed and/or fruit-flavoured  
breakfast cereals 25 mg/kg

#### PART E

Colours Permitted in Foodstuffs Other Than Those Mentioned in Parts  
B and C

#### SECTION 1

The following colours may be used in foodstuffs mentioned in Part E  
Section 2 and in all other foodstuffs other than those listed in  
Parts B and C at quantum satis.

E 101(i) Riboflavin(ii) Riboflavin-5'- phosphate E 140 Chlorophylls and  
chlorophyllins E 141 Copper complexes of chlorophylls and chlorophyllins E  
150a Plain caramel E 150b Caustic sulphite caramel E 150c Ammonia caramel E  
150d Sulphite ammonia caramel E 153 Vegetable carbon E 160a Carotenes E  
160c Paprika extract, capsanthin, capsorubin E 162 Beetroot Red, betanin E  
163 Anthocyanins E 170 Calcium carbonate E 171 Titanium dioxide E 172 Iron  
oxides and hydroxides

#### SECTION 2

The following colours may be used singly or in combination in the  
following foods up to the maximum level specified in the table.  
However, for non-alcoholic flavoured drinks, edible ices, desserts,  
fine bakery wares and confectionery, colours may be used up to the  
limit indicated in the appropriate table but the quantities of each  
of the colours E 110, E 122, E 124 and E 155 may not exceed 50  
mg/kg or mg/l.

E 100 Curcumin E 102 Tartrazine E 104 Quinoline Yellow E 110 Sunset Yellow FCF  
Orange Yellow SE 120 Cochineal, Carminic acid, Carmines E 122 Azorubine,  
Carmoisine E 124 Ponceau 4R, Cochineal Red AE 129 Allura Red ACE  
131 Patent Blue VE 132 Indigotine, Indigo carmine E 133 Brilliant Blue  
FCFE 142 Green SE 151 Brilliant Black BN, Black PNE 155 Brown HTE  
160d Lycopene E 160e Beta-apo-8' carotenal (C 30) E 160f Ethyl ester of  
beta-apo-8'-carotenic acid (C 30) E 161b Lutein

Foodstuffs	Maximum Level
Non-alcoholic flavoured drinks	100 mg/l
Candied fruits and vegetables, Mostarda di frutta	200 mg/kg
Preserves of red fruits	200 mg/kg
Confectionery	300 mg/kg
Decorations and coatings	500 mg/kg
Fine bakery wares (e.g. viennoiserie, biscuits, cakes and wafers)	200 mg/kg
Edible ices	150 mg/kg
Flavoured processed cheese	150 mg/kg
Desserts including flavoured milk products	100 mg/kg
Sauces, seasonings (for example, curry powder, tandoori), pickles, relishes, chutney and piccalilli	500 mg/kg
Mustard	300 mg/kg
Fish paste and crustacean paste	100 mg/kg
Pre-cooked crustaceans	250 mg/kg
Salmon substitutes	500 mg/kg
Surimi	500 mg/kg
Fish roe	300 mg/kg
Smoked fish	100 mg/kg
Snacks': dry, savoury potato, cereal or starch-based snack products:—Extruded or expanded savoury snack products	200 mg/kg
—Other savoury snack products and savoury coated nuts	100 mg/kg
Edible cheese rind and edible casings	quantum satis
Complete formulae for weight control intended to replace total daily food intake or an individual meal	

50 mg/kg Complete formulae and nutritional supplements for use under medical supervision

50 mg/kg Liquid food supplements/dietary integrators  
100 mg/l Solid food supplements/dietary integrators  
300 mg/kg Soups  
50 mg/kg Meat and fish analogues based on vegetable proteins  
100 mg/kg Spirituous beverages (including products less than 15% alcohol by volume), except those mentioned in Part B and C

200 mg/l Aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails as mentioned in Regulation (EEC) No. 1601/91, except those mentioned on Parts B and C

200 mg/l Fruit wines (still or sparkling) cider (except cider bouche) and perry  
aromatised fruit wines, cider and perry  
200 mg/l

## SCHEDULE V

Specific Purity Criteria concerning Colours for use in Foodstuffs

### 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 of 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** Synonyms CI Natural Yellow 3, Turmeric Yellow, Diferoyl

**Methane**  
**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 occurring 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 Dicinnoylmethane Colour Index

No. 75300 Einics 207-280-5 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-dione

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

C<sub>21</sub>H<sub>20</sub>O<sub>6</sub> II C<sub>20</sub>H<sub>18</sub>O<sub>5</sub> III C<sub>19</sub>H<sub>16</sub>O<sub>4</sub> Molecular weight I. 368,39 II. 338,39

III. 308,39 AssayContent not less than 90% total colouring matters  
1 607 at ca 426 nm in ethanolDescriptionOrange-yellow crystalline  
powder

Identification A. SpectrometryMaximum in ethanol at ca 426 nm B.  
Melting Range179-182 °CPurityEthylacetateNot more than 50 mg/kg, singly  
or in combination Solvent  
residuesAcetonen-butanolMethanolEthanolHexaneDichloromethane: not more than  
10 mg/kg ArsenicNot more than 3 mg/kg LeadNot more than 10 mg/kg  
MercuryNot more than 1 mg/kg CadmiumNot more than 1 mg/kg Heavy  
Metals (as Pb)Not more than 40 mg/kg

E 101 (i) RIBOFLAVINSynonymsLactoflavin ClassIsoalloxazine  
Einces201—507-1 Chemical names7, 8—Dimethyl-10-(D-ribo-2, 3, 4,  
5-tetrahydroxypentyl) benzo(g)—pteridine-2, 4-(3H,  
10H)-dione7,8—dimethyl-10 (1'-D-ribityl) isoalloxazine Chemical  
formulaC<sub>17</sub>H<sub>20</sub>N<sub>4</sub>O<sub>6</sub> Molecular weight376,37 AssayContent not less than 98%  
on the anhydrous basis 328 at ca 444 nm in aqueous  
solutionDescriptionYellow to orange-yellow crystalline powder, with  
slight odour.Identification A. SpectrometryThe ratio A<sub>375</sub>/A<sub>267</sub> is  
between 0,31 and 0,33  
The ratio A<sub>444</sub>/A<sub>267</sub> is between 0,36 and 0,39In aqueous  
solutionMaximum in water at ca 375 nm. B. Specific rotation(a )  
between -115° and -140° in a 0,05 N sodium hydroxide solutionPurity  
Loss on dryingNot more than 1,5% after drying at 105°C for 4 hrs  
Sulfated ashNot more than 0,1% Primary aromatic aminesNot more than  
100 mg/kg (calculated as aniline) ArsenicNot more than 3 mg/kg  
LeadNot more than 10 mg/Kg MercuryNot more than 10mg/kg CadmiumNot  
more than 1 mg/kg Heavy metals (as Pb) Not more than 40 mg/kg

E 101 (ii) (ii) RIBOFLAVIN-5'-PHOSPHATESynonymsRiboflavin-5'-phosphate  
sodiumDefinitionThese specifications apply to riboflavin -5—'phosphate  
together with minor amounts of free riboflavin diphosphate  
ClassIsoalloxazine Einics204—988-6 Chemical namesMonosodium(2R, 3R,  
4S)—5—(3) 10'-dihydro-7, 8'-dimethyl-2', 4'-dioxo-10-'benzo  
[y]pteridinyl]-2, 3, 4-trihydroxypentyl phosphate; monosodium salt of  
5'-monophosphate ester of riboflavin Chemical formulaFor the dihydrate  
form: C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>NaO<sub>9</sub>P.2H<sub>2</sub>OFor the anhydrous form: C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>NaO<sub>9</sub>P Molecular  
weight541,36 AssayContent not less than 95% total colouring matters  
calculated as C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>NaO<sub>9</sub>P.2H<sub>2</sub>O  
250 at ca 375 nm in aqueous solutionDescriptionYellow to orange  
crystalline hygroscopic powder, with slight odour and a bitter  
tasteIdentification A. SpectrometryThe ratio A<sub>375</sub>/A<sub>267</sub> is between 0,30  
and 0,34  
The ratio A<sub>444</sub>/A<sub>267</sub> is between 0,35 and 0,40In aqueous  
solutionMaximum in water at ca 375 nm. B. Specific rotation(a )  
between +38° and +42° in a 5 molar HCl solutionPurity Loss on  
dryingNot more than 8% (100°C, 5 hrs in vacuum over P<sub>2</sub>O<sub>5</sub>) for the  
dihydrate form Sulfated ashNot more than 25% Inorganic phosphateNot  
more than 1,0% (calculated as PO<sub>4</sub> on the anhydrous basis) Subsidiary

colouring matters  
Riboflavin (free): Not more than 6%  
Riboflavin 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 TARTRAZINES  
Synonyms: CI Food Yellow 4  
Definition: Tartrazine 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  
Einics: 217—699-5

Chemical

names: Trisodium-5—hydroxy-1-(4-sulfonatophenyl)—4-(4-sulfonatophenylazo)-H-pyrazole-3-carboxylate

Chemical formula:  $C_{16}H_9N_4Na_3O_9S_2$   
Molecular weight: 534,37  
Assay: Content not less than 85% total colouring matters calculated as the sodium salt

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

Total not more than 0,5% 4—aminobenzene-1-sulfonic acid

5—oxo-1-(4-sulfophenyl)—2-pyrazolin-e-3-carboxylic acid  
4, 4'-diazaminodi (benzene sulfonic acid)  
Tetrahydroxysuccinic acid  
Unulfonated 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 104 QUINOLINE YELLOW  
Synonyms: CI Food Yellow 13  
Definition: Quinoline Yellow is prepared by sulfonating 2—(2-quinolyl) indan-1, 3-dione.

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: Quinophthalone Colour Index No 47005  
Einics: 305—897-5  
Chemical name: The disodium salts of the disulfonates of 2—(2-quinolyl) indan-1,3-dione (principal component)

Chemical formula:  $C_{18}H_9NNa_2O_8S_2$  (principal component)  
Molecular weight: 477,38 (principal component)  
Assay: 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 865 (principal component) at ca 411 nm in aqueous acetic acid solution  
Description Yellow powder or granules  
Identification A. Spectrometry Maximum in aqueous acetic acid solution of pH 5 at ca 411 nm  
B. Yellow solution in water

E 104 QUINOLINE YELLOW—contd. Purity Water insoluble matter Not more than 0.2%  
Subsidiary colouring matters Not more than 4.0% Organic compounds other than colour matters 2-methylquinoline-sulfonic acid Total not more than 0.5% Phthalic acid 2,6-dimethyl quinoline 2,6-dimethyl quinoline sulfonic acid 2-(2-quinolyl) indan-1,3 dione Not more than 4 mg/kg  
Un sulfonated 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 110 SUNSET YELLOW FCF 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 Eincs 220—491-7  
Chemical names Disodium 2—hydroxy-1-(4-sulfonatophenylazo) naphthalene-6-sulfonate  
Chemical formula  $C_{16}H_{10}N_2Na_2O_7S_2$  Molecular weight 452,37  
Assay Content not less than 85% total colouring matters calculated as the sodium salt  
555 at ca 485 nm in aqueous solution at pH 7  
Description Orange-red powder or granules  
Identification A. Spectrometry Maximum in water at ca 485 nm at pH 7  
B. Orange solution in water  
Purity Water insoluble matter Not more than 0.2%  
Subsidiary colouring matters: Not more than 5.0% Organic compounds other than colouring matters  
4-[aminobenzene-1-sulfonic acid Total not more than 0.5%  
3-hydroxymaphthalene-2,7-disulfonic acid 6-hydroxymaphthalene-2-sulfonic acid 7-hydroxymaphthalene-1, 3-disulfonic acid 4, 4'-diazoaminodi (benzene sulfonic acid) 6,6'-oxydi(naphthalene-2-sulfonic acid)  
Un sulfonated 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 120 COCHINEAL, CARMINIC ACID, CARMINES 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 75470. 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); Chemical formula Carmine is the hydrated aluminum chelate of this acid C<sub>22</sub>H<sub>20</sub>O<sub>13</sub> (carminic acid). Molecular weight 492,39 (carminic acid). Assay Content not less than 2,0% carminic acid in the extracts containing carminic 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 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, CARMOISINES. Synonyms CI Food Red 3. Definition Azorubine consists essentially of disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. 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<sub>20</sub>H<sub>12</sub>N<sub>2</sub>Na<sub>2</sub>O<sub>7</sub>S<sub>2</sub>. Molecular weight 502,44. Assay Content not less than 85% total colouring matters, calculated as the sodium salt. 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-1-sulfonic acid Total not more than 0,5%. 4-hydroxynaphthalene-1-sulfonic 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 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-hydroxyl-(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 Colour

Index No16185 EINECS213-022-2 Chemical nameTrisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-3,6-disulfonate Chemical formulaC<sub>20</sub>H<sub>11</sub>N<sub>2</sub>Na<sub>3</sub>O<sub>10</sub>S<sub>3</sub> Molecular weight604,48 AssayContent not less than 85% total colouring matters, calculated as the sodium salt 440 at ca 520 nm in aqueous solution DescriptionReddish-brown powder or granulesIdentification A. SpectrometryMaximum in water at ca 520 nm B. Red solution in waterPurity Water insoluble matterNot more than 0,2% Subsidiary colouring mattersNot more than 3,0% Organic compounds other than colouring matters: 4-aminonaphthalene-1-sulfonic acidTotal not more than 0,5% 3-hydroxynaphthalene-2,7-disulfonic acid 6-hydroxynaphthalene-2-sulfonic acid 7-hydroxynaphthalene-1,3-trisulfonic acid 7-hydroxynaphthalene-1,3,6-trisulfonic acid Unsulfonated primary aromatic aminesNot more than 0,01% (calculated as aniline) Ether extractable matterNot more than 0,2% under neutral conditions ArsenicNot more than 3 mg/kg LeadNot more than 10 mg/Kg MercuryNot more than 1 mg/kg CadmiumNot more than 1 mg/kg Heavy metals (as Pb)Not more than 40 mg/Kg

E 124 PONCEAU 4R, COCHINEAL RED ASynonymsCI Food Red 7, New CoccineDefinitionPonceau 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 componentsPonceau 4-R is described as the sodium salt. The calcium and the potassium salt are also permitted ClassMonoazo Colour Index No16255 EINECS220-036-2 Chemical

nameTrisodium-2-hydroxy-1-(4-sulfonato-1-naphthylazo)—naphthalene-6,8-disulfonate Chemical formulaC<sub>20</sub>H<sub>11</sub>N<sub>2</sub>Na<sub>3</sub>O<sub>10</sub>S<sub>3</sub> Molecular weight604,48 AssayContent not less than 80% total colouring matters, calculated as the sodium salt 430 at ca 505 nm in aqueous solutionDescriptionReddish powder or granulesIdentification A. SpectrometryMaximum in water at ca 505 nm B. Red solution in waterPurity Water insoluble matter Subsidiary colouring mattersNot more than 0,2% Organic compounds other than colouring matters:Not more than 1,0% 4-aminonaphthalene-1-sulfonic acidTotal not more than 0,5% 7-hydroxynaphthalene-1,3-disulfonic acid 3-hydroxynaphthalene-2,7-disulfonic acid 6-hydroxynaphthalene-2-sulfonic acid 7-hydroxynaphthalene-1,3,6-trisulfonic acid Unsulfonated primary aromatic aminesNot more than 0,01% (calculated as aniline) Ether extractable matterNot more than 0,2% under neutral conditions ArsenicNot more than 3 mg/kg LeadNot more than 10 mg/Kg MercuryNot more than 1 mg/kg CadmiumNot more than 1 mg/kg Heavy metals (as Pb)Not more than 40 mg/kg

E 127 ERYTHROSINESynonymsCI Food Red 14DefinitionErythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-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 ClassXanthene Colour Index No45430 EINECS240-474-8 Chemical nameDisodium

2-(2,4,5,7-tetraido-3-oxido-6-oxoxanthen-9-yl) benzoate monohydrate  
Chemical formula  $C_{20}H_{14}Na_2O_5H_2O$  Molecular weight 897,88 Assay Content not less than 87% total colouring matters, calculated as the anhydrous sodium salt 1 100 at ca 526 nm in aqueous solution at pH7  
Description Red powder or granules Identification A. Spectrometry Maximum in water at ca 526 nm at pH7 B. Red solution in water Purity Inorganic iodides calculated as sodium iodide Not more than 0,1% Water insoluble matter Not more than 0,2% Subsidiary colouring matters (except fluorescein) Not more than 4,0% Fluorescein 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 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, Azogermanine Definition Red 2G consists essentially of disodium 8-acetamido-1-hydroxy-2-phenylazonaphthalene-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 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, Total not more than 0,5% 7-disulfonic acid 5-amino-4-hydroxynaphthalene-2,7-disulfonic 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 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 129 ALLURA RED ACSynonyms CI Food Red 17 Definition Allura Red AC consists essentially of disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo) 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-methy-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 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-2-methylbenzene 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-(a-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene)-2,5-cyclohexadien-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 is also permitted Class Triarylmethane Colour Index No 42051 EINECS 222-573-8 Chemical names The calcium or sodium compound of [4-(a-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene),-2,5-cyclohexadien-1-ylidene] diethyl-ammonium hydroxide inner salt Chemical formula Calcium compound:  $C_{27}H_{31}N_2O_7S_2Ca_{1/2}$  Sodium Compound;  $C_{27}H_{31}N_2O_7S_2Na$  Molecular weight Calcium compound: 579,72 Sodium compound: 582,67 Assay Content not less than 85% total colouring matters, calculated as the sodium salt 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 Total not more than 0,5% 3-hydroxy benzoic acid 3-hydroxy-4-sulfobenzoic acid N,N-diethylamino benzene sulfonic acid Leuco base Not more than 4,0% Unsulfonated primary aromatic amines Not more than 0,01% (calculated as aniline) 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 CARMINES Synonyms CI Food Blue 1 Definition Indigotine consists essentially of a mixture of disodium 3,3'-dioxo-2,2'-bi-indolyldiene-5,5'-disulfonate, and disodium 3,3'-dioxo-2,2'-bi-indolyldiene-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% 480 at ca 610 nm in aqueous solution Description Dark-blue powder or granules Identification A. Spectrometry Maximum in water at ca 610 nm 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 than 1,0% Organic compounds other than colouring matters: Isatin-5-sulfonic acid Total not more than 0,5% 5-sulfoanthranilic acid Anthranilic 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 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 133 BRILLIANT BLUE FCF Synonyms CI Food Blue 2 Definition Brilliant Blue FCF consists essentially of disodium a-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-a-(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 EINECS 223-339-8 Chemical names Disodium a-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-a-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate. Chemical formula  $C_{37}H_{34}N_2 Na_2O_9 S_3$  Molecular weight 792,84 Assay Content not less than 85% total colouring matters, calculated as the sodium salt 1 630 at ca 630 nm in aqueous solution Description reddish-blue powder or granules 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 Not more than 1,5% 3-((ethyl)(4-sulfophenyl amino)methyl benzene sulfonic acid Not more than 0,3% 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% 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 Heavy metals (as Pb) Not more than 40 mg/kg

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. ClassPorphyrin Colour Index No75810

EinecsChlorophylls: 215-800-7, Chlorophyll a: 207-536-6, Chlorophyll b: 208-272-4

Chemical namesThe major colouring principles are: Phytol(132-R,17S,18S)-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) Phytol (132-R,17S, 18S)-3-(8-ethyl-7-formyl-132-methoxycarbonyl-2, 12, 18-trimethyl-13'-oxo-3-vinyl-131-132-17,18-tetrahydrocyclopenta [at]-porphyrin-17-yl) propionate, (Pheophytin b), or as the magnesium complex (Chlorophyll b)

Chemical formulaChlorophyll a (magnesium complex): C<sub>55</sub>H<sub>72</sub> MgN<sub>4</sub>O<sub>5</sub>Chlorophyll a: C<sub>55</sub>H<sub>74</sub>N<sub>4</sub>O<sub>5</sub>Chlorophyll b (magnesium complex): C<sub>55</sub>H<sub>70</sub> MgN<sub>4</sub>O<sub>6</sub>Chlorophyll b: C<sub>55</sub>H<sub>72</sub>N<sub>4</sub>O<sub>6</sub>

Molecular weightChlorophyll a (magnesium complex): 893,51Chlorophyll a: 871,22Chlorophyll b (magnesium complex): 907,49Chlorophyll b: 885,20

AssayContent of total combined Chlorophylls and their magnesium complexes is not less than 10% 700 at ca 409 nm in chloroform

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

Identification SpectrometryMaximum in chloroform at ca 409 nm

PurityAcetoneNot more than 50 mg/kg, singly or in combination Solvent residuesMethyl Ethyl ketoneMethanolEthanolPropan-2-olHexaneDichloromethane: Not more than 10 mg/kg ArsenicNot more than 3 mg/kg LeadNot more than 10 mg/kg MercuryNot more than 1 mg/kg CadmiumNot more than 1 mg/kg Heavy metals (as Pb)Not more than 40 mg/kg

E 140 (ii) CHLOROPHYLLINSSynonymsCI Natural Green 5, Sodium Chlorophyllin, Potassium Chlorophyllin

DefinitionThe 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. ClassPorphyrin Colour Index No75815

Einecs287-483-3

Chemical namesThe major colouring principles in their acid forms are:—3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylporbin-7-yl) propionate (chlorophyllin a) and—3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylporbin-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):  $C_{34}H_{34}N_4O_5$  Chlorophyllin b (acid form):  $C_{34}H_{32}N_4O_6$  Molecular weight Chlorophyllin a: 578,68 Chlorophyllin b: 592,66 Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved. Assay Content of total chlorophyllins is not less than 95% of the sample dried at ca 100°C for 1 hour. 700 at ca 405 nm in aqueous solution at pH 9 140 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

E 140 (ii) CHLOROPHYLLINS—contd. Purity Solvent residues Acetone Not more than 50 mg/kg, singly or in combination 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, Cooper 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, 17S, 18S)-3-(8-ethyl-132-methoxycarbonyl-2,7,12,18-tetramethyl-13'-oxo-3-vinyl-131-132-17,18-tetrahydrocyclopenta [at]-porphyrin-17-yl)propionate] copper (II) (Copper Chlorophyll a) [Phytyl (132R, 17S, 18S)-3-(8-ethyl-7-formyl-132-methoxycarbonyl-2,-12,18-trimethyl-13'-oxo-3-vinyl-131-132-17,18-tetrahydrocyclopenta [at]-porphyrin-17-yl)propionate] copper (II) (Copper chlorophyll b) Chemical formula Copper chlorophyll a:  $C_{55}H_{72}CuN_4O_5$  Copper chlorophyll b:  $C_{55}H_{70}CuN_4O_6$  Molecular weight Copper chlorophyll a: 932,75 Copper chlorophyll b: 946,73 Content to total copper chlorophylls is not less than 10% Assay 540 at ca 422 nm in chloroform 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

E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS—contd. Purity Solvent residues Acetone Not more than 50 mg/kg, singly or in combination 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 Copper  
ions 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 neutralised 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 Chemical names The major colouring principles in their acid  
forms are 3-(10-Carboxylato-4-ethyl-1, 3, 5,

8-tetramethyl-9-oxo-2-vinylporbin-7-yl) propionate, copper complex

(Copper chlorophyllin a) and 3-(10-Carboxylato-4-ethyl-3-formyl-1, 5,

8-trimethyl-9-oxo-2-vinylporbin-7-yl) propionate, copper complex (Copper

chlorophyllin b) Chemical formula Copper chlorophyllin a (acid form:

C<sub>34</sub>H<sub>32</sub> Cu N<sub>4</sub>O<sub>5</sub> Copper chlorophyllin b (acid form: C<sub>34</sub>H<sub>32</sub> Cu N<sub>4</sub>O<sub>6</sub>

Molecular formula Copper chlorophyllin a: 640,20 Copper chlorophyllin b:

654,18 Each may be increased by 18 daltons if the cyclopentenyl ring

is cleaved. Content of total copper chlorophyllins is not less than

95% of the sample dried at 100°C for 1 hr. Assay 565 at ca 405

nm in aqueous phosphate buffer at pH 7,5 145 at ca 603 nm in

aqueous phosphate buffer at pH 7,5 Description Dark green to blue/black

powder Identification Spectrometry Maximum in aqueous phosphate buffer at

pH 7,5 at ca 405 nm and at 630 nm

E 141 (ii) COPPER COMPLEXES OF CHLOROPHYLLINS—contd. Purity Solvent

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

ions 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-methylmethanaminium 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-cyclonexadien-1-ylidene]-N-methylmethanaminium;

Sodium

5-[4-dimethylamino-a-(4-dimethyliminocyclohexa-2,5-dienylidene)benzyl]-6-hydroxy-7-sulfonato-naphthalene-2-sulfonate

(alternative chemical name). Chemical formula  $C_{27}H_{25}N_2Na O_7S_2$  Molecular

weight 576,63 Assay Content not less than 80% total matters calculated

as the sodium salt 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 Water insoluble matter Not

more than 0,2% Subsidiary colouring matters Not more than 1,0% Organic

compounds other than colouring matters: 4,

4'-bis(dimethylamino)-benzhydrol 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 caramelisation, acids,

alkalis and salts may be employed, with the exception of ammonium

compounds and sulphites. Eines 232-435-9 Description Dark brown to black

liquids or solids Purity Colour bound by DEAE cellulose Not more than

50% Colour bound by phosphoryl cellulose Not more than 50% Colour

intensity (1) 0,01-0,12 Total nitrogen Not more than 0,1% Total

sulphur Not more than 0,2% 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 (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. 1

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.

Eines 232-435-9 Description Dark brown to black liquids or solids Purity

Colour bound by DEAE cellulose More than 50% Colour intensity

(1) 0,05—0,13 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 More than 40% Absorbance ratio of colour bound by DEAE cellulose Absorbance ratio (A 280/560) Greater 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

(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.

E 150c AMMONIA CAMEL 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. Eines 232-435-9 Description Dark brown to black liquids or solids Purity Colour bound by DEAE cellulose More than 50% Colour bound by phosphoryl cellulose More than 50% Colour intensity (1) 0,08-0,36 Ammoniacal nitrogen Not more than 0,3% (2) 4-methylimidazole Not more than 250 mg/kg (2)

2-acetyl-4-tetrahydroxy-butylimidazole Not more than 10 mg/kg (2) Total sulphur Not more than 0,2% (2) Total nitrogen 0,7-3,3% (2) Absorbance ratio of colour bound by phosphoryl cellulose 13-35 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

(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.

E 150d SULPHITE AMMONIA CAMEL Definition Sulphite 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 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) Eines 232-435-9 Description Dark brown to black liquids or solids Purity Colour bound by DEAE cellulose More than 50% Colour intensity (1) 0,10-0,60 Ammoniacal nitrogen Not more than 0,6% (2) Sulphur dioxide Not more than 0,2% (2) 4-methylimidazole Not more than 250 mg/kg (2) Total nitrogen 0,3-1,7% (2) Total sulphur 0,8-2,5% (2)

Nitrogen/sulphur ratio of alcohol precipitate 0,7—2,7 Absorbance ratio of alcohol precipitate (1)8—14 Absorbance ratio (A<sub>280</sub>/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 (1) 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). 1(2) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units. 2

**E 151 BRILLIANT BLACK BN, BLACK PN** Synonyms CI Food Black 1 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 530 at ca 570 nm in solution Description Black powder or granules Identification A. Spectrometry Maximum in water at ca 570 nm B. Black-bluish solution in water 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-Total not more than 0,8% 1,7,-disulfonic acid 4-amino-5-hydroxynaphthalene- 1,7-disulfonic acid 8-aminophthalene-2-sulfonic acid 4,4'-diazoaminodi-(benzenesulfonic 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 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 CARBONS** 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 carbonized 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 Content not less than 95% of carbon calculated on an anhydrous and ash-free basis Assay Black powder, odourless and tasteless Description Identification A. Solubility Insoluble in water and organic solvents B. Burning What 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 (benzenesulfonate)  
VI trisodium 4,4',4''-(2,4-diaminobenzene-1,3,5-trisazo)tri-(benzenesulfonate)  
Chemical formula I C<sub>12</sub>H<sub>11</sub>N<sub>4</sub> NaO<sub>3</sub>S II C<sub>13</sub>H<sub>13</sub>N<sub>4</sub> NaO<sub>3</sub>S III C<sub>18</sub>H<sub>14</sub>N<sub>6</sub> Na<sub>2</sub>O<sub>6</sub>S<sub>2</sub> IV C<sub>18</sub>H<sub>14</sub>N<sub>6</sub> Na<sub>2</sub>O<sub>6</sub>S<sub>2</sub> V C<sub>19</sub>H<sub>16</sub>N<sub>6</sub> Na<sub>2</sub>O<sub>6</sub>S<sub>2</sub> VI C<sub>24</sub>H<sub>17</sub>N<sub>8</sub> Na<sub>3</sub>O<sub>9</sub>S<sub>3</sub>  
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 m-phenylenediamine and Not more than 0,7%  
4-methyl-m-phenylenediamine Not more than 0,35%  
Unulfonated primary aromatic amines other than m-phenylene diamine and 4-methyl-m-phenylene diamene 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  
Heavy metals (as Pb) 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. 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. Synonyms: CI Food Orange 5. Definition: Mixed carotenoids 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, dichloromethane and carbon dioxide. Class: Carotenoid Colour Index No 75130. EINECS 230-636-6. Chemical names: Chemical formula:  $\beta$ -Carotene:  $C_{40}H_{56}$ . Molecular weight:  $\beta$ -Carotene: 536,88. Assay: Content of carotenoids (calculated as  $\beta$ -carotene) is not less than 5%. For products obtained by extraction of vegetable oils: not less than 0,2% in edible fats. 2500 at ca 440-457 nm in cyclohexane. Identification: Spectrometry: Maximum in cyclohexane at 440-457 nm and 470 nm-486 nm. Purity: Solvent residues: Acetone: Not more than 50 mg/kg, singly or in combination. Methyl ethyl ketone, Methanol, Propan-2-ol, Hexane, Ethanol, 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 160a (ii) BETA-CAROTENE. Synonyms: CI Food Orange 5. Definition: These specifications apply predominantly to all trans isomer of  $\beta$ -carotene together with minor amounts of other carotenoids. Diluted and stabilized preparations may have different cis/trans isomer ratios. Class: Carotenoid Colour Index No 40800. EINECS 230-636-6. Chemical names:  $\beta$ -Carotene,  $\beta$ , $\beta$ -Carotene. Chemical formula:  $C_{40}H_{56}$ . Molecular

weight 536,88 Assay Not less than 96% total colouring matters (expressed as  $\beta$ -carotene) 2 500 at ca 453-456 nm in cyclohexane Description Red to brownish-red crystals or crystalline powder Identification Spectrometry Maximum in cyclohexane at ca 453-456 nm Purity Sulphated ash Not more than 0,2% Subsidiary colouring matters Carotenoids other than  $\beta$ -carotene: 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 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: C<sub>25</sub>H<sub>30</sub>O<sub>4</sub> Norbixin: C<sub>24</sub>H<sub>28</sub>O<sub>4</sub> 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

E 160b ANNATTO, BIXIN, NORBIXIN—contd.(i) SOLVENT EXTRACTED BIXIN AND NORBIXIN 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 trans-forms may be present Assay Content of bixin powders not less than 75% total carotenoids calculated as bixin Content of norbixin powders not less than 25% total carotenoids calculated as norbixin Bixin: 2 870 at ca 502 nm in chloroform Norbixin: 2 870 at ca 482 nm in KOH solution Purity Solvent residues Acetone Not more than 50 mg/kg, singly or in combination Methanol 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 160b ANNATTO, BIXIN, NORBIXIN—contd.(ii) ALKALI EXTRACTED ANATTOD 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 Assay Contains not less than 0,1% of total carotenoids expressed as norbixin Norbixin: 2 870 at ca 482 nm in KOH solution 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 160b ANNATTO, BIXIN, NORBIXIN—contd.(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: 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 annum* 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 Einesc 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: C<sub>40</sub>H<sub>56</sub>O<sub>3</sub> Capsorubin: C<sub>40</sub>H<sub>56</sub>O<sub>4</sub> 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 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

E 160c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN—contd. Purity Ethyl acetate Not more than 50 mg/kg, singly or in combination Solvent residues Methanol Ethanol Acetone Hexane Dichloromethane: Not more than 10 mg/kg Capsaicin Not more than 250 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 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, fats, waxes, and flavour components naturally occurring in tomatoes. Class Carotenoid Colour Index No 75125 Chemical names Lycopene,  $\gamma,\gamma$ -carotene Chemical formula  $C_{40}H_{56}$  Molecular weight 536,85 Assay Content not less than 5% total colouring matters 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 Not more than 50 mg/kg, singly or in combination Methanol Ethanol Acetone Hexane Propan-2-ol Dichloromethane: Not more than 10 mg/kg Sulphated 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  $\beta$ -apo-8'-carotenal together with minor amounts of other carotenoids. Diluted and stabilized forms are prepared from  $\beta$ -apo-8'-carotenal meeting these specifications and include solutions or suspensions of  $\beta$ -apo-8' carotenal in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios. Class Carotenoid Colour Index No 40820 Eines 214-171-6 Chemical names  $\beta$ -P-Apo-8'-carotenal, Trans- $\beta$ -apo-8' carotene-aldehyde Chemical formula  $C_{30}H_{40}O$  Molecular weight 416,65 Assay Not less than 96% of total colouring matters 2 640 at 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 Sulphated ash Not more than 0,1% Subsidiary colouring matters Carotenoids other than  $\beta$ apo8'-carotenal: 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 10 mg/kg

E 160f ETHYL ESTER OF BETA -APO-8'-CAROTENOIC ACID (C30)  
Synonyms CI Food Orange 7,  $\beta$ -apo-8'-carotenoic ester  
Definition These specifications apply to predominantly all trans isomer of  $\beta$ -apo-8'-carotenoic acid ethyl ester together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from  $\beta$ -apo-8'-carotenoic acid ethyl ester meeting these specifications and include solutions or suspensions of  $\beta$ -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

No40825 EINECS214-173-7 Chemical names $\beta$ -Apo-8'-carotenoic acid ethyl ester, ethyl 8'-apo- $\beta$ -caroten-8'-oate Chemical formulaC<sub>32</sub>H<sub>44</sub>O<sub>2</sub> Molecular weight460,70 AssayNot less than 96% of total colouring matters 2 550 at ca 449 nm in cyclohexaneDescriptionRed to violet-red crystals or crystalline powderIdentification SpectrometryMaximum in cyclohexane at ca 449 nmPurity Sulphated ashNot more than 0,1% Subsidiary colouring mattersCarotenoids other than  $\beta$ -apo-8'-carotenoic acid ethyl ester: not more than 3,0% of total colouring matters ArsenicNot more than 3 mg/kg LeadNot more than 10 mg/kg MercuryNot more than 1 mg/kg CadmiumNot more than 1 mg/kg Heavy metals (as Pb)Not more than 40 mg/kg

E 161b LUTEINSynonymsMixed Carotenoids, XanthophyllsDefinitionLutein 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 materialOnly the following solvents may be used for the extraction: methanol, ethanol, propan-2-ol, hexane, acetone, methyl ethyl ketone, dichloromethane and carbon dioxideClassCarotenoidEINECS204-840-0Chemical names3,3'-dihydroxy-d-caroteneChemical formulaC<sub>40</sub>H<sub>56</sub>O<sub>2</sub>Molecular weight568,88AssayContent of total colouring matter not less than 4% calculated as lutein 2 550 at ca 445 nm in chloroform/ethanol (10+90) or in hexane/ethanol/acetone (80 + 10 + 10)DescriptionDark, yellowish brown liquidIdentificationSpectrometryMaximum in chloroform/ethanol (10 + 90) at ca 445 nmPuritySolvent residuesAcetoneNot more than 50 mg/kg, singly or in combinationMethyl ethyl ketoneMethanolEthanolPropan-2-olHexaneDichloromethane: not more than 10 mg/kgArsenicNot more than 3 mg/kgLeadNot more than 10 mg/KgMercuryNot more than 1 mg/kgCadmiumNot more than 1 mg/kgHeavy metals (as Pb)Not more than 40 mg/Kg

E 161g CANTHAXANTHINSynonymsCI Food Orange 8DefinitionThese 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.ClassCarotenoidColour Index No40850EINECS208-187-2Chemical names $\beta$ -Carotene-4,4'-dione, canthaxanthin, 4,4'-dioxo- $\beta$ -caroteneChemical formulaC<sub>40</sub>H<sub>52</sub>O<sub>2</sub>Molecular weight564,86AssayNot less than 96% of total colouring matters (expressed as canthaxanthin) 2 200 at ca 485 nm in chloroform at 468—472 nm in cyclohexane at 464—467 nm in petroleum etherDescriptionDeep violet crystals or crystalline powderIdentificationSpectrometryMaximum in chloroform at ca 485 nmMaximum in cyclohexane at 468—472 nmMaximum in petroleum ether at 464—467 nmPuritySulphated ashNot more than 0,1%Subsidiary colouring

matters Carotenoids other than canthaxanthin: Not more than 5,0% 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 162 BEETROOT RED, BETANINS**  
**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-glycylol)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-glucopyranosyloxy)-6-hydroxyindolium-2-carboxylate  
**Chemical formula** Betanin: C<sub>24</sub>H<sub>26</sub>N<sub>2</sub>O<sub>13</sub>  
**Molecular weight** 550,48  
**Assay** Content of red colour (expressed as betanine) is not less than 0,4% 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**  
**Definition** Anthocyanins are obtained by extraction with sulphited water, acidified water, carbon dioxide, methanol or ethanol from the natural strains of vegetables and edible fruits. Anthocyanins contain common components of the source material, namely anthocyanine, organic acids, tannins, sugars, minerals, etc., but not necessarily in the same proportions as found in the source material  
**Class** Anthocyanin  
**Einecs** 208-438-6 (cyanidin); 205-125-6 (peonidin); 208-4-370 (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-benzopyrylium chloride (pelargonidin)  
**Chemical formula** Cyanidin: C<sub>15</sub>H<sub>11</sub>O<sub>6</sub>  
C<sub>1</sub> Peonidin: C<sub>16</sub>H<sub>13</sub>O<sub>6</sub>  
C<sub>1</sub> Malvidin: C<sub>17</sub>H<sub>15</sub>O<sub>7</sub>  
C<sub>1</sub> Delphinidin: C<sub>15</sub> H<sub>11</sub>O<sub>7</sub>  
C<sub>1</sub> Petunidin: C<sub>16</sub>H<sub>13</sub>O<sub>7</sub>  
C<sub>1</sub> Pelargonidin: C<sub>15</sub>H<sub>11</sub>O<sub>5</sub>  
C<sub>1</sub>  
**Molecular weight** Cyanidin: 322,6 Peonidin:

336,7Malvidin: 366,7Delphinidin: 340,6Petunidin: 352,7Pelargonidin:  
306,7Assay 300 for the pure pigment at 515—535 nm at pH3,0

E 163 ANTHOCYANINS—contd.DescriptionPurplish-red liquid, powder or  
paste, having a slight characteristic  
odourIdentificationSpectrometryMaximum in methanol with 0,01% conc.  
HC1Cyanidin: 535 nmPeonidin: 532 nmMalvidin: 542 nmDelphinidin: 546  
nmPetunidin: 543 nmPelargonidin: 530 nmPuritySolvent residuesMethanol  
Not more than 50 mg/kg, singly or in combinationEthanol Sulphur  
dioxideNot more than 1 000 mg/kg per percent pigmentArsenicNot more  
than 3 mg/kgLeadNot more than 10 mg/kgMercuryNot more than 1  
mg/kgCadmiumNot more than 1 mg/kgHeavy metals (as Pb)Not more than  
40 mg/kg

E 170 CALCIUM CARBONATESynonymsCI Pigment White 18,  
ChalkDefinitionCalcium carbonate is the product obtained from ground  
limestone or by the precipitation of calcium ions with carbonate  
ions.ClassInorganicColour Index No.77220EinecsCalcium carbonate:  
207-439-9Limestone: 215-279-6Chemical namesCalcium carbonateChemical  
formulaCaCO<sub>3</sub>Molecular weight100,1AssayContent not less than 98% on the  
anhydrous basisDescriptionWhite Crystalline or amorphous, odourless and  
tasteless powderIdentificationSolubilityPractically 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 solution, after boiling, give positive tests for  
calcium.PurityLoss on dryingNot more than 2,0% (200°C, 4  
hours)Acid-insoluble substancesNot more than 0,2%Magnesium and alkali  
saltsNot more than 1,5%FlourideNot more than 50 mg/kgAntimony (as  
Sb)Not more than 100 mg/kg, singly or in combinationCopper (as  
Cu)Chromium (as Cr)Zinc (as Zn)Barium (as Ba)ArsenicNot more than 3  
mg/kgLeadNot more than 10 mg/kgCadmiumNot more than 1 mg/kg

E 171 TITANIUM DIOXIDESynonymsCI Pigment White 6DefinitionTitanium  
Dioxide consists essentially of pure anatase titanium dioxide which  
may be coated with small amounts of alumina and/or silica to  
improve the technological properties of the product.ClassInorganicColour  
Index No.77891Einecs236-675-5Chemical namesTitanium dioxideChemical  
formulaTiO<sub>2</sub>Molecular weight79,88AssayContent not less than 99% on an  
alumina and silica-free basisDescriptionAmorphous white  
powderIdentificationSolubilityInsoluble in water and organic solvents.  
Dissolves slowly in hydrofluoric acid and in hot concentrated  
sulphuric acid.PurityLoss on dryingNot more than 0,5% (105°C, 3  
hours)Loss on ignitionNot more than 1,0% on a volatile matter free  
basis (800°C)Aluminium oxide and/or silicon dioxideTotal not more than  
2,0%Matter soluble in 0,5N HClNot 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 matterNot more than 0,5%CadmiumNot more than 1  
mg/kgAntimonyNot more than 50 mg/kg by total dissolutionArsenicNot  
more than 3 mg/kg by total dissolutionLeadNot more than 10 mg/kg by

total dissolutionMercuryNot more than 1 mg/kg by total  
dissolutionZincNot more than 50 mg/kg by total dissolution

E 172 IRON OXIDES AND IRON HYDROXIDES  
SynonymsIron Oxide Yellow: CI Pigment Yellow 42 and 43Iron Oxide Red: CI Pigment Red101 and 102Iron Oxide Black: CI Pigment Black 11  
DefinitionIron oxides and iron hydroxides are produced synthetically and consist essentially 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.  
ClassInorganicColour Index No.Iron Oxide Yellow: 77492Iron Oxide Red: 77491Iron Oxide Black: 77499  
EinecsIron Oxide Yellow: 257-098-5Iron Oxide Red: 215-168-2Iron Oxide Black: 235-442-5  
Chemical namesIron Oxide Yellow: hydrated ferric oxide, hydrated iron (III) oxideIron Oxide Red: anhydrous ferric oxide, anhydrous iron (III) oxideIron Oxide Black: ferrous ferric oxide, iron (II, III) oxide  
Chemical formulaIron Oxide Yellow:  $\text{FeO}(\text{OH}) \cdot x\text{H}_2\text{O}$ Iron Oxide Red:  $\text{Fe}_2\text{O}_3$ Iron Oxide Black:  $\text{FeO} \cdot \text{Fe}_2\text{O}_3$   
Molecular weight88,85:  $\text{FeO}$  (OH)159,70:  $\text{Fe}_2\text{O}_3$ 231,55:  $\text{FeO} \cdot \text{Fe}_2\text{O}_3$   
AssayYellow not less than 60%, red and black not less than 68% total iron, expressed as iron  
DescriptionPowder; yellow, red, brown or black in hue  
IdentificationSolubilityInsoluble in water and in organic solventsSoluble in concentrated mineral acids  
PurityWater soluble matterNot more than 1,0%  
By total dissolutionArsenicNot more than 5 mg/kgBariumNot more than 50 mg/kgCadmiumNot more than 5 mg/kgChromiumNot more than 100 mg/kgCopperNot more than 50 mg/kgLeadNot more than 20 mg/kgMercuryNot more than 1 mg/kgNickelNot more than 200 mg/kgZincNot more than 100 mg/kg

E 173 ALUMINIUMS  
SynonymsCI Pigment Metal, A  
DefinitionAluminium 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  
Einecs231-072-3  
Chemical namesAluminium  
Chemical formulaAl  
Atomic weight26,98  
AssayNot less than 99% calculated as Al on an oil-free basis  
DescriptionA silvery grey powder or tiny sheets  
IdentificationSolubilityInsoluble in water and in organic solvents. Soluble in dilute hydrochloric acid. The resulting solution gives positive tests for aluminium  
PurityLoss on dryingNot more than 0,5% (105°C, to constant weight)  
ArsenicNot more than 3 mg/kgLeadNot more than 10 mg/kgMercuryNot more than 1 mg/kgCadmiumNot more than 1 mg/kgHeavy metals (as Pb)Not more than 40 mg/kg

E 174 SILVERS  
SynonymsArgentum, Ag  
ClassInorganicColour Index No.77820  
Einecs231-131-3  
Chemical nameSilver  
Chemical formulaAg  
Atomic weight107,87  
AssayContent not less than 99,5% Ag  
DescriptionSilver-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 name 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% After complete dissolution  
Copper Not more than 4%

E 180 LITHOL RUBINE BK  
Synonyms CI Pigment Red 57, Rubinpigment, carmine  
6B  
Definition Lithol Rubine BK consists essentially of calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-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-naphthalenecarboxylate  
Chemical formula  $C_{18}H_{12}CaN_2O_6S$   
Molecular weight 424,45  
Assay Content not less than 90% total colouring matters 200 at ca 442 nm in dimethylformamide  
Description Red powder  
Identification A. Spectrometry  
Maximum in dimethylformamide at ca 442 nm  
Purity Subsidiary colouring matters Not more than 0,5%  
Organic compounds other than colouring matters: 2 Amino-5-methylbenzene-sulfonic acid, calcium salt Not more than 0,2%  
3-hydroxy-2-naphthalenecarboxylic acid, calcium salt Not more than 0,4%  
Un sulfonated primary aromatic amines Not more than 0,01% (expressed 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

GIVEN under the Official Seal of the Minister for Health, this 19th day of December, 1995.

MICHAEL NOONAN,  
Minister for Health.

#### EXPLANATORY NOTE

These Regulations implement the Directives on food additives generally and on colours and sweeteners in particular, which are listed below.  
Council Directive 89/107/EEC(1) on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.

(1) OJ No. L40, 11.2.89, pp 27-33

European Parliament and Council Directive 94/35/EC(2) on sweeteners for use in foodstuffs.

(2) OJ No. L237, 10.9.94, pp 3-12

European Parliament and Council Directive 94/36/EC(3) on colours for use in foodstuffs.

(3) OJ No. L237, 10.9.94, pp 13-29

Commission Directive 95/31/EC(4) laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

(4)OJ No. L178, 28.7.95, pp 1-19

Commission Directive 95/45/EC(5) laying down specific purity criteria concerning colours for use in foodstuffs.

(5)OJ No. L226 22.9.95, pp 1-45

All food additives must comply with the provisions in Part I of the Regulations while, in addition, sweeteners and colours used as food additives must comply with the provisions in Parts II and III respectively.

These Regulations, cited as the European Communities (General Provisions on the Control of Additives, and in particular Colours and Sweeteners for use in Foodstuffs) Regulations, 1995 come into effect on 31st December 1995.