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 STATUTORY INSTRUMENTS
 

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1974 No. 1121

## FOOD AND DRUGS

## COMPOSITION AND LABELLING

**The Miscellaneous Additives in Food Regulations 1974**

Made - - - - 28th June 1974  
 Coming into Operation 1st August 1974  
 To be Laid before Parliament

The Minister of Agriculture, Fisheries and Food and the Secretary of State for Social Services, acting jointly, in exercise of the powers conferred on them by sections 4, 7 and 123 of the Food and Drugs Act 1955(a) as amended by section 4(1) of, and paragraph 3(1) of Schedule 4 to, the European Communities Act 1972(b) and as read with the Secretary of State for Social Services Order 1968(c), and of all other powers enabling them in that behalf, hereby make the following regulations, after consultation with such organisations as appear to them to be representative of interests substantially affected by the regulations and after reference to the Food Hygiene Advisory Council under section 82 of the Food and Drugs Act 1955 (in so far as the regulations are made in exercise of the powers conferred by the said section 7):—

*Citation and commencement*

1. These regulations may be cited as the Miscellaneous Additives in Food Regulations 1974, and shall come into operation on 1st August 1974.

*Interpretation*

2.—(1) In these regulations, unless the context otherwise requires—

“ the Act ” means the Food and Drugs Act 1955 ;

“ acid ” means—

(a) any substance which is capable, and generally used for the purpose, of increasing the acidity of a food,

(b) nicotinic acid,

and, in each case, includes the ammonium, sodium, potassium and calcium salts of such substance ;

“ anti-caking agent ” means any substance which is capable of reducing the tendency of individual particles of food to adhere to one another or of improving their flow characteristics ;

“ anti-foaming agent ” means any substance which is capable of preventing or dispersing a foam ;

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(a) 4 & 5 Eliz. 2. c. 16. (b) 1972 c. 68. (c) S.I. 1968/1699 (1968 III, p. 4585).

“appropriate designation” means, as respects any permitted miscellaneous additive, a name or description or a name and description sufficiently specific, in each case, to indicate to an intending purchaser the true nature of the permitted miscellaneous additive to which it is applied ;

“base” means any substance which is capable, and generally used for the purpose, of increasing the alkalinity of a food ;

“buffer” means any substance which is capable, and generally used for the purpose, of altering and controlling the acidity or alkalinity of a food ;

“chocolate confectionery” means any solid or semi-solid product complete in itself and suitable for consumption without further preparation or processing, of which the characteristic ingredient is chocolate or cocoa, with or without the addition of nuts or fruit ; and includes any kind of chocolate and products made by enrobing, coating or embedding sugar confectionery or other ingredients in chocolate, but does not include chocolate-coated, chocolate-filled or chocolate-flavoured biscuits, flour confectionery, any kind of ice-cream including chocolate ice-cream, or pharmaceutical products ;

“container” includes any form of packaging of food for sale as a single item, whether by way of wholly or partly enclosing the food or by way of attaching the food to some other article, and in particular includes a wrapper or confining band ;

“European Pharmacopoeia Volume I, 1969” and “European Pharmacopoeia Volume II, 1971” mean respectively Volume I of the European Pharmacopoeia published in 1969 and Volume II of the European Pharmacopoeia published in 1971, in each case by Maisonneuve SA, 57-Sainte-Ruffine, France under the direction of the Council of Europe ;

“firming agent” means any substance which is capable of making or keeping tissues of fruit or vegetables firm or crisp ;

“food” means food intended for sale for human consumption and includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products, but does not include—

- (a) water, live animals or birds,
- (b) fodder or feeding stuffs for animals, birds or fish, or
- (c) articles or substances used only as drugs ;

“food and drugs authority” has the meaning assigned to it by section 198 of the Local Government Act 1972(a) ;

“Food Chemicals Codex 1972” means the edition of the Food Chemicals Codex published in 1972 by the National Academy of Sciences—National Research Council, Washington DC, United States of America ;

“glazing agent” means any substance, other than a mineral hydrocarbon, which, when applied to the external surfaces of food, is capable of imparting a shiny appearance or of providing a protective coating ;

“human consumption” includes use in the preparation of food for human consumption ;

“humectant” means any substance which is capable of off-setting wholly or partially the effect on a food of humidity in the atmosphere to which the food is exposed ;

“liquid freezant” means any liquid or any liquefiable gas other than air, which is capable of converting food into a frozen state ;

“mineral hydrocarbon” has the meaning assigned to it by the Mineral Hydrocarbons in Food Regulations 1966(a) ;

“miscellaneous additive” means any acid, anti-caking agent, anti-foaming agent, base, buffer, firming agent, glazing agent, humectant, liquid freezant, packaging gas, propellant, release agent or sequestrant, but does not include—

- (a) any natural food substance,
- (b) any permitted antioxidant,
- (c) any permitted artificial sweetener,
- (d) any permitted bleaching agent,
- (e) any permitted colouring matter,
- (f) any permitted emulsifier,
- (g) any permitted improving agent,
- (h) any permitted preservative,
- (j) any permitted solvent,
- (k) any permitted stabiliser,
- (l) starches, whether modified or not,
- (m) caseinates,
- (n) proteins, protein concentrates and protein hydrolysates,
- (o) common salt (sodium chloride),
- (p) normal straight chain fatty acids derived from food fats ;

“natural food substance” means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment and includes malt extract and glucose syrup ;

“packaging gas” means any gas other than air, introduced into a container before, during or after the placing of food in that container ;

“permitted antioxidant” means any antioxidant in so far as its use is permitted by the Antioxidant in Food Regulations 1974(b) ;

“permitted artificial sweetener” means any artificial sweetener in so far as its use is permitted by the Artificial Sweeteners in Food Regulations 1969(c) ;

“permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour Regulations 1963(d), as amended(e) ;

“permitted colouring matter” means any colouring matter in so far as its use is permitted by the Colouring Matter in Food Regulations 1973(f) ;

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(a) S.I. 1966/1073 (1966 II, p. 2644).

(b) S.I. 1974/1120 (1974 II, p. 4210).

(c) S.I. 1969/1817 (1969 III, p. 5638).

(d) S.I. 1963/1435 (1963 II, p. 2464).

(e) The relevant amending instrument is S.I. 1972/1391 (1972 III, p. 4246).

(f) S.I. 1973/1340 (1973 II, p. 4097).

“permitted emulsifier” means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1962(a), as amended(b) ;

“permitted improving agent” means any improving agent in so far as its use is permitted by the Bread and Flour Regulations 1963, as amended ;

“permitted miscellaneous additive” means any miscellaneous additive specified in Part I of Schedule 1 to these regulations which satisfies the specific purity criteria in relation to that additive specified or referred to in Part II of that Schedule and, so far as is not otherwise provided by any such specific purity criteria, satisfies the general purity criteria specified in Part III of that Schedule, or any combination of two or more such additives ;

“permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food Regulations 1974(c) ;

“permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food Regulations 1967(d), as amended(e) ;

“permitted stabiliser” means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1962, as amended ;

“propellent” means any liquid or any gas, other than air, which is capable of expelling food from a container ;

“release agent” means any substance, other than a mineral hydrocarbon, which facilitates the ready separation of food from surfaces with which it may come in contact during the manufacture or conveyance but does not include any substance or material which forms an integral part of machinery or conveyor belts or food containers, or silicone resins baked on to baking tins ;

“sell” includes offer or expose for sale or have in possession for sale, and “sale” and “sold” shall be construed accordingly ;

“sequestrant” means any substance which is capable of complexing with metallic ions ;

“specified food” means any food of a description specified in column 1 of Schedule 2 to these regulations ;

“sugar confectionery” means any solid or semi-solid product complete in itself and suitable for consumption without further preparation or processing of which the characteristic ingredient is carbohydrate sweetening matter with or without the addition of any edible fat, dairy product, gelatine, edible gums, nuts or preserved fruit ; and includes sweetened liquorice and chewing gum but does not include sugar, chocolate confectionery, sugared flour confectionery, any kind of ice-cream, ice-lollies, table jellies, table jelly preparations, soft drink crystals, soft drink preparations, slab marzipan, meringues or pharmaceutical products ;

AND other expressions have the same meaning as in the Act.

(2) The Interpretation Act 1889(f) shall apply to the interpretation of these regulations as it applies to an Act of Parliament.

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(a) S.I. 1962/720 (1962 I, p. 729).

(b) The relevant amending instrument is S.I. 1970/1101 (1970 II, p. 3468).

(c) S.I. 1974/1119 (1974 II, p. 4183).

(d) S.I. 1967/1582 (1967 III, p. 4385).

(e) S.I. 1967/1939 (1967 III, p. 5389).

(f) 1889 c. 63.



(3) Unless a contrary intention is expressed, all proportions mentioned in these regulations are proportions calculated by weight of the product as sold.

(4) Any reference in these regulations to a label borne on a container shall be construed as including a reference to any legible marking on the container however effected.

(5) For the purposes of these regulations, the supply of food, otherwise than by sale, at, in or from any place where food is supplied in the course of a business shall be deemed to be a sale of that food.

(6) Any reference in these regulations to any other regulations shall be construed as a reference to such regulations as amended by any subsequent regulations.

#### *Exemptions*

3. The provisions of these regulations shall not apply to food having any miscellaneous additive in it or on it, or to any miscellaneous additive, intended at the time of sale, consignment, delivery or importation, as the case may be, for exportation to any place outside the United Kingdom.

#### *Sale etc. of food containing miscellaneous additives*

4.—(1) Subject to paragraph (2) of this regulation, no food sold, consigned, delivered or imported into England and Wales shall have in it or on it any added miscellaneous additive other than a permitted miscellaneous additive.

(2) Save as hereinafter provided, no food sold, consigned, delivered or imported into England and Wales shall have in it or on it any added permitted miscellaneous additive specified in column 2 of Schedule 2 to these regulations :

Provided that—

(a) any specified food may have in it or on it any such permitted miscellaneous additive of the description and in the proportion specified in relation thereto in columns 2 and 3 respectively of Schedule 2 to these regulations ;

(b) any food containing as an added ingredient any specified food may contain any such permitted miscellaneous additive of the description specified for, and in the amount appropriate to the quantity of, such specified food in accordance with the preceding subparagraph of this proviso.

(3) No person shall sell, consign or deliver, or import into England and Wales any food which does not comply with this regulation.

#### *Sale, advertisement and labelling of miscellaneous additives*

5.—(1) No person shall sell, consign, deliver, import into England and Wales or advertise for sale any miscellaneous additive (including any miscellaneous additive with which any other substance has been mixed) for use as an ingredient in the preparation of food unless such miscellaneous additive is a permitted miscellaneous additive.

(2) No person shall sell, consign or deliver any permitted miscellaneous additive (including any permitted miscellaneous additive with which any other substance has been mixed) for use as an ingredient in the preparation of food except in a container bearing a label in accordance with the requirements of Schedule 3 to these regulations.

#### *Condemnation of food*

6. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 of these regulations to sell, consign, deliver or import into England and Wales, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

#### *Penalties and enforcement*

7.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable to a fine not exceeding one hundred pounds or to imprisonment for a term not exceeding three months, or to both, and, in the case of a continuing offence, to a further fine not exceeding five pounds for each day during which the offence continues after conviction.

(2) Each food and drugs authority shall enforce and execute such provisions in their area :

Provided that each port health authority shall enforce and execute in their district the provisions of regulations 4 and 5 of these regulations in so far as they relate to importation.

(3) The requirements of section 109(3) of the Act (which requires notice to be given to the Minister of Agriculture, Fisheries and Food of intention to institute proceedings for an offence against any provisions of these regulations relating to the labelling, advertising or description of food) shall not apply as respects any proceedings instituted by a council for an offence against any such provisions of these regulations.

#### *Defences*

8.—(1) In any proceedings for an offence against these regulations in relation to the publication of an advertisement, it shall be a defence for the defendant to prove that, being a person whose business it is to publish or arrange for the publication of advertisements, he received the advertisement for publication in the ordinary course of business.

(2) In any proceedings against the manufacturer or importer of any miscellaneous additive for use as an ingredient in the preparation of food, or of any food having any miscellaneous additive in it or on it, for an offence against these regulations in relation to the publication of an advertisement, it shall rest on the defendant to prove that he did not publish, and was not a party to the publication of, the advertisement.

#### *Application of various sections of the Act*

9.—(1) Sections 108(3) and (4) (which relate to prosecutions), 110(1), (2) and (3) (which relate to evidence of analysis), 112 (which relates to the power of a court to require analysis by the Government Chemist), 113 (which relates to a contravention due to some person other than the person charged), 115(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 116 (which relates to offences in relation to

warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under these regulations and as if the reference in the said section 112 to subsection (4) of section 108 included a reference to that subsection as applied by these regulations.

(2) Paragraph (b) of the proviso to section 108(1) of the Act shall apply for the purposes of these regulations as if the reference therein to section 116 of the Act included a reference to that section as applied by these regulations.

*Amendment of the Labelling of Food Regulations 1970*

10. The Labelling of Food Regulations 1970(a), as amended(b), shall be further amended—

(a) by inserting in regulation 2(1) thereof after the definition of permitted improving agent the following definition :—

“ ‘permitted miscellaneous additive’ means any acid, anti-caking agent, anti-foaming agent, base, buffer, firming agent, glazing agent, humectant, liquid freezant, packaging gas, propellant, release agent or sequestrant in so far as its use in food is, in each case, permitted by the Miscellaneous Additives in Food Regulations 1974 ; ” ;

(b) by inserting in item 2 of Part I of Schedule 2 thereto, after the entry relating to permitted solvents when prepacked for sale as such, the following entry :—

“ Column 1	Column 2
Description of Food	Extent of exemption from regulation 5(2)
Permitted miscellaneous additives when pre-packed for sale as such.	Wholly exempt if labelled in accordance with Schedule 3 to the Miscellaneous Additives in Food Regulations 1974.”

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th June 1974.

(L.S.)

*Frederick Peart,*  
Minister of Agriculture, Fisheries and  
Food.

*Barbara Castle,*  
Secretary of State for Social Services.

28th June 1974.

Regulation 2(1)

## SCHEDULE 1

## PART I

*Permitted Miscellaneous Additives*

Column 1	Column 2
Name of Miscellaneous Additive	Serial number
Acetic acid ... ..	E 260
Sodium acetate, anhydrous ... ..	—
Sodium acetate ... ..	—
Sodium hydrogen diacetate ... ..	E 262
Potassium acetate ... ..	E 261
Calcium acetate ... ..	E 263
Adipic acid ... ..	—
Beeswax, white ... ..	—
Beeswax, yellow ... ..	—
Calcium phytate ... ..	—
Carbon dioxide ... ..	E 290
Ammonium carbonate ... ..	—
Ammonium hydrogen carbonate ... ..	—
Sodium carbonate ... ..	—
Sodium hydrogen carbonate ... ..	—
Sodium sesquicarbonate ... ..	—
Magnesium carbonate, heavy ... ..	—
Magnesium carbonate, light ... ..	—
Potassium carbonate ... ..	—
Potassium hydrogen carbonate ... ..	—
Calcium carbonate ... ..	E 170
Carnauba wax ... ..	—
Citric acid ... ..	E 330
<i>tri</i> Ammonium citrate ... ..	—
Sodium dihydrogen citrate ... ..	E 331
<i>tri</i> Sodium citrate ... ..	E 331
Potassium dihydrogen citrate ... ..	E 332
<i>tri</i> Potassium citrate ... ..	E 332
Calcium citrate ... ..	E 333
Ammonium ferric citrate ... ..	—
Ammonium ferric citrate, green ... ..	—
Dimethylpolysiloxane ... ..	—
<i>di</i> Sodium dihydrogen ethylenediamine— NNN'N' tetra-acetate ... ..	—
Calcium disodium ethylenediamine— NNN'N' tetra-acetate ... ..	—
Sodium ferrocyanide ... ..	—
Potassium ferrocyanide ... ..	—

Column 1	Column 2
Name of Miscellaneous Additive	Serial number
Fumaric acid ... ..	—
D-Glucono-1,5-lactone ... ..	—
Sodium gluconate ... ..	—
Potassium gluconate ... ..	—
Calcium gluconate ... ..	—
Glycine ... ..	—
1, 4-Heptonolactone ... ..	—
Sodium heptonate ... ..	—
Calcium heptonate ... ..	—
Hydrochloric acid ... ..	—
Ammonium chloride ... ..	—
Potassium chloride ... ..	—
Calcium chloride, anhydrous ... ..	—
Calcium chloride ... ..	—
Hydrogen ... ..	—
Ammonium hydroxide ... ..	—
Sodium hydroxide ... ..	—
Magnesium hydroxide ... ..	—
Magnesium oxide, heavy ... ..	—
Magnesium oxide, light ... ..	—
Potassium hydroxide ... ..	—
Calcium hydroxide ... ..	—
Calcium oxide ... ..	—
Lactic acid ... ..	E 270
Sodium lactate ... ..	E 325
Potassium lactate ... ..	E 326
Calcium lactate ... ..	E 327
DL-Malic acid ... ..	—
L-Malic acid ... ..	—
Sodium hydrogen malate ... ..	—
Sodium malate ... ..	—
Potassium malate ... ..	—
Calcium malate ... ..	—
Mannitol ... ..	E 421
Metatartaric acid ... ..	—
Nicotinic acid ... ..	—
Nitrogen ... ..	—
Nitrous oxide ... ..	—
Octadecylammonium acetate ... ..	—
Oxygen ... ..	—
Oxystearin ... ..	—
Orthophosphoric acid ... ..	E 338

Column 1	Column 2
Name of Miscellaneous Additive	Serial number
Ammonium dihydrogen orthophosphate ...	—
<i>di</i> Ammonium hydrogen orthophosphate ...	—
Sodium dihydrogen orthophosphate ...	E 339(a)
<i>di</i> Sodium hydrogen orthophosphate ...	E 339(b)
<i>tri</i> Sodium orthophosphate ... ..	E 339(c)
Potassium dihydrogen orthophosphate ...	E 340(a)
<i>di</i> Potassium hydrogen orthophosphate ...	E 340(b)
<i>tri</i> Potassium orthophosphate ... ..	E 340(c)
Calcium tetrahydrogen diorthophosphate ...	E 341(a)
Calcium hydrogen orthophosphate ... ..	E 341(b)
<i>tri</i> Calcium diorthophosphate ... ..	E 341(c)
Calcium hydroxyphosphate ... ..	—
Sodium aluminium phosphate, acidic ...	—
Sodium aluminium phosphate, basic ...	—
<i>di</i> Sodium dihydrogen diphosphate ... ..	E 450(a)
<i>tetra</i> Sodium diphosphate ... ..	E 450(a)
<i>tetra</i> Potassium diphosphate ... ..	E 450(a)
<i>di</i> Calcium diphosphate ... ..	—
<i>penta</i> Sodium triphosphate ... ..	E 450(b)
<i>penta</i> Potassium triphosphate ... ..	E 450(b)
Ammonium, sodium, potassium and calcium polyphosphates ... ..	—
Edible bone phosphate ... ..	—
Shellac ... ..	—
Silicon dioxide ... ..	—
Bentonite ... ..	—
Kaolin, heavy ... ..	—
Kaolin, light ... ..	—
Aluminium sodium silicate ... ..	—
Aluminium calcium silicate ... ..	—
Calcium silicate ... ..	—
Magnesium silicate, synthetic ... ..	—
Magnesium trisilicate ... ..	—
Talc ... ..	—
Sorbitol ... ..	E 420
Spermaceti ... ..	—
Sperm oil ... ..	—
Magnesium stearate ... ..	—
Calcium stearate ... ..	—
Butyl stearate ... ..	—
Succinic acid ... ..	—
Sulphuric acid ... ..	—

Column 1	Column 2
Name of Miscellaneous Additive	Serial number
Ammonium sulphate ... ..	—
Sodium sulphate ... ..	—
Magnesium sulphate ... ..	—
Potassium sulphate ... ..	—
Aluminium potassium sulphate ... ..	—
Calcium sulphate ... ..	—
Tannic acid ... ..	—
Tartaric acid ... ..	E 334
Sodium tartrate ... ..	E 335
Potassium tartrate ... ..	E 336
Potassium hydrogen tartrate ... ..	E 336
Potassium sodium tartrate ... ..	E 337

## PART II

*Specific Purity Criteria Applicable to  
Permitted Miscellaneous Additives**E 260 Acetic acid*

The specific purity criteria for acetic acid contained in Directive 65/66/EEC of the Council(a).

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(a) O.J. No. 22, 9.2.65, p. 373/65 (O.J./S.E. 1965-1966, p. 25).

*Sodium acetate, anhydrous*

The criteria in the monograph for sodium acetate, anhydrous contained in the Food Chemicals Codex 1972 at page 718.

*Sodium acetate*

The criteria in the monograph for sodium acetate contained in the Food Chemicals Codex 1972 at page 717 except that the alkalinity shall be not more than 0.1 per centum (as sodium carbonate, Na<sub>2</sub>CO<sub>3</sub>).

*E262 Sodium hydrogen diacetate*

Synonym ... .. Sodium diacetate.

The specific purity criteria for sodium diacetate contained in Directive 65/66/EEC of the Council.

*E261 Potassium acetate*

The specific purity criteria for potassium acetate contained in Directive 65/66/EEC of the Council.

*E263 Calcium acetate*

The specific purity criteria for calcium acetate contained in Directive 65/66/EEC of the Council.

*Adipic acid*

The criteria in the monograph for adipic acid contained in the Food Chemicals Codex 1972 at page 21.

*Beeswax, white*

The criteria in the monograph for beeswax, white contained in the Food Chemicals Codex 1972 at page 75, except that the ester value shall be not less than 70 and not more than 80.

*Beeswax, yellow*

The criteria in the monograph for beeswax, yellow contained in the Food Chemicals Codex 1972 at page 77, except that the ester value shall be not less than 70 and not more than 80.

*Calcium phytate*

Synonym	...	...	...	Calcium <i>meso</i> inositolhexaphosphate.
Description	...	...	...	White powder with an acid taste.
Solubility	...	...	...	Commercially the product exists as the trihydrate. Slightly soluble in water.
Volatile matter	...	...	...	Soluble in acids. Not more than 12 per centum (determined by drying at 100°C. to constant weight).
Ash	...	...	...	Not less than 60 per centum and not more than 72 per centum (determined by ignition at about 550°C.).



Matter insoluble in acids	Not more than 2 per centum in hydrochloric acid and not more than 2 per centum in orthophosphoric acid, determined as follows:  Treat 1g. of calcium phytate with 7ml. N hydrochloric acid and 93ml. of distilled water. Treat another 1g. sample of calcium phytate with 50ml. distilled water and 1.5ml. orthophosphoric acid (50 per centum $H_3PO_4$ ; density 1.34). Stir and filter each solution and collect, wash, dry (at 100°C.) and weigh the residue in each case.
Protein nitrogen ... ..	Not more than 0.38 per centum.
Total phosphorus ... ..	Not less than 16 per centum on a volatile matter-free basis.
Mineral phosphate (expressed as phosphorus) ...	Not more than 0.5 per centum.
Iron ... ..	Not more than 100mg. per kg.
Arsenic ... ..	Not more than 5mg. per kg.

*E 290 Carbon dioxide*

The specific purity criteria for carbon dioxide contained in Directive 65/66/EEC of the Council. Solid or liquid carbon dioxide shall be of equivalent purity to the gas.

*Ammonium carbonate*

The criteria in the monograph for ammonium carbonate contained in the Food Chemicals Codex 1972 at page 45.

*Ammonium hydrogen carbonate*

Synonym ... .. Ammonium bicarbonate.

The criteria in the monograph for ammonium bicarbonate contained in the Food Chemicals Codex 1972 at page 44.

*Sodium carbonate*

Description ... ..	Colourless crystals or white granular or crystalline powder. The anhydrous salt is hygroscopic and the decahydrate is efflorescent.
Content ... ..	Not less than 98 per centum of $Na_2CO_3$ on a volatile matter-free basis.
Volatile matter ... ..	Not more than: 2 per centum for the non-hydrated substance; 15 per centum for the monohydrate; 65 per centum for the decahydrate; (determined by the method for loss on drying in the monograph for sodium carbonate in the Food Chemicals Codex 1972 at page 731).

Matter insoluble in dilute ammonia solution	...	...	...	Not more than 0.12 per centum on a volatile matter-free basis, determined by the following method: Boil 5g. of hydrated sodium carbonate, or 2.5g. of anhydrous sodium carbonate, with 50ml. of water and 10ml. of dilute ammonia solution (about 10 per centum $\text{NH}_3$ ). Filter and wash the residue with water, then ignite to constant weight.
Sulphate	...	...	...	Not more than 0.4 per centum on a volatile matter-free basis.
Chloride	...	...	...	Not more than 0.4 per centum on a volatile matter-free basis.
Iron	...	...	...	Not more than 40mg. per kg. on a volatile matter-free basis.

*Sodium hydrogen carbonate*

Synonym ... .. Sodium bicarbonate.

The criteria in the monograph for sodium bicarbonate contained in the Food Chemicals Codex 1972 at page 727.

*Sodium sesquicarbonate*

The criteria in the monograph for sodium sesquicarbonate contained in the Food Chemicals Codex 1972 at page 765.

*Magnesium carbonate, heavy*

The criteria in the monograph for heavy magnesium carbonate contained in the European Pharmacopoeia Vol. I, 1969 at page 322.

*Magnesium carbonate, light*

The criteria in the monograph for light magnesium carbonate contained in the European Pharmacopoeia, Vol. I, 1969 at page 321.

*Potassium carbonate*

Description	...	...	...	The anhydrous form is a white granular powder. The hydrated form consists of small white translucent crystals or granules.
Content	...	...	...	Not less than 98 per centum of $\text{K}_2\text{CO}_3$ on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than: 2 per centum for the non-hydrated substance; 18 per centum for the hydrated substance; (determined by drying at $180^\circ\text{C}$ . for 4 hours).

*Potassium hydrogen carbonate*

Synonym ... .. Potassium bicarbonate.

The criteria in the monograph for potassium bicarbonate contained in the Food Chemicals Codex 1972 at page 642.

*E 170 Calcium carbonate*

Description ... .. Fine white microcrystalline or amorphous powder.

Content	...	...	...	Not less than 97 per centum of CaCO <sub>3</sub> on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than 1 per centum (determined by drying at 105°C. to constant weight).
Matter insoluble in hydrochloric acid	...	...	...	Shall comply with the requirement for aluminium, iron, phosphate and matter insoluble in hydrochloric acid in the monograph for chalk in the British Pharmacopoeia 1973 at page 93.
Arsenic	...	...	...	Not more than 5 mg. per kg.
Lead	...	...	...	Not more than 20 mg. per kg.
Other inorganic impurities				Not more than 100 mg. per kg. of any of the following substances, namely antimony, copper, chromium, zinc or barium sulphate, or more than 200 mg. per kg. of any combination of those substances.

*Carnauba wax*

The criteria in the monograph for carnauba wax contained in the Food Chemicals Codex 1972 at page 170.

*E 330 Citric acid*

Description	...	...	...	Colourless or translucent crystalline solid, or white crystalline powder.
Content	...	...	...	Not less than 99.5 per centum of C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than: 0.5 per centum for the non-hydrated substance; 8.8 per centum for the monohydrate (determined by drying at 105°C. to constant weight).
Oxalates (expressed as oxalic acid)	...	...	...	Not more than 0.05 per centum on a volatile matter-free basis.
Sulphated ash	...	...	...	Not more than 0.05 per centum on a volatile matter-free basis.
Sulphuric acid test (readily carbonisable substances)				Shall comply with the requirement for readily carbonisable substances in the monograph for citric acid contained in the British Pharmacopoeia 1973 at page 113.

*triAmmonium citrate*

Synonym ... .. Ammonium citrate.

The criteria in the monograph for ammonium citrate contained in the British Pharmaceutical Codex 1973 at page 830.

*E 331 Sodium dihydrogen citrate*

Description	...	...	...	White crystalline powder.
Content	...	...	...	Not less than 99 per centum of C <sub>6</sub> H <sub>7</sub> O <sub>7</sub> Na on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than 0.4 per centum (determined by drying at 105°C. to constant weight).

Oxalates (expressed as oxalic acid) ... ..	as ...	Not more than 0.02 per centum on a volatile matter-free basis.
<i>E 331 triSodium citrate</i>		
Synonym ... ..	...	Sodium citrate.
Description ... ..	...	White crystalline powder or colourless crystals.
Content ... ..	...	Not less than 99 per centum of $C_6H_5O_7Na_3$ on a volatile matter-free basis.
Volatile matter ... ..	...	Not more than: 1 per centum for the non-hydrated substance; 13 per centum for the dihydrate; 30 per centum for the pentahemihydrate; (determined by drying at 180°C. to constant weight).
Oxalates (expressed as oxalic acid) ... ..	as ...	Not more than 0.05 per centum on a volatile matter-free basis.
<i>E 332 Potassium dihydrogen citrate</i>		
Description ... ..	...	White granules or crystals.
Content ... ..	...	Not less than 98 per centum of $C_6H_7O_7K$ on a volatile matter-free basis.
Volatile matter ... ..	...	Not more than 0.4 per centum (determined by drying at 105°C. to constant weight).
Oxalates (expressed as oxalic acid) ... ..	as ...	Not more than 0.05 per centum on a volatile matter-free basis.
<i>E 332 triPotassium citrate</i>		
Synonym ... ..	...	Potassium citrate.
Description ... ..	...	White granular hygroscopic powder or transparent crystals. Commercially the product occurs as the monohydrate.
Content ... ..	...	Not less than 99 per centum of $C_6H_5O_7K_3$ on a volatile matter-free basis.
Volatile matter ... ..	...	Not more than 6 per centum (determined by drying at 180°C. for 4 hours).
Oxalates (expressed as oxalic acid) ... ..	as ...	Not more than 0.05 per centum on a volatile matter-free basis.
<i>E 333 Calcium citrate</i>		
Description ... ..	...	Fine white powder. Commercially the product occurs as the tetrahydrate.
Content ... ..	...	Not less than 97.5 per centum of $(C_6H_5O_7)_2Ca_3$ on a volatile matter-free basis.
Volatile matter ... ..	...	Not more than 13 per centum (determined by drying at 180°C. to constant weight).
Carbonates ... ..	...	When 1g. of calcium citrate is dissolved in 10ml. of dilute hydrochloric acid (approximately 2N) only a few isolated bubbles should be released.

Oxalates (expressed as oxalic acid) ... ..	Not more than 0.05 per centum on a volatile matter-free basis.
Fluoride ... ..	Not more than 30mg. per kg. on a volatile matter-free basis.

*Ammonium ferric citrate*

Synonym ... .. Ferric ammonium citrate.

The criteria in the monograph for ferric ammonium citrate contained in the British Pharmacopoeia 1973 at page 201.

*Ammonium ferric citrate, green*

Synonym ... .. Green ferric ammonium citrate.

The criteria in the monograph for green ferric ammonium citrate contained in the British Pharmaceutical Codex 1954 at page 303.

*Dimethylpolysiloxane*

Synonym ... ..	Dimethyl silicone.
Appearance ... ..	Clear colourless odourless liquid free from extraneous matter.
Solubility ... ..	Insoluble in water. Soluble in most aliphatic and aromatic hydrocarbon solvents.
Volatile matter ... ..	Not more than 2 per centum (determined by drying at 200°C. for 4 hours).
Identification ... ..	Shall comply with the identification tests in the monograph for dimethicone in the British Pharmaceutical Codex 1973 at page 168.
Acidity ... ..	Shall comply with the requirement for acidity in the monograph for dimethicone in the British Pharmaceutical Codex 1973 at page 168.
Total silicon ... ..	Not less than 37.3 and not more than 38.5 per centum.
Refractive index $n_D^{25^\circ\text{C}}$ ... ..	Not less than 1.400 and not more than 1.405.
Viscosity (25°C) ... ..	Not less than 300 and not more than 1050 centistokes.
Relative density $d_{4^\circ\text{C}}^{20^\circ\text{C}}$ ... ..	Not less than 0.960 and not more than 0.980.

*disodium dihydrogen ethylenediamine-NNN'N'-tetra-acetate*

Synonym ... .. Disodium edetate.

The criteria in the monograph for disodium edetate contained in the British Pharmacopoeia 1973 at page 176.

*Calcium disodium ethylenediamine-NNN'N'-tetra-acetate*

Synonym ... .. Sodium calciumedetate.

The criteria in the monograph for sodium calciumedetate contained in the British Pharmacopoeia 1973 at page 425.

*Sodium ferrocyanide*

The criteria in the monograph for sodium ferrocyanide contained in the Food Chemicals Codex 1972 at page 741.

*Potassium ferrocyanide*

Description	...	...	Odourless lemon yellow crystals.
Solubility	...	...	Soluble in water and in acetone. Insoluble in ethanol, in ether and in hydrocarbons.
Content	...	...	Not less than 98 per centum of $K_4Fe(CN)_6 \cdot 3H_2O$ .
Free moisture	...	...	Not more than 1 per centum (determined by the method for free moisture in the monograph for sodium ferrocyanide in the Food Chemicals Codex 1972 at page 741).
Chloride	...	...	Not more than 0.1 per centum.
Sulphate	...	...	Not more than 0.1 per centum.

*Fumaric acid*

The criteria in the monograph for fumaric acid contained in the Food Chemicals Codex 1972 at page 331.

*D-Glucono-1,5-lactone*

Synonym	...	...	Glucono <i>delta</i> -lactone.
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The criteria in the monograph for glucono *delta*-lactone contained in the Food Chemicals Codex 1972 at page 346.

*Sodium gluconate*

The criteria in the monograph for sodium gluconate contained in the Food Chemicals Codex 1972 at page 742.

*Potassium gluconate*

Description	...	...	White free-flowing powder.
Solubility	...	...	Freely soluble in water. Practically insoluble in ethanol and in ether.
Content	...	...	Not less than 97 per centum of $C_6H_{11}O_7K$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 3 per centum (determined by drying in a vacuum at 105°C. for 4 hours).
Reducing substances (expressed as glucose)	...	...	Not more than 0.5 per centum.

*Calcium gluconate*

The criteria in the monograph for calcium gluconate contained in the Food Chemicals Codex 1972 at page 129.

*Glycine*

The criteria in the monograph for glycine contained in the Food Chemicals Codex 1972 at page 359.

*1,4-Heptonolactone*

Synonym	...	...	...	Heptonolactone.
Description	...	...	...	Colourless crystals.
Solubility	...	...	...	Freely soluble in water. Slightly soluble in ethanol. Insoluble in ether.
Content	...	...	...	Not less than 99.5 per centum of $C_7H_{12}O_7$ .
Melting point	...	...	...	148°C.
Specific rotation [ $\alpha$ ] $20^\circ C$ . D				Not less than $-54.0^\circ$ and not more than $-53.0^\circ$ (using a 25 per centum weight/ volume aqueous solution).
Sulphated ash	...	...	...	Not more than 0.1 per centum.

*Sodium heptonate*

Description	...	...	...	White to tan crystalline powder.
Solubility	...	...	...	Sparingly soluble in ethanol. Very soluble in water.
Content	...	...	...	Not less than 98 per centum of $C_7H_{13}O_8Na.2H_2O$ .
Reducing substances (expressed as glucose)				Not more than 0.5 per centum.
Sulphate	...	...	...	Not more than 0.1 per centum.
Chloride	...	...	...	Not more than 0.01 per centum.

*Calcium heptonate*

Description	...	...	...	White crystalline powder.
Solubility	...	...	...	Soluble in water. Insoluble in ethanol.
Content	...	...	...	Not less than 99 per centum of $(C_7H_{13}O_8)_2Ca.2H_2O$ .
Reducing substances (expressed as glucose)				Not more than 0.5 per centum.
Sulphate	...	...	...	Not more than 0.12 per centum.
Chloride	...	...	...	Not more than 0.07 per centum.

*Hydrochloric acid*

The criteria in the monograph for concentrated hydrochloric acid contained in the European Pharmacopoeia Vol. II, 1971 at page 145.

*Ammonium chloride*

The criteria in the monograph for ammonium chloride contained in the Food Chemicals Codex 1972 at page 47.

*Potassium chloriae*

The criteria in the monograph for potassium chloride contained in the Food Chemicals Codex 1972 at page 646.

*Calcium chloride, anhydrous*

The criteria in the monograph for calcium chloride, anhydrous contained in the Food Chemicals Codex 1972 at page 124.

*Calcium chloride*

Description	...	...	...	The dihydrate consists of deliquescent white odourless fragments or granules. The hexahydrate consists of deliquescent colourless and odourless crystals.
Content	...	...	...	Not less than: 98 per centum of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ for the dihydrate; 97 per centum of $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$ for the hexahydrate.
Magnesium and alkali salts				Not more than 2 per centum, determined by the method in the monograph for calcium chloride contained in the Food Chemicals Codex 1972 at page 123 except that the weight of the residue shall not exceed 10mg.
Fluoride	...	...	...	Not more than 40mg. per kg. on an anhydrous basis.

*Hydrogen*

Description	...	...	...	Colourless odourless gas.
Content	...	...	...	Not less than 99.9 per centum volume/volume of hydrogen.
Moisture	...	...	...	Not more than 10 ppm. volume/volume.
Oxygen	...	...	...	Not more than 3 ppm. volume/volume.
Carbon monoxide, carbon dioxide and hydrocarbons	...	...	...	Not more than 10 ppm. volume/volume in total.
Nitrogen	...	...	...	Not more than 100 ppm. volume/volume.
Mercury	...	...	...	Not more than 2mg. per kg.

*Ammonium hydroxide*

The criteria in the monograph for ammonium hydroxide contained in the Food Chemicals Codex 1972 at page 48.

*Sodium hydroxide*

The criteria in the monograph for sodium hydroxide contained in the Food Chemicals Codex 1972 at page 743.

*Magnesium hydroxide*

The criteria in the monograph for magnesium hydroxide contained in the British Pharmaceutical Codex 1973 at page 277.



*Magnesium oxide, heavy*

Description	...	...	White fine odourless powder.
Solubility	...	...	Practically insoluble in water. Soluble in dilute acids with, at most, slight effervescence.
Apparent volume	...	...	20g. of heavy magnesium oxide occupies a volume of about 50ml.
Content	...	...	Not less than 98 per centum of MgO calculated with reference to the ignited substance and determined by the assay method contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol I, 1969 at page 319.
Loss on ignition	...	...	Not more than 5 per centum (determined by ignition at 900°C. to 950°C. to constant weight).
Matter soluble in water	...	...	Not more than 2 per centum, determined by the method for soluble substances contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol I, 1969 at page 319.
Matter insoluble in acetic acid.			Not more than 0.1 per centum when determined by the following method: Dissolve 5g. heavy magnesium oxide in a mixture of 70ml. acetic acid (see note 1) and 30ml. water. Heat to boiling for 2 minutes, cool and dilute to 100ml. with dilute acetic acid (see note 2). Filter through a sintered glass filter. Any residue, after washing with water, drying and ignition at 600°C., shall weigh not more than 5mg.
Sulphate	...	...	Not more than 0.75 per centum.
Chloride	...	...	Not more than 0.07 per centum.
Calcium	...	...	Not more than 2 per centum.
Iron	...	...	Not more than 0.1 per centum.
Arsenic	...	...	Not more than 4mg. per kg.
Heavy metals	...	...	Not more than 40mg. per kg.

*Note 1:* Acetic acid: contains not less than 29 per centum weight/volume and not more than 31 per centum weight/volume of  $C_2H_4O_2$ . Dilute 30g. glacial acetic acid (98 per centum weight/volume  $C_2H_4O_2$ ) to 100 ml. with water.

*Note 2:* Dilute acetic acid: contains not less than 11.5 per centum weight/volume and not more than 12.5 per centum weight/volume of  $C_2H_4O_2$ . Dilute 12g. or 11.7ml. glacial acetic acid (98 per centum weight/volume  $C_2H_4O_2$ ) to 100ml. with water and, if necessary, adjust the concentration of the solution.

*Magnesium oxide, light*

The criteria in the monograph for light magnesium oxide contained in the European Pharmacopoeia Vol. I, 1969 at page 319.

*Potassium hydroxide*

The criteria in the monograph for potassium hydroxide contained in the Food Chemicals Codex 1972 at page 652.

*Calcium hydroxide*

Description	...	...	Soft white powder.
Solubility	...	...	1g. dissolves in 630ml. of water at 25°C. and in 1300ml. of boiling water. Soluble in glycerol and in a saturated solution of sucrose. Insoluble in ethanol.
Content	...	...	Not less than 92 per centum of Ca(OH) <sub>2</sub> .
Matter insoluble in dilute hydrochloric acid (about 10 per centum weight/volume HCl).			Not more than 0.5 per centum.
Magnesium and alkali salts			Not more than 6 per centum, determined by the method in the monograph for calcium hydroxide contained in the Food Chemicals Codex 1972 at page 131 except that the weight of the residue shall not exceed 15mg.
Carbonate	...	...	When 2g. of calcium hydroxide is mixed with 50ml. of water and an excess of dilute hydrochloric acid (approximately 2N) is added, no more than a slight effervescence is produced.
Sulphate	...	...	Not more than 0.35 per centum.
Fluoride	...	...	Not more than 50mg. per kg.

*Calcium oxide*

The criteria in the monograph for calcium oxide contained in the Food Chemicals Codex 1972 at page 138.

*E 270 Lactic acid*

The specific purity criteria for lactic acid contained in Directive 65/66/EEC of the Council(a).

*E 325 Sodium lactate*

Description	...	...	White hygroscopic mass which by absorption of water changes into an almost colourless odourless liquid.
Content	...	...	Not less than 98 per centum of C <sub>3</sub> H <sub>5</sub> O <sub>2</sub> Na (after drying at 105°C. to constant weight).
Acidity	...	...	Neutralisation of 1g. of the sample shall require not more than 0.5ml. of 0.1N sodium hydroxide solution using phenolphthalein as indicator.
Reducing substances	...	...	Sodium lactate shall not cause any reduction of Fehling's solution.

(a) O.J. No. 22, 9.2.65, p. 373/65 (O.J./S.E. 1965-1966, p. 25).

*E 326 Potassium lactate*

Description	...	...	Slightly syrupy almost odourless clear aqueous solution.
Content	...	...	Not less than 57 per centum and not more than 63 per centum of $C_3H_5O_3K$ .
Acidity	...	...	Neutralisation of 1g. of the solution shall require not more than 0.22ml. of 0.1N sodium hydroxide using phenolphthalein as indicator (see note).
Reducing substances	...	...	Potassium lactate shall not cause any reduction of Fehling's solution.

*Note:* The acidity of concentrated aqueous solutions containing more than 63 per centum of  $C_3H_5O_3K$  may be proportionately greater.

*E 327 Calcium lactate*

Description	...	...	Almost odourless crystalline powder or white granules.
Content	...	...	Not less than 98 per centum of $(C_3H_5O_3)_2Ca$ on a volatile matter-free basis.
Acidity	...	...	Neutralisation of 1g of the sample shall require not more than 0.5ml. of 0.1N sodium hydroxide solution using phenolphthalein as indicator.
Volatile matter	...	...	Not more than: 3 per centum for the non-hydrated substance; 8 per centum for the monohydrate; 20 per centum for the trihydrate; 30 per centum for the pentahydrate; (determined by drying at 120°C. for 4 hours).
Reducing substances	...	...	Calcium lactate shall not cause any reduction of Fehling's solution.
Fluoride	...	...	Not more than 30 mg. per kg. calculated on a volatile matter-free basis.

*DL-Malic acid*

The criteria in the monograph for malic acid contained in the Food Chemicals Codex 1972 at page 484.

*L-Malic acid*

Description	...	...	White or nearly white crystalline powder or granules.
Content	...	...	Not less than 99 per centum of $C_4H_6O_5$ .
Melting range	...	...	99°C to 101°C.
Specific rotation $[\alpha]_D^{20}$	...	...	Not less than $-2.4^\circ$ and not more than $-2.2^\circ$ (using a solution containing 8.5g. L-malic acid in 100ml. water).

Maleic acid	...	...	} Shall comply with the limits given in the monograph for malic acid in the Food Chemicals Codex 1972 at page 484.
Fumaric acid	...	...	
Residue on ignition	...	...	
Water insoluble matter	...	...	
<i>Sodium hydrogen malate</i>			
Description	...	...	White odourless powder. Sodium hydrogen malate may be derived from either DL-malic acid or L-malic acid.
Content	...	...	Not less than 99 per centum of $C_4H_5O_5Na$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 2 per centum (determined by drying at $110^\circ C.$ for 3 hours).
Maleic acid	...	...	Not more than 0.05 per centum.
<i>Sodium malate</i>			
Description	...	...	Colourless or almost colourless aqueous solution. Sodium malate may be derived from either DL-malic acid or L-malic acid.
Content	...	...	Not less than 59.5 per centum of $C_4H_4O_5Na_2$ .
Maleic acid	...	...	Not more than 0.05 per centum calculated on the $C_4H_4O_5Na_2$ content.
<i>Potassium malate</i>			
Description	...	...	Colourless or almost colourless aqueous solution. Potassium malate may be derived from either DL-malic acid or L-malic acid.
Content	...	...	Not less than 59.5 per centum of $C_4H_4O_5K_2$ .
Maleic acid	...	...	Not more than 0.05 per centum calculated on the $C_4H_4O_5K_2$ content.
<i>Calcium malate</i>			
Description	...	...	White odourless powder. Calcium malate may be derived from either DL-malic acid or L-malic acid.
Content	...	...	Not less than 97.5 per centum of $C_4H_4O_5Ca$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 2 per centum (determined by drying at $110^\circ C.$ for 3 hours).
Maleic acid	...	...	Not more than 0.05 per centum.
Fluoride	...	...	Not more than 30mg. per kg. on a volatile matter-free basis.

*E 421 Mannitol*

The criteria in the monograph for mannitol contained in the Food Chemicals Codex 1972 at page 496.

*Metatartaric acid*

Description	...	...	White or yellow powder which consists chiefly of a mixture of polyesters obtained by the controlled dehydration of L(+) tartaric acid, together with unchanged L(+) tartaric acid.
Specific absorption 1 per centum $E_{1\text{cm}}^{1\%}$	...	...	Not more than $1.5 \times 10^{-2}$ at 430nm. (determined using a filtered aqueous solution).
Identification	...	...	Place 5 to 10mg. of sample in a test tube. Add 2ml. sulphuric acid (about 94 per centum $\text{H}_2\text{SO}_4$ ) plus two drops of resorcinol reagent (2g. resorcinol dissolved in 100 ml. water plus 0.5 ml. sulphuric acid) and heat to $150^\circ\text{C}$ . An intense violet colour is produced.
Content	...	...	Not less than the equivalent of 105 per centum of tartaric acid ( $\text{C}_4\text{H}_6\text{O}_6$ ). The esterified tartaric acid content shall be not less than 27 per centum and not more than 38 per centum of the tartaric acid equivalent when determined by the following method: Add three drops of bromothymol blue indicator (0.04 per centum weight/volume solution of bromothymol blue in 95 per centum volume/volume ethanol) to 50 ml. of freshly prepared 2 per centum weight/volume cold aqueous solution of metatartaric acid. Titrate with N aqueous sodium hydroxide solution to a blue-green colour ( $T_1$ ml.). Add a further 20 ml. of N aqueous sodium hydroxide solution and leave for 2 hours at room temperature. Titrate with N aqueous sulphuric acid solution ( $T_2$ ml.). Calculations: Tartaric acid equivalent = $7.5 (T_1 + 20 - T_2)$ per centum. Esterified tartaric acid = $\frac{100 (20 - T_2)}{T_1 + 20 - T_2}$ per centum.
Specific rotation $[\alpha]_D^{20^\circ\text{C}}$	...	...	Not less than $+12.5^\circ$ and not more than $+13.5^\circ$ (using a filtered 10 per centum weight/volume aqueous solution).
Matter insoluble in water (at about $20^\circ\text{C}$ .)	...	...	Not more than 2.5 per centum (insoluble matter weighed after drying for 3 hours at $70^\circ\text{C}$ . in a vacuum oven).
Pyruvic acid	...	...	Not more than 0.5 per centum.

*Nicotinic acid*

The criteria in the monograph for nicotinic acid contained in the British Pharmacopœia 1973 at page 318.

*Nitrogen*

The standard for nitrogen type 2 contained in British Standard 4366: 1968.

*Nitrous oxide*

The criteria in the monograph for nitrous oxide contained in the European Pharmacopoeia Vol. II, 1971 at page 316.

*Octadecylammonium acetate*

Synonym	...	...	...	Octadecylamine acetate.
Description	...	...	...	White waxy solid which consists essentially of the acetic acid salts of a mixture of mainly stearyl and palmityl primary aliphatic amines.
Solubility	...	...	...	Soluble in water (above 70°C.) and in mineral and vegetable oils.
Total aliphatic amine acetate	...	...	...	Not less than 98 per centum.
Primary aliphatic amine acetate	...	...	...	Not less than 93 per centum.
Melting range	...	...	...	80°C. to 85°C.
Moisture	...	...	...	Not more than 1 per centum (Karl Fischer).
Iodine value	...	...	...	Not more than 5 (Wijs).

*Oxygen*

The criteria in the monograph for oxygen contained in the European Pharmacopoeia Vol. II, 1971 at page 328.

*Oxystearin*

The criteria in the monograph for oxystearin contained in the Food Chemicals Codex 1972 at page 569 with the additional requirements that the maximum temperature of oxidation during manufacture of the oxystearin shall not exceed 260°C.; the urea non-adduct content of the total fatty acid methyl esters shall not be more than 40 per centum and the epoxide content shall not be more than 50 mg. per kg.

*E 338 Orthophosphoric acid*

Description	...	...	...	Colourless viscous clear liquid.
Content	...	...	...	Not less than 85 per centum of H <sub>3</sub> PO <sub>4</sub> and not more than 15 per centum of water.
Volatile acids (expressed as acetic acid)	...	...	...	Not more than 0.001 per centum on an anhydrous basis.
Nitrate (expressed as NaNO <sub>3</sub> )	...	...	...	Not more than 0.0005 per centum on an anhydrous basis.
Sulphate (expressed as CaSO <sub>4</sub> )	...	...	...	Not more than 0.15 per centum on an anhydrous basis.
Chloride	...	...	...	Not more than 0.02 per centum on an anhydrous basis.
Fluoride	...	...	...	Not more than 10mg. per kg. on an anhydrous basis.

*note:* Values for solutions of different concentrations shall be calculated according to their H<sub>3</sub>PO<sub>4</sub> content.

*Ammonium dihydrogen orthophosphate*

Synonym ... .. Ammonium phosphate, monobasic.

The criteria in the monograph for ammonium phosphate, monobasic contained in the Food Chemicals Codex 1972 at page 50.

*diAmmonium hydrogen orthophosphate*

Synonym ... .. Ammonium phosphate, dibasic.

The criteria in the monograph for ammonium phosphate, dibasic contained in the Food Chemicals Codex 1972 at page 49.

*E 339(a) Sodium dihydrogen orthophosphate*

Synonym ... .. Sodium phosphate, monobasic.

Description ... .. Slightly deliquescent white powder, crystals or granules.

Content ... .. Not less than 97 per centum and not more than 103 per centum of  $\text{NaH}_2\text{PO}_4$  on a volatile matter-free basis.

Volatile matter ... .. Not more than:  
2 per centum for the non-hydrated substance;  
15 per centum for the monohydrate;  
25 per centum for the dihydrate;  
(determined by drying at 60°C. for 1 hour and then at 105°C. for 4 hours).

Matter insoluble in water ... .. Not more than 0.2 per centum on a volatile matter-free basis.

Fluoride ... .. Not more than 10 mg. per kg. on a volatile matter-free basis.

*E 339(b) di Sodium hydrogen orthophosphate*

Synonym ... .. Sodium phosphate, dibasic.

Description ... .. The anhydrous form is a white hygroscopic powder; the dihydrate is a white crystalline solid; the heptahydrate is a granular powder or white efflorescent crystals; the dodecahydrate is a white powder or white efflorescent crystals.

Content ... .. Not less than 98 per centum of  $\text{Na}_2\text{HPO}_4$  on a volatile matter-free basis.

Volatile matter ... .. Not more than:  
5 per centum for the non-hydrated substance;  
21 per centum for the dihydrate;  
50 per centum for the heptahydrate;  
61 per centum for the dodecahydrate;  
(determined by drying at 60°C. for 1 hour and then at 105°C. for 4 hours).

Matter insoluble in water ... .. Not more than 0.2 per centum on a volatile matter-free basis.

Fluoride	...	...	...	Not more than 10 mg. per kg. on a volatile matter-free basis.
<i>E 339(c) triSodium orthophosphate</i>				
Synonym	...	...	...	Sodium phosphate, tribasic.
Description	...	...	...	White powder, crystals or granules. Commercially the substance exists in the anhydrous form and as the monohydrate and the dodecahydrate.
Content	...	...	...	Not less than 97 per centum of $\text{Na}_3\text{PO}_4$ on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than: 2 per centum for the non-hydrated substance; 9 per centum for the monohydrate; 55 per centum for the dodecahydrate; (determined by ignition at 800°C. for 30 minutes).
Matter insoluble in water...				Not more than 0.2 per centum on a volatile matter-free basis.
Fluoride	...	...	...	Not more than 10 mg. per kg. on a volatile matter-free basis.
<i>E 340 (a) Potassium dihydrogen orthophosphate</i>				
Synonym	...	...	...	Potassium phosphate, monobasic.
Description	...	...	...	Colourless crystals or white granular or crystalline powder.
Content	...	...	...	Not less than 98 per centum of $\text{KH}_2\text{PO}_4$ on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than 2 per centum (determined by drying at 105°C. for 4 hours).
Matter insoluble in water				Not more than 0.2 per centum on a volatile matter-free basis.
Fluoride	...	...	...	Not more than 10 mg. per kg. on a volatile matter-free basis.
<i>E 340 (b) diPotassium hydrogen orthophosphate</i>				
Synonym	...	...	...	Potassium phosphate, dibasic.
Description	...	...	...	Deliquescent, colourless or white granules.
Content	...	...	...	Not less than 98 per centum of $\text{K}_2\text{HPO}_4$ on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than 2 per centum (determined by drying at 105°C. for 4 hours).
Matter insoluble in water				Not more than 0.2 per centum on a volatile matter-free basis.
Fluoride	...	...	...	Not more than 10 mg. per kg. on a volatile matter-free basis.



*E 340 (c) triPotassium orthophosphate*

Synonym ... ..	Potassium phosphate, tribasic.
Description ... ..	White hygroscopic crystals or granules. Commercially the substance exists in the anhydrous form and as the hygroscopic hydrate.
Content ... ..	Not less than 97 per centum of $K_3PO_4$ on a volatile matter-free basis.
Volatile matter ... ..	Not more than: 3 per centum for the non-hydrated substance; 20 per centum for the hydrated substance; (determined by ignition at 800°C. for 30 minutes).
Matter insoluble in water	Not more than 0.2 per centum on a volatile matter-free basis.
Fluoride ... ..	Not more than 10 mg. per kg. on a volatile matter-free basis.

*E 341 (a) Calcium tetrahydrogen diorthophosphate*

Synonyms ... ..	Calcium phosphate, monobasic. Acid calcium phosphate.
Description ... ..	Deliquescent white granules, granular powder or crystals.
Content ... .. (expressed as CaO)	Not less than 23.0 per centum and not more than 25.0 per centum for the non-hydrated substance. Not less than 22.2 per centum and not more than 24.7 per centum for the monohydrate.
Volatile matter ... ..	Not less than 14.0 per centum and not more than 15.5 per centum for the non-hydrated substance (determined by ignition at 800°C. for 30 minutes). Not more than 0.6 per centum for the monohydrate (determined by drying at 60°C. for 3 hours).
Fluoride ... ..	Not more than 30 mg. per kg. on an anhydrous basis.

*E 341 (b) Calcium hydrogen orthophosphate*

Synonym ... ..	Calcium phosphate, dibasic.
Description ... ..	Impalpable white powder.
Content ... .. (expressed as CaO)	Not less than 39.0 per centum and not more than 42.0 per centum for the non-hydrated substance. Not less than 31.9 per centum and not more than 33.5 per centum for the dihydrate.

Volatile matter	...	...	Not less than 7.0 per centum and not more than 8.5 per centum for the non-hydrated substance. Not less than 24.5 per centum and not more than 26.5 per centum for the dihydrate. (determined by ignition at 800°C. to 825°C. to constant weight).
Fluoride	...	...	Not more than 50 mg. per kg. on an anhydrous basis.

*E 341(c) tri-Calcium diorthophosphate*

Synonym	...	...	Calcium phosphate, tribasic.
Description	...	...	Impalpable white powder.
Content	...	...	Not less than 90 per centum of $\text{Ca}_3(\text{PO}_4)_2$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 10 per centum (determined by ignition at 800°C. to 825°C. to constant weight).
Fluoride	...	...	Not more than 50 mg. per kg. on a volatile matter-free basis.

*Calcium hydroxyphosphate*

Synonym	...	...	Hydroxy-apatite.
Description	...	...	Impalpable white powder.
Content	...	...	Not less than 90 per centum of $3\text{Ca}_3(\text{PO}_4)_2 \cdot \text{Ca}(\text{OH})_2$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 10 per centum (determined by ignition at 800°C. to 825°C. to constant weight).
Fluoride	...	...	Not more than 50 mg. per kg. on a volatile matter-free basis.

*Sodium aluminium phosphate, acidic*

The criteria in the monograph for sodium aluminium phosphate, acidic contained in the Food Chemicals Codex 1972 at page 722.

*Sodium aluminium phosphate, basic*

The criteria in the monograph for sodium aluminium phosphate, basic contained in the Food Chemicals Codex 1972 at page 724.

*E 450(a) diSodium dihydrogen diphosphate*

Synonyms	...	...	<i>di</i> Sodium dihydrogen pyrophosphate Sodium acid pyrophosphate Acid sodium pyrophosphate.
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The criteria in the monograph for sodium acid pyrophosphate contained in the Food Chemicals Codex 1972 at page 719.

*E 450(a) tetraSodium diphosphate*

Synonyms	...	...	<i>tetra</i> Sodium pyrophosphate Sodium pyrophosphate.
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The criteria in the monograph for sodium pyrophosphate contained in the Food Chemicals Codex 1972 at page 762 with the additional requirement that the fluoride content shall not be greater than 10 mg. per kg.

*E450(a) tetraPotassium diphosphate*

Synonyms ... .. *tetra*Potassium pyrophosphate  
Potassium pyrophosphate.

The criteria in the monograph for potassium pyrophosphate contained in the Food Chemicals Codex 1972 at page 667.

*diCalcium diphosphate*

Synonyms ... .. *di*Calcium pyrophosphate  
Calcium pyrophosphate.

The criteria in the monograph for calcium pyrophosphate contained in the Food Chemicals Codex 1972 at page 153.

*E 450(b) pentaSodium triphosphate*

Synonyms ... .. Sodium tripolyphosphate  
Sodium triphosphate.

The criteria in the monograph for sodium tripolyphosphate contained in the Food Chemicals Codex 1972 at page 780 with the additional requirement that the fluoride content shall not be greater than 10 mg. per kg.

*E 450(b) pentaPotassium triphosphate*

Synonyms ... .. Potassium tripolyphosphate  
Potassium triphosphate.

Description ... .. Fine white powder.

Solubility ... .. Gives a slightly cloudy solution in water.

Content  
(expressed as P<sub>2</sub>O<sub>5</sub>) ... Not less than 47 per centum.  
(expressed as K<sub>2</sub>O) ... Not less than 51 per centum.

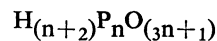
pH (1 per centum aqueous solution) ... .. Not less than 9·6 and not more than 10·2.

Fluoride ... .. Not more than 10 mg. per kg.

*Ammonium, sodium, potassium and calcium polyphosphates*

Description ... .. Ammonium, sodium, potassium and calcium polyphosphates exist as fine white powders or crystals or colourless glassy platelets.

They are reproducible heterogenous mixtures of ammonium or sodium or potassium or calcium salts, or mixtures thereof, of condensed polyphosphoric acids of general formula:



where n shall be not less than 2.

Content (expressed as P<sub>2</sub>O<sub>5</sub>) Not less than 50 per centum and not more than 71 per centum on an anhydrous basis.

pH (1 per centum aqueous solution). For water soluble phosphates only: not less than 4·0 and not more than 9·0.

Cyclic phosphate ... .. Not more than 8 per centum calculated on the P<sub>2</sub>O<sub>5</sub> content.

Fluoride ... .. Not more than 15 mg. per kg. calculated on the P<sub>2</sub>O<sub>5</sub> content.

*Edible bone phosphate*

Description	...	...	Edible bone phosphate is a pale cream-coloured powder, prepared from selected animal bones which are crushed, degreased and then subjected to a high pressure steam extraction. The main constituent is hydroxy-apatite with some carbonate-apatite and a trace of fluoro-apatite.
Content (expressed as CaO) (expressed as P <sub>2</sub> O <sub>5</sub> )			Not less than 45 per centum. Not less than 34 per centum.
Fluoride	...	...	Total: Not more than 700 mg. per kg. Water soluble: Not more than 2 mg. per kg.
Copper	...	...	Not more than 25 mg. per kg.
Zinc	...	...	Not more than 150 mg. per kg.

*Shellac*

The standard for machine-made shellac contained in British Standard 3722:1964.

*Silicon dioxide*

Synonym	...	...	Silica, chemically prepared.
Description	...	...	Silica aerogel is a white fluffy powdered or granular microcellular silica. Hydrated silica is a precipitated hydrated silicon dioxide occurring as a fine white amorphous powder or as beads or granules.
Content	...	...	Silica aerogel: Not less than 90 per centum of SiO <sub>2</sub> . Hydrated silica: Not less than 91 per centum of SiO <sub>2</sub> on a volatile matter-free basis.
Volatile matter	...	...	Hydrated silica: Not more than 7 per centum (determined by drying at 105°C. for 2 hours).
Loss on ignition	...	...	Not more than 13 per centum (determined by ignition at 1000°C. to constant weight).
Soluble ionisable salts (expressed as Na <sub>2</sub> SO <sub>4</sub> )			Not more than 5 per centum.

*Bentonite*

The criteria in the monograph for bentonite contained in the British Pharmacopoeia 1973 at page 47.

*Kaolin, heavy*

The criteria in the monograph for heavy kaolin contained in the British Pharmacopoeia 1968 at page 538 as amended by the 1969 Addendum at page 54.

*Kaolin, light*

The criteria in the monograph for light kaolin contained in the British Pharmacopoeia 1968 at page 539 as amended by the 1969 Addendum at page 54.

*Aluminium sodium silicate*

Synonyms ... ..	Sodium aluminium silicate. Sodium aluminosilicate. Sodium silicoaluminate.
Description ... ..	Fine white amorphous powder or beads.
Content (expressed as SiO <sub>2</sub> )	Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.
(expressed as Al <sub>2</sub> O <sub>3</sub> )	Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed as Na <sub>2</sub> O)	Not less than 5 per centum and not more than 10 per centum on a volatile matter-free basis.
Volatile matter ... ..	Not more than 8 per centum (determined by drying at 105°C. for 2 hours).
Loss on ignition ... ..	Not less than 10 per centum and not more than 14 per centum (determined by ignition at 1000°C. to constant weight).

*Aluminium calcium silicate*

Synonyms ... ..	Calcium aluminium silicate. Calcium aluminosilicate. Calcium silicoaluminate.
Description ... ..	Fine white free-flowing powder.
Content (expressed as SiO <sub>2</sub> )	Not less than 44 per centum and not more than 50 per centum on a volatile matter-free basis.
(expressed as Al <sub>2</sub> O <sub>3</sub> )	Not less than 3 per centum and not more than 5 per centum on a volatile matter-free basis.
(expressed as CaO)	Not less than 32 per centum and not more than 38 per centum on a volatile matter-free basis.
(expressed as Na <sub>2</sub> O)	Not less than 0.5 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter ... ..	Not more than 10 per centum (determined by drying at 105°C. for 2 hours).
Loss on ignition ... ..	Not less than 14 per centum and not more than 18 per centum (determined by ignition at 1000°C. to constant weight).

*Calcium silicate*

Description ... ..	White to off-white free-flowing powder.
Solubility ... ..	Insoluble in water. Forms a gel with mineral acids.

Content (expressed as SiO <sub>2</sub> )	Not less than 72 per centum and not more than 78 per centum on a volatile matter-free basis.
(expressed as CaO)	Not less than 16 per centum and not more than 21 per centum on a volatile matter-free basis.
(expressed as Na <sub>2</sub> O)	Not less than 2 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter ... ..	Not more than 6 per centum (determined by drying at 105°C. for 2 hours).
Loss on ignition ... ..	Not less than 7 per centum and not more than 14 per centum (determined by ignition at 1000°C. to constant weight).

*Magnesium silicate, synthetic*

The criteria in the monograph for magnesium silicate contained in the Food Chemicals Codex 1972 at page 479.

*Magnesium trisilicate*

The criteria in the monograph for magnesium trisilicate contained in the British Pharmacopoeia 1973 at page 276.

*Talc*

Description ... ..	Talc is a native hydrous magnesium silicate sometimes containing a small proportion of aluminium silicate.
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It shall comply with the requirements for appearance, characteristics and limits of impurities in the monograph for magnesium silicate contained in the Nutrition Meetings Report Series 46B 1970 of the Food and Agriculture Organisation of the United Nations at page 114. The amount of material soluble in dilute hydrochloric acid shall be not more than 2 per centum and the amount of water soluble substances shall be not more than 0.2 per centum.

*E 420 Sorbitol*

Descriptions ... ..	(a) Sorbitol is a sweet-tasting white hygroscopic crystalline powder. (b) Sorbitol solution and (c) non-crystallising sorbitol solution are sweet-tasting clear colourless liquids.
Contents ... ..	(a) Sorbitol contains not less than 98 per centum of glycitols (see note 1) and related higher polyols derived from sugars (see note 2), and not less than 91 per centum of D-sorbitol, on a volatile matter-free basis in each case. (b) Sorbitol solution is an aqueous solution of sorbitol which complies with the description at (a), containing not less than 69 per centum of total solids. (c) Non-crystallising sorbitol solution is an aqueous solution containing not less than 69 per centum total solids and not less than 60 per centum of D-sorbitol, the remaining solids being glycitols other than D-sorbitol, related higher polyols derived from sugars, and sugars.

Volatile matter	...	...	For (a) only: Not more than 1.5 per centum determined by drying in a vacuum at 80°C. for 6 hours.
Sulphated ash	...	...	Not more than 0.1 per centum on a dry-matter basis, for (a), (b) and (c).
Chloride	...	...	Not more than 0.005 per centum on a dry-matter basis, for (a), (b) and (c).
Reducing sugars (expressed as glucose)	...	...	Not more than 0.3 per centum on a dry-matter basis, for (a) and (b).
Total sugars (expressed as glucose)	...	...	Not more than 0.7 per centum on a dry-matter basis, for (a) and (b).

*note 1:* "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.

*note 2:* "Sugars" means any soluble carbohydrate sweetening matter.

*Spermaceti*

The criteria in the monograph for spermaceti contained in the British Pharmaceutical Codex 1968 at page 773.

*Sperm Oil*

The standard for filtered sperm oil contained in Part 2 of British Standard 997: 1963.

*Magnesium stearate*

The criteria in the monograph for magnesium stearate contained in the British Pharmacopoeia 1973 at page 275.

*Calcium stearate*

The criteria in the monograph for calcium stearate contained in the Food Chemicals Codex 1972 at page 158 except that for the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for salts of fatty acids and fatty acids from edible fat sources) there shall be substituted the requirement that calcium stearate shall be prepared using commercial food-grade stearic acid.

*Butyl stearate*

Description	...	...	White solid with a slightly yellow tinge; melts at about room temperature to a clear liquid and consists chiefly of the butan-1-ol ester of commercial food-grade stearic acid.
Solidification point	...	...	Between 14°C. and 26°C.
Saponification value	...	...	Not less than 160 and not more than 180.
Iodine value	...	...	Not more than 7 (Wijs).
Acid value	...	...	Not more than 2.5 mg. KOH per g.

*Succinic acid*

The criteria in the monograph for succinic acid contained in the Food Chemicals Codex 1972 at page 800.

*Sulphuric acid*

The criteria in the monograph for sulphuric acid contained in the Food Chemicals Codex 1972 at page 802.

*Ammonium sulphate*

The criteria in the monograph for ammonium sulphate contained in the Food Chemicals Codex 1972 at page 52.

*Sodium sulphate*

The criteria in the monograph for sodium sulphate contained in the Food Chemicals Codex 1972 at page 775.

*Magnesium sulphate*

The criteria in the monograph for magnesium sulphate contained in the European Pharmacopoeia Vol I, 1969 at page 324.

*Potassium sulphate*

The criteria in the monograph for potassium sulphate contained in the Food Chemicals Codex 1972 at page 670.

*Aluminium potassium sulphate*

Synonyms	...	...	Potassium aluminium sulphate. Potash alum.
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The criteria in the monograph for alum contained in the European Pharmacopoeia Vol. I, 1969 at page 243.

*Calcium sulphate*

The criteria in the monograph for calcium sulphate contained in the Food Chemicals Codex 1972 at page 163.

*Tannic acid*

Synonym	...	...	...	Tannin.
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The criteria in the monograph for tannins contained in the Nutrition Meetings Report Series 48B 1971 of the Food and Agriculture Organisation of the United Nations at page 41.

*E 334 Tartaric acid*

Description	...	...	Tartaric acid, which may be either the L(+) form or the DL form, occurs as a white crystalline powder or as colourless or translucent crystals.	
Content	...	...	...	Not less than 99.5 per centum of $C_4H_6O_6$ on a volatile matter-free basis.
Volatile matter	...	...	...	Not more than 0.5 per centum (determined by drying at 105°C. to constant weight).
Sulphated ash	...	...	...	Not more than 0.1 per centum on a volatile matter-free basis.
Oxalates (expressed as oxalic acid)	...	...	...	Not more than 0.05 per centum on a volatile matter-free basis.



*E 335 Sodium tartrate*

Description	...	...	Colourless transparent crystals. Sodium tartrate may be derived from either DL-tartaric acid or L(+) tartaric acid.
Content	...	...	Not less than 99 per centum of $C_4H_4O_6Na_2$ on a volatile matter-free basis.
Volatile matter	...	...	Not less than 14 per centum and not more than 17 per centum for the dihydrate (determined by drying at 150°C. for 3 hours).
Oxalates (expressed as oxalic acid)			Not more than 0.05 per centum on a volatile matter-free basis.

*E 336 Potassium tartrate*

Description	...	...	White crystalline or granular powder. Potassium tartrate may be derived from either DL-tartaric acid or L(+) tartaric acid.
Content	...	...	Not less than 99 per centum of $C_4H_4O_6K_2$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 4 per centum (determined by drying at 160°C. to constant weight).
Oxalates (expressed as oxalic acid)			Not more than 0.05 per centum on a volatile matter-free basis.

*E 336 Potassium hydrogen tartrate*

Synonyms	...	...	Potassium acid tartrate. Cream of Tartar.
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The criteria in the monograph for potassium acid tartrate contained in the Food Chemicals Codex 1972 at page 639, except that potassium acid tartrate may be derived from either DL-tartaric acid or L(+) tartaric acid.

*E 337 Potassium sodium tartrate*

Synonym	...	...	Sodium potassium tartrate.
Description	...	...	Colourless crystals or a white crystalline powder. Potassium sodium tartrate may be derived from either DL-tartaric acid or L(+) tartaric acid. Commercially the product occurs as the tetrahydrate.
Content	...	...	Not less than 99 per centum of $C_4H_4O_6KNa$ on a volatile matter-free basis.
Volatile matter	...	...	Not more than 26 per centum for the tetrahydrate (determined by drying at 150°C. for 3 hours).
Oxalates (expressed as oxalic acid)			Not more than 0.05 per centum on a volatile matter-free basis.

## PART III

*General purity criteria applicable to permitted miscellaneous additives except where otherwise provided by specific purity criteria*

Each miscellaneous additive shall not contain—

- (a) more than 3 milligrams per kilogram of arsenic ;
- (b) more than 10 milligrams per kilogram of lead ;
- (c) more than 50 milligrams per kilogram of copper, or 25 milligrams per kilogram of zinc, or 50 milligrams per kilogram of any combination of copper and zinc.

**SCHEDULE 2**  
**MISCELLANEOUS ADDITIVES PERMITTED ONLY IN CERTAIN FOODS**

Regulation 4

Column 1	Column 2	Column 3
Specified food	Permitted Miscellaneous Additive	Except where otherwise stated, milligrams per kilogram not exceeding—
Ammonium chloride ... ..	Octadecylammonium acetate	500
Brandy ... ..	<i>dl</i> Sodium dihydrogen ethylenediamine- <i>NNN'N'</i> -tetra-acetate	25 milligrams per litre.
Canned fish ... ..	Calcium disodium ethylenediamine- <i>NNN'N'</i> -tetra-acetate	In accordance with good manufacturing practice.
Canned shellfish ... ..	Calcium disodium ethylenediamine- <i>NNN'N'</i> -tetra-acetate	In accordance with good manufacturing practice.
Chocolate confectionery ... ..	Carnauba wax	200
Glacé cherries ... ..	Calcium disodium ethylenediamine- <i>NNN'N'</i> -tetra-acetate	In accordance with good manufacturing practice.
Sugar confectionery ... ..	Aluminium potassium sulphate	10,000 (on a dry matter basis).
Wine ... ..	Carnauba wax	200
	Metatartaric acid	100 milligrams per litre.

## Regulation 5(2)

## SCHEDULE 3

## LABELLING OF PERMITTED MISCELLANEOUS ADDITIVES

1. Each container to which regulation 5(2) of these regulations applies shall bear a label on which is printed a true statement,—
  - (a) in respect of each permitted miscellaneous additive present, of the serial number, if any, as specified in relation thereto in column 2 of Part I of Schedule 1 to these regulations, and of the common or usual name or an appropriate designation of that permitted miscellaneous additive ;
  - (b) where any other substance or substances is or are present, of the common or usual name or an appropriate designation of each such substance ; and
  - (c) if two or more such substances are present, of the proportion of each permitted miscellaneous additive and each other substance present save that the label shall only have printed on it a statement of the proportion of any such other substance present if any regulations (other than these regulations) or any amendment to these regulations) made under the Act contain a requirement to that effect.
2. Any statement required by the preceding paragraph—
  - (a) shall be clear and legible ;
  - (b) shall be in a conspicuous position on the label which shall be marked on, or securely attached to, the container in such a manner that it will be readily discernible and easily read by an intending purchaser under normal conditions of purchase ;
  - (c) shall not be in any way hidden or obscured or reduced in conspicuousness by any other matter, whether pictorial or not, appearing on the label.
3. The figures and letters in every word in any statement to which the preceding paragraph applies—
  - (a) shall be in characters of uniform colour and size (being not less than 1.5 millimetres in height for a label on a container of which the greatest dimension does not exceed 12 centimetres, and not less than 3 millimetres in height for a label on a container of which the greatest dimension exceeds 12 centimetres), but so that the initial letter of any word may be taller than any other letter in the word ;
  - (b) shall appear on a contrasting ground, so however that where there is no ground other than such as is provided by a transparent container and the contents of that container are visible behind the letters, those contents shall be taken to be the ground for the purposes of this paragraph ;
  - (c) shall be within a surrounding line and no other written or pictorial matter shall appear within that line.
4. For the purposes of this Schedule—
  - (a) the height of any lower case letter shall be taken to be the x-height thereof, disregarding any ascender or descender thereof ;
  - (b) any requirement that figures or letters shall be of uniform height, colour or size, shall be construed as being subject to the saving that any inconsiderable variations in height, colour or size, as the case may be, may be disregarded.

## EXPLANATORY NOTE

*(This Note is not part of the Regulations.)*

These Regulations, which apply to England and Wales only, come into operation on 1st August 1974.

The regulations implement, in part, Council Directive of 23rd October 1962 (OJ No. 115, 11.11.62, p. 2645/62: OJ/SE 1959-1962 p. 279) on the approximation of the rules of Member States concerning colouring matters authorised for use in food intended for human consumption, as amended; Council Directive No. 64/54/EEC (OJ No. 12, 27.1.64, p. 161: OJ/SE 1963-1964, p. 99) on the approximation of the laws of Member States covering the preservatives authorised for use in foodstuffs intended for human consumption, as amended in particular by Council Directive No. 68/420/EEC (OJ No. L309, 24.12.68, p. 25; OJ/SE 1968 (II) p. 598), Council Directive No. 70/359/EEC (OJ No. L157, 18.7.70, p. 38: OJ/SE 1970 (II) p. 436), Council Directive No. 72/2/EEC (OJ No. L2, 4.1.72, p. 22: OJ/SE 1972 (I) p. 11) and Council Directive No. 72/444/EEC (OJ No. L298, 31.12.72, p. 48: OJ/SE 1972 (30-31 Dec.) p. 75); Council Directive No. 65/66/EEC (OJ No. 22, 9.2.65, p. 373/65: OJ/SE 1965-1966 p. 25) laying down specific criteria of purity for preservatives authorised for use in foodstuffs intended for human consumption, as amended; Council Directive No. 70/357/EEC (OJ No. L157, 18.7.70, p. 31: OJ/SE 1970 (II) p. 429) on the approximation of the laws of Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption; and the Act annexed to the Treaty of Accession to the European Economic Community (Annex I: XI; Annex VII: IX and Annex XI: X).

The regulations—

- (a) specify permitted miscellaneous additives and prescribe purity criteria for those miscellaneous additives (regulation 2(1) and Schedule 1);
- (b) prohibit the sale or importation of food having in it or on it any added miscellaneous additive other than a permitted miscellaneous additive and limit the use of certain particular miscellaneous additives to specified foods subject to prescribed limits (regulation 4(1), 4(2) proviso (a); 4(3) and Schedule 2);
- (c) permit food containing as an added ingredient any specified food described in Schedule 2 to contain miscellaneous additives of a description, and to an amount, specified in that Schedule for that ingredient (regulation 4(2) proviso (b));
- (d) prohibit the importation, sale or advertising for sale, for use as an ingredient in the preparation of food, of any miscellaneous additive other than a permitted miscellaneous additive (regulation 5(1));
- (e) prescribe labelling requirements for permitted miscellaneous additives when sold as such (regulation 5(2) and Schedule 3);
- (f) make consequential amendments to the Labelling of Food Regulations 1970, as amended (regulation 10).

The regulations do not apply to any miscellaneous additive or to any food having a miscellaneous additive in it or on it which is sold, consigned, delivered or imported for export (regulation 3).

The Food Chemicals Codex 1972 and the European Pharmacopoeia Volume I, 1969 and Volume II, 1971 referred to in regulation 2(1) and Part II of Schedule 1 may be inspected at the Science Reference Library (Holborn Division), 25 Southampton Buildings, Chancery Lane, London WC2A 1AW (telephone 01-405 8721), or at Liverpool City Libraries, William Brown Street, Liverpool, L3 8EW (telephone 051-207 2147). Copies of the European Pharmacopoeia can be obtained from the Pharmaceutical Press, 17 Bloomsbury Square, London WC1A 2NN.

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