Subsidiary Legislation made under ss. 6, 8 and 58.

Miscellaneous Additives in Food Regulations, 1987

LN.1987/044

Commencement **1.8.1987**

Amending enactments	Relevant current provisions	Commencement date
LN. 1990/053	r. 2	1.7.1990

ARRANGEMENT OF REGULATIONS

Regulation

Title and commencement.

1.(1) These regulations may be cited as the Miscellaneous Additives in Food Regulations, 1987.

(2) These regulations shall come into operation on the 1st day of August, 1987.

Interpretation.

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

"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;

"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;

"bulking aid" means any substance, other than air, water or chewing gum base, which is capable, and generally used for the purpose, of-

(a) contributing to the bulk of food without contributing significantly to its available energy value, or

(b) producing bulk upon ingestion;

"chocolate product" has the meaning assigned to it by the Cocoa and Chocolate Products Regulations 1987;

"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;

"dietetic food" means any food which-

(a) has been specially made for a class of persons whose digestive process or metabolism is disturbed or who, by reason of their special physiological conditions, obtain special benefit from a controlled consumption of certain substances, and

(b) is suitable for fulfilling the particular nutritional requirements of that class of persons;

"European Pharmacopoeia Volume I, 1969" and "European Pharmacopoeia Volume II, 1971" mean respectively Volume I of the European Pharmacopoeia published in 1969 and Volume 1! 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;

"flavour modifier" means any substance which is capable of enhancing, reducing or otherwise modifying the taste or odour, or both, of a food, but does not include enzymes or water or any substance primarily used to impart taste or odour, or both, to a food;

"flour bleaching agent" means any substance which is capable, and generally used for the purpose, of removing colour from flour;

"flour improver" means L-Cysteine hydrochloride and sulphur dioxide or sodium metabisuiphite when used as prescribed by the Bread and Flour Regulations 1987 and any substance which is capable, and generally used for the purpose, of simulating the effects produced by the natural ageing of flour;

"food" has the same meaning as in the Act, except that it is limited to food intended for sale for human consumption;

"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;

"Food Chemicals Codex 1981" means the edition of the Food Chemicals Codex published in 1981 by the National Academy Press, 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 providing a protective coating;

"humectant" means any substance which is capable of offsetting 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, 1987.

"miscellaneous additive" means any acid, anti-caking agent, anti-foaming agent, base, buffer, bulking aid, firming agent, flavour modifier, flour bleaching agent, flour improver, 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 sweetener,

(d) any permitted colouring matter,

(e) any permitted emulsifier,

(f) any permitted preservative,

(g) any permitted solvent,

(h) any permitted stabiliser,

(i) starches, whether modified or not,

(j) caseinates,

(k) proteins, protein concentrates and protein hydrolysates,

(l) sodium chloride,

(m) 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;

"the Act" means the Food and Drugs Act;

"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 Antioxidants in Food Regulations 1987;

"permitted colouring matter" means any colouring matter in so far as its use is permitted by the Colouring Matter in Food Regulations 1980;

"permitted emulsifier" means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1990;

"permitted miscellaneous additive" means any miscellaneous additive specified in Part I of Schedule I 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 1987;

"permitted solvent" means any solvent in so far as its use is permitted by the Solvents in Food Regulations 1987;

"permitted stabiliser" means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1990;

"permitted sweetener" means any sweetener in so far as its use is permitted by the Sweeteners in Food Regulations 1987;

"propellant" 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;

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

(3) 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.

(4) 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.

(5) Any reference in these regulations to a numbered regulation or schedule shall, unless the reference is to a regulation of, or schedule to, specified regulations, be construed as a reference to the regulation or schedule bearing that number in these 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 or importation, as the case may be, for exportation to any place outside Gibraltar.

Sale etc. of food containing miscellaneous additives.

4.(1) Subject to paragraph (2) of this regulation, no food sold or imported shall have in it or on it any added miscellaneous additive other than a permitted miscellaneous additive:

Provided that any dietetic food may have in it or on it added L-glutamic acid, potassium hydrogen L-glutamate or calcium dihydrogen di-L-glutamate.

(2) Save as hereinafter provided, no food sold or imported shall have in it or on it any added permitted miscellaneous additive specified in column 2 of Schedule 2:

Provided that, subject to regulation 6-

(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;

(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 sub-paragraph of this proviso.

(3) No person shall sell or import any food which does not comply with this regulation.

Sale, advertisement and labelling of miscellaneous additives.

5.(1) No person shall sell, import 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 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.

Food for babies and young children.

6. No person shall sell any food that is specially prepared for babies or young children if it has in it or on it any added 2-aminoethanol, alpha-cellulose, sodium hydrogen L-glutamate, guanosine 5-(disodium phosphate), inosine 5-(disodium phosphate), polydextrose or sodium 5-ribonucleotide.

Condemnation of Food.

7. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell or import, that food may be treated for the purposes of section 10 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

8. 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 on summary conviction to a fine not exceeding £1,000.

Defences

9.(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.

Applications of various sections of the Act

10. Sections 46(2) and (3) (which relate to prosecutions), 47(1) and (2) (which relate to evidence of analysis), 49 (which relates to the power of a court to require analysis by the Government Chemist in the United Kingdom), 50 (which relates to a contravention due to some person other than the person charged), 51(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 52 (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 49 to subsection (3) of Section 46 included a reference to that subsection as applied by these regulations.

Schedule 1

Part 1: Permitted Miscellaneous Additives

Column 1 *Name of Miscellaneous Additive*	*Column 2* *Serial number*
Acetic acid	E260
Sodium acetate, anhydrous	
Sodium acetate	
Sodium hydrogen diacetate	E262
Potassium acetate	E261
Calcium acetate	E263
Adipic acid	
2-Aminoethanol	
Azodicarbonamide	E927
Beeswax, white	
Beeswax, yellow	
Benzoyl peroxide	
Potassium bromate	E924
Calcium phytate	
Carbon dioxide	E290
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	E170
Carnauba wax	
Alpha-cellulose	E460(ii)
Chlorine	E925
Chlorine dioxide	E926
Citric acid	E330
triAmmonium citrate	
Sodium dihydrogen citrate	E331
diSodium citrate	E331
tnSodium citrate	E331
Potassium dihydrogen citrate	E332
triPotassium citrate	E332
monoCalcium citrate	E333

diCalcium citrate	E333
triCalcium citrate	E333
Ammonium ferric citrate	
Ammonium ferric citrate, green	
L-Cysteine hydrochloride	E920
Dichlorodifluoromethane	
Dimethylpolysiloxane	
diSodium dihydrogen ethylenediaminc-NNN'N' tetra-acetate	
Calcium disodium ethylenediamine-NNN'N' tetra acetate	
Calcium disodium ethylenediamine-NNN'N' tetra acetate	
Sodium ferrocyanide	
Potassium ferrocyanide	
Fumaric acid	
D-Glucono-1 5-lactone	
Sodium gluconate	
Potassium gluconate	
Calcium gluconate	
Sodium hydrogen L-glutamate	
Glycine	
1 ,4-Heptonolactone	
Sodium heptonate	
Calcium heptonate	
Hydrocholoric acid	
Ammonium chloride	
Potassium chloride	
Calcium chloride, anhydrous	
Calcium chloride	
Hydrogen	
Ammonium hydroxide	
Sodium hydroxide	
Magnesium hydrdxide	
Magnesium oxide, heavy	
Magnesium oxide, light	
Potassium hydroxide	
Calcium hydroxide	
Calcium oxide	
Lactic acid	E270
Sodium lactate	E325
Potassium lactate	E326
Calcium lactate	E327
DL-Malic acid	
L-Malic acid	
Sodium hydrogen malate	

Sodium malate	
Potassium malate	
Calcium hydrogen malate	
Calcium malate	
Metatartaric acid	
Nicotinic acid	
Nitrogen	
Nitrous oxide	
Octadecylammonium acetate	
Oxygen	
Oxystearin	
Orthophosphoric acid	E338
Ammonium dihydrogen orthophosphate	
diAmmonium hydrogen orthophosphate	
Sodium dihydrogen orthophosphate	E339
diSodium hydrogen orthophosphate	E339
triSodium orthophosphate	E339
Potassium dihydrogen orthophosphate	E340
diPotassium hydrogen orthophosphate	E340
triPotassium orthophosphate	E340
Calcium tetrahydrogen diorthophosphate	E341
Calcium hydrogen orthophosphate	E341
triCalcium diorthophosphate	E341
Sodium aluminium phosphate, acidic	
Sodium aluminium phosphate, basic	
diSodium dihydrogen diphosphate	E450(a)
triSodium diphosphate	E450(a)
tetraSodium diphosphate	E450(a)
tetraPotassium diphosphate	E450(a)
diCalcium diphosphate	
pentaSodium triphosphate	E450(b)
pentaPotassium triphosphate	E450(b)
Sodium polyphosphates	E450(c)
Potassium polyphosphates	E450(c)
Ammonium and calcium polyphosphates	
Edible bone phosphate	
Guanosine 5'-(disodium phosphate)	
Inosine 5'-(disodium phosphate)	
Polydextrose	
Sodium 5'-ribonucl~otide	
Shellac	
Silicon dioxide	
Bentonite	

Kaolin, heavy	
Kaolin, light	
Aluminium sodium silicate	
Aluminium calcium silicate	
Calcium silicate	
Magnesium silicate, synthetic	
Magnesium trisilicate	
Talc	
Spermaceti	
Sperm oil	
Magnesium stearate	
Calcium stearate	
Butyl stearate	
Succinic acid	
Sulphuric acid	
Ammonium sulphate	
Sodium sulphate	
Magnesium sulphate	
Potassium sulphate	
Aluminium potassium sulphate	
Calcium sulphate	
Tannic acid	
L-(+)-Tartaric acid	E334
DL-Tartaric acid	
monoSodium L-(+)-tartrate	E335
monoSodium DL-tartrate	
diSodium L-(+)-tartrate	E335
diSodium DL-tartrate	
monoPotassium L-(+)-tartrate	E336
monoPotassium DL-tartrate	
diPotassium L-(+)-tartrate	E336
diPotassium DL-tartrate	
Potassium sodium L-(+)-tartratc	E337
Potassium sodium DL-tartrate	

Part II: Specific Purity Criteria Applicable to Permitted Miscellaneous Additives

E260 Acetic acid
The specific purity criteria for acetic acid contained in Council Directive 65/66/EEC.

Sodium acetate, anhydrous
The criteria' in the monograph for sodium acetate, anhydrous contained in the Food Chemicals Codex 1972.

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, $Na2CO_3$).

E262 Sodium hydrogen diacetate
Synonym Sodium diacetate.

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

E261 Potassium acetate
The specific purity criteria for potassium acetate contained in Council Directive 65/66/EEC.

E263 Calcium acetate
The specific purity criteria for calcium acetate contained in Council Directive 65/66/EEC.

Adipic acid
The criteria in the monograph for adipic acid contained in the Food Chemicals Codex 1972 at page 21.
2-A minoethanol
Synonym Monoethanolamine.
Description Colourless to yellowish viscous hygroscopic liqiuid miscible with water in all proportions.
Content Not less than 98% of $H2NCH2CH_2OH$.
Water Not more than 0.5%
Distillation range 166^0C to 176^0C (at 760 mm Hg).
Ethylene oxide Not more than 10 mg/kg

Azodicarbonamide
The criteria in the monograph for azodicarbonamide contained in the Food Chemicals Codex 1981 at page 31.

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 7(1 and not more than 80.

Benzoyl peroxide

The criteria in the monograph for benzoyl peroxide in the Food Chemicals Codex 1981 at page 35.

Potossium bromate
The criteria in the monograph for potassium bromate contained in the Food Chemicals Codex 1981 at page 240.

Calcium phytate

Synonym	Calcium *meso*inositolhexaphosphate.
Description	White powder with an acid taste. Commercially the product exists as the trihydrate.
Solubility	Slightly soluble in water. Soluble in acids.
Volatile matter	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 550^0C).
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 7 ml. N hydrochloric acid and 93 ml. of distilled water. Treat another 1g. sanuple of calcium phytate with 50ml. distilled water and l.5ml. Orthophosphoric acid (50 per centum $H3P0_4$; density 1.34). Stir and filter each solution and collect, wash, dry (at 100^0C.) 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 100 mg. per kg.
Arsenic	Not more than 5 mg. per kg.

E290 Carbon dioxide
The specific purity criteria for carbon dioxide contained in Council Directive 65/66/EEC. 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 annonium bicarbonate contained in the Food Chemicals Codex 1972 at page 44.

Sodium carbonate

Description	Colourless crystals of white granular or crystalline powder. The anhydrous salt is hygroscopic and the decahydrate is efflorescent.
Content	Not less than 98 per centum of $Na2CO_3$ 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 Chemical 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 an-hydrous sodium carbonate, with 50ml. of water and 50ml. of dilute ammonia solution (about 10 per centum NH3). 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 40 mg. 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.1, 1969 at page 322.

Magnesium carbonate, light
The criteria in the monograph for light magnesium carbonate contained in the European Pharmacopoeia Vol.1, 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 K2C03 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 180^0C. 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.

E170 Calcium carbonate

Description	Fine white microcrystalline or amorphous powder.
Content	Not less than 97 per centum of $CaCO_3$ on a volatile matter-free basis.
Volatile matter	Not more than 1 per centum (determined by drying at 105c. 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 Pharma copoeia 1973 at page 93.
Arsenic	Not more than 5 mg. per kg.
Lead	Not more than 20 mg. per kg.
Other in organic 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.

Alpha-cellulose
Synonym Powdered cellulose.
The criteria in the monograph for cellulose, powdered, contained in the Food Chemicals Codex 1981 at page 80. Additionally the level of lead present shall not exceed 1 mg/kg.

Chlorine
The standard for chlorine contained in British Standard 3947:1976.

Chlorine dioxide
A gaseous mixture with air containing not more than 4% v/v of chlorine dioxide and not more than 1% v/v of chlorine.

E330 Citric acid
The criteria for citric acid contained in Council Directive 78/664/EEC.

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

El31 Sodium dihydrogen citrate
The criteria for monosodium citrate contained in Council Directive 78/664/EEC.

E331 diSodium citrate
The criteria for disodium citrate contained in Council Directive 78/664/EEC.

E331 triSodium citrate
The criteria for trisodium citrate contained in Council Directive 78/664/EEC.

E332 Potassium dihydrogen citrate
The criteria for monopotassium citrate contained in Council Directive 78/664/EEC.

E333 tripotassium citrate
The criteria for tripotassium citrate contained in Council Directive 78/664/EEC.

E333 monoCalcium citrate
The criteria for monocalcium citrate contained in Council Directive 78/664/EEC.

E333 diCalcium citrate
The criteria for dicalcium citrate contained in Council Directive 78/664/EEC.

E333 triCalcium citrate
The criteria for tricalcium citrate contained in Council Directive 78/664/EEC.

Ammonium ferric citrate
Synonym Ferric ammonium citrate.
The criteria in the monograph for ferric ammonium 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.

L-Cysteine hydrochloride

Chemical description	L2-amino-3-mercaptopropanoic acid hydrochloride or L-2-amino-3-mercaptopropanoic acid hydrochloride monohydrate.
Description	White, crystalline powder or colourless crystals.
Content	Not less than 98% of C3H7N025.HCL calculated on an anhydrous basis.
Specific rotation [x] 2OC D	5.5 to +7.80 for 8g of sample made up to l00ml with N hydrochloric acid.
Sulphated ash	Not more than 0.1%.

Dichiorodifluoromethane

Description	Clear, colourless liquefied gas.
Content	Not less than 99.97 per centum CCl2F2.
Trichlorofluoromethane CCI3F	Not more than 290 mg. per kg. singly or in combination.
Dichiorofluoromethane CMCI2F	Not more than 10 mg. per kg.
Chlorodifluoromethane CHClF2	Not more than 0.01 per centum by volume (after evaporation at 0^0C.)
Chlorotrifluoromethane CCIF2	
Other organic compounds Non-volatile matter	

Dimethylpolysiloxane

Synonym	Deimethyl 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 200^0C. for 4 hours).
Identification	Shall comply with the identification tests in the mono graph for dimethicone in the British Parmaceutical Codex 1973 at page 168.
Acidity	Shall comply with the requirement for acidity in the monograph for dimethicone in the British Paramaceutical Codex 1973 at page 168.
Total silicon	Not less than 37.3 and not than 38.5 per centum.
Refractive index n25CD	Not less than 1.400 and not more than 1.405.
Viscosity (25^0C.)	Not less than 300 and not more than 1050 centistokes.
Relative density d 20c 4c	Not less than 0.960 and not more than 0.980.
diSodium dihydrogen ethylenediamine-NNN'N'-tetra-acelate	
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 in the British Pharmacopoeia 1973 at page 425.

Sodium ferrocyanide
Synonym Sodium hexacyanoferrate(II).
The criteria in the monograph for sodium ferrocyanide contained in the Food Chemicals Codex 1972 at page 741.

Potassium ferrocyanide

Synonym	Potassium hexacyanoferrate(II)
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 $K_4Fe(CN)_6.3H_20$.
Free moisture	Not more than 1 per centum (determined by the method for free moisture in the monograph of 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 delta- lactone.

The criteria in the monograph for glucono delta-lactone contained in the Food Chemicals Codex 1972 at page 346.

Sodium gluconale

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 105^0C. 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.

Sodium hydrogen L-glutamate

Synonyms	monoSodium glutamate. Sodium glutamate. Glutamic acid, sodium salt.
Formula	$C_5H_8NNaO_4H_20$ (molecular weight 187.13).

The criteria in the monograph for monosodium L-glutamate contained in the Food Chemicals Codex 1981 at page 203.

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

I 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 cen turn of $C_7H_{12}0_7$.
Melting point	148^0C
Specific rotation 20^0C [x] D	Not less than -54.00 and not more than -53.00 (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 $C_7H_{13}O_8)_2Ca.2H_20$.
Reducing substances	Not more than 0.5 per centum. (expressed as glucose)
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.11, 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 chloride
The criteria in the monograph for potassium chloride contained in the Food Chemicals Codex 1972 at page 646.

Calcium chloride, anhydro
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 crystal–.
Content	Not less than: 98 per centum of $CaC1_2.2H_20$ for the dihydrate, 97 per centum of $CaCl_26H_20$ for the hexahydrate.
Magnesium and alkali	Not more than 2 per centim, determined by the method in the monograph for calciuim chloride contained in the Food (Chemicals Codex 1972 at page 123 except that the weight of the residue shall not exceed l0)mg.
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 2 mg. 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 50 ml.
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.1, 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.1, 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 I) and 30m1. water. Heat to boiling for 2 minutes, cool and dilute to l00ml. with dilute acetic acid (see note 2). Filter through a sintered glass filter. Any residue, after washing with water, drying and ignition at 600^0C., 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 4 mg. per kg.
Heavy metals	Not more than 40 mg. 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 l00ml. 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 .7m1. glacial acetic acid (98 per centum weight/volume $C_2H_4O_2$) to 100 ml. 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.1, 1969 at page 319.

Potassium hydroxide
The critria 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 630m1. of water at 25°C. and in 1300ml. of boiling water. Soluble in gycerol and in a saturated solution of sucrose. Insoluble in ethanol.
Content	Not less than 92 per centum of Ca(OH)2.
Matter insoluble in dilute hydrochloric	Not more than 0.5 per centum.acid (about 10 per centum weight/volume HCl).
Magnesium and alkali salt	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 l5mg.
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.

E270 Lactic acid
The specific purity criteria for lactic acid contained in Council Directive 65/66/EEC.

E325 Sodium lactate
The criteria for sodium lactate contained in Council Directive 78/664/EEC.

E326 Potassium lactate
The criteria for potassium lactate contained in Council Directive 78/664/EEC.

E327 Calcium lactate
The criteria for calcium lactate contained in Council Directive 78/664/EEC.

DL-Malic acid
The criteria in the monograph for malic acid contained in the Food Chemicals Codex 1972 at page 484 as amended by the Second Supplement to that Codex at page 27, except that the melting range shall be 130^0C. to 132^0C. (corrected) and that the method for determining the melting range shall be that specified or a method of equivalent accuracy.

L-Malic acid

Description	White or nearly white crystalline powder or granules.
Content	Not less than 99 per centum of C4H605.
Melting range	99^0C. to 101^0C.
Specific rotation	

20^0C[x] D	Not less than -2.4o and not more than -2.2° (using a solution containing 8.5g. L-malic acid in 100ml. water).

Maleic acid
Fumaric acid
Residue on ignition
Water insoluble matter

} Shall comply with the limits given in the monograph for malic acid in the Food Chemicals Codex 1972 at page484.

Sodium hydrogen malate

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 110^0C. for 3 hours).
Maleic acid	Not more than 0.05 per centum.

Sodium malate

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.

Potassium malate

Description	Colourless or almost colourless aqueous soution. Potassium malate may be derived from either DL-malic acid or L-ma lie acid.
Content	Not less than 59.5 per centum of $C_4H_40_5K_2$
Maleic acid	Not more than 0.05 per centum calculated on the $C_4H_4O_5K_2$ content.

Calcium hydrogen ma/ate

Description	White odourless powder. Calcium hydrogen malate may be derived from either DL-malic acid or L-malic acid.
Content	Not less than 97.5 per centum of $(C_4H_5O_5)_2Ca$ on a volatile matter-free basis.
Volatile matter	Not more than 2 per centum (determined by drying at 110^0C. for 3 hours).
Maleic acid	Not more than 0.05 per centum.
Fluoride	Not more than 30 mg. per kg. on a volatile matter-free basis.

Calcium malate

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°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.

Metatartaric acid

Description	White or yellow powder which consists chiefly of a mixture of polyester obtained by the controlled dehydration of L-(+)-tartaric acid, together with unchanged L-(+)-tartaric acid.
Specific absorption E1/1 cm centum identification	Not more than 1.5 xl0^{-2}at 430nm. (determined using centum a filtered aqueous solution). Place 5 to l0mg. of sample in a test tube. Add 2ml. sulphuric acid (about 94 per centum H2S04) plus two drops of resorcinol reagent (2g.resorcinol dissolved in l00ml. water plus 0.5m1. sulphuric acid) and heat to 150^{0}C. An intense violet colour is produced.
Content	Not less than the equivalent of 105 per centum of tartaric acid (C_4H_606). 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 50ml. 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_1m1.). 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_2ml.). Calculations: Tartaric acid equivalent = 7.5 (T_1+20-T_2) Per centum Esterified tartaric acid = $\frac{100(T_1 + 20 - T_2)}{T_1 + 20 - T_2}$ per centum.

Specific rotation [X] 20°C D	Not less than +12.50 and not more than +13.5° (using a filtered 10 per centum weight/volume aqueous solution).
Matter insoluble in water (at about 20^0C)	Not more than 2.5 per centum (insoluble matter weighed after drying for 3 hours at 70°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 Pharmacopoeia 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.11, 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 arnines.
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	80^0C. to 85^0C.
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.11, 1971 at page 328.

Oxystearin
The criteria in the monograph for oxystearin contained in the Food Chernicals 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.

E338 Orthophosphoric acid
The criteria contained in Council Directive 78/664/EEC.

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.

di mmonium hydrogen orthophosphate
Synonym Ammonium phosphate, dibasic.
The criteria in the monograph for ammonium phosphate, dibasic contained in the Food Chemicajs Codex 1972 at page 49.

E339Sodium dihydrogen orthophosphate
The criteria for monosodium orthophosphate contained in Council Directive78/664/EEC.

E339 disodium hydrogen orthophosphate
The criteria for disodium orthophosphate contained in Council Directive78/664/EEC.

E339 triSodium orthophosphate
The criteria for trisodium orthophosphate contained in Council Directive78/664/EEC.

E340 Potassium dihydrogen orthophosphate
The criteria for monopotassium orthophosphate contained in Council Directive 78/664/EEC.

E340 diPotassium hydrogen orthophosphate
The criteria for dipotassium orthophosphate contained in Council Directive78/664/EEC.

E340 triPotassium orthophosphate
The criteria for tripotassium orthophosphate contained in Council Directive78/664/EEC.

E341 Calcium letrahydrogen diorthophosphate
The criteria for monocalcium orthophosphate contained in Council Directive 78/664/EEC.

E341 Calcium hydrogen orthophosphate
The criteria for dicalcium orthophosphate contained in Council Directive 78/664/EEC.

F34/ triCalcium diorthophosphate
The criteria for tricalcium orthophosphate contained in Council Directive 78/663/EEC.

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.

E450(a) diSodium dihydrogen diphosphate
The criteria for disodium dihydrogen diphosphate contained in Council Directive 78/663/EEC.

F450(a) triSodium diphosphate
The criteria for trisodium diphosphate contained in Council Directive 78/663/EEC.

F450(a) tetraSodium diphosphate
The criteria for tetrasodium diphosphate contained in Council Directive78/663/EEC.

F450(a) tetraPotassium diphosphate
The criteria for tetrapotassium diphosphate contained in Council Directive 78/663/EEC.

di Calcium diphosphate
Synonyms diCalcium pyrophosphate.
Calcium pyrophosphate.

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

E450(b) pen taSodium tiphosphate
The criteria for pentasodium triphosphate contained in Council Directive 78/663/EEC.

E450(b) pentaPotassium triphosphat
The criteria for pentapotassium triphosphate contained in Council Directive 78/663/EEC.

E450(c) Sodium polyphosphates
The criteria for sodium polyphosphates contained in Council Directive 78/663/EEC.

E450(c) Potassium polvphosphates
The criteria for potassium polyphosphates contained in Council Directive 78/663/EEC.

Ammonium and calcium polyphosphates
Description Ammounium and calcium polyphosphates exist as fine white powders or crystals or colourless glassy platelets.
They are reproducible heterogeneous mixtures of am monium or calcium salts, or mixtures thereof, of condensed polyphosphoric

	acids of general formula: $H(n.2)PnO(3m.1)$ where n shall be not less than 2.
Content(expressed as P_2O_5)	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 than 4.0 and not more than9.0.
Cyclic phosphate	Not more than 8 per centum calculated on the P_2O_5 content.
Fluoride	Not more than 15 mg. per kg. calculated on the P_2O_5 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 fluoride-a patite.
Content (expressed as CaO)	Not less than 45 per centum.
(expressed as P_20_5)	Not less than 45 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.

Guanosine5'-(disodium phosphate)

Synonyms	Sodium 5'-guanylate. diSodium guanosine 5'-monophosphate.
Formula	$C_{10}H_{12}N_{12}N_5Na_2OgP.xR_2O$ (molecular weight (anhydrous) 407.20).

The criteria in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105.

inosine 5,- (disodium phosphate)

Synonyms	Sodium 5'-inosinate. diSodium inosine 5 '-monophosphate.
Formula	$C_{10}H_{12}N_{12}N_5Na_2OgP.xR_2O$ (molecular weight (anhydrous) 392.19).

The criteria in the monograph for disodium inosinate contained in the Food Chemicals Codex 1981 at page 106.

Polydextrose

Description	Polydextrose is an off-white to light tan coloured, water-soluble powder. It consists of a randomly bonded condensation polymer produced by the reaction of D glucose with sorbitol and citric acid. Free acid groups may be neutralised with potassium hydroxide.

Content	Not less than 90 per centum of polymer on an ash-free and water-free basis.
Free glucose	Not more than 4 per centum on an ash-free and water-free basis.
Free 1 ,6-anhydro -D-glucose	Not more than 4 per centum on an ash-free and water- free basis.
Free sorbitol	Not more than 2 per centum on an ash-free and water- free basis.
Water	Not more than 4 per centum (Karl Fischer).
pH (10 per centum solution).	Not less than 2.5 and not more than 3.5 (not less than aqueous 5.0 and not more than 6.0 for the neutralised product).
Sulphatedash	Not more than 0.3 per centum (not more than 3.0 per centum for the neutralised product).
Arsenic	Not more than 1 mg/kg.
Lead	Not more than 1 mg/kg.

Sodium 5'-ribonucleotide

Description	White or nearly white crystalline powder consisting of a mixture of guanosine 5'-(disodium phosphate) and inosine 5'-(disodium phosphate) in approximately equal proportions. Soluble in water, practically insoluble in ethanol.
Content	Not less than 97 per centum and not more than 102 per centum of $C_{10}H_{12}N_5Na_2O_8P$ and $C_{10}H_{11}N_5Na_2O_8P$, and not less than 47 per centum and not more than 53 per centum of $C_{10}H_{12}N_5Na_2O_8P$ or of $C_{10}H_{11}N_5Na_2O_8P$ in every case calculated on an anhydrous basis.
Moisture	Not less than 22 per centum and not more than 26 per centum (Karl Fischer).
pH (5 per centum aqueous solution)	Not less than 7.0 and not more than 8.5.
Ammonium salts	Place 100 mg of sample in a test tube. Add 50mg magnesium oxide plus 1 ml of water. Heat on a water bath for 5 minutes; the vapour evolved does not affect the colour of moist litmus paper.
Amino acids	Place 5ml of a 0.1 per centum (weight/volume) solution in a test tube. Add 1 ml of a 2 per centum (weight/volume) solution of ninhydrin and heat for 3 minutes; no blue colour is produced.
Other nucleotides	The paper chromatogram obtained when sodium 5'- ribonucleotide is analysed using the procedure described for 'other nucleotides' in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105 shall show no spots other than those for guanosine 5'-(disodium phosphate) and inosine 5'-(disodium phosphate).

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_2 Hydrated silica: not less than 91 per centum of SiO_2 on a volatile matter-free basis.
Volatile matter	Hydrated silica: not more than 7 per centum (determined by drying at 105^0C. for 2 hours).
Loss on ignition	Not more than 13 per centum (determined by ignition at 1000^0C. to constant weight).
Soluble ionisable salts (expressed as Na_2SO_4)	Not more than 5 per cen turn.

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_2)	Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.
(expressed as Al_2O_3)	Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed as Na_2O)	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 more than 10 per centum and not more than 14 per centum (determined by ignition at 1000^0C. to constant weight).

Alunimium calcium silicate

Synonymous	Calcium aluminum Silicate, Calcium aluminosilicate. Calcium silicoaluminate.
Description	Fine white free-tjowing powder.
Content	
(expressed as SiO_2)	Not less than 44 per centum and not more than So per centum on a volatile matter-free basis.
(expressed as Al_2O_3)	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_2O)	Not less than 0.5 per centum and not more than 4 per ceutum on a volatile matter-free basis.
Volatile matter	Not more than l0 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 1000c to constant weight.

Calcium silicate

Description	White to off-white free-flowing powder.
Solubility	Insoluble in water. Forms a gel with mineral acids.
Content	Not less than 72 per centum and not more (expressed as SiO_2) than 78 per centum on a volatile matter-free basis.
(expressed asCaO)	Not less than 16 per centum and not more than 21 per centum on a volatile matter-free basis.
(expressed as Na_2O)	Not less than 2 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter	Not more than () per centum (determined by drying at 105 C for 2 hours;).
Loss on ignition	Not less than 7 per centum and bit 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.

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.

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	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.
The criteria in the monograph for alum contained in the European Pharmacopoeia Vol.1, 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
Synonum Tannin.

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.

E334 L- (+)- Tartaric acid
The criteria for tartaric acid contained in Council Directive 78/664/EEC.

DL- *Tartaric acid*

Description	DL-Tartaric acid occurs as a white crystalline powder
or as colourless or translucent crystals.	
Content	Not less than 99.5 per centum of $C_4H_60_6$ on a volatile matter-free basis.
Volatile matter	Not more than 0.5 per centum (determined by drying at 105^0C. to constant weight).
Sulphated ash	Not more than 0. 1 per centum on a volatile matter-free basis.
Oxalates (expressed as acid)	Not more than 0.05 per centum on a volatile oxalic matter-freebasis.

E335 monoSodium L-(+)-tartrate

The criteria for monosodium tartrate contained in Council Directive 78/664/EEC.

monoSodium DL-tartrate

Description	Colourless transparent crystals.
Content	Not less than 99 per centum of $C_4H_4O_6HNa$ on a volatilematter-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.

E335 diSodium L- (+)-tartrate

The criteria for disodium contained in Council Directive 78/664/EEC.

diSodiun DL-tartrate

Description	olourless transparent crystals.
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 percentum for the dihydrate (determined by a drying at 150^0C. for 3 hours).
Oxalates (expressed as oxalic acid)	Not more than 0.05 per centum on a volatile matter-free basis.

E336 monoPotassium L-(+)-tartrate

The criteria for monopotassium tartrate contained in Council Directive 78/664/EEC.

mono Potassium L-tartrate

The criteria in the monograph for potassium acid tartrate contained in the Food Chemicals Codex 1972 at page 639, except that potassium acid tartate shall be derived from DL-tartaric acid.

E336 diPotassium L-(+)-tartrate
The criteria for dipotassium tartrate contained in Council Directive 78/664/EEC.

diPotassium DL-tartrate

Description	White crystalline or granular powder.
Content	Not less than 99 per centum of $C_4H_40_6K_2$ on a volatile matter-free basis.
Volatile matter	Not more than 4 per centum (determined by a drying at160^0C. to constant weight).
Oxalates (expressed as	Not more than 0.05 per centum on d volatile oxalic acid)matter-free basis

E337 Potassium sodium L-(+)-tartrate
The criteria for potassium sodium tartrate contained in Council Directive 78/664/EEC.

Potassium sodium DL-tartrate

Description	Colourless crystals or a white crystalline powder. 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 150^0C 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

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	diSodium dihydrogen ethylenediamine-NNN'N'-tetra-acetate	25 milligrams per litre.
Bread	Azodicarbonamide Benzoyl peroxide Potassium bromate Chlorine dioxide L-Cysteine hydrochloride	As prescribed by the Bread and Flour Regulations 1987.
Canned fish	Calcium disodium ethylenediamine NNN'N' -tetra-acetate	In accordance with good manufacturing practice.
Canned shellfish	Calcium disodium ethylenediamine-NNN'N'-tetra-acetate	In accordance with good manufacturing practice.
Chocolate confectionery	Carnauba wax	200
Chocolate products	Carnauba wax	200
Flour	Azodicarbonamide	As prescribed by the Bread and Flour Regulations 1987.
	Benzoyl Peroxide Potassium bromate Chlorine dioxide Chlorine L-Cysteine hydrochloride	
Frozen food	Dichiorodifluoromethane	100 (determined when the food is fully thawed at and to 20^0C).
Glace cherries	Calcium disodium ethylenediamine-NNN'N'-tetra-acetate	In accordance with good manufacturing practice.
	Aluminium potassium sulphate	10,000 (on a dry matter basis).
Peeled fruit	2-Aminoethanol	100

Peeled vegetables	2-Aminoethanol	100
Sugar confectionery	Carnauba wax	200
Wine	Metatartaric acid	100 milligrams per litre

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;

(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 letters 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.