

FOOD AND DRUGS**Composition and Labelling****Miscellaneous Additives in Food Regulations 1974**

REGULATIONS, DATED 5TH AUGUST 1974, MADE BY THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES UNDER SECTIONS 4, 7, 68 AND 68(a) OF THE FOOD AND DRUGS ACT (NORTHERN IRELAND) 1958.

The Department of Health and Social Services, in exercise of the powers conferred upon it by sections 4, 7, 68 and 68(a) of the Food and Drugs Act (Northern Ireland) 1958(a) and of all other powers enabling it in that behalf, after consultation with such organisations as appear to it to be representative of interests substantially affected by these regulations, hereby makes the following regulations:—

Citation and commencement

1. These regulations may be cited as the Miscellaneous Additives in Food Regulations (Northern Ireland) 1974, and shall come into operation on 1st September 1974.

Interpretation

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

“the Act” means the Food and Drugs Act (Northern Ireland) 1958;

“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;

- “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;
- “district council” has the meaning assigned to it in section 1 of the Local Government Act (Northern Ireland) 1972(b);
- “European Pharmacopeia Volume I 1969” and “European Pharmacopeia Volume II, 1971” means respectively Volume I of the European Pharmacopeia published in 1969 and Volume II of the European Pharmacopeia 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 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 (Northern Ireland) 1966(c);
- “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 Antioxidants in Food Regulations (Northern Ireland) 1974(d);

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

“permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour Regulations (Northern Ireland) 1964(f);

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

“permitted emulsifier” means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations (Northern Ireland) 1962(h);

“permitted improving agent” means any improving agent in so far as its use is permitted by the Bread and Flour Regulations (Northern Ireland) 1964;

“permitted miscellaneous additive” means any miscellaneous additive specified in Part I of Schedule I 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;

(d) S.R. (N.I.) 1974, No. 197.

(e) S.R. & O. (N.I.) 1969, No. 346.

(f) S.R. & O. (N.I.) 1964, No. 172.

(g) S.R. & O. (N.I.) 1973, No. 466.

(h) S.R. & O. (N.I.) 1962, No. 90.

- “permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food Regulations (Northern Ireland) 1974(i);
- “permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food Regulations (Northern Ireland) 1967(j);
- “permitted stabiliser” means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations (Northern Ireland) 1962;
- “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 into 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;
- “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) 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 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 or delivery, 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 or delivered 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 or delivered shall have in it or on it any permitted miscellaneous additive specified in column 2 of Schedule 2:

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;
- (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, consign, deliver or have in his possession for the purpose of sale any food which does not comply with this regulation.

Sale, advertisement and labelling of miscellaneous additives

5.—(1) No person shall sell, consign, deliver, have in his possession for the purpose of sale 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.

Condemnation of food

6. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell, consign, deliver or to have in his possession for sale, 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 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 district council shall enforce and execute such provisions in their area.

(3) The requirements of section 47(3) of the Act (which requires notice to be given to the Department of Health and Social Services 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 district 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.

Amendment of the Labelling of Food Regulations (Northern Ireland) 1970

9. The Labelling of Food Regulations (Northern Ireland) 1970(k) shall be amended—

(a) by inserting in regulation 2(1) 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 (Northern Ireland) 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 (Northern Ireland) 1974.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 5th day of August 1974.

(L.S.)

N. I. Kells,
Assistant Secretary.

SCHEDULE 1

Regulation 2(1)

PART I

Permitted Miscellaneous Additives

Column 1	Column 2
<i>Name of miscellaneous additive</i>	<i>Serial number</i>
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	—
Fumaric acid	—
D-Glucono-1,5-lactone	—
Sodium gluconate	—
Potassium gluconate	—
Calcium gluconate	—
Glycine	—
1, 4-Heptonolactone	—
Sodium heptonate	—
Calcium heptonate	—

Column 1	Column 2
<i>Name of miscellaneous additive</i>	<i>Serial number</i>
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
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)

Column 1	Column 2
Name of miscellaneous additive	Serial number
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	—
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(1).

Sodium acetate, anhydrous

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

(1) OJ No. 22, 9.2.65, p. 373/65 (OJ/SE 1965-1966, p. 25).

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_2CO_3).

E 262 Sodium hydrogen diacetate

Synonym Sodium diacetate

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

E 261 Potassium acetate

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

E 263 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 mesoinositolhexaphosphate.
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°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 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 K_2CO_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°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 $CaCO_3$ 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 5mg. per kg.
Lead	Not more than 20mg. per kg.
Other inorganic impurities	Not more than 100mg. per kg. of any of the following substances, namely antimony, copper, chromium, zinc or barium sulphate, or more than 200mg. 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 $C_6H_8O_7$ 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 substance)	Shall comply with the requirements 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 $C_6H_7O_7Na$ 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)	Not more than 0.02 per centum on a volatile matter-free basis.

E 331 triSodium citrate

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)	Not more than 0.05 per centum on a volatile matter-free basis.

E 332 Potassium dihydrogen citrate

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)	Not more than 0.05 per centum on a volatile matter-free basis.

E 332 triPotassium citrate

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)	Not more than 0.5 per centum on a volatile matter-free basis.

E 333 Calcium citrate

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 25°C. (n_D)	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 20°C. d 4°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 delta-lactone.*

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
20°C. Not less than—54.0° and not more than—53.0° (using a 25 per centum weight/volume aqueous solution).

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D

Sulphated ash Not more than 0.1 per centum.

Sodium heptonate

Description White to tan crystalline powder.

Solubility Very soluble in water.
Sparingly soluble in ethanol.

Content Not less than 98 per centum of $C_7H_{13}O_8Na \cdot 2H_2O$.

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 $(C_7H_{11}O_8)_2Ca \cdot 2H_2O$.
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 chloride

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 $CaCl_2 \cdot 2H_2O$ for the dihydrate; : 97 per centum of $CaCl_2 \cdot 6H_2O$ 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.
<i>Hydrogen</i>	
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 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 100ml. 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 $Ca(OH)_2$.
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(m).

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 $C_3H_5O_3Na$ (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.

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 30mg. 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 20°C.	Not less than -2.4° and not more than -2.2° (using a solution containing 8.5g. L-malic acid in 100ml. water).
[α] D	
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	

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 $110^\circ C.$ 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 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.

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 $110^\circ C.$ 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 1cm.	Not more than 1.5×10^{-2} at 430 nm. (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 H_2SO_4) plus two drops of resorcinol reagent (2g. resorcinol dissolved in 100ml. water plus 0.5ml. sulphuric acid) and heat to 150°C. An intense violet colour is produced.
Content	Not less than the equivalent of 105 per centum of tartaric acid ($C_4H_6O_6$). 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 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_1 ml.). Add a further 20ml. 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 20°C. [α] _D	Not less than +12.5° and not more than +13.5° (using a filtered 10 per centum weight/volume aqueous solution).
Matter insoluble in water (at about 20°C.)	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.
<i>Nicotinic acid</i>	
The criteria in the monograph for nicotinic acid contained in the British Pharmacopoeia 1973 at page 318.	
<i>Nitrogen</i>	
The standard for nitrogen type 2 contained in British Standard 4366: 1968.	
<i>Nitrous oxide</i>	
The criteria in the monograph for nitrous oxide contained in the European Pharmacopoeia Vol II, 1971 at page 316.	
<i>Octadecylammonium acetate</i>	
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_3PO_4 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 $NaNO_3$)	Not more than 0.0005 per centum on an anhydrous basis.
Sulphate (expressed as $CaSO_4$)	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_3PO_4 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 NaH_2PO_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 10mg. per kg. on a volatile matter-free basis.

E 339(b) diSodium 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 Na_2HPO_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 10mg. per kg. on a volatile matter-free basis.

E 339(c) triSodium orthophosphate

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 Na_3PO_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 10mg. per kg. on a volatile matter-free basis.

E 340(a) Potassium dihydrogen orthophosphate

Synonym	Potassium phosphate, monobasic.
Description	Colourless crystals or white granular or crystalline powder.
Content	Not less than 98 per centum of KH_2PO_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 10mg. per kg. on a volatile matter-free basis.

E 340(b) diPotassium hydrogen orthophosphate

Synonym	Potassium phosphate, dibasic.
Description	Deliquescent, colourless or white granules.
Content	Not less than 98 per centum of K_2HPO_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 10mg. 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 10mg. 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 30mg. 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 50mg. per kg. on an anhydrous basis.

E 341(c) triCalcium 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 50mg. 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 $3\text{Ca}_2(\text{PO}_4)_2 \cdot \text{Ca}(\text{OH})_2$ 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 50mg. 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 diSodium dihydrogen pyrophosphate
Sodium acid pyrophosphate
Acid sodium pyrophosphate.

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 tetraSodium pyrophosphate
Sodium pyrophosphate.

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 10mg. per kg.

E 450(a) tetraPotassium diphosphate

Synonyms tetraPotassium pyrophosphate
Potassium pyrophosphate.

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

diCalcium diphosphate

Synonyms diCalcium 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 10mg. 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_2O_5) Not less than 47 per centum

(expressed as K_2O) 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 10mg. 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: $\begin{array}{c} \text{H} \quad \text{P} \quad \text{O} \\ \text{(n+2)} \quad \text{n} \quad \text{(3n+1)} \end{array}$ where n shall be not less than 2.
Content (expressed as P ₂ O 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 and not more than 9.0.
Cyclic phosphate	Not more than 8 per centum calculated on the P ₂ O ₅ content.
Fluoride	Not more than 15mg. per kg. calculated on the P ₂ O 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 fluoro-apatite.
Content (expressed as CaO)	Not less than 45 per centum.
(expressed as P ₂ O ₅)	Not less than 34 per centum.
Fluoride	Total: Not more than 700mg. per kg. Water soluble: Not more than 2mg. per kg.
Copper	Not more than 25mg. per kg.
Zinc	Not more than 150mg. per kg.

Shellac

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

Silicone 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°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 ₂ SO ₄)	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 ₂)	Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.
(expressed as Al ₂ O ₃)	Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed as Na ₂ 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 ₂)	Not less than 44 per centum and not more than 50 per centum on a volatile matter-free basis.
(expressed as Al ₂ O 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 ₂ 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 ₂)	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 ₂ 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.

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 Not more than 0.3 per centum on a dry-matter (expressed as glucóse) basis, for (a) and (b).

Total sugars Not more than 0.7 per centum on a dry-matter (expressed as glucose) basis, for (a) and (b).

Note 1: "Glycitol" 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 2.5mg. 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 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.

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 $105^\circ C.$ 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 $150^\circ C.$ 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

Regulation 4

Miscellaneous additives permitted only in certain foods

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

SCHEDULE 3

Regulation 5(2)

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 considerable variations in height, colour or size, as the case may be, may be disregarded.

EXPLANATORY NOTE

(This note is not part of the regulations, but is intended to indicate their general purport.)

These regulations come into operation on 1st September 1974.

The regulations implement, in part, Council Directive of 23rd October 1962 (Official Journal No. 115, 11.11.62, pages 2645/62) (Special Edition 1959-1962, page 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/European Economic Community (Official Journal No. 12, 27.1.64, pages 161/64) (Special Edition 1963-1964, page 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/European Economic Community (Official Journal No. L309, 24.12.68, page 25) (Special Edition 1968 (II) page 598), Council Directive No. 70/359/European Economic Community (Official Journal No. L157, 18.7.70, page 38) (Special Edition 1970 (II) page 436), Council Directive No. 72/2/European Economic Community (Official Journal No. L2, 4.1.72, page 22) (Special Edition 1972 (I) page 11) and Council Directive No. 72/444/European Economic Community (Official Journal No. L298, 31.12.72, page 48) (Special Edition 1972 (30-31 December) page 75); Council Directive No. 65/66/European Economic Community (Official Journal No. 22, 9.2.65, pages 373/65) (Special Edition 1965-1966 page 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/European Economic Community (Official Journal No. L157, 18.7.70, page 31) (Special Edition 1970 (II) page 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 (regulations 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 (Northern Ireland) 1970 (regulation 9).

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 Pharmacopeia Volume I, 1969 and Volume II, 1971 referred to in regulation 2(1) and Part II of Schedule 1 may be inspected at the office of the Chief Pharmacist, Department of Health and Social Services for Northern Ireland, Dundonald House, Upper Newtownards Road, Belfast BT4 3SF (telephone Belfast 650111, Extension 582). Copies of the European Pharmacopeia can be obtained from the Pharmaceutical Press, 17 Bloomsbury Square, London WC1A 2NN.