

1981 No. 193

**FOOD AND DRUGS**  
**Composition and Labelling**

**Miscellaneous Additives in Food Regulations**  
**(Northern Ireland) 1981**

*Made* . . . . . 10th June 1981  
*Coming into operation* . . . . . 22nd July 1981

The Department of Health and Social Services(a) in exercise of the powers conferred on it by sections 4, 7, 68 and 68(A)(b) of the Food and Drugs Act (Northern Ireland) 1958(c) and of every other power enabling it in that behalf and 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) 1981 and shall come into operation on 22nd July 1981.

*Interpretation*

2.—(1) In these regulations—

“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;

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(a) See S.R. & O. (N.I.) 1964 No. 205 art. 5 and Sch. 2 Part 1 and 1973 c. 36 s. 40 and Sch. 5 para. 8  
(b) Added by S.R. & O. (N.I.) 1972 No. 363  
(c) 1958 c. 27 (N.I.)

“chocolate confectionery” has the meaning assigned to it by the Labelling of Food Regulations (Northern Ireland) 1970(a);

“chocolate product” has the meaning assigned to it by the Cocoa and Chocolate Products Regulations (Northern Ireland) 1976(b);

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

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

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

“food” 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;

“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;

“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,

(a) S.R. & O. (N.I.) 1970 No. 80; the relevant amending regulation is S.R. 1976 No. 183

(b) S.R. 1976 No. 183

(c) S.R. & O. (N.I.) 1966 No. 200

- (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) 1978(a);
- “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(b);
- “permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour Regulations (Northern Ireland) 1964(c);
- “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(d);
- “permitted emulsifier” means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations (Northern Ireland) 1981(e);
- “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 1 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 (Northern Ireland) 1980(f);
- “permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food Regulations (Northern Ireland) 1967(g);
- “permitted stabiliser” means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations (Northern Ireland) 1981;
- “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;
- “sequestrant” means any substance which is capable of complexing with metallic ions;

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(a) S.R. 1978 No. 112, amended by S.R. 1981 No. 191

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

(c) S.R. & O. (N.I.) 1964 No. 172; the relevant amending regulation is S.R. & O. (N.I.) 1972 No. 275

(d) S.R. & O. (N.I.) 1973 No. 466; the relevant amending regulations are S.R. 1975 No. 283, S.R. 1976 No. 382, S.R. 1979 No. 49

(e) S.R. 1981 No. 194

(f) S.R. 1980 No. 28, amended by S.R. 1980 No. 380

(g) S.R. & O. (N.I.) 1967 No. 282, amended by S.R. 1981 No. 192

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

“sugar confectionery” has the meaning assigned to it by the Labelling of Food Regulations (Northern Ireland) 1970.

(2) 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.

#### *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, for exportation to any place outside the United Kingdom.

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

4.—(1) Subject to paragraph (2) no food which is sold shall have in it or on it any added miscellaneous additive other than a permitted miscellaneous additive.

(2) Save as hereinafter provided, no food which is sold shall have in it or on it any added-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) A person shall not sell any food which does not comply with this regulation.

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

5.—(1) A person shall not sell 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) A person shall not 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.

#### *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, 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 any of the foregoing provisions he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding

one hundred pounds or to imprisonment for a term not exceeding three months, or to both such fine, and such imprisonment, 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 the provisions of these regulations in its district.

(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 regulations relating to 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 and did not himself make, or cause to be made, any material alteration in the substance of that advertisement.

(2) Where, in any proceedings against the manufacturer 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, the court is satisfied that an advertisement has been published in terms which could constitute an offence against these regulations, the manufacturer shall be guilty of such offence, unless he proves that he did not publish, and was not a party to the publication of, the advertisement.

#### *Revocations*

9. The regulations specified in the first column of Schedule 4 are hereby revoked to the extent specified in relation thereto in the third column of that Schedule.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 10th June 1981.

(L.S.)

*S. W. McDowell*

Assistant Secretary

## SCHEDULE 1

Regulation 2(1)

## PART I

## Permitted miscellaneous additives

Column 1	Column 2
Name of miscellaneous additive	Serial number
Acetic acid	E 260
Sodium acetate, anhydrous	—
Sodium acetate	—
Sodium hydrogen diacetate	E 262
Potassium acetate	E 261
Calcium acetate	E 263
Adipic acid	—
Beeswax, white	—
Beeswax, yellow	—
Calcium phytate	—
Carbon dioxide	E 290
Ammonium carbonate	—
Ammonium hydrogen carbonate	—
Sodium carbonate	—
Sodium hydrogen carbonate	—
Sodium sesquicarbonate	—
Magnesium carbonate, heavy	—
Magnesium carbonate, light	—
Potassium carbonate	—
Potassium hydrogen carbonate	—
Calcium carbonate	E 170
Carnauba wax	—
Citric acid	E 330
<i>tri</i> Ammonium citrate	—
Sodium dihydrogen citrate	E 331
<i>di</i> Sodium citrate	E 331
<i>tri</i> Sodium citrate	E 331
Potassium dihydrogen citrate	E 332
<i>tri</i> Potassium citrate	E 332
<i>mono</i> Calcium citrate	E 333
<i>di</i> Calcium citrate	E 333
<i>tri</i> Calcium citrate	E 333
Ammonium ferric citrate	—
Ammonium ferric citrate, green	—
Dichlorodifluoromethane	—
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	—
Hydrochloric acid	—

Column 1	Column 2
<i>Name of miscellaneous additive</i>	<i>Serial number</i>
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 hydrogen malate	—
Calcium malate	—
Mannitol	E 421
Metatartaric acid	—
Nicotinic acid	—
Nitrogen	—
Nitrous oxide	—
Octadecylammonium acetate	—
Oxygen	—
Oxystearin	—
Orthophosphoric acid	E 338
Ammonium dihydrogen orthophosphate	—
diAmmonium hydrogen orthophosphate	—
Sodium dihydrogen orthophosphate	E 339
diSodium hydrogen orthophosphate	E 339
triSodium orthophosphate	E 339
Potassium dihydrogen orthophosphate	E 340
diPotassium hydrogen orthophosphate	E 340
triPotassium orthophosphate	E 340
Calcium tetrahydrogen diorthophosphate	E 341
Calcium hydrogen orthophosphate	E 341
triCalcium diorthophosphate	E 341
Sodium aluminium phosphate, acidic	—
Sodium aluminium phosphate, basic	—
diSodium dihydrogen diphosphate	E 450(a)
triSodium diphosphate	E 450(a)
tetraSodium diphosphate	E 450(a)
tetraPotassium diphosphate	E 450(a)
diCalcium diphosphate	—
pentaSodium triphosphate	E 450(b)
pentaPotassium triphosphate	E 450(b)
Sodium polyphosphates	E 450(c)
Potassium polyphosphates	E 450(c)
Ammonium and calcium polyphosphates	—
Edible bone phosphate	—

Column 1	Column 2
Name of miscellaneous additive	Serial number
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
Sorbitol syrup	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	—
L-(+)-Tartaric acid	E 334
DL-Tartaric acid	—
monoSodium L-(+)-tartrate	E 335
monoSodium DL-tartrate	—
diSodium L-(+)-tartrate	E 335
diSodium DL-tartrate	—
monoPotassium L-(+)-tartrate	E 336
monoPotassium DL-tartrate	—
diPotassium L-(+)-tartrate	E 336
diPotassium DL-tartrate	—
Potassium sodium L-(+)-tartrate	E 337
Potassium sodium DL-tartrate	—

## PART II

**Specific purity criteria applicable to permitted miscellaneous additives***E 260 Acetic acid*

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

*Sodium acetate, anhydrous*

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

*Sodium acetate*

The criteria in the monograph for sodium acetate contained in the Food Chemicals Codex 1972 at page 717 except that the alkalinity shall be not more than 0.1 per centum (as sodium carbonate,  $\text{Na}_2\text{CO}_3$ ).

(a) O.J. No. 22, 9.2.65, p. 373/65 (O.J./S.E. 1965-66, p. 25)



*E 262 Sodium hydrogen diacetate*

Synonym ..... Sodium diacetate.

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

*E 261 Potassium acetate*

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

*E 263 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.

*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 *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°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 7 ml. N hydrochloric acid and 93 ml. of distilled water. Treat another 1g. sample of calcium phytate with 50 ml. distilled water and 1.5 ml. orthophosphoric acid (50 per centum H<sub>3</sub>PO<sub>4</sub>; 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 100 mg. per kg.
Arsenic .....	Not more than 5 mg. per kg.

*E 290 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 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 $\text{Na}_2\text{CO}_3$ 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 5 g. of hydrated sodium carbonate, or 2.5 g. of anhydrous sodium carbonate, with 50 ml. of water and 10 ml. of dilute ammonia solution (about 10 per centum $\text{NH}_3$ ). Filter and wash the residue with water, then ignite to constant weight.
Sulphate .....	Not more than 0.4 per centum on a volatile matter-free basis.
Chloride .....	Not more than 0.4 per centum on a volatile matter-free basis.
Iron .....	Not more than 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. 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 5 mg. per kg.

Lead .....	Not more than 20 mg. per kg.
Other inorganic impurities .....	Not more than 100 mg. per kg. of any of the following substances, namely antimony, copper, chromium, zinc or barium sulphate, or more than 200 mg. per kg. of any combination of those substances.

*Carnauba wax*

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

*E 330 Citric acid*

The criteria for citric acid contained in Council Directive 78/664/EEC(a).

*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*

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

*E 331 diSodium citrate*

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

*E 331 triSodium citrate*

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

*E 332 Potassium dihydrogen citrate*

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

*E 332 triPotassium citrate*

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

*E 333 monoCalcium citrate*

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

*E 333 diCalcium citrate*

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

*E 333 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 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.

*Dichlorodifluoromethane*

Description ..... Clear, colourless liquefied gas.  
 Content ..... Not less than 99.97 per centum  $\text{CCl}_2\text{F}_2$ .

Trichlorofluoromethane $\text{CCl}_3\text{F}$	}	Not more than 290 mg. per kg. singly or in combination.
Dichlorofluoromethane $\text{CHCl}_2\text{F}$		
Chlorodifluoromethane $\text{CHClF}_2$		
Chlorotrifluoromethane $\text{CClF}_3$		

Other organic compounds ..... Not more than 10 mg. per kg.  
 Non-volatile matter ..... Not more than 0.01 per centum by volume.  
 (after evaporation at  $0^\circ\text{C}$ .)

*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  $200^\circ\text{C}$ . for 4 hours).

Identification ..... Shall comply with the identification tests in the  
monograph for dimethicone in the British  
Pharmaceutical Codex 1973 at page 168.

Acidity ..... Shall comply with the requirement for acidity  
in the monograph for dimethicone in the  
British Pharmaceutical Codex 1973 at page  
168.

Total silicon ..... Not less than 37.3 and not more than 38.5 per  
centum.

Refractive index  $n_D^{25^\circ\text{C}}$  ..... Not less than 1.400 and not more than 1.405.

Viscosity ( $25^\circ\text{C}$ .) ..... Not less than 300 and not more than 1050  
centistokes.

Relative density  $d_{4^\circ\text{C}}^{20^\circ\text{C}}$  ..... Not less than 0.960 and not more than 0.980.

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

Synonym ..... diSodium edetate.

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

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

Synonym ..... Sodium calciumedetate.

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

*Sodium ferrocyanide*

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

*Potassium ferrocyanide*

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

*Fumaric acid*

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

*D-Glucono-1, 5-lactone*

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

*Sodium gluconate*

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

*Potassium gluconate*

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

*Calcium gluconate*

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

*Glycine*

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

*1,4-Heptonolactone*

Synonym .....	Heptonolactone.
Description .....	Colourless crystals.

Solubility .....	Freely soluble in water. Slightly soluble in ethanol. Insoluble in ether.
Content .....	Not less than 99.5 per centum of $C_7H_{12}O_7$ .
Melting point .....	148°C.
Specific rotation [ $\alpha$ ] <sub>D</sub> <sup>20°C.</sup> .....	Not less than -54.0° and not more than -53.0° (using a 2.5 per centum weight/volume aqueous solution).
Sulphated ash .....	Not more than 0.1 per centum.

*Sodium heptonate*

Description .....	White to tan crystalline powder.
Solubility .....	Sparingly soluble in ethanol. Very soluble in water.
Content .....	Not less than 98 per centum of $C_7H_{13}O_8Na \cdot 2H_2O$ .
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 $(C_7H_{13}O_8)_2Ca \cdot 2H_2O$ .
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 $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ for the dihydrate; 97 per centum of $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$ for the hexahydrate.
Magnesium and alkali salts .....	Not more than 2 per centum, determined by the method in the monograph for calcium chloride contained in the Food Chemicals Codex 1972 at page 123 except that the weight of the residue shall not exceed 10 mg.
Fluoride .....	Not more than 40 mg. 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 .....	20 g. 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. 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 5 g. heavy magnesium oxide in a mixture of 70 ml. acetic acid (see note 1) and 30 ml. water. Heat to boiling for 2 minutes, cool and dilute to 100 ml. 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 5 mg.
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 30 g. glacial acetic acid (98 per centum weight/volume  $C_2H_4O_2$ ) to 100 ml. with water.

*Note 2:* Dilute acetic acid: contains not less than 11.5 per centum weight/volume and not more than 12.5 per centum weight/volume of  $C_2H_4O_2$ . Dilute 12 g. or 11.7 ml. 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. 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 .....	1 g. dissolves in 630 ml. of water at 25°C. and in 1300 ml. of boiling water. Soluble in glycerol and in a saturated solution of sucrose. Insoluble in ethanol.
Content .....	Not less than 92 per centum of Ca(OH) <sub>2</sub> .
Matter insoluble in dilute hydrochloric acid (about 10 per centum weight/volume HCl).	Not more than 0.5 per centum.
Magnesium and alkali salts .....	Not more than 6 per centum, determined by the method in the monograph for calcium hydroxide contained in the Food Chemicals Codex 1972 at page 131 except that the weight of the residue shall not exceed 15 mg.
Carbonate .....	When 2 g. of calcium hydroxide is mixed with 50 ml. 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 50 mg. 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 Council Directive 65/66/EEC.

*E 325 Sodium lactate*

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

*E 326 Potassium lactate*

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

*E 327 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°C. to 132°C. (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 C <sub>4</sub> H <sub>6</sub> O <sub>5</sub> .
Melting range .....	99°C. to 101°C.
Specific rotation [ $\alpha$ ] <sub>D</sub> <sup>20°C.</sup>	Not less than -2.4° and not more than -2.2° (using a solution containing 8.5 g. L-malic acid in 100 ml. water).

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

Volatile matter .....	Not more than 2 per centum (determined by drying at 110°C. 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.

*E 421 Mannitol*

The criteria for mannitol contained in Council Directive 78/663/EEC(a).

*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	E 1 per centum 1 cm.
Identification .....	Not more than $1.5 \times 10^{-2}$ at 430 nm. (determined using a filtered aqueous solution).
Content .....	Place 5 to 10 mg. of sample in a test tube. Add 2 ml. sulphuric acid (about 94 per centum $H_2SO_4$ ) plus two drops of resorcinol reagent (2 g. resorcinol dissolved in 100 ml. water plus 0.5 ml. sulphuric acid) and heat to 150°C. An intense violet colour is produced.
	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 50 ml. of freshly prepared 2 per centum weight/volume cold aqueous solution of metatartaric acid. Titrate with N aqueous sodium hydroxide solution to a blue-green colour ( $T_1$ ml.).
	Add a further 20 ml. of N aqueous sodium hydroxide solution and leave for 2 hours at room temperature. Titrate with N aqueous sulphuric acid solution ( $T_2$ ml.).
	Calculations:
	Tartaric acid equivalent = $\frac{7.5 (T_1 + 20 - T_2)}{\text{per centum}}$
	Esterified tartaric acid = $\frac{100 (20 - T_2)}{T_1 + 20 - T_2}$ per centum.

Specific rotation  $[\alpha]_D^{20^\circ\text{C}}$  ..... Not less than  $+12.5^\circ$  and not more than  $+13.5^\circ$  (using a filtered 10 per centum weight/volume aqueous solution).

Matter insoluble in water (at about  $20^\circ\text{C}$ .) ..... Not more than 2.5 per centum (insoluble matter weighed after drying for 3 hours at  $70^\circ\text{C}$ . in a vacuum oven).

Pyruvic acid ..... Not more than 0.5 per centum.

#### *Nicotinic acid*

The criteria in the monograph for nicotinic acid contained in the British 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. II, 1971 at page 316.

#### *Octadecylammonium acetate*

Synonym ..... Octadecylamine acetate.

Description ..... White waxy solid which consists essentially of the acetic acid salts of a mixture of mainly stearyl and palmityl primary aliphatic amines.

Solubility ..... Soluble in water (above  $70^\circ\text{C}$ .) 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 .....  $80^\circ\text{C}$ . to  $85^\circ\text{C}$ .

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  $260^\circ\text{C}$ .; 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*

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.

*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 Sodium dihydrogen orthophosphate*

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

*E 339 diSodium hydrogen orthophosphate*

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

*E 339 triSodium orthophosphate*

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

*E 340 Potassium dihydrogen orthophosphate*

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

*E 340 diPotassium hydrogen orthophosphate*

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

*E 340 triPotassium orthophosphate*

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

*E 341 Calcium tetrahydrogen diorthophosphate*

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

*E 341 Calcium hydrogen orthophosphate*

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

*E 341 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.

*E 450(a) diSodium dihydrogen diphosphate*

The criteria for disodium dihydrogen diphosphate contained in Council Directive 78/663/EEC.

*E 450(a) triSodium diphosphate*

The criteria for trisodium diphosphate contained in Council Directive 78/663/EEC.

*E 450(a) tetraSodium diphosphate*

The criteria for tetrasodium diphosphate contained in Council Directive 78/663/EEC.

*E 450(a) tetraPotassium diphosphate*

The criteria for tetrapotassium diphosphate contained in Council Directive 78/663/EEC.

*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*

The criteria for pentasodium triphosphate contained in Council Directive 78/663/EEC.

*E 450(b) pentaPotassium triphosphate*

The criteria for pentapotassium triphosphate contained in Council Directive 78/663/EEC.

*E 450(c) Sodium polyphosphates*

The criteria for sodium polyphosphates contained in Council Directive 78/663/EEC.

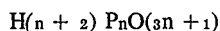
*E 450(c) Potassium polyphosphates*

The criteria for potassium polyphosphates contained in Council Directive 78/663/EEC.

*Ammonium and calcium polyphosphates*

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

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



where n shall be not less than 2.

Content, (expressed as  $P_2O_5$ ) ..... 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 and not more than 9.0.

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 fluoro-apatite.

Content (expressed as CaO)  
(expressed as  $P_2O_5$ ) ..... Not less than 45 per centum.  
Not less than 34 per centum.

Fluoride ..... Total: Not more than 700 mg. per kg.  
Water soluble: Not more than 2 mg. per kg.

Copper ..... Not more than 25 mg. per kg.

Zinc ..... Not more than 150 mg. per kg.

*Shellac*

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

*Silicon dioxide*

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

*Bentonite*

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

*Kaolin, heavy*

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

*Kaolin, light*

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

*Aluminium sodium silicate*

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



*Aluminium calcium silicate*

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

*Calcium silicate*

Description .....	White to off-white free-flowing powder.
Solubility .....	Insoluble in water. Forms a gel with mineral acids.
Content (expressed as SiO <sub>2</sub> )	Not less than 72 per centum and not more than 78 per centum on a volatile matter-free basis.
(expressed as CaO)	Not less than 16 per centum and not more than 21 per centum on a volatile matter-free basis.
(expressed as Na <sub>2</sub> O)	Not less than 2 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter .....	Not more than 6 per centum (determined by drying at 105°C. for 2 hours).
Loss on ignition .....	Not less than 7 per centum and not more than 14 per centum (determined by ignition at 1000°C. to constant weight).

*Magnesium silicate, synthetic*

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

*Magnesium trisilicate*

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

*Talc*

Description .....	Talc is a native hydrous magnesium silicate sometimes containing a small proportion of aluminium silicate.
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It shall comply with the requirements for appearance, characteristics and limits of impurities in the monograph for magnesium silicate contained in the Nutrition Meetings Report

Series 46B 1970 of the Food and Agriculture Organisation of the United Nations at page 114. The amount of material soluble in dilute hydrochloric acid shall be not more than 2 per centum and the amount of water soluble substances shall be not more than 0.2 per centum.

*E 420 Sorbitol*

The criteria for sorbitol contained in Council Directive 78/663/EEC.

*E 420 Sorbitol syrup*

The criteria for sorbitol syrup contained in Council Directive 78/663/EEC.

*Spermaceti*

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

*Sperm Oil*

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

*Magnesium stearate*

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

*Calcium stearate*

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

*Butyl stearate*

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

*Succinic acid*

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

*Sulphuric acid*

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

*Ammonium sulphate*

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

*Sodium sulphate*

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

*Magnesium sulphate*

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

*Potassium sulphate*

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

*Aluminium potassium sulphate*

Synonyms ..... Potassium aluminium sulphate.  
Potash alum.

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 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 $C_4H_6O_6$ on a volatile matter-free basis.
Volatile matter .....	Not more than 0.5 per centum (determined by drying at 105°C. to constant weight).
Sulphated ash .....	Not more than 0.1 per centum on a volatile matter-free basis.
Oxalates (expressed as oxalic acid) .....	Not more than 0.05 per centum on a volatile matter-free basis.

*E 335 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 volatile matter-free basis.
Volatile matter .....	Not less than 14 per centum and not more than 17 per centum for the dihydrate (determined by drying at 150°C. for 3 hours).

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

*E 335 diSodium L-(+)-tartrate*

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

*diSodium DL-tartrate*

Description ..... Colourless 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 per centum for the dihydrate (determined by drying at 150°C. for 3 hours).

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

*E 336 monoPotassium L-(+)-tartrate*

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

*monoPotassium DL-tartrate*

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

*E 336 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  $C_4H_4O_6K_2$  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 337 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°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 or 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 ...	diSodium 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
Chocolate products ...	Carnauba wax	200
Frozen food ...	Dichlorodifluoromethane	100 (determined when the food is fully thawed at and to 20°C.)
Glacé cherries ...	Calcium disodium ethylenediamine-NNN 'N'-tetra-acetate	In accordance with good manufacturing practice
	Aluminium potassium sulphate	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) 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, 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; and
  - (d) in the case of sorbitol syrup E 420 containing after hydrolysis a level of total sugars exceeding one per centum, the words "contains after hydrolysis a level of total sugars of more than 1%".
2. Any statement required by the preceding paragraph—
  - (a) shall be clear and legible;
  - (b) shall be in a conspicuous position on the label which shall be marked on, or securely attached to, the container in such a manner that it will be readily discernible and easily read by an intending purchaser under normal conditions of purchase;
  - (c) shall not be in any way hidden or obscured or reduced in conspicuousness by any other matter, whether pictorial or not, appearing on the label.
3. The figures and letters in every word in any statement to which the preceding paragraph applies—
  - (a) shall be in characters of uniform colour and size (being not less than 1.5 millimetres in height for a label on a container of which the greatest dimension does not exceed 12 centimetres, and not less than 3 millimetres in height for a label on a container of which the greatest dimension exceeds 12 centimetres), but so that the initial letter of any word may be taller than any other letter in the word;
  - (b) shall appear on a contrasting ground, so however that where there is no ground other than such as is provided by a transparent container and the contents of that container are visible behind the letters, those contents shall be taken to be the ground for the purposes of this paragraph;
  - (c) shall be within a surrounding line and no other written or pictorial matter shall appear within that line.
4. For the purposes of this Schedule—
  - (a) the height of any lower case letter shall be taken to be the x-height thereof, disregarding any ascender or descender thereof;
  - (b) any requirement that figures or letters shall be of uniform height, colour or size, shall be construed as being subject to the saving that any inconsiderable variations in height, colour or size, as the case may be, may be disregarded.

## SCHEDULE 4

Regulation 9

<i>Title</i>	<i>References</i>	<i>Extent of revocation</i>
Miscellaneous Additives in Food Regulations (Northern Ireland) 1974	S.R. 1974 No. 196	All the regulations
Miscellaneous Additives in Food (Amendment) Regulations (Northern Ireland) 1975	S.R. 1975 No. 275	Regulation 3
Specified Sugar Products Regulations (Northern Ireland) 1976	S.R. 1976 No. 165	Regulation 13
Cocoa and Chocolate Products Regulations (Northern Ireland) 1976	S.R. 1976 No. 183	Regulation 19



## EXPLANATORY NOTE

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

These regulations re-enact with amendments the Miscellaneous Additives in Food Regulations (Northern Ireland) 1974, as amended, and come into operation on 22nd July 1981.

The 1974 Regulations, as amended, implemented in part—

Council Directive of 23rd October 1962 (O.J. No. 115, 11.11.62; p. 2645/62; O.J./S.E. 1959/1962, p. 279) on the approximation of the rules of the Member States concerning colouring matters authorised for use in foodstuffs intended for human consumption, as amended;

Council Directive No. 64/54/EEC (O.J. No. 12, 27.1.64, p. 161; O.J./S.E. 1963-1964, p. 99) on the approximation of the laws of Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption, as amended;

Council Directive No. 65/66/EEC (O.J. No. 22, 9.2.65, p. 373/65; O.J./S.E. 1965-1966, p. 25) laying down specific criteria of purity for preservatives authorised for use in foodstuffs intended for human consumption, as amended; and

Council Directive No. 70/357/EEC (O.J. No. L157, 18.7.70, p. 31; O.J./S.E. 1970 (II) p. 429) on the approximation of the laws of Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption.

These regulations implement in part—

Council Directive 78/612/EEC (O.J. No. L197, 22.7.78, p. 22) amending for the first time Directive 74/329/EEC on the approximation of the laws of the Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs;

Council Directive 78/663/EEC (O.J. No. L223, 14.8.78, p. 7) laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs; and

Council Directive 78/664/EEC (O.J. No. L223, 14.8.78, p. 30) laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption.

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 of food which has in it or on it any added miscellaneous additive other than a permitted miscellaneous additive (regulation 4(1));
- (c) restrict to certain specified foods and within prescribed limits the use of certain permitted miscellaneous additives (regulation 4(2) and Schedule 2);
- (d) permit food which contains as an added ingredient any food specified in Schedule 2 to contain any permitted miscellaneous additive of the description specified for, and in the amount appropriate to the quantity of, that specified food (regulation 4(2));
- (e) prohibit the sale and the advertisement for sale of any miscellaneous additive, other than a permitted miscellaneous additive, for use as an ingredient in the preparation of food (regulation 5(1));

- (f) prescribe labelling requirements for permitted miscellaneous additives sold for use as ingredients in the preparation of food (regulation 5(2) and Schedule 3).

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

The principal changes effected by the regulations are—

- (a) the insertion in the list of permitted miscellaneous additives in Part I of Schedule 1 of disodium citrate (E 331), calcium hydrogen malate, trisodium diphosphate (E 450(a)) and the consequent insertion of specific purity criteria in Part II of Schedule 1;
- (b) the deletion from the list of permitted miscellaneous additives in Part I of Schedule 1 of calcium hydroxyphosphate (which is now covered by the new specific purity criteria for the permitted miscellaneous additive tricalcium diorthophosphate) and the consequent deletion of specific purity criteria from Part II of Schedule 1;
- (c) the replacement of the entries in Part I of Schedule 1 relating to—  
calcium citrate (E 333), ammonium, sodium, potassium and calcium polyphosphates including sodium and potassium polyphosphates (E 450(c)), sorbitol (E 420), tartaric acid (E 334), sodium tartrate (E 335), potassium tartrate (E 336), potassium hydrogen tartrate (E 336), and potassium sodium tartrate (E 337)

by entries for—

monocalcium citrate (E 333), dicalcium citrate (E 333), tricalcium citrate (E 333), sodium polyphosphates (E 450(c)), potassium polyphosphates (E 450(c)), ammonium and calcium polyphosphates, sorbitol (E 420), sorbitol syrup (E 420), L-(+)-tartaric acid (E 334), DL-tartaric acid, monosodium L-(+)-tartrate (E 335), monosodium DL-tartrate, disodium L-(+)-tartrate (E 335), disodium DL-tartrate, monopotassium L-(+)-tartrate (E 336), monopotassium DL-tartrate, dipotassium L-(+)-tartrate (E 336), dipotassium DL-tartrate, potassium sodium L-(+)-tartrate (E 337), and potassium sodium DL-tartrate

and consequent amendments in Part II of Schedule 1;

- (d) the replacement in appropriate cases of the specific purity criteria for permitted miscellaneous additives in Part II of Schedule 1 by the specific purity criteria laid down in Council Directive No. 78/663/EEC and Council Directive No. 78/664/EEC; and
- (e) the insertion in Schedule 3 of a new labelling requirement for sorbitol syrup (E 420) in certain circumstances.

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