MISCELLANEOUS ADDITIVES IN FOOD REGULATIONS, 1987

(LN. 1987/044)

1.8.1987

Amending enactments
1990/053

Relevant current provisions
reg. 2

Commencement date
1.7.1990

EU Legislation/International Agreements involved:

Directive 65/66/EEC
Directive 78/663/EEC
Directive 78/664/EEC
ARRANGEMENT OF REGULATIONS.

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6. Food for babies and young children.
7. Condemnation of food.
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SCHEDULE 1.

SCHEDULE 2.

SCHEDULE 3.
Title and commencement.

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

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

Interpretation.

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

“acid” means-

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

(b) nicotinic acid,

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

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

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

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

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

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

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

(a) contributing to the bulk of food without contributing significantly to its available energy value, or
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(b) producing bulk upon ingestion;

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

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

“dietetic food” means any food which-

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

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


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

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

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

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

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


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

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

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

“mineral hydrocarbon” has the meaning assigned to it by the Mineral Hydrocarbons in Food Regulations, 1987.

“miscellaneous additive” means any acid, anti-caking agent, anti-foaming agent, base, buffer, bulking aid, firming agent, flavour modifier, flour bleaching agent, flour improver, glazing agent, humectant, liquid freezant, packaging gas, propellant, release agent or sequestrant, but does not include-

(a) any natural food substance,
(b) any permitted antioxidant,
(c) any permitted sweetener,
(d) any permitted colouring matter,
(e) any permitted emulsifier,
(f) any permitted preservative,
(g) any permitted solvent,
(h) any permitted stabiliser,
(i) starches, whether modified or not,
(j) caseinates,

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(k) proteins, protein concentrates and protein hydrolysates,

(l) sodium chloride,

(m) normal straight chain fatty acids derived from food fats;

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

“the Act” means the Food and Drugs Act;

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

“permitted antioxidant” means any antioxidant in so far as its use is permitted by the Antioxidants in Food Regulations 1987;

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

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

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

“permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food Regulations 1987;

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

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

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

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

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

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

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

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

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

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

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

(5) Any reference in these regulations to a numbered regulation or schedule shall, unless the reference is to a regulation of, or schedule to, specified regulations, be construed as a reference to the regulation or schedule bearing that number in these regulations.

Exemptions

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

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

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

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

Provided that, subject to regulation 6-

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

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

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

Sale, advertisement and labelling of miscellaneous additives.

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

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

Food for babies and young children.

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

7. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell or import, that food may be treated for the purposes of section 10 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

Penalties

8. If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000.

Defences

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

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

Applications of various sections of the Act

10. Sections 46(2) and (3) (which relate to prosecutions), 47(1) and (2) (which relate to evidence of analysis), 49 (which relates to the power of a court to require analysis by the Government Chemist in the United Kingdom), 50 (which relates to a contravention due to some person other than the person charged), 51(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 52 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution, as the case may be, taken or brought for an offence under these regulations and as if the reference in the said Section 49 to subsection (3) of Section 46 included a reference to that subsection as applied by these regulations.
### Part 1: Permitted Miscellaneous Additives

<table>
<thead>
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<tbody>
<tr>
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<td>Serial number</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>E260</td>
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<tr>
<td>Sodium acetate, anhydrous</td>
<td></td>
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<tr>
<td>Sodium acetate</td>
<td></td>
</tr>
<tr>
<td>Sodium hydrogen diacetate</td>
<td>E262</td>
</tr>
<tr>
<td>Potassium acetate</td>
<td>E261</td>
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<tr>
<td>Calcium acetate</td>
<td>E263</td>
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<tr>
<td>Adipic acid</td>
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<td>2-Aminoethanol</td>
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<td>Azodicarbonamide</td>
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<td>Calcium phytate</td>
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<td>Carbon dioxide</td>
<td>E290</td>
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<td>Magnesium carbonate, light</td>
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<td>Alpha-cellulose</td>
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<td>Chlorine</td>
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<td>Dichlorodifluoromethane</td>
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<td>Nicotinic acid</td>
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<td>Nitrogen</td>
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<td>Nitrous oxide</td>
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</table>
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Octadecylammonium acetate
Oxide
Oxystearin
Orthophosphoric acid E338
Ammonium dihydrogen orthophosphate
DiAmmonium hydrogen orthophosphate
Sodium dihydrogen orthophosphate E339
diSodium hydrogen orthophosphate E339
triSodium orthophosphate E339
Potassium dihydrogen orthophosphate E340
diPotassium hydrogen orthophosphate E340
triPotassium orthophosphate E340
Calcium tetrahydrogen diorthophosphate E341
Calcium hydrogen orthophosphate E341
triCalcium diorthophosphate E341
Sodium aluminium phosphate, acidic
Sodium aluminium phosphate, basic
diSodium dihydrogen diphasphate E450(a)
triSodium diphasphate E450(a)
tetaSodium diphasphate E450(a)
tetaPotassium diphasphate E450(a)
diCalcium diphasphate
PentaSodium triphasphate E450(b)
PentaPotassium triphasphate E450(b)
Sodium polyphosphates E450(c)
Potassium polyphosphates E450(c)
Ammonium and calcium polyphosphates
Edible bone phosphate
Guanosine 5'- (disodium phosphate)
Inosine 5'- (disodium phosphate)
Polydextrose
Sodium 5'- ribonucitol -otide
Shellac
Silicon dioxide
Bentonite
Kaolin, heavy
Kaolin, light
Aluminium sodium silicate
Aluminium calcium silicate
Calcium silicate
Magnesium silicate, synthetic
Magnesium trisilicate
Talc
Spermaceti
Sperm oil
Magnesium stearate
Calcium stearate
Butyl stearate

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Succinic acid
Sulphuric acid
Ammonium sulphate
Sodium sulphate
Magnesium sulphate
Potassium sulphate
Aluminium potassium sulphate
Calcium sulphate
Tannic acid
L-(+)-Tartaric acid E334
DL-Tartaric acid
monoSodium L-(+)-tartrate E335
monoSodium DL-tartrate
diSodium L-(+)-tartrate E335
diSodium DL-tartrate
monoPotassium L-(+)-tartrate E336
monoPotassium DL-tartrate
diPotassium L-(+)-tartrate E336
diPotassium DL-tartrate
Potassium sodium L-(+)-tartrate E337
Potassium sodium DL-tartrate

Part II: Specific Purity Criteria Applicable to Permitted Miscellaneous Additives

E260 Acetic acid

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

Sodium acetate
The criteria in the monograph for sodium acetate contained in the Food Chemicals Codex 1972 at page 717 except that the alkalinity shall be not more than 0.1 per centum (as sodium carbonate, Na2CO3).

E262 Sodium hydrogen diacetate
Synonym Sodium diacetate.


E261 Potassium acetate
E263 Calcium acetate

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

2-Aminoethanol
Synonym Monoethanolamine.
Description Colourless to yellowish viscous hygroscopic liquid miscible with water in all proportions.
Content Not less than 98% of H2NCH2CH2OH.
Water Not more than 0.5%
Distillation range 166°C to 176°C (at 760 mm Hg).
Ethylene oxide Not more than 10 mg/kg

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

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

Beeswax, yellow
The criteria in the monograph for beeswax, yellow contained in the Food Chemicals Codex 1972 at page 77, except that the ester value shall be not less than 7(1 and not more than 80.

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

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

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 7 ml. N hydrochloric acid and 93 ml. of distilled water. Treat another 1g. sanuple of calcium phytate with 50ml. distilled water and 1.5ml. Orthophosphoric acid (50 per centum H3PO4; 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.

E290 Carbon dioxide

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 of white granular or crystalline powder. The anhydrous salt is hygroscopic and the decahydrate is efflorescent.

Content Not less than 98 per centum of Na2CO3 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;
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65 per centum for the decahydrate; (determined by the method for loss on drying in the monograph for sodium carbonate in the Food Chemical Codex 1972 at page 731).

Matter insoluble in dilute ammonia solution

Not more than 0.12 per centum on a volatile matter-free basis, determined by the following method:

Boil 5g. of hydrated sodium carbonate, or 2.5g. of anhydrous sodium carbonate, with 50ml. of water and 50ml. of dilute ammonia solution (about 10 per centum NH3). Filter and wash the residue with water, then ignite to constant weight.

Sulphate

Not more than 0.4 per centum on a volatile matter-free basis.

Chloride

Not more than 0.4 per centum on a volatile matter-free basis.

Iron

Not more than 40 mg. per kg. on a volatile matter-free basis.

Sodium hydrogen carbonate

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

Sodium sesquicarbonate

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

Magnesium carbonate, heavy

The criteria in the monograph for heavy magnesium carbonate contained in the European Pharmacopoeia Vol.1, 1969 at page 322.

Magnesium carbonate, light


Potassium carbonate

Description

The anhydrous form is a white granular powder. The hydrated form consists of small white translucent crystals or granules.

Content

Not less than 98 per centum of K2C03 on a volatile matter-free basis.

Volatile matter

Not more than:
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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.

E170 Calcium carbonate
Description Fine white microcrystalline or amorphous powder.
Content Not less than 97 per centum of CaCO₃ 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 Prof. 4 hydrochloric acid Shall comply with the requirement for aluminium,
iron, phosphate and matter insoluble in hydrochloric acid in the monograph for chalk in the
British Pharma copoeia 1973 at page 93.
Arsenic Not more than 5 mg. per kg.
Lead Not more than 20 mg. per kg.
Other in organic impurities Not more than 100 mg. per kg. of any of the
following substances, namely antimony, copper, chromium, zinc or barium sulphate, or more than
200 mg. per kg. of any combination of those substances.

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

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

Chlorine

Chlorine dioxide
A gaseous mixture with air containing not more than 4% v/v of chlorine
dioxide and not more than 1% v/v of chlorine.
E330 Citric acid
The criteria for citric acid contained in Council Directive 78/664/EEC.

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

E131 Sodium dihydrogen citrate

E331 diSodium citrate

E331 triSodium citrate

E332 Potassium dihydrogen citrate

E333 tripotassium citrate

E333 monoCalcium citrate

E333 diCalcium citrate

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

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

Ammonium ferric citrate, green
Synonym Green ferric ammonium citrate.
L-Cysteine hydrochloride

Chemical description: L2-amino-3-mercaptopropanoic acid hydrochloride or L-2-amino-3-mercaptopropanoic acid hydrochloride monohydrate.

Description: White, crystalline powder or colourless crystals.

Content: Not less than 98% of C3H7N025.HCL calculated on an anhydrous basis.

Specific rotation: [x] 2OC D 5.5 to +7.80 for 8g of sample made up to 100ml with N hydrochloric acid.

Sulphated ash: Not more than 0.1%.

Dichlorodifluoromethane

Description: Clear, colourless liquefied gas.

Content: Not less than 99.97 per centum CCl2F2.

Trichlorofluoromethane

CHClF2

Chlorodifluoromethane

CMCl2F

Chlorotrifluoromethane

CCIF2

Other organic compounds

Non-volatile matter: Not more than 290 mg. per kg. singly or in combination.

Not more than 10 mg. per kg.

Not more than 0.01 per centum by volume (after evaporation at 0°C.)

Dimethylpolysiloxane

Synonym: Deimethyl silicone.

Appearance: Clear colourless odourless liquid free from extraneous matter.

Solubility: Insoluble in water Soluble in most aliphatic and aromatic hydrocarbon solvents.

Volatile matter: Not more than 2 per centum (determined by drying at 200°C. for 4 hours).

Identification: Shall comply with the identification tests.
The criteria in the monograph for disodium edetate contained in the British Pharmacopoeia 1973 at page 176.

Calcium disodium ethylenediamine-NNN'N'-tetra-acetate
Synonym Sodium calciumedetate.
The criteria in the monograph for sodium calciumedetate in the British Pharmacopoeia 1973 at page 425.

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

*Potassium ferrocyanide*
Synonym Potassium hexacyanoferrate(II)
Description Odourless lemon yellow crystals.
Solubility Soluble in water and in acetone.
Insoluble in ethanol, in ether and in hydrocarbons.
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Subsidiary
1987/044

Content
Not less than 98 per centum of K₄Fe(CN)₆·3H₂O.

Free moisture
Not more than 1 per centum (determined by the method for free moisture in the monograph of sodium ferrocyanide in the Food Chemicals Codex 1972 at page 741).

Chloride
Not more than 0.1 per centum.

Sulphate
Not more than 0.1 per centum.

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

D- Glucono-1,5-lactone
Synonym Glucono delta-lactone.
The criteria in the monograph for glucono delta-lactone contained in the Food Chemicals Codex 1972 at page 346.

Sodium 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 C₆H₁₁O₇K 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.

Sodium hydrogen L-glutamate
Synonyms monoSodium glutamate.
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Sodium glutamate.
Glutamic acid, sodium salt.

Formula \( \text{C}_5\text{H}_8\text{NNaO}_4\text{H}_2\text{O} \) (molecular weight 187.13).

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

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

I 4-Heptonolactone

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonym</td>
<td>Heptonolactone.</td>
</tr>
<tr>
<td>Description</td>
<td>Colourless crystals.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Slightly soluble in ethanol. Insoluble in ether.</td>
</tr>
<tr>
<td>Content</td>
<td>Not less than 99.5 per cent turn of ( \text{C}<em>7\text{H}</em>{12}\text{O}_7 ).</td>
</tr>
<tr>
<td>Melting point</td>
<td>148°C</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>Not less than -54.00 and not more than -53.00 ( 20^\circ\text{C} ) ([x] D)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 per centum.</td>
</tr>
</tbody>
</table>

Sodium heptonate

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>White to tan crystalline powder.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Sparingly soluble in ethanol. Very Soluble in water.</td>
</tr>
<tr>
<td>Content</td>
<td>Not less than 98 per centum of ( \text{C}<em>7\text{H}</em>{13}\text{O}_8 ) ( 2\text{Ca}.2\text{H}_2\text{O} ).</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 0.5 per centum. (expressed as glucose)</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not more than 0.1 per centum.</td>
</tr>
<tr>
<td>Chloride</td>
<td>Not more than 0.01 per centum.</td>
</tr>
</tbody>
</table>

Calcium heptonate

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>White crystalline powder.</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water. Insoluble in ethanol.</td>
</tr>
<tr>
<td>Content</td>
<td>Not less than 99 per centum of ( \text{C}<em>7\text{H}</em>{13}\text{O}_8 ) ( 2\text{Ca}.2\text{H}_2\text{O} ).</td>
</tr>
</tbody>
</table>
Reducing substances (expressed as glucose) Not more than 0.5 per centum.

Sulphate Not more than 0.12 per centum.

Chloride Not more than 0.07 per centum.

*Hydrochloric acid*
The criteria in the monograph for concentrated hydrochloric acid contained in the European Pharmacopoeia Vol. 11, 1971 at page 145.

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

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

*Calcium chloride, 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 crystal.

Content Not less than:
98 per centum of CaCl$_2$.2H$_2$O for the dihydrate,
97 per centum of CaCl$_2$.6H$_2$O for the hexahydrate.

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

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

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

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

**Magnesium oxide, heavy**
Description: White fine odourless powder.
Solubility: Practically insoluble in water.
Soluble in dilute acids with, at most, slight effervescence.
Apparent volume: 20g. of heavy magnesium oxide occupies a volume of about 50 ml.
Content: Not less than 98 per centum of MgO calculated with reference to the ignited substance and determined by the assay method contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol.1, 1969 at page 319.
Loss on ignition: Not more than 5 per centum (determined by ignition at 900°C to 950°C. to constant weight).
Matter 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 4 mg. per kg.
Heavy metals Not more than 40 mg. per kg.

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

Magnesium oxide, light

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 Not more than 0.5 per centum acid (about 10 per centum weight/volume HCl).
Magnesium and alkali salt Not more than 6 per centum, determined by the method in the monograph for calcium hydroxide contained in the Food Chemicals Codex 1972 at page 131 except that the weight of the residue shall not exceed 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.

**E270 Lactic acid**

**E325 Sodium lactate**

**E326 Potassium lactate**

**E327 Calcium lactate**

**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 C4H6O5.
Melting range  99°C. to 101°C.
Specific rotation 20°C[α] D  Not less than -2.4° and not more than -2.2° (using a solution containing 8.5g. L-malic acid in 100ml. water).

**Maleic acid**
Fumaric acid

**Residue on ignition**

**Water insoluble matter**
Shall comply with the limits given in the monograph for malic acid in the Food Chemicals Codex 1972 at page 484.

**Sodium hydrogen malate**
Description  White odourless powder.
Sodium hydrogen malate may be derived from either DL-malic acid or L-malic acid.
### 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 hydrogen malate

**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.

### Calcium malate

**Description**  
White odourless powder. Calcium malate may be derived from either DL-malic acid or L-malic acid.

**Content**  
Not less than 97.5 per centum of $C_4H_4O_5Ca$ on a volatile matter-free basis.

**Volatile matter**  
Not more than 2 per centum (determined by drying at 110°C for 3 hours).

**Maleic acid**  
Not more than 0.05 per centum.

**Fluoride**  
Not more than 30 mg. per kg. on a volatile matter-free basis.

### Metatartaric acid

**Description**  
White or yellow powder which consists chiefly of a
mixture of polyester obtained by the controlled dehydration of L-(+)-tartaric acid, together with unchanged L-(+)-tartaric acid.

Specific absorption identification
Place 5 to 10mg. of sample in a test tube. Add 2ml. sulphuric acid (about 94 per centum H2SO4) 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 (C4H6O6).
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 (T1ml.).
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 (T2ml.).
Calculations:
Tartaric acid equivalent = 7.5 (T1 + 20 - T2) Per centum
Esterified tartaric acid = \( \frac{100(T_1 + 20 - T_2)}{T_1 + 20 - T_2} \) per centum.

Specific rotation
\( [\alpha]_{20^\circ} \text{D} \)
Not less than +12.50 and not more than +13.5° (using a filtered 10 per centum weight/volume aqueous solution).

Matter insoluble in water (at about 20°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.

Nicotinic acid
The criteria in the monograph for nicotinic acid contained in the British Pharmacopoeia 1973 at page 318.
Nitrogen

Nitrous oxide
The criteria in the monograph for nitrous oxide contained in the European Pharmacopoeia Vol.11, 1971 at page 316.

Octadecylammonium acetate
Synonym Octadecylamine acetate.
Description White waxy solid which consists essentially of the acetic acid salts of a mixture of mainly stearyl and palmityl primary aliphatic 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 80⁰C. to 85⁰C.
Moisture Not more than 1 per centum (Karl Fischer).
Iodine Value Not more than 5 (Wijs).

Oxygen
The criteria in the monograph for oxygen contained in the European Pharmacopoeia Vol.11, 1971 at page 328.

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

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

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

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

E339 Sodium dihydrogen orthophosphate

E339 disodium hydrogen orthophosphate

E339 trisodium orthophosphate

E340 potassium dihydrogen orthophosphate

E340 diopotassium hydrogen orthophosphate

E340 tripotassium orthophosphate

E341 calcium tetrahydrogen diorthophosphate

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

F341 tricalcium diorthophosphate
The criteria for tricalcium orthophosphate contained in Council Directive 78/663/EEC.

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

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

E450(a) disodium dihydrogen diphosphate

F450(a) trisodium diphosphate

**F450(a) tetraSodium diphosphate**

**F450(a) tetraPotassium diphosphate**

di Calcium diphosphate
Synonyms diCalcium pyrophosphate.  
Calcium pyrophosphate.

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

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

**E450(b) pentaPotassium tripophosphate**

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

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

**Ammonium and calcium polyporphates**

**Description**  
Ammounium and calcium polyporphates 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: \( H(n_{-2})PnO(3m,1) \) where \( n \) shall be not less than 2.

**Content (expressed as \( P_2O_5 \))**
Not less than 50 per centum and not more than 71 per centum on an anhydrous basis.

**pH (1 per centum aqueous solution)**
For water soluble phosphates only: not less than 4.0 and not more than 9.0.

**Cyclic phosphate**
Not more than 8 per centum calculated on the \( P_2O_5 \)
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Fluoride
Not more than 15 mg. per kg. calculated on the P₂O₅ content.

**Edible bone phosphate**

**Description**
Edible bone phosphate is a pale cream-coloured powder, prepared from selected animal bones which are crushed, degreased and then subjected to a high pressure steam extraction. The main constituent is hydroxy-apatite with some carbonate-apatite and a trace of fluoride-apatite.

**Content** (expressed as CaO)
Not less than 45 per centum.

(expressed as P₂O₅) Not less than 45 per centum.

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

Copper
Not more than 25 mg. per kg.

Zinc
Not more than 150 mg. per kg.

**Guanosine5'- (disodium phosphate)**

**Synonyms**
Sodium 5'-guanylate.
diSodium guanosine 5'-monophosphate.

**Formula**
C₁₀H₁₂N₁₂N₅Na₂O₁₇P₅.xR₂O (molecular weight (anhydrous) 407.20).

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

**Inosine 5'- (disodium phosphate)**

**Synonyms**
Sodium 5'-inosinate.
diSodium inosine 5'-monophosphate.

**Formula**
C₁₀H₁₂N₁₂N₅Na₃O₁₇P₅.xR₂O (molecular weight (anhydrous) 392.19).

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

**Polydextrose**

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

**Content**
Not less than 90 per centum of polymer on an ash-free and water-free basis.

Free glucose
Not more than 4 per centum on an ash-free and water-free basis.

Free
Not more than 4 per centum on an ash-free and water-free basis.
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1 ,6-anhydro -D- glucose  water- free basis.
Free sorbitol  Not more than 2 per centum on an ash-free and water- free basis.
Water  Not more than 4 per centum (Karl Fischer).

pH (10 per centum solution).  Not less than 2.5 and not more than 3.5 (not less than aqueous 5.0 and not more than 6.0 for the neutralised product).

Sulphatedash  Not more than 0.3 per centum (not more than 3.0 per centum for the neutralised product).
Arsenic  Not more than 1 mg/kg.
Lead  Not more than 1 mg/kg.

Sodium 5'-ribonucleotide

Description  White or nearly white crystalline powder consisting of a mixture of guanosine 5'- (disodium phosphate) and inosine 5'-(disodium phosphate) in approximately equal proportions. Soluble in water, practically insoluble in ethanol.

Content  Not less than 97 per centum and not more than 102 per centum of C\textsubscript{10}H\textsubscript{12}N\textsubscript{5}Na\textsubscript{2}O\textsubscript{8}P and C\textsubscript{10}H\textsubscript{11}N\textsubscript{5}Na\textsubscript{2}O\textsubscript{8}P, and not less than 47 per centum and not more than 53 per centum of C\textsubscript{10}H\textsubscript{12}N\textsubscript{5}Na\textsubscript{2}O\textsubscript{8}P or of C\textsubscript{10}H\textsubscript{11}N\textsubscript{5}Na\textsubscript{2}O\textsubscript{8}P in every case calculated on an anhydrous basis.

Moisture  Not less than 22 per centum and not more than 26 per centum (Karl Fischer).

pH (5 per centum aqueous solution)  Not less than 7.0 and not more than 8.5.

Ammonium salts  Place 100 mg of sample in a test tube. Add 50 mg magnesium oxide plus 1 ml of water. Heat on a water bath for 5 minutes; the vapour evolved does not affect the colour of moist litmus paper.

Amino acids  Place 5 ml of a 0.1 per centum (weight/volume) solution in a test tube. Add 1 ml of a 2 per centum (weight/volume) solution of ninhydrin and heat for 3 minutes; no blue colour is produced.

Other nucleotides  The paper chromatogram obtained when sodium 5'-ribonucleotide is analysed using the procedure described for 'other nucleotides' in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105 shall show no spots other than those for guanosine 5'- (disodium phosphate) and inosine 5'- (disodium phosphate).

Shellac
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 SiO₂
Hydrated silica: not less than 91 per centum of SiO₂ 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 Na₂SO₄)
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 SiO₂) Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.
(expressed as Al₂O₃) Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed as Na₂O) 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).
**Aluminium calcium silicate**

**Synonymous**
- Calcium aluminum Silicate,
- Calcium alumino-silicate,
- 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).

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**Calcium silicate**

**Description**
White to off-white free-flowing powder.

**Solubility**
Insoluble in water.
Forms a gel with mineral acids.

**Content**
- Not less than 72 per centum and not more (expressed as SiO$_2$) than 78 per centum on a volatile matter-free basis.
- (expressed 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 0 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).

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**Magnesium silicate, synthetic**

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

**Magnesium trisilicate**

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

Description: Talc is a native hydrous magnesium silicate sometimes containing a small proportion of aluminium silicate.

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

**Spermaceti**

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

**Sperm Oil**


**Magnesium stearate**

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

**Calcium stearate**

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

**Butyl stearate**

Description: White solid with a slightly yellow tinge; melts at about room temperature to a clear liquid and consists chiefly of the butan-1-ol ester of commercial food-grade stearic acid.

- Solidification: between 14°C and 26°C.
- Saponification value: Not less than 160 and not more than 180.
- Iodine value: Not more than 7 (Wijs).
- Acid value: Not more than 2.5 mg KOH per g.

**Succinic acid**

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

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.

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.

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

DL-Tartaric acid
Description DL-Tartaric acid occurs as a white crystalline powder
or as colourless or translucent crystals.
Content Not less than 99.5 per centum of C₄H₆O₆ on a volatile matter-free basis.
### MISCELLANEOUS ADDITIVES IN FOOD REGULATIONS, 1987

<table>
<thead>
<tr>
<th>Additive</th>
<th>Content</th>
<th>Volatile matter</th>
<th>Oxalates (expressed as oxalic acid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E335 monoSodium L- (+)-tartrate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>monoSodium DL-tartrate</td>
<td>Colourless transparent crystals.</td>
<td>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).</td>
<td>Not more than 0.05 per centum on a volatile matter-free basis.</td>
</tr>
<tr>
<td>E335 diSodium L- (+)-tartrate</td>
<td>Colourless transparent crystals.</td>
<td>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).</td>
<td>Not more than 0.05 per centum on a volatile matter-free basis.</td>
</tr>
<tr>
<td>E336 monoPotassium L- (+)-tartrate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mono Potassium L-tartrate</td>
<td>The criteria in the monograph for potassium acid tartrate contained in the Food Chemicals Codex 1972 at page 639, except that potassium acid tartarate shall be derived from DL-tartaric acid.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
diPotassium DL-tartrate
Description White crystalline or granular powder.
Content Not less than 99 per centum of C₄H₄O₆K₂ on a volatile matter-free basis.
Volatile matter Not more than 4 per centum (determined by a 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.

E337 Potassium sodium L-(+)-tartrate

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 C₄H₄O₆KNa 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,
### MISCELLANEOUS ADDITIVES IN FOOD REGULATIONS, 1987

#### SCHEDULE 2

**Miscellaneous Additives Permitted only in Certain foods**

<table>
<thead>
<tr>
<th>Specified food</th>
<th>Permitted Miscellaneous Additive</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium chloride Brandy</td>
<td>Octadecylammonium acetate</td>
<td>500 milligrams per kilogram not exceeding-</td>
</tr>
<tr>
<td>Bread</td>
<td>Azodicarbonamide</td>
<td>As prescribed by the Bread and Flour Regulations 1987.</td>
</tr>
<tr>
<td>Bread</td>
<td>Benzoyl peroxide</td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td>Potassium bromate</td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td>Chlorine dioxide</td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td>L-Cysteine hydrochloride</td>
<td></td>
</tr>
<tr>
<td>Canned fish</td>
<td>Calcium disodium ethylenediamine-NNN’N’-tetra-acetate</td>
<td>In accordance with good manufacturing practice.</td>
</tr>
<tr>
<td>Canned shellfish</td>
<td>Calcium disodium ethylenediamine-NNN’N’-tetra-acetate</td>
<td>In accordance with good manufacturing practice.</td>
</tr>
<tr>
<td>Chocolate confectionery</td>
<td>Carnauba wax</td>
<td>200</td>
</tr>
<tr>
<td>Chocolate products</td>
<td>Carnauba wax</td>
<td>200</td>
</tr>
<tr>
<td>Flour</td>
<td>Azodicarbonamide</td>
<td>As prescribed by the Bread and Flour Regulations 1987.</td>
</tr>
<tr>
<td>Frozen food</td>
<td>Dichlorodifluoromethane</td>
<td>100 (determined when the food is fully thawed at and to 20°C).</td>
</tr>
<tr>
<td>Glace cherries</td>
<td>Calcium disodium ethylenediamine-NNN’N’-tetra-acetate</td>
<td>In accordance with good manufacturing practice. 10,000 (on a dry matter basis).</td>
</tr>
<tr>
<td>Peeled fruit</td>
<td>2-Aminoethanol</td>
<td>100</td>
</tr>
<tr>
<td>Peeled vegetables</td>
<td>2-Aminoethanol</td>
<td>100</td>
</tr>
<tr>
<td>Sugar</td>
<td>Carnauba wax</td>
<td>200</td>
</tr>
</tbody>
</table>
### MISCELLANEOUS ADDITIVES IN FOOD REGULATIONS, 1987

<table>
<thead>
<tr>
<th>Confectionery</th>
<th>Wine</th>
<th>Metatartaric acid</th>
<th>100 milligrams per litre</th>
</tr>
</thead>
</table>
Labelling of Permitted Miscellaneous Additives

1. Each container to which regulation 5(2) of these regulations applies shall bear a label on which is printed a true statement,—

   (a) in respect of each permitted miscellaneous additive present, of the serial number, if any, as specified in relation thereto in column 2 of Part I of Schedule 1 to these regulations, and of the common or usual name or an appropriate designation of that permitted miscellaneous additive;

   (b) where any other substance or substances is or are present, of the common or usual name or an appropriate designation of each such substance;

   (c) if two or more such substances are present, of the proportion of each permitted miscellaneous additive and each other substance present save that the label shall only have printed on it a statement of the proportion of any such other substance present if any regulations (other than these regulations or any amendment to these regulations) made under the Act contain a requirement to that effect,

2. Any statement required by the preceding paragraph—

   (a) shall be clear and legible;

   (b) shall be in a conspicuous position on the label which shall be marked on, or securely attached to, the container in such a manner that it will be readily discernible and easily read by an intending purchaser under normal conditions of purchase;

   (c) shall not be in any way hidden or obscured or reduced in conspicuousness by any other matter, whether pictorial or not, appearing on the label.

3. The figures and letters in every word in any statement to which the preceding paragraph applies—

   (a) shall be in characters of uniform colour and size (being not less than 1.5 millimetres in height for a label on a container of which the greatest dimension does not exceed 12 centimetres, and not less than 3 millimetres in height for a label on a container of which the greatest dimension exceeds 12 centimetres), but so that the initial letter of any word may be taller than any other letter in the word,
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(b) shall appear on a contrasting ground, so however that where there is no ground other than such as is provided by a transparent container and the contents of that container are visible behind the letters, those contents shall be taken to be the ground for the purposes of this paragraph.

(c) shall be within a surrounding line and no other written or pictorial matter shall appear within that line.

4. For the purposes of this Schedule-

(a) the height of any lower case letters shall be taken to be the x-height thereof, disregarding any ascender or descender thereof;

(b) any requirement that figures or letters shall be of uniform height, colour or size, shall be construed as being subject to the saving that any inconsiderable variations in height, colour or size, as the case may be, may be disregarded.