# 1976 No. 36

THE FOOD AND DRUGS (MISCELLANEOUS ADDITIVES IN FOOD) ORDER, 1976

Made ... 27th May, 1976.. Laid before the States ... Coming into operation ... 27th May, 1976

# ARRANGEMENT OF SECTIONS

- 1. Citation and commencement.
- 2. Interpretation.
- 3. Exemptions.

\$

- 4. Sale, etc. of food containing miscellaneous additives.
- 5. Sale, advertisement and labelling of miscellaneous additives.
- 6. Condemnation of food.
- 7. Penalties.
- 8. Defences.
- 9. Application of various sections of the Law.
- 10. Extent.

Schedule	1.	Permitted miscellaneous additives and purity criteria.
Schedule	2.	Miscellaneous additives permitted only in certain foods.
Schedule	3.	Labelling of permitted miscellaneous additives.
Schedule	4.	Permitted bleaching or improving agents.
Schedule	5.	Permitted solvents.

THE FOOD AND DRUGS (MISCELLANEOUS ADDITIVES IN FOOD) ORDER, 1976

THE STATES BOARD OF HEALTH, in exercise of the powers conferred upon it by sections four, seven and forty-seven of the Food and Drugs (Guernsey) Law, 1970 (a), as amended (b), and of all other powers enabling it in that behalf, hereby orders:-

1. Citation and Commencement

This Order may be cited as the Miscellaneous Additives in Food Order, 1976, and shall come into operation on the twenty-seventh day of May, nineteen hundred and seventy six.

### Interpretation

- 2. (1) In this Order, 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) nicotinie 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;

"bleaching agent" means any substance capable of removing colour from ground bolted wheat;

"the Board" means the States of Guernsey Board of Health;

"bread" has the meaning assigned to it by the Colouring Matter in Food Order, 1976 (c);

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

"cheese" and "cheese spread" have the meanings assigned to them respectively by the Colouring Matter in Food Order, 1976;

- (a) Ordres en Conseil Vol XXII, p.412
- (b) Ordre en Conseil No. XIV of 1975
- (c) SI 1976 No. 34

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

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

"European Pharmacopoeia Volume 1, 1969" and "European Pharmacopoeia Wolume 11, 1971" mean respectively Volume 1 of the European Pharmacopoeia published in 1969 and Volume 11 of the European Pharmacopoeia published in 1971, in each case by Meisonneuve 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;

"flour" has the meaning assigned to it by the Colouring Matter in Food Order, 1976;

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

(a) water, live animals or birds,

(b) fodder or feeding stuffs for enimals, birds or fish,

(c) articles or substances used only as drugs;

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

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

"hard cheese" has the meaning assigned to it by the Colouring Matter in Food Order, 1976;

"human consumption" includes use in the preparation of food for human consumption;

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

"improving agent" means any substance simulating the effects produced by the natural ageing of flour and includes sulphar dioxide;

"the Island" includes the Islands of Guernsey, Alderney, Herm and Jethou;

"the Law" means the Food and Drugs (Guernsey) Law, 1970;

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

"mineral hydrocarbon" means any hydrocerbon product, whether liquid, semi-liquid or solid, derived from any substance of mineral origin and includes liquid paraffin, white oil, petroleum jelly, hard paraffin and microcrystalline wax;

"miscellaneous additive" means any acid, anti-caking agent, anti-foaming agent, base, buffer, firming agent, glazing egent, humectont, liquid freezant packaging gas, propellent, release agent or sequestrant, but does not include -

(a) any natural food substance,

÷

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

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

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

"permitted antioxidant" means any antioxidant in so far as its use is permitted by the (Antioxidant in Food) Order, 1976(d);

"permitted artificial sweetner" means seccharin, seccharin calcium or saccharin sodium;

"permitted bleaching agent" means, in relation to a food of a kind set out in columm 1 of Schedule 4 to this Order, a bleaching agent set out in columm 2 thereof in relation to such food, if the food contains the bleaching agent in a proportion not exceeding the proportion, if any, set out in relation to such bleaching agent in column 3 of the said Schedule;

"permitted colouring matter" means any colouring matter in so far as its use is permitted by the Colouring Matter in Food Order, 1976; "permitted emulsifier" means any emulsifier in so far as its use is permitted by The Emulsifiers and Stabilisers in Food Order, 1976(e);

"permitted improving agent" means, in relation to *e* food of a kind set out in column 1 of Schedule 4 to this Order, an improving agent set out in column 2 thereof in relation to such food, if the food contains the improving agent in a proportion not exceeding the proportion, if any, set out in relation to such improving agent in column 3 of the said Schedule;

"permitted miscellaneous additive" means any miscellaneous additive specified in Part 1 of Schedule 1 to this Order which satisfies the specific purity criteria in relation to that additive specified or referred to in Part 11 of thet Schedule and, so far as is not otherwise provided by any such specific purity criteria, satisfies the general purity criteria specified in Part 111 of thet 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 Order, 1976(f)

"permitted solvent" means any solvent set out in the first column of Schedule 5 to this Order which complies with the specification set out in relation thereto in the second column of that Schedule, and includes any such solvent when it has been subsequently diluted with water;

"permitted stabiliser" means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Order, 1976;

"processed cheese" has the meaning assigned to it by the Colouring matter in Food Order, 1976;

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

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

"saccharin" means the substance conforming to the description, specifications and requirements for saccharin contained in the British Pharmacopocia 1968;

"saccharin calcium" means the substance conforming to the description, specifications and requirements for saccaharin calcium contained in Schedule 1 to these regulations;

"saccharin sodium" means the substance conforming to the description, specifications and requirements for saccabarin sodium contained in the British Pharmacopeia 1968;

"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;

"soft cheese" has the meaning assigned to it by the Colouring Matter in Food Order, 1976;

<sup>(</sup>d) SI 1976 No. 35 (e) SI 1976 No. 37 (f) SI 1976 No. 33

"specified food" means any food of a description specified in column 1 of Schedule 2 to this Order;

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

"whey cheese" has the meaning assigned to it by the Colouring Matter in Food Order, 1976;

and other expressions have the same meaning as in the Law.

- (2) The Interpretation (Guernsey) Law, 1948(g) shall apply to the interpretation of this Order as it applies to the interpretation of a Guernsey enactment.
- (3) Unless a contrary intention is expressed, all proportions mentioned in this Order are proportions calculated by weight of the product as sold.
- (4) Any reference in this Order to a label borne on a container shall be construed as including a reference to any legible marking on the container however effected.
- (5) For the purposes of this Order the supply of food, otherwise then by sale, at, in or from any place where food is supplied in the course of a business shall be deemed to be a sale of that food.
- (6) Except in so far as the context otherwise requires, any reference in this Order to any enactment or order shall be construed as a reference to that enactment or order as amended, repealed and replaced, extended or applied by or under any other enactment or order including this Order.

## Exemptions

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

## Sale, etc of food containing miscellaneous additives

- 4.-(1) Subject to subsection (2) of this section, no food sold, consigned, delivered or imported into the Island shall have in it or on it any added miscellaneous additive other than a permitted miscellaneous additive;
  - (2) Save as hereinafter provided, no food sold, consigned, delivered or imported into the Island shall have in it or on it any added permitted miscellaneous additive specified in column 2 of Schedule 2 to this Order;

Provided that -

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

(g) Ordres en Conseil Vol XIII, P.355

- (b) any food containing as an added ingredient any specified food may contain any such permitted miscellaneous additive of the description specified for, and in the amount appropriate to the quantity of, such specified food in accordance with the preceding subparagraph of this proviso.
- (3) No persons shall sell, consign or deliver, or import into the Island any food which does not comply with this Order.

### Sale, advertisement and labelling of miscallaneous additives

- 5.-(1) No person shall sell, consign, deliver or import into the Island or advertise for sale any miscellaneous additive (including any miscellaneous additive with which any other substance has been mixed) for use as an ingredient in the preparation of food unless such miscellaneous additive is a permitted miscellaneous additive.
  - (2) No person shall sell, consign or deliver any permitted miscellaneous additive (including any permitted miscellaneous additive with which any other substance has been mixed) for use as an ingredient in the preparation of food except in a container bearing a label in accordance with the requirements of Schedule 3 to this Order.

Condemnation of food

6. Where any food is certified by the States Analyst as being food which it is an offence against section 4 of this Order to sell, consign, deliver or import into the Island, that food may be treated for the purposes of section 9 of the Law (under which food may be seized and destroyed on the order of the Magistrate's Court) as being unfit for human consumption.

### Penalties

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

## Defences

- 8.-(1) In any proceedings for an offence against this Order 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 this Order in relation to the publication of an advertisement, it shall rest on the defendant to prove that he did not publish, and was not a party to the publication of, the advertisement.

### Application of various sections under the Law

9. Subsections (2) and (3) of section thirty-seven (which relate to prosecutions), section thirty-eight (which relates to evidence of analysis), section forty (which relates to a contravention due to some person other than the person charged) subsection (2) of section forty-one (which relates to the conditions under which a warranty may be pleaded as a defence)

• · 9. Cont ...

and sertion forty-two (which relates to offences in relation to warranties and certificates of analysis) of the Law shall apply for the purposes of this Order as if references therein to proceedings, or a prosecution, under or taken or brought under the Law included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under this Order.

# Extent

10. This Order shall have effect in the Islands of Guernsey, Alderney, Herm and Jethou.

Dated this Twenty seventh day of May, nineteen hundred and seventy-six.

Ich R R Llew President of the States Board of Health for and on behalf of the Board

Column 1		Column 2
Name of Miscellaneous Ac	dditive	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 carbona	to	[·
Sodium carbonate		
Sodium bydrogen carbonate		-
Sodium sesoulcarbonate		·
Magnanium cathonata heavy		_
Magnesium carbonate, heavy	••• •••	
References and a set and the set of the set		
Polassium budenen enshante	4+1 114	
Colision nyurogen caroonate		
Calcium carbonate		8110
Carnauda wax	*** ***	E 320
Citrie acid	· ••• •••	0000
Transpontum citrate		12 221
Solitin dinydrogen chrate	••••	2 331
Peterium dibudacer citate		E 351
Potassium diayurogen chrate		1 B 332
Orbien sitests	••• •••	, <u>5</u> ,554
Calcium citrate	••• •••	( CC CI
Ammonium Jerrie citrate		
Ammonium ferrie citrate, green	1 	
Dichlorodifluoromethane		-
Dimethylpolysiloxane		, ₁ →
diSodium dihydrogen eth	ylenediamine—	j.
NNN <sup>1</sup> N <sup>1</sup> tetra-acetate		)
Calcium disodium ethy	ylenediamine	
NNN <sup>1</sup> N <sup>1</sup> tetra-acetate		) —
Spdium ferroevanide	•• •••	) ····
Potassium ferroevanide		( · _

المرسية مالا المراسم مستملك المرسية المرابع

ļ

۰÷

				(
Column 1		-~		Column 2
Name of Miscellaneo	ous Add	litive		Serial number
Fumaric acid				· · -
D-Glucono-1,5-lactone	•••		•••	
Sodium gluconate	•••			)
Potassium gluconate	•	•••		<u> </u>
Calcium gluconate	•••			· · ·
Glycine	• • •		•••	
1, 4-Heptonolactone				
Sodium heptonate	•••		•••	·
Calcium heptonate	•••			<u>→</u>
Hydrochloric acid			•••	_
Ammonium chloride				·
Potassium chloride				_
Calcium chloride, anhvd	rous			
Calcium chloride				
Hydrogen				
Ammonium bydroxide				
Sodium hydroxide		•••	•••	_
Magnasium budrovida	•••			
Magnesium ovide heavy	•••			
Magnesium oxide, heavy				—
Magnesium bud wide	•••	•••	•••	
Polassium 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	•••		•••	<u> </u>
Sodium hydrogen malate				—
Sodium malate	•••	•••		
Potassium malate	•••			_
Calcium malate	•••			—
Mannitol				E 421
Metatartaric acid	•••			-
Nicotinic acid				
Nitrogen				—
Nitrous oxide				
Octadecylammonium ace	tate			_
Oxygen	•••			
Oxystearin				
Orthophosphoric acid				E 338

ł

÷.

- 347590

	Column 1	Column 2	
	Name of Miscellaneous Additive	Serial number	
	Annagium dihudragan asthenharnhata		
	diAmmonium hydrogen orthophosphate	· · ·	
	Sodium dihydrogen orthophosphate	E 339(a)	,
	diSodium hydrogen orthophosphate	E 339(b)	•
	triSodium orthophosphate	E 339(c)	
	Potassium dihydrogen orthophosphate	. E 340(a)	•
	diPotassium hydrogen orthophosphate	E 340(b)	1
•	triPotassium orthophosphate	E 340(c)	
	Calcium tetrahydrogen diorthophosphate	E 341(a)	
	Calcium hydrogen orthophosphate	E 341(b)	÷
	triCalcium diorthophosphate	E 341(c)	
	Calcium hydroxyphosphate		•
1	Sodium aluminium phosphate, acidic	— ,	
	diSodium dihudranan dinhambata		,
	tetraSodium dinhogenerato	E 450(a)	
	tetraPotassium diphosphate	E 450(a)	•
	diCalcium diphosphate	2	,
	pentaSodium triphosphate	Е 450(b)	
	pentaPotassium triphosphate	E 450(b)	
	Ammonium		•
.`>	and calcium advision		
i	including sodium and potessium		
· · · · · · · · · · · · · · · · · · ·	polyphosphates	EASO(-) Q	
		L450(8)	
	Edible bone phosphate		
	Shellac	-	
	Silicon dioxide	· _	
	Bentonite		
	Kaolin, heavy		
	Aluminium and the set	·	
	Aluminium poloine alliant	·	
	Calcium silicate	• ·	,
	Magnesium silicate synthetia	-	
	Magnesium trisilicate		
	Tale		
	SerbiteI	_	
	Spermaceti	E 420	
	Sperm oil	. —	
	Magnesium stearate	·	
	Calcium stearate		.t
	Butyl stearate	—	
	Succinic acid	—	
	Sulphuric acid	-	
	···· ··· ··· ···		

Column 1	ļ	Column 2 Serial number				
Name of Miscellaneous A						
Ammonium sulphate			······································			
Sodium sulphate		)				
Magnesium sulphate	•••					
Potassium sulphate						
Aluminium potassium sulphate	Aluminium potassium sulphate					
Calcium sulphate			_			
Tannic acid						
Tartaric acid	•••		E 334			
Sodium tartrate	•••		E 335			
Potassium tartrate		}	E 336			
Potassium hydrogen tartrate		}	E 336			
Potassium sodium tartrate			E 337			

ι

# PART II

Specific Purity Criteria Applicable to Permitted Miscellaneous Additives

E 260 Acetic acid

۶.

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

1.7421

1

12

The criteria in the monograph for sodium acetate contained in the Food Chemicals Codex 1972 at page 717 except that the alkalinity shall be not more than 0-1 per centum (as sodium carbonate, Na<sub>3</sub> CO<sub>3</sub>).

# E262 Sodium hydrogen diacetate

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

## E261 Potassium acetate

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

## E263 Calcium acetate

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

### Adipic acid

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

# Beeswax, white

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

### Beeswax, yellow

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

### Calcium phytate

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

Matter insoluble in acids	Not more than 2 per centum in hydrochloric acid and not more than 2 per centum in orthophosphoric acid, determined as follows:
	Treat 1g. of calcium phytate with 7ml. N hydrochloric acid and 93ml. of distilled water. Treat another 1g. sample of calcium phytate with 50ml. distilled water and 1-5ml. orthophosphoric acid (50 per centum H <sub>2</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 (expres- sed as phosphorus)	Not more than 0.5 per centum.
Iron	Not more than 100mg, per kg.

Not more than 5mg. per kg. ••• ••• ...

F 290 Carbon dioxide

Arsenic

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

Ammonium carbonate

The criteria in the monograph for animonium 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 efflorescont.
Content	•••	•••	Not less than 98 per centum of Na <sub>2</sub> CO <sub>3</sub> on a volatile matter-free basis.
Volatile matter	•••		Not more than: 2 ner centum for the non-hydrated sub-

j,

2 per centum for the non-nyurate suc stance; 15 per centum for the monohydrate; 65 per centum for the decabydrate; (determined by the method for loss on drying in the monograph for sodium carbonate in the Food Chemicals Codex 1972 at page 731).

	Content	•••	Not less than 97 per centum of CaCO, 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 hyd chloric acid	ro- 	Shall comply with the requirement for aluminium, iron, phosphate and matter insoluble in hydrochloric acid in the mono- graph for chalk in the British Pharmacopocia 1973 at page 93.	
	Arsenic		Not more than 5 mg, per kg.	
	Lead		Not more than 20 mg. per kg.	
	Other inorganic impuri	ರಣ	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 com- bination of those substances.	• •
	Carnauba wax			
	The criteria in the mo Chemicals Codex 1972 at p	onograj Saga 17	ph for carnauba wax contained in the Food 0.	
	E 330 Citric acid			
	Description	•••	Colourless or translucent crystalline solid, or white crystalline powder.	
	Content	•••	Not less than 99.5 per centum of C <sub>6</sub> H <sub>4</sub> O <sub>7</sub> on a volatile matter-free basis.	
	Volatile matter	••••	Not more than: 0.5 per centum for the non-hydrated substance;	
			8.8 per centum for the monohydrate	
			(determined by drying at 105°C, to constant weight).	
	Oxalates (expressed oxalic acid)	as 	Not more than 0.05 per centum on a volatile matter-free basis.	
	Sulphated ash		Not more than 0.05 per centum on a volatile matter-free basis.	
	Sulphuric acid test (read carbonisable substances	ily s)	Shall comply with the requirement for readily carbonisable substances in the monograph for ciric acid contained in the British Pharmacopoeia 1973 at page 113.	
	tri <i>A inmonium citrate</i> Synonym		Ammonium citrate.	
	The criteria in the mono Pharmaceutical Codex 1973	graph at pag	for ammonium citrate contained in the British ge 830.	
	E 331 Sodium dihydrogen c	itrate		
	Description		White crystalline powder.	•
	Content		Not less than 99 per centum of C. H. O. Na on a volatile matter-free bisis.	
	Volatile matter		Not more than 0.4 per centum (determined by drying at 105°C. to constant weight).	

i.

.

્યસ્ટ

ί

Matter insoluble in dilute ammonia solution	Not more than 0.12 per centum on a volatile matter-free basis, determined by the follow- ing method: Boil 5g. of hydrated sodium carbonate, or 2.5g. of anhydrous sodium carbonate, with 50ml. of water and 10ml. of dilute ammonia solution (about 10 per centum NH <sub>2</sub> ). Filter and wash the residue with water, then ignite to constant weight.
Sulphate	Not more than 0.4 per centum on a volatile matter-free basis.
Chloride	Not more than 0.4 per centum on a volatile matter-free basis.
Iron	Not more than 40mg, per kg, on a volatile matter-free basis,

Sodium hydrogen carbonate

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

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

Magnesium carbonate, heavy

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

Magnesium carbonate, light

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

Potassium carbonate

Description	•••	•••	The anhydrous form is a white granular powder.
			The hydrated form consists of small white translucent crystals or granules.
Content		•••	Not less than 98 per centum of K <sub>3</sub> CO, 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

Potassium bicarbonate. Synonym ... ...

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.

Orrelator (a	Totocrad		L Not more than 0.02 per centum on a valatil
oxalic acid	l)		matter-free basis.
E 331 triSodium	citrate		
Synonym	•••	•••	Sodium citrate.
Description	•••	•••	White crystalline powder or colourless crystals
Content	· ··· ·	•••	Not less than 99 per centum of C <sub>6</sub> H <sub>5</sub> O <sub>7</sub> Na, on a volatile matter-free basis.
Volatile matt	er	••••	Not more than: I per centum for the non-hydrated substance; 13 per centum for the dihydrate; 30 per centum for the pentahemihydrate; (determined by drying at 180°C. to con- stant weight).
Oxalates (e oxalic acid)	xpressed 	as 	Not more than 0.05 per centum on a volatile matter-free basis.
E 332 Potassium	dihydrog	gen citra	ie
Description	,	•••	White granules or crystals.
Content		•••	Not less than 98 per centum of C <sub>e</sub> H <sub>7</sub> O <sub>7</sub> K on a volatile matter-free basis.
Volatile matte	r	•••	Not more than 0.4 per centum (determined by drying at 105°C, to constant weight).
Oxalates (ex oxalic`acid)	pressed	as '	Not more than 0.05 per centum on a volatile matter-free basis.
E 332 triPotassiu	m citrate		
Synonym			Potassium citrate.
Description			White granular hygroscopic powder or trans- parent crystals. Commercially the product occurs as the monohydrate.
Content		•••	Not less than 99 per centum of $C_6H_8O_7K_3$ on a volatile matter-free basis.
Volatile matter	• •••	•••	Not more than 6 per centum (determined by drying at 180°C. for 4 hours).
Oxalates (ex oxalic acid)	pressed 	as 	Not more than 0.05 per centum on a volatile matter-free basis.
E 333 Calcium c	itrate		
Description	•••	•••	Fine white powder. Commercially the pro- duct occurs as the tetrahydrate.
Content	•••	•••	Not less than 97.5 per centum of (C,H,O <sub>1</sub> ) <sub>2</sub> Ca, on a volatile matter-free basis,
Volatile matter	·	•••	Not more than 13 per centum (determined by drying at 180°C, to constant weight).
Carbonates	` <b>•</b> ••		When 1g. of calcium citrate is dissolved in 10ml. of dilute hydrochloric acid (approxi- mately 2N) only a few isolated bubbles should be released.

1

,

;

.

\*

:

,

-

ŀ

¥

- Aline Addist Annual Addition annual Annua

Ovalate	(avarant a	Not more than 0.05 per centum on a volatile
oxalic	acid)	matter-free basis.
, Fluoride	·	Not more than 30mg, per kg, on a volatile matter-iree basis.
• Ammoniu	n ferric citrate	,
Synonyn	)	Ferrie ammonium citrate.
The crite British Pha	eria in the monogr rmacopoeia 1973 at	aph for ferrie ammonium citrate contained in the .
Ammorius	i ferrio citrota orea	
Synonyn	· ··· ··· ···	Green ferric ammonium citrate.
The crite in the Britis	ria in the monogr h Pharmaceutical C	aph for green ferric ammonium citrate contained odex 1954 at page 303.
Dicklorediffus		
Decorieties	i omemane	
· Contont	1994 - 1995	Clear, colouriess liquefied gas.
Content	11 ··· 1 Manua, ++ Alexandr, have y	Not less than 99-97 per centum
Trichlorofluo	romethane CCl.	F)
Dichlorofluo Chlorodifluo Chlorotrifluo	romethane CHCla romethane CHClF	F Not more than 290 mg, per kg. $2 \int singly or in combination.$
Chorototillito		
Other organi	c compounds	Not more than 10 mg per kg
Other organi Non volatile	compounds	Not more than 10 mg, per kg.
Other organic Non volatile	natter	Not more than 10 mg, per kg. Not more than 0.01 per centum.
Other organi Non volatile . (after evap	c conpounds matter oration at 0°C.)	Not more than 10 mg, per kg. Not more than 0.01 per centum.
Other organi Non volatile , (after evap Dimethylpolysiloxane	conpounds matter oration at 0°C.)	Not more than 10 mg, per kg. Not more than 0.01 per centum.
Other organi Non volatile . (after evap Dimethylpolysiloxane Synonym	compounds matter oration at 0°C.)	Not more than 10 mg. per kg. Not more than 0.01 per centum.
Dimethylpolysiloxane Synonym Appearance	Dimethyl s Clear cold extraneo	Not more than 10 mg. per kg. Not more than 0.01 per centum. ilicone. purless odourless liquid free from us matter.
Dimethylpolysiloxane Synonym Appearance	Dimethyl s Dimethyl s Clear colo extraneo Insoluble in Soluble in carbon s	Not more than 10 mg, per kg. Not more than 0.01 per centum. illicone. purless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents.
Other organi Non volatile . (after evap Dimethylpolysiloxane Synonym Appearance Solubility Volatile matter	Dimethyl s matter oration at 0°C.) Clear colo extraneo Insoluble in carbon s Not more drying a	Not more than 10 mg. per kg. Not more than 0.01 per centum. illicone. uurless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents. than 2 per centum (determined by t 200°C. for 4 hours).
Other organi Non volatile . (after evap Dimethylpolysiloxane Synonym Appearance Solubility Volatile matter Identification	compounds     matter     oration at 0°C.)      Clear colo     extraneo     Insoluble in         Soluble in         carbon s      Not more         drying a     Shall comp         the mone     Pharmace	Not more than 10 mg, per kg, Not more than 0.01 per centum. illicone. burless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents. than 2 per centum (determined by t 200°C. for 4 hours). bly with the identification tests in bgraph for dimethicone in the British eutical Codex 1973 at mge 168.
Other organi Non volatile . (after evap Dimethylpolysiloxane Synonym Appearance Solubility Volatile matter Identification Acidity	Dimethyl s matter oration at 0°C.) Clear colo extraneo Insoluble in carbon s Not more drying a Shall comp the mone Pharmac Shall comp in the n British P 168.	Not more than 10 mg, per kg. Not more than 0.01 per centum. Not more than 0.01 per centum. illicone. ourless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents. than 2 per centum (determined by t 200°C, for 4 hours). ply with the identification tests in ograph for dimethicone in the British eutical Codex 1973 at mage 168. ly with the requirement for acidity nonograph for dimethicone in the harmaceutical Codex 1973 at page
Other organi Non volatile . (after evap Dimethylpolysiloxane Synonym Appearance Solubility Volatile matter Identification Acidity	Dimethyl s matter oration at 0°C.) Clear colo extraneo Insoluble in carbon s Not more drying a Shall comp in the non Pharmac Shall comp in the n British P 168. Not less tha centum.	Not more than 10 mg, per kg. Not more than 0.01 per centum. Not more than 0.01 per centum. illicone. burless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents. than 2 per centum (determined by t 200°C, for 4 hours). ply with the identification tests in ograph for dimethicone in the British eutical Codex 1973 at mage 168. ly with the requirement for acidity nonograph for dimethicone in the harmaceutical Codex 1973 at page
Other organi Non volatile (after evap Dimethylpolysiloxane Synonym Appearance Solubility Volatile matter Identification Acidity Total silicon Refractive index n 25 <sup>c</sup>	Dimethyl s     Dimethyl s     Clear colc     extraneo     Insoluble in         Soluble in         carbon s     Not more         drying a     Shall comp         in the n         British P         I68.     Not less tha         centum.     C. Not less tha	Not more than 10 mg, per kg, Not more than 0.01 per centum. Not more than 0.01 per centum. illicone. purless odourless liquid free from us matter. In water. In oper centum (determined by t 200°C. for 4 hours). In graph for dimethicone in the British eutical Codex 1973 at mage 168. Iy with the requirement for acidity nonograph for dimethicone in the harmaceutical Codex 1973 at page an 37-3 and not more than 1-405.
Dimethylpolysiloxane Synonym Appearanos Volatile matter Identification Acidity Total silicon Refractive index n 25° Dimethylpolysiloxane	<ul> <li>Dimethyl s</li> <li>Dimethyl s</li> <li>Clear colo extraneo</li> <li>Insoluble in Soluble in carbon s</li> <li>Not more drying a</li> <li>Shall comp in the n British P. 168.</li> <li>Not less tha centum.</li> <li>Not less tha</li> <li>Not less tha</li> </ul>	Not more than 10 mg, per kg. Not more than 0.01 per centum. Not more than 0.01 per centum. illicone. purless odourless liquid free from us matter. n water. most aliphatic and aromatic hydro- olvents. than 2 per centum (determined by t 200°C. for 4 hours). ply with the identification tests in ograph for dimethicone in the British cutical Codex 1973 at page An 37-3 and not more than 38-5 per an 1.400 and not more than 1050 is.

Synoným ... ... Disodium edetate.

, î

: ;

÷

.

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

Calcium disodium ethylenediamine-NNN<sup>a</sup>N<sup>a</sup>-tetra-acetate Synonym ... Sodium calciumedetate. The criteria in the monograph for sodium calciumedetate contained in the British Pharmacopoela 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 ferrocy	anide		
Description		•••	Odourless lemon yellow crystals.
Solubility	••••	•••	Soluble in water and in acetone. Insoluble in ethanol, in ether and in hydro- carbons.
Content			Not less than 98 per centum of K.Fe(CN). 3H.O.
Free moisture		•••	Not more than 1 per centum (determined by the method for free moisture in the mono- graph 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

.

1

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 *della*-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.H.O.K 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 substa pressed as glu	inces cose)	(ex- 	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. u
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 <sub>1</sub> H <sub>12</sub> O <sub>2</sub> ,
Melting point	148°C.
Specific rotation $\begin{bmatrix} \alpha \end{bmatrix} \begin{array}{c} 20 \ ^{\circ}C, \\ D \end{array}$	Not less than54.0° and not more than 53.0° (using a 25 per centum weight/ volume aqueous solution).
Sulphated ash	Not more than 0.1 per centum.
Sodium heptonate	
Description	White to tan crystalline powder.
Solubility	Sparingly soluble in ethanol. Very soluble in water.
Content	Not less than 98 per centum of $C_1H_{13}O_1Na.2H_2O_2$ .
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,H <sub>1</sub> ,O,),Ca.2H,O.
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.

: (\*

ì . .

4

۶. ł

ł

.

•

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

1100

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

• •

,

J.

1

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 dibydrate consists of deliquescent white odourless fragments or granules. The bexahydrate consists of deliquescent colourless and odourless crystals.
Conient	Not less than: 98 per centum of CaC1,2H,O for the dihydrate; 97 per centum of CaC1,6H,O for the hexahydrate.
Magnesium and alkali salts	Not more than 2 per centum, determined by the method in the monograph for calcium chloride contained in the Food Chemicals Codex 1972 at page 123 except that the weight of the residue shall not exceed 10mg.
Fluoride	Not more than 40mg, per kg. on an anhydrous basis.
Hydrogen	
Description	Colourless odourless gas.
Content	Not less than 99.9 per centum volume/volume of hydrogen.
Moisture	Not more than 10 ppm. volume/volume.
Oxygen	Not more than 3 ppm. volume/volume.
Carbon monoxide, carbon dioxide and hydro- carbons	Not more than 10 ppm. volume/volume in total.
Nitrogen	Not more than 100 ppm. volume/volume.
Mercury	Not more than 2mg. per kg.
Ammonium hydroxide	

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

Sodium hydroxide The criteria in the monograph for sodium hydroxide contained in the Food Chemicais 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		and the Construction operation
Description	•••	white fine odourless powder.
Solubility	•••	Practically insoluble in water. Soluble in dilute acids with, at most, slight effervescence.
Apparent volume	•••	20g. of heavy magnesium oxide occupies a volume of about 50ml.
Content	•••	Not less than 98 per centum of MgO calculated with reference to the ignited substance and determined by the assay method contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol I, 1969 at page 319.
Loss on ignition	•••	Not more than 5 per centum (determined by ignition at 900°C, to 950°C, to constant weight).
Matter soluble in water	•••	Not more than 2 per centum, determined by the method for soluble substances contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol I, 1969 at page 319.
Matter insoluble in acc acid.	etic	Not more than 0.1 per centum when deter- mined by the following method: Dissolve 5g, heavy magnesium oxide in a mixture of 70ml, acetic acid (see note 1) and 30ml, water. Heat to boiling for 2 minutes, cool and dilute to 100ml, with dilute acetic acid (see note 2). Filter through a sintered glass filter. Any residue, after washing with water, drying and ignition at 600°C, shall weigh not more than 5mg.
Sulphate	•••	Not more than 0.75 per centum.
Chloride	•••	Not more than 0.07 per centum,
Calcium	•••	Not more than 2 per centum.
Iron		Not more than 0.1 per centum.
Arsenic		Not more than 4mg. per kg.
Heavy metals		Not more than 40mg, per kg.
Note 1: Acetic acid: c	ontains	not less than 29 per centum weight/volume and

.

ł

Ì.

E

Note 1: Acetic acid: contains not less than 29 per centum weight/volume and not more than 31 per centum weight/volume of  $C_1H_{O.0}$ . Dilute 30g, glacial acetic acid (98 per centum weight/volume  $C_1H_1O_2$ ) 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  $C_1H_1O_2$ . Dilute 12g, or 11-7ml. glacial acetic acid (98 per centum weight/volume  $C_1H_1O_2$ ) to 100ml. with water and, if necessary, adjust the concentration of the solution.

----

Magnesium axide, light The eriteria in the monograph for light magnesium oxide contained in the Buropean Pharmacopoeia Vol. 1, 1969, at page 349, 2000

-----

-----

1

ī

----

- ----

.

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

: :'

į

ł

2 1 4

Description	•••	•••	Soft white powder.
Solubility	•••		Ig. 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).
Matter insoluble hydrochloric a 10 per centur volume HCI).	e in di cid (ab n weig	lute out .ht/	Not more than 0.5 per centum.
Magnesium and	alkali s	alts	Not more than 6 per centum, determined by the method in the monograph for calcium hydroxide contained in the Food Chemicals Codex 1972 at page 131 except that the weight of the residue shall not exceed 15mg.
Carbonate		•••	When 2g. of calcium hydroxide is mixed with 50ml. of water and an excess of dilute hydrochloric acid (approximately 2N) is added, no more than a slight effervescence is produced.
Sulphate	•••		Not more than 0.35 per centum.
Fluoride			Not more than 50mg. per kg.

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

E 270 Lactic acid The specific purity criteria for lactic acid contained in Directive 65/66/EEC of the Council(a).

E 325 Sodiw	m lact	ate		
Description	n	•••	•••	White hygroscopic mass which by absorption of water changes into an almost colourless odourless liquid.
Content	•••	•••	•••	Not less than 98 per centum of C,H,O,Na (after drying at 105°C, to constant weight).
Acidity	••••	:	•••	Neutralisation of 1g. of the sample shall require not more than 0-5ml. of 0-1N sodium hydr- oxide solution using phenolphthalein as indicator,
Reducing	substa	nces	•••	Sodium lactate shall not cause any reduction of Fchling's solution.

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

• • • • •

: \/

ļ

ļ

清

7

	E 326 Potassium Description Content Acidity Reducing subs Note : The a 63 per centum o E 327 Calcium I Description	a lactate   stances cidity o f C <sub>2</sub> H <sub>2</sub> C	  f concent ,K may b	<ul> <li>Slightly syrupy almost odourless clear aqueous solution.</li> <li>Not less than 57 per centum and not more than 63 per centum of C,H<sub>2</sub>O,K.</li> <li>Neutralisation of 1g, of the solution shall require not more than 0.22ml, of 0.1N sodium hydroxide using phenolphthalein as indicator (see note).</li> <li>Potassium lactate shall not cause any reduction of Fehling's solution.</li> <li>trated aqueous solutions containing more than be proportionately greater.</li> </ul>	
	E 326 Potassium Description Content Acidity Reducing subs Note : The a 63 per centum o E 327 Calcium I Description	tactate  stances cidity o f C <sub>2</sub> H <sub>2</sub> C	  of concent JK may b	<ul> <li>Slightly syrupy almost odourless clear aqueous solution.</li> <li>Not less than 57 per centum and not more than 63 per centum of C,H<sub>4</sub>O,K.</li> <li>Neutralisation of 1g, of the solution shall require not more than 0·22ml, of 0·1N sodium hydroxide using phenolphthalein as indicator (see note).</li> <li>Potassium lactate shall not cause any reduction of Fehling's solution.</li> <li>trated aqueous solutions containing more than be proportionately greater.</li> </ul>	
	Description Content Acidity Reducing subs Note : The a 63 per centum o E 327 Calcium I Description	 stances cidity o f C,H,C	   of concept J,K may §	<ul> <li>Slightly syrupy almost odourless clear aqueous solution.</li> <li>Not less than 57 per centum and not more than 63 per centum of C,H<sub>2</sub>O,K.</li> <li>Neutralisation of 1g. of the solution shall require not more than 0.22ml, of 0.1N sodium hydroxide using phenolphthalein as indicator (see note).</li> <li>Potassium lactate shall not cause any reduction of Fehling's solution.</li> <li>trated aqueous solutions containing more than be proportionately greater.</li> </ul>	
	Content Acidity Reducing subs Note : The a 63 per centum o E 327 Calcium I Description	 stances cidity o f C <sub>2</sub> H <sub>2</sub> C	  of concent J,K may b	<ul> <li>Not less than 57 per centum and not more than 63 per centum of C,H<sub>2</sub>O,K.</li> <li>Neutralisation of 1g. of the solution shall require not more than 0.22ml. of 0.1N sodium hydroxide using phenolphthalein as indicator (see note).</li> <li>Potassium lactate shall not cause any reduction of Fehling's solution.</li> <li>trated aqueous solutions containing more than be proportionately greater.</li> </ul>	
	Acidity Reducing subs Note: The a 63 per centum o E 327 Calcium I Description	stances cidity o f C.H.C	 of concent D,K may {	Neutralisation of 1g. of the solution shall require not more than 0-22ml. of 0-1N sodium hydroxide using phenolphthalein as indicator (see note). Potassium lactate shall not cause any reduction of Fehling's solution. trated aqueous solutions containing more than be proportionately greater.	
	Reducing subs Note : The a 63 per centum o E 327 Calcium I Description	stances cidity o f C₃H₄C actate	 of concent O.K may b	Potassium lactate shall not cause any reduction of Fehling's solution. trated aqueous solutions containing more than be proportionately greater.	
	Note; The a 63 per centum o E 327 Calcium I Description	cidity o f C₃H₄C actate	of concent ),K may {	trated aqueous solutions containing more than be proportionately greater.	
	E 327 Calcium l Description	actate			
	Description				• • •
	_		••••	Almost odourless crystalline powder or white granules.	
· · · · · · · · · · · · · · · · · · ·	Content	•••		Not less than 98 per centum of (C,H,O,),Ca on a volatile matter-free basis.	
*1 • ] • ;	Acidity	•••	•••	Neutralisation of Ig of the sample shall require not more than 0.5ml. of 0.1N sodium hydr- oxide solution using phenolphthalein as indicator.	
	Volatile matte	er	••••	Not more than: 3 per centum for the non-hydrated sub- stance; 8 per centum for the monohydrate; 20 per centum for the trihydrate; 30 per centum for the pentahydrate;	
				(determined by drying at 120°C, for 4 hours).	
	, Reducing sub	stances	•••	Calcium lactate shall not cause any reduction of Fehling's solution.	
	Fluoride		•••• •	Not more than 30 mg. per kg. calculated on a volatile matter-free basis.	
	DL-Malic acid The criteria in Codex 1972 at p	a the mo bage 484	onograph	for malic acid contained in the Food Chemicals	
	L-Malic acid				
	Description	•••	•••	White or nearly white crystalline powder or granules.	
•	Content		•••	Not less than 99 per centum of C.H.O.	
	Melting rang	e	•••	99°C to 101°C.	
 	Specific rotati	ion [a]	20°C.	Not less than -2.4° and not more than -2.2° (using a solution containing \$-5g. L-malic- acid in 100ml. water).	

-----

Maleic acid	•••	•••	
Fumaric acid		•••	Shall comply with the limits given in the mono-
Residue on igni	tion	•••	graph for malic acid in the Food Chemicals
Water insoluble	matter		Codex 1972 at page 484.
0 . 7 7 . 7			
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.H.O.Na on a volatile matter-free basis.
Volatile matter	•••	•••	Not more than 2 per centum (determined by drying at 110°C. for 3 hours).
Maleio acid		•••	Not more than 0.05 per centum.
Sodium malate '			
Description	•••	•••	Colourless or almost colourless aqueous solu- tion. Sodium malate may be derived from either DL-malic acid or L-malic acid.
Content		•••	Not less than 59.5 per centum of C.H.O.Na.
Maleic acid	•••	•••	Not more than 0.05 per centum calculated on the C.H.O.Na, content.
Potassium malate			
Description		•••	Colourless or almost colourless aqueous solu- tion.
			Potassium malate may be derived from either DL-malic acid or L-malic acid.
Content	•••	•••	Not less than 59.5 per centum of C.H.O.K.
Maleic acid	•••	••••	Not more than 0.05 per centum calculated on the C.H.O.K. content.
Calcium malate			
Description	•••	••••	White odourless powder. Calcium malate may be derived from either DL-malic acid or L-malic acid.
Content	•••	•••	Not less than 97-5 per centum of C.H.O.Ca on a volatile matter-free basis.
Volatile matter	•••	••••	Not more than 2 per centum (determined by drying at 110°C, for 3 hours).
Maleic acid	•••	•••	Not more than 0.05 per centum.
Fluoride		•••	Not more than 30mg, per kg. on a volatile matter-free basis.

į 1

í

.

.

 $\cdot$  E 421 Mannitol The criteria in the monograph for mannitol contained in the Pool Chemicals Codex 1972 at page 496. .

,

23 - <del>2</del>7

.

i

.

ł

.

,

.

Metatartaric actd	
Description	White or yellow powder which consists chicfly of a mixture of polyesters obtained by the controlled dehydration of L(+) tartaric acid, together with unchanged L(+) tartaric acid.
Specific absorption $E \begin{bmatrix} 1 & \text{per centum} \\ 1 & \text{cm} \end{bmatrix}$	Not more than $1.5 \times 10^{-2}$ at 430nm. (determined using a filtered aqueous solution).
Identification	Place 5 to 10mg, of sample in a test tube. Add 2ml. sulphuric acid (about 94 per centum HaSO.) plus two drops of resorcinol reagent (2g. resorcinol dissolved in 100 ml. water plus 0.5 ml. sulphuric acid) and heat to 150°C. An intense violet colour is produced.
Content	Not less than the equivalent of 105 per centum of tartaric acid ( $C_1H_1O_1$ ).
•	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 indica- tor (004 per centum weight/volume solution of bromothymol blue in 95 per centum volume/volume ethanoi) 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, 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 <sub>1</sub> ml.).
	Tartaric acid equivalent = 7.5 (T <sub>1</sub> + 20 - T <sub>2</sub> ) per centum. Esterified tartaric acid = $\frac{100 (20 - T_2)}{T_1 + 20 - T_2}$
	per centum.
Specific rotation $[\alpha] \frac{20^{\circ}C}{D}$	Not less than +12:5° and not more than +13:5° (using a filtered 10 per centum weight/volume aqueous solution).
Matter insoluble in water (at about 20°C.)	Not more than 2.5 per centum (insoluble matter weighed after drying for 3 hours at 70°C. in a vacuum oven).
Pyruvic acid	Not more than 0.5 per centum.
<i>Nicotinic acid</i> The criteria in the monograp Pharmacopœia 1973 at page 318.	h for nicotinic acid contained in the British
Nitrogen The standard for nitrogen type 2	2 contained in British Standard 4366: 1968.

.

,

 $\vec{p}$  :

1.1

•

- z

್ರಾಂಗ

Nitrous oxide

÷

ł

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

ι

۰,

1

 $z^{j}$ 

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	S0°C. to 85°C.
Moisture	Not more than 1 per centum (Karl Fischer).
Iodine value	Not more than 5 (Wijs).

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

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

E 338 Orthophosphoric acid

Description		•••	•••	Colourless viscous clear liquid.
Content .		•••	•••	Not less than 85 per centum of H <sub>1</sub> PO <sub>4</sub> and not more than 15 per centum of water.
Volatile ac as acetic	eids ( acid)	expres	sed	Not more than 0.001 per centum on an anhydrous basis.
Nitrate ( NaNO,)	expres	ised 	as 	Not more than 0.0005 per centum on an anhydrous basis.
Sulphate CaSO <sub>4</sub> )	(expre	ssed	as 	Not more than 0.15 per centum on an anhydrous basis.
Chloride .			••••	Not more than 0.02 per centum on an anbydrous basis.
Fluoride .	••	•••	•••	Not more than 10mg, per kg, on an anhydrous basis,

note: Values for solutions of different concontrations shall be calculated according to their HaPO, content.

1940<u>1</u> : ÷

-

Ammonium dihydrogen orthophosphate Ammonium phosphate, monobasic. Synonym ... ... The criteria in the monograph for ammonium phosphate, monobasic con-tained in the Food Chemicals Codex 1972 at page 50. diAmmonium hydrogen orthophosphate Synonym ... ... ... Ammonium phosphate, dibasic. The criteria in the monograph for ammonium phosphate, dibasic contained in the Food Chemicals Codex 1972 at page 49. E 339(a) Sodium dihydrogen orthophosphate ... Sodium phosphate, monobasic. Synonym ... Description Slightly deliquescent white powder, crystals or ... .... granules. - 185 <sup>-</sup> Not less than 97 per centum and not more than 103 per centum of NaH,PO, on a volatile matter-free basis. • ••• Content ... ... Not more than: 2 per centum for the non-hydrated sub-stance; 15 per centum for the monohydrate; 25 per centum for the dihydrate; Volatile matter .... ... (determined by drying at 60°C. for I hour and then at 105°C. for 4 hours). Not more than 0.2 per centum on a volatile Matter insoluble in water matter-free basis. Not more than 10 mg, per kg, on a volatile matter-free basis. Fluoride ... ... E 339(b) di-Sodium hydrogen orthophosphate Sodium phosphate, dibasic. Synonym ... .... ... The anhydrous form is a white hygroscopic powder; the dihydrate is a white crystalline solid; the heptahydrate is a granular powder or white efflorescent crystals; the dodecahy-drate is a white powder or white efflorescent Description • • • • • • crystals. Not less than 98 per centum of Na, HPO, on a volatile matter-free basis. Content \*\*\* ••• ... Not more than: Volatile matter ... ... 5 per centum for the non-hydrated sub-stance; 21 per centum for the dihydrate ; 50 per centum for the heptahydrate; 61 per centum for the dodecahydrate; (determined by drying at 60°C. for 1 hour and then at 105°C. for 4 hours), Not more than 0.2 per centum on a volatile matter-free basis. Muttee insoluble in water

:

• •

Fluoride	••••	•••	Not more than 10 mg, per kg, on a volatile matter-free basis.
5 339(c) triSodium	ortho	phosph	ile
Synonym	•••		Sodium phosphate, tribasic.
Description	•••	•••	White powder, crystals or granules. Com- mercially the substance exists in the an- hydrous form and as the monohydrate and the dodecabydrate.
Content		•••	Not less than 97 per centum of Na,PO, on a volatile matter-free basis.
Volatile matter	•••	···	Not more than:
		·	2 per centum for the non-hydrated sub- stance;
			55 per centum for the mononygrate; 55 per centum for the dodecahydrate; (determined by ignition at 800°C. for 30
Matter insoluble	in wat	er	minutes). Not more than 0-2 per centum on a volatile natter-free basis.
Fluorido		•••	Not more than 10 mg. per kg. on a volatile matter-free basis.
340 (a) Potossiu	m đih	drocen	orthophosphate
Synonym			Potassium phosphate, monobasic.
Description	•••	•••	Colourless crystals or white granular or crystalline powder.
Content	•••	•••	Not less than 98 per centum of KH,PO, on a volatile matter-free basis.
Volatile matter		•••	Not more than 2 per centum (determined by drying at 105°C. for 4 hours).
Matter insoluble	in w	ater	Not more than 0.2 per centum on a volatile matter-free basis.
Fluoride	•••	•••	Not more than 10 mg. per kg. on a volatile matter-free basis.
: 340 (b) diPotassi	um hy	drogen	orthophosphate
Synonym	'		Potassium phosphate, dibasic.
Description		•••	Deliquescent, colourless or white granules.
Content <sup>1</sup>		•••	Not less than 98 per centum of K.HPO, on a volatile matter-free basis.
Volatile matter	•••		Not more than 2 per centum (determined by drying at 105°C. for 4 hours).
Matter insoluble	in wa	ater	Not more than 0.2 per centum on a volatile matter-free basis.

, , , ,

A STREET

·

ł

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

# E 341 (a) Calcium tetrahydrogen diorthophosphate

Synonyms	•••	Calcium phosphate, monobasic. Acid calcium phosphate.
Description	•••	Deliquescent white granules, granular powder or crystals.
Content (expressed as CaO)	•••	Not less than 23.0 per centum and not more than 25.0 per centum for the non-hydrated substance.
		Not less than 22.2 per centum and not more than 24.7 per centum for the monohydrate.
Volatile matter		Not less than 14-0 per centum and not more than 15-5 per centum for the non-hydrated substance (determined by ignition at 800°C. for 30 minutes).
		Not more than 0.6 per centum for the mono- hydrate (determined by drying at 60°C. for 3 hours).
Fluoride	•••	Not more than 30 mg. per kg. on an anhydrous basis.

# E 341 (b) Calcium hydrogen orthophosphate

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

Not less than 31.9 per centum and not more than 33.5 per centum for the dihydrate.

.

ï

11

. 1

.

۰.

12. T

.

ì

ź

.

	Volatile matter	••••	<b>***</b>	Not less than 7.0 per centum and not more than 8.5 per centum for the non-hydrated substance.
				Not less than 24.5 per centum and not more than 26.5 per centum for the dibydrate.
				(determined by ignition at 800°C. to 825°C. to constant weight).
	Fluoride	•••	•••	Not more than 50 mg. per kg. on an anhydrous basis.
	E 341(c) tri-Calciu	m dior	thophos	phate
	Synonym			Calcium phosphate, tribasic.
	Description		•••	Impalpable white powder.
•	Content	•••	•••	Not less than 90 per centum of $Ca_3(PO_4)_3$ on a volatile matter-free basis.
	Volatile matter		•••	Not more than 10 per centum (determined by ignition at \$00°C. to \$25°C, to constant weight).
	Fluoride		•••	Not more than 50 mg. per kg. on a volatile matter-free basis.
	Calcium hydroxyph	iosphat	e	
	Synonym	•••		Hydroxy-apatite.
	Description	´ <b></b>	•••	Impalpable white powder.
	Content	•••	•••	Not less than 90 per centum of $3Ca_3$ (PO <sub>4</sub> ) <sub>2</sub> . Ca(OH), on a volatile matter-free basis.
	Volatile matter	•••	•••	Not more than 10 per centum (determined by ignition at 800°C, to 825°C, to constant weight).
	Fluoride		•••	Not more than 50 mg, per kg, on a volatile matter-free basis.
	Sodium aluminium	phospl	hate, acid	lic
	The criteria in t tained in the Food	he mo Chemie	nograph cals Cod	for sodium aluminium phosphate, acidic con- ex 1972 at page 722
	Sodium aluminium	phospl	hate. bas	ic
	The criteria in t tained in the Food	he mo chemic	nograph als Cod	for sodium aluminium phosphate, basic con- ex 1972 at page 724.

2

- f

- E 450(a) diSodium dihydrogen diphosphate . diSodium dihydrogen pyrophosphate Sodium acid pyrophosphate Synonyms ... ...

Acid sodium pyrophosphate. The criteria in the monograph for sodium acid pyrophosphate contained in the Food Chemicals Codex 1972 at page 719.

E 450(a) tetraSodium diphosphate

Synonyms ... ... tetraSodium pyrophosphate

.

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

्रिक्ट

Synonymis			***	tetraPotassium pyrophosphate
• •				Potassium pyrophosphate.
The criter Food Chemi	ria in icals (	the m Codex	onograpi 1972 at j	h for potassium pyrophosphate contained in the page 667.
diCalcium di	iphosi	phate .		•
Synonyms			•••	diCalcium pyrophosphate Calcium pyrophosphate.
The criter Food Chemic	ia in cals C	the n Codex I	onograp 972 at p	h for calcium pyrophosphate contained in the age 153.
E 450(b) pen	1ta <i>Soc</i>	tium tr.	iphospha	ite .
Synonyms				Sodium tripolyphosphate
				Sodium triphosphate.
The criteri Food Chemi- the fluoride c	ia in cals ( conter	the mo Codex nt shall	nograph 1972 at not be	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg.
The criteri Food Chemi- the fluoride o E 450(b) pen	ia in cals ( conter ita <i>Pol</i>	the mo Codex nt shall assium	nograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. whate
The criteri Food Chemi- the Лuoride c E 450(b) pen Synonyms	ia in cals ( conter ita <i>Pol</i>	the mo Codex nt shall assi4m 	nograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate
The criteri Food Chemi- the Juoride c E 450(b) pen Synonyms	ia in cals ( conter ita <i>Pol</i>	the mo Codex nt shall assium 	onograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg, thate Potassium tripolyphosphate Potassium tripolyphosphate.
The criteri Food Chemi- the fluoride of <i>E 450(b)</i> pen Synonyms Description	ia in cals C conter ita <i>Pol</i> 	the mo Codex nt shall assium 	onograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder.
The criteri Food Chemie the fluoride of <i>E 450(b)</i> pen Synonyms Description Solubility	ia in cals ( conter nta <i>Pol</i> 	the mo Codex nt shall assium 	nograph 1972 at not be triphosp	Sodium triphosphate. a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder. Gives a slightly cloudy solution in water.
The criteri Food Chemi- the fluoride of E 450(b) pen Synonyms Description Solubility Content	ia in cals ( conter ita <i>Pol</i> 	the mo Dodex nt shall assium 	nograph 1972 at not be triphosp	Sodium triphosphate. A for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder. Gives a slightly cloudy solution in water.
The criteri Food Chemi- the fluoride of E 450(b) pen Synonyms Description Solubility Content (expresse	ia in cals ( conter ita <i>Poli</i>  d as 1	the mo Codex nt shall assium   P <sub>2</sub> O <sub>4</sub> )	nograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder. Gives a slightly cloudy solution in water. Not less than 47 per centum.
The criteri Food Chemis the fluoride of E 450(b) pen Synonyms Description Solubility Content (expresse	ia in cals ( conter ita <i>Pol</i>  d as d as	the mo Codex nt shall assium  P.O.) K.O)	onograph 1972 at not be <i>triphosp</i>	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder. Gives a slightly cloudy solution in water. Not less than 47 per centum. Not less than 51 per centum.
The criteri Food Chemis the fluoride of E 450(b) pen Synonyms Description Solubility Content (expresse pH (1 per of	ia in cals ( conter ita <i>Pol</i>  d as d as centus	the mc Codex nt shall assium  P.O.) K.O) m aque	nograph 1972 at not be triphosp	Sodium triphosphate, a for sodium tripolyphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium tripolyphosphate. Fine white powder. Gives a slightly cloudy solution in water. Not less than 47 per centum. Not less than 51 per centum.
The criteri Food Chemi- the fluoride of E 450(b) pen Synonyms Description Solubility Content (expresse (expresse PH (1 per solution)	ia in cals C conter ita <i>Poli</i>  d as d as centur	the mc Codex nt shall assium  P.O.) K.O) m aque	nograph 1972 at not be triphosp 	Sodium triphosphate. a for sodium triphosphate contained in the page 780 with the additional requirement that greater than 10 mg. per kg. thate Potassium tripolyphosphate Potassium triphosphate. Fine white powder. Gives a slightly cloudy solution in water. Not less than 47 per centum. Not less than 51 per centum. Not less than 9-6 and not more than 10-2.

.

•,

1

1

1

t

i

. .- ļ

.

ļ

ς .

. .

î

:

÷

į

ι

Ammonium, sodium, potassium and calcium polyphosphates including E450(c) sodium and potassium polyphosphates .

	Description	Ammonium, sodium, potassium and calcium polyphosphates exist as fine white powders or crystals or colourless glassy platelets.
		They are reproducible heterogenous mixtures of ammonium or sodium or potassium or calcium salts, or mixtures thereof, of con- densed polyphosphoric acids of general formula:
		$H_{(n+2)}P_{n}O_{(3n+1)}$
		where n shall be not less than 2.
	Content (expressed as P <sub>2</sub> O <sub>4</sub> )	Not less than 50 per centum and not more than 71 per centum on an anhydrous basis.
	pH (I 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.O. content.
÷.,	Flugtido some su m	
	. ?	

Edible bone	phos	phate	•	
Descriptio	'n	••••	••• •	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- apatile with some carbonate-apatite and a trace of fluoro-apatite.
Content (ex (e:	press apress	ed as i sed as i	CaO) 2,0,)	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				

d

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 aerogei: Not less than 90 per centum of SiO. Hydrated silica: Not less than 91 per centum of SiO, 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 (expressed a	s salts s Na <sub>2</sub>	so,)	Not more than 5 per centum.

.**ļ**. Ê

Į,

Bentonite The criteria in the monograph for bentonite contained in the British Pharma-copoeia 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

સ (

.

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

Aluminium sodium	silicat	e	
Synonyms	•••	•••	Sodium aluminiura silicate. Sodium aluminosilicate. Sodium silicoaluminate.
Description		•••	Fine white amorphous powder or beads.
Content (expresse	ed as Si	0,)	Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.
(expressed	as A1,	0,)	Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed	l as Na	,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).

Synonyms	Calcium aluminium silicate, Calcium aluminosilicate. Calcium silicoaluminate.
Description	Fine white free-flowing powder.
Content (expressed as SiO <sub>1</sub> )	Not less than 44 per centum and not more than 50 per centum on a volatile matter- free basis.
(expressed as A1,O,)	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	

alcium silicate			
Description			White to off-white fr
Solubility or	··· <sup>°</sup>	•••	Insoluble in water.

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

,

÷

۰.

...

1

a.

•

.

.

Content (expressed as SiO <sub>3</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

1

ť

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

Talc				
Description	•••	•••	Tale is a native hydrous magnesium s sometimes containing a small proporti aluminium silicate.	ilicate ion of

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

E 420 Sorbitol Descriptions

(a) Sorbitol is a sweet-tasting white bygroscopic crystalline powder.
(b) Sorbitol solution and (c) non-crystallising sorbitol solution are sweet-tasting clear colourless liquids.

..... 1 

Contents ... • • • ...

... •••

- (a) Sorbitol contains not less than 98 per centum of glycitois (see note 1) and related higher polyols derived from sugars (see note 2), and not less than 91 per centum of D-sorbitol, on a volatile matter-free basis in each case.
  - in each case.
     (b) Sorbitol solution is an aqueous solution of sorbitol which complies with the description at (a), containing not less than 69 per centum of total solids.
  - (c) Non-crystallising sorbitol solution is an aqueous solution containing not less than 69 per centum total solids and not less than 60 per centum of D-sorbitol, the remaining solid heing glycilols offer than D-sorbitol, related higher polyofs derived from sugers, and compared. and sugars.

.....

. . .

요즘 너희

•	Volatile m	aiter		••••	For (a) only: Not more than 1.5 per centum determined by drying in a vacuum at 80°C for 6 hours.
	Sulphated	ash		•••	Not more than 0.1 per centum on a dry- matter basis, for $(a)$ , $(b)$ and $(c)$ .
	Chloride	<i>.</i>	•••	•••	Not more than 0.005 per centum on a dry- matter basis, for $(a)$ , $(b)$ and $(c)$ .
	Reducing s as gluco	sugars ()se)	(expres:	seđ 	Not more than 0.3 per centum on a $dry$ -matter basis, for (a) and (b).

Total sugars (expressed as Not more than 0.7 per centum on a dry-glucose) ... matter basis, for (2) and (b). note 1: "Glycitols" are compounds with the structural formula CH<sub>2</sub>OH. (CHOH)a. CH<sub>2</sub>OH where n is an integer. note 2: "Sugars" means any soluble carbohydrate sweetening matter.

### Spermaceti

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

## Sperm Oil

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

## Magnesium stearate

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

## Calcium stearate

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

### Butyl stearate Description

		at about room temperature to a clear liquid and consists chiefly of the butan-l-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.

White solid with a slightly vellow tinge melts

## Succinic acid

The criteria in the monograph for succinic acid contained in the Food Chemicals Codex 1972 at page 800, 300,

ì

ł

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

: 1

.r.

# 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

Potassium aluminium sulphate, Synonyms ••• •.. Potash alum,

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

۲,

Synonym ... Tannin. ... •••

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

E 334 Tartaric acia	ł	•
Description		Tartaric acid, which may be either the L(+) form or the DL form, occurs as a white crystalline powder or as colourless or trans- lucent crystals.
Content	••• •••	Not less than 99.5 per cenium of C.H.O. 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	••• <sub>•</sub> •••	Not more than 0.1 per centum on a volatile
Oxalates (expressed as ox	alio acid)	Not more than 0.05 per centum on a volatile matter-free basis.

T 225 C. Burn to 19-14		·
E 333 Soalum tarifale		Colourlass transmont ametala Sodium
Description	. <b></b>	trate may be derived from either DL-tarl acid or L(+) tartaric acid.
Content		Not less than 99 per centum of C.H.O.Na a volatile matter-free basis.
Volatile matter	•••	Not less than 14 per centum and not m than 17 per centum for the dihydrate (de mined by drying at 150°C. for 3 hours).
Oxalates (expressed as oxalic .	acid)	Not more than 0.05 per centum on a vola matter-free basis.
E 336 Potassium tartrat	е	
Description		White crystalline or granular powder. Po sium tartrate may be derived from eit DL-tartaric acid or L(+) tartaric acid.
Content		Not less than 99 per centum of C <sub>4</sub> H <sub>4</sub> O, on a volatile matter-free basis.
Volatile matter	•••	Not more than 4 per centum (determined drying at 160°C, to constant weight).
Oxalates (expressed as oxalic a	acid)	Not more than 0.05 per centum on a vola matter-free basis.
E 336 Potassium hydrog	en tartra	le l
Synonyms		Potassium acid tartrate. Cream of Tartar.
The criteria in the m Food Chemicals Codex 1 be derived from either D	onograph 972 at pa L-tartaric	for potassium acid tartrate contained in the formation $r_{0} = 639$ , except that potassium acid tartrate metadod or $L(+)$ tartaric acid.
F 337 Potassium radium	tortrate	
Synonym		Sodium potassium tartrate.
Description		Colourless crystals or a white crystalline pe der. Potassium sodium tartrate may be rived from either DL-tartaric acid or L( tartaric acid. Commercially the prod occurs as the tertahydrate.
Content	•••	Not less than 99 per centum of C.H.O.K on a volatile matter-free basis.
Volatile matter	•••	Not more than 26 per centum for the tet hydrate (determined by drying at 150°C. 3 hours).
Oxalates (expressed as oxalic a	acid)	Not more than 0.05 per centum on a volar matter-free basis,



5. Ž

i

PART III

.

į,

ň

4 •

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

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 stilogram of zinc, or 50 milligrams per kilogram of any combination of bet copper and zinc.

SCHIDULE 2

Section 4

Miscellaneous Additives Permitted only in Certain Foods

Column 1	Column 2	Column 3
Specified Food	Permittod Miscellaneous Additive	Except where otherwise stated, milligrams per kilogram not exceeding -
Ammonium chloride	Octadecylammonium acetate	500
Drandy	diSodium dihydrogen ethylenediamin NNU'N'-tetra-acctate	e- 25 milligrams per litre
Janned fish	Calcium disodium ethylonediamine- NNN'N'-tetra-acctate	In accordance with good manufacturing practice.
Canned shellfish Chocolate confectionery	Calcium disodium ethylenediamine- NNN'N'-totra-acetate Carnauba wax	in accordance with good manufacturing practice. 200
Wezen food	Dichlorodiflowromethane	100 (determined then the food is fully thaned at end to 20°C)
Gloce charries	Calcium disodium ethylenediamine- MR'N'-tetra-acetate	In accordance with good manufacturing practice
	Aluminium potassium sulphate	10,000 (on a dry matter basis)
Sugar confectionery	Carnauba yax	200
line	Motatartaric acid	100 milligrams per litre
Hard chaese, soft cheese, whey cheese, hard sage cheese	Calcium chloride anhydrous, calciu chloride, calcium hydroxide	m In accordance with good manufacturing practice
Processed cheese, cheese spread	Calcium chloride anhydrous, calciu chloride, calcium hydroxide	m In accordance with good manufacturing practice

### Labelling of Permitted Miscellaneous Additives

1. Each container to which section 5(2) of this Order 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 Bert 1 of Schedule 1 to this Order and of the common or usual name or an appropriate designation of that permitted miscellaneous additive;
- (b) where any other substance or substances is or are present, of the common or usual name or an appropriate designation of each such substance; and
- (c) if two or more such substances are present, of the proportion of each permitted miscellaneous additive and each other substance present save that the label shall only have printed on it a statement of the proportion of any such other substance present if any Order (other than this Order or any amendment to this Order) made under the Law contains 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  $% \left( {{{\left( {{{{{\bf{n}}}} \right)}_{{{\bf{n}}}}}} \right)$
  - (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 graund, 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 of 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.

ť

s services and se

# PERMITTED BLEACHING OR IMPROVING AGENTS

Column 1	. Column 2	Column 3
Specified food	Permitted bleaching or improving agent	Parts per million - not exceeding
Bread and all flour,	Ammonium persulphate	
other than wholemeal.	Ascorbic acid	
n, <b>.</b>	Azodicarbonamide	45 (calculated by . weight)
	Benzoyl peroxide	50 (calculated by weight)
	Chlorine dioxide containing not more than 20 per centum of chlorine (calculated by volume)	
	L-cysteine hydrochloride or L-cysteine hydrochloride monohydrate or both	75 (calculated by weight as L-cysteine hydrochloride)
	Monocalcium phosphate	
	Potassium bromate	
	Potassium persulphate	
Flour, other than	Chlorine	
wholemeal, intended		
for use in the making		
of cakes.		
Flour, other than	Sulphur Dioxide	200
wholemeal, intended		
for use in the bas		

۰.

	SCHEDULE 5	Section <sup>2(1)</sup>	
	PERMITTED SOLVENTS		,
Name	Specific	ation	
Ethyl Alcohol (Ethanol) Ethyl Acetate Diethyl Ether (Solvent Ether)	As set out in the British Phar British Standard 553: 1965. As set out in the British Phar	macopocia 1963 at page 28. nacopocia 1963 at page 308.	
Glycerol Glycerol mono-acetate (Monoacetin)	British Standard 2625: 1964 It shall have a boiling point and shall be of a standard good manufacturing practi	of 158°C. at 165 mm. Hg. d of purity consistent with ce.	
Glycerol di-acetate (Diacetin)	Relative Density: 1.180—1.1 Ash: 0.02% W/W max, Acidity: 0.3% W/W max,	195 g/ml. at 20°C.	
• •	Ester Content: \$5-95% W/W (COOCH3)2 Sulphates: 0.05% W/W ma: Chlorides: 0.05% W/W ma: Ash, acidity, ester content, si be determined by the m	V calculated as C <sub>3</sub> H <sub>5</sub> (OH) x. calculated as SO <sub>4</sub> . x. calculated as Cl. liphates and chlorides shall ethods set out in British	
Glycerol tri-acetate (Triacetin)	Relative Density: 1.156-1.1 Refractive Index: 1.430-1. D line.	66 g/ml. at 20°C. 434 at 20°C. for sodium	•
	Water: 0.2% W/W max. Ash: 0.02% W/W max. Total Acidity: 0.05% W CH <sub>3</sub> COOH.	//W max, calculated as	
-	Colour: 15 Hazen Units.	calculated as (CH3COO)3	
	determined by the methods 1997; 1962. Colour sha method set out in British S	set out in British Standard Il be determined by the Standard 4117: 1967.	
Propyl Alcohol	As set out in the British Pharn As set out in the British Pharn	nacopocia 1963 at page 431, nacopocia 1963 at page 681.	

. '

۶.

·

,

· •

٠,

ι

\* \*\* \*\*

.

? I ,

;

,

.

-

.

-

## EXPLANATORY NOTE (This Note is not part of the Order)

The Order -

4

į

- (a) specifies permitted miscellaneous additives and prescribes purity criteria for those miscellaneous additives (section 2(1) and Schedule 1);
- (b) prohibits the sale or importation of food having in it or on it any added miscellaneous additive other than a permitted miscellaneous additive and limits the use of certain particular miscellaneous additives to specified foods subject to prescribed limits (section 4(1), 4(2) proviso (a) 4(3) and Schedule 2);
- (c) permits food containing as an added ingredient any specified food described in Schedule 2 to contain miscellaneous additives of a description, and to an amount, specified in that Schedule for that ingredient (section 4(2) proviso (b));
- (d) prohibits the importation, sale or advertising for sale, for use as an ingredient in the preparation of food, of any miscellaneous additive other than a permitted miscellaneous additive (section 5(1));
- (e) prescribes labelling requirements for permitted miscellaneous additives when sold as such (section 5(2) and Schedule 3);

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