

## **HEALTH (EMULSIFIERS, STABILISERS, THICKENERS AND GELLING AGENTS IN FOOD) REGULATIONS 1994**

In exercise of the powers conferred on the Minister for Health, by sections 5 of the Health Act, 1947 (No. 28 of 1947), and section 54 of that Act as amended by the European Communities (Health Act 1947), Amendment of Sections 54 and 61) Regulations, 1991 (S.I. 333 of 1991), and section 38 (3) of the Health Act, 1953 (No. 26 of 1953), which said powers are delegated to me by the Health (Delegation of Ministerial Functions) Order, 1993 (S.I. No. 62 of 1993), I, WILLIAM O'DEA, Minister of State at the Department of Health and after consultation with the Minister for Enterprise and Employment and the Minister for Agriculture, Food and Forestry, hereby make the following Regulations:—

### **PART I PRELIMINARY AND GENERAL**

#### **REG 1**

1. These Regulations may be cited as the Health (Emulsifiers, Stabilisers, Thickeners and Gelling Agents in Food) Regulations, 1994.

#### **REG 2**

2. These Regulations shall come into operation on the 11th day of April, 1994.

#### **REG 3**

3. (1) In these Regulations, unless the context otherwise requires—

"the Act" means the Health Act, 1947;

"appropriate description" means, as respects any permitted emulsifier or permitted stabiliser, a name or description or a name or description sufficiently specific in each case, to indicate to an intending purchaser the true nature of the permitted emulsifier or permitted stabiliser to which it is applied;

"authorised officer" means an authorised officer for the purposes of Part IX of the Act;

"bread" includes the following and any part of the following — baps, breadrolls, fancy bread, milk bread, malt bread and fruit bread;

"cheese spread" means cheese which has been melted and mixed with milk products other than cheese with or without the addition of emulsifying salts;

"processed cheese" means cheese which has been subjected to a process of melting and mixing with or without the addition of emulsifying salts;

"soft cheese" means cheese which is readily deformed by moderate pressure but does not include whey cheese, processed cheese or cheese spread and any reference to soft cheese includes a reference to cream cheese or curd cheese;

"whey cheese" means the product obtained by

(i) concentrating whey with or without the addition of milk and

milk fat and moulding such concentrated whey, or  
(ii) coagulating whey with or without the addition of milk and milk fat;

"container" includes any form of packaging of food and any wrapper or band;

"cream" means that portion of milk rich in milk-fat which has been separated by skimming or otherwise;

"emulsifier, stabiliser, thickener and gelling agent" mean, respectively, any substance which, when added to a food, is capable—

(a) in the case of an emulsifier, of aiding the formation of, and in the case of a stabiliser, of maintaining a uniform dispersion of two or more immiscible substances;

(b) in the case of a thickener, of increasing its viscosity; and

(c) in the case of a gelling agent, of giving it the consistency of a gel;

but do not in any case include:—

(i) any natural food substance;

(ii) products containing pectin and derived from dried apple pomace or dried peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization with sodium or potassium salts;

(iii) caseins and caseinates;

(iv) proteins, protein concentrates and protein hydrolysates;

(v) starches, whether modified or not;

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

(vii) acids, bases and salts which, when added to a food during the process of manufacture, change or stabilise the Ph;

(viii) any substance, the use of which is permitted under Regulations, other than these Regulations, for the time being in force under Part V of the Act, with the exception of lecithin, potassium orthophosphates, sodium orthophosphates, calcium orthophosphates, potassium pyrophosphate, sodium pyrophosphate, sodium acid salt of pyrophosphoric acid and sodium tripolyphosphate.

"Food Chemicals Codex 1972", "First Supplement, 1974" and "Second Supplement, 1975" mean, respectively, the second edition of the Food Chemicals Codex published in 1972, the First Supplement to that edition published in 1974 and the Second Supplement to that edition published in 1975, in each case, by the National Academy of Sciences, Washington D.C., United States of America;

"food" has the meaning assigned to it in Part V of the Act;

"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 but does not include edible gums;

"permitted emulsifier" and "permitted stabiliser" mean, respectively, any emulsifier and any stabiliser in Part I of Schedule I which complies with the specific purity criteria in relation to that emulsifier or stabiliser referred to in part II of that Schedule and, so far as is not otherwise provided in any such specific purity criteria, with the general purity criteria in Part III of that Schedule, and includes any mixture of two or more such emulsifiers or stabilisers or emulsifiers and stabilisers;

"sell" includes supply, offer or expose for sale or have in possession for sale and cognate words shall be construed accordingly;

"specified food" means any food of a description specified in Column 1 of Part I or Part II of Schedule 2.

(2) Any reference in these Regulations to an emulsifier or stabiliser shall be construed as including a reference to a thickener or gelling agent.

(3) Unless a contrary intention is expressed, all proportions mentioned in these Regulations are proportions calculated by weight of the product as manufactured, prepared, imported, distributed or sold.

(4) Any reference to a label borne on a container shall be construed as including a reference to any legible marking on the container.

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

(6) Any reference in these Regulations to an owner or to a person responsible for food shall, in the case of food purchased from a vending machine, be construed as a reference—

( a ) where the name and address of the proprietor is stated on the machine and such address is in the State, to the proprietor of the machine;

( b ) in other cases, to the occupier of the premises at or on which the machine stands or to which it is affixed.

(7) Any reference in these Regulations to any other Regulations shall be construed as a reference to such Regulations as amended by subsequent Regulations.

(8) Any reference in these Regulations to a numbered article or schedule shall, unless the reference is to an article or schedule of specified Regulations, be construed as a reference to the articles or schedules bearing that number in these Regulations.

#### REG 4

4. These Regulations shall be enforced and executed by health boards in their functional areas.

#### REG 5

5. (1) Where a sample of any food has been certified under the Health (Official Control of Food) Regulations, 1991 (S.I. No. 332 of 1991) not to comply with these Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption.

(2) With the consent in writing of the owner or person responsible for such food, an authorised officer may destroy or otherwise dispose of it so as to prevent its use for human consumption.

(3) An authorised officer who has seized any food in pursuance of this article may, on giving notice in writing to the owner or person responsible for such food of his intention to do so, apply to a Judge of the District Court for an order directing that such food be destroyed or otherwise disposed of as being food which is unfit for human consumption.

(4) A Judge of the District Court to whom the application is made for an order under sub-article (3) of this article shall, if

satisfied that such food does not comply with these Regulations, order that it be destroyed or otherwise disposed of after such period, not exceeding fourteen days, as may be specified in such order, as being food which is unfit for human consumption and an authorised officer shall destroy or dispose of it accordingly.

#### REG 6

6. A person shall give to any authorised officer all reasonable assistance that the officer may require in the performance of his duties under these Regulations and such assistance shall include the giving of information in relation to the composition and use of any food and the identity of the person from whom or the place from which any such food has been obtained and the person to whom and the place to which it has been consigned or the manner in which it has otherwise been disposed of.

#### REG 7

7. In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to show that the food in respect of which the offence is alleged to have been committed was intended for export and complied with the domestic food legislation of the importing country relevant to the alleged offence.

### **PART II.**

### **SALE, DISTRIBUTION AND IMPORTATION OF FOOD CONTAINING EMULSIFIERS AND STABILISERS.**

#### REG 8

8. (1) Subject to the provisions of these Regulations no food which is manufactured, prepared, imported, distributed, or sold shall contain any added emulsifier or added stabiliser other than a permitted emulsifier or a permitted stabiliser.

(2) Subject to sub-article (4) of this article any specified food described in Column 1 of Part 1 of Schedule 2, but no other food, which is manufactured, prepared, imported, distributed or sold, may contain any permitted emulsifier or permitted stabiliser of the description and in the proportion specified in relation thereto in Column 2 and Column 3 respectively, of that Part of that Schedule.

(3) Subject to sub-article (5) of this article any specified food described in Column 1 of Part II of Schedule 2 which is manufactured, prepared, imported, distributed or sold may, subject to the provisions of the footnote to that Part, contain any permitted emulsifier or permitted stabiliser of the description and in the proportion specified in relation thereto in Column 2 and Column 3, respectively, of that Part of that Schedule, and any such specified food shall contain no other permitted emulsifier or permitted stabiliser.

(4) ( a ) Nothing in sub-articles (2) and (3) of this article shall prohibit the presence in or on any food, which contains any specified food as an ingredient, of any permitted emulsifier or permitted stabiliser of the description specified for, and in the

amount appropriate to the quantity of that specified food in accordance with the said sub-articles.

( b ) Notwithstanding the provisions of paragraph (a) of this sub-article, where, by reason of the use of a tin-greasing emulsion in its preparation, any food contains—

(i) the permitted emulsifier oxidatively polymerised soya bean oil, that permitted emulsifier shall be present in a proportion not exceeding 50 milligrams per kilogram;

(ii) the permitted emulsifier polyglycerol esters of dimerised fatty acids of soya bean oil, that permitted emulsifier shall be present in a proportion not exceeding 20 milligrams per kilogram.

(5) Nothing in sub-article (3) of this article shall prohibit the presence in or on any bread, by reason of the use of a tin-greasing emulsion in its preparation, of any permitted emulsifier or permitted stabiliser not specified in the proviso to the preceding sub-article or in Column 2 of item (a) of Part II of Schedule 2 in a proportion not exceeding 50 milligrams per kilogram.

(6) No flour, intended for sale for human consumption, shall contain any emulsifier or stabiliser.

(7) Subject to the exception made in Part II of Schedule 2 for whipping cream or whipped cream which is sold, consigned or delivered to a manufacturer for the purposes of his manufacturing business or to a caterer for the purposes of his catering business no cream when sold as such shall contain an emulsifier or stabiliser.

(8) The emulsifiers listed in Part 1, Schedule 1 of these Regulations under serial numbers E407 and E440 may contain one or more of the sugars as defined in the Food Standards (Certain Sugars) (European Communities) Regulations 1975 (S.I. No. 118 of 1975).

(9) A person shall not manufacture, prepare, import, distribute or sell any food which does not comply with these regulations.

### **PART III.**

#### **SALE, ADVERTISEMENT AND LABELLING OF EMULSIFIERS AND STABILISERS.**

##### **REG 9**

9. (1) The package or container in which any permitted emulsifier or permitted stabiliser, either alone or in combination with any other substance, is imported, distributed or sold for use as an ingredient in the manufacture or preparation of food, shall bear a label containing the information specified in Schedule 3.

(2) A person shall not sell any permitted emulsifier or permitted stabiliser which does not comply with these Regulations.

(3) A person shall not publish any advertisement of any permitted emulsifier or permitted stabiliser for sale for use as an ingredient in the preparation of food, which bears or includes any words, device or description calculated to indicate either directly or indirectly that emulsifier or stabiliser is a nutritive substitute for fat or eggs.

**PART IV.  
AMENDMENTS AND REVOCATIONS.**

REG 10

10. The Health (Emulsifiers, Stabilisers, Thickening and Gelling Agents in Food) Regulations, 1980 (S.I. No. 35 of 1980), the Health (Emulsifiers, Stabilisers, Thickening and Gelling Agents) (Amendment) Regulations, 1982 (S.I. No. 273 of 1982), the Health (Emulsifiers, Stabilisers, Thickening and Gelling Agents in Food) (Amendment) Regulations, 1985 (S.I. No. 186 of 1985), the Health (Emulsifiers, Stabilisers, Thickening and Gelling Agents in Food) (Amendment) Regulations, 1990 (S.I. No. 102 of 1990), and the Health (Emulsifiers, Stabilisers, Thickening and Gelling Agents in Food) (Amendment) Regulations, 1992 (S.I. No. 24 of 1992) are hereby revoked.

**SCHEDULE I.**

**PART I.  
PERMITTED EMULSIFIERS AND PERMITTED STABILISERS.**

Name of Emulsifier or Stabiliser	Serial Number
Lecithins	E 322
Sodium orthophosphates	E 339
Potassium orthophosphates	E 340
Calcium orthophosphates	E 341
Alginic acid	E 400
Sodium alginate	E 401
Potassium alginate	E 402
Ammonium alginate	E 403
Calcium alginate	E 404
Propane-1,2—diol alginate	E 405
Agar	E 406
Carrageenan	E 407
Locust bean gum	E 410
Guar gum	E 412
Tragacanth	E 413
Acacia or gum arabic	E 414
Zanthan gum	E 415
Karaya gum or sterculia gum	E 416
(i) Sorbitol	E 420
(ii) Sorbitol syrup	E 420
Mannitol	E 421
Glycerol	E 422
Polyoxyethylene (20) sorbitan monolaurate or polysorbate	20E 432
Polyoxyethylene (20) sorbitan monooleate or polysorbate	80E 433
Polyoxyethylene (20) sorbitan monopalmitate or polysorbate	40E 434
Polyoxyethylene (20) sorbitan monostearate or polysorbate	60E 435
Polyoxyethylene (20) sorbitan tristearate or polysorbate	65E 436
(i) Pectin	E 440
(ii) Amidated pectin	E 440
Ammonium phosphatides or Emulsifier YNE	442
(i) disodium dihydrogen diphosphate or sodium acid salt of pyrophosphoric acid	E 450
(a) (ii) trisodium diphosphate or sodium pyrophosphate	(iii) Tetra
Sodium diphosphate or tetra	Sodium pyrophosphate
(iv) tetra	Potassium diphosphate or potassium pyrophosphate
(i) penta	Sodium triphosphate or sodium tripolyphosphate
E 450	(b) (ii) penta
Potassium triphosphate	(i) sodium polyphosphate
E 450	(c) (ii) potassium polyphosphate
(i) Microcrystalline cellulose	E 460
(ii) Powdered cellulose	E 460
Methylcellulose	E 461
Hydroxypropylcellulose	E 463
Hydroxypropylmethylcellulose	E 464
Ethylmethylcellulose	E 465
Carboxymethylcellulose	E 466
Sodium, potassium and calcium salts of fatty acids	E 470
Mono and diglycerides of fatty acids	E 471
Acetic acid esters of mono- and diglycerides of fatty acids	E 472
(a) Lactic acid esters of mono- and diglycerides of fatty acids	E 472
(b) Citric acid esters of mono- and diglycerides of fatty acids	E 472
(c) Tartaric Acid esters of mono- and diglycerides of fatty acids	E 472
(d) Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids	E 472
(e) Mixed acetic/tartaric acid	E 472

esters of mono and diglycerides of food fatty acids E 472 (f) Sucrose esters of fatty acids E 473 Sucroglycerides E 474 Polyglycerol esters of fatty acids E 475 Partial polyglycerol esters of polycondensed fatty acids of castor oil (polyglycerol polyricinoleate) E 476 Propane-1, 2—diol esters of fatty acids E 477 Oxidatively polymerised soya bean oil E 479a Polyglycerol esters of dimerised fatty acids of soya bean oil E 479b Sodium Stearoyl-2—lactylate E 481 Calcium stearoyl-2—lactylate E 482 Stearyl tartrate E 483 Sorbitan monostearate E 491 Sorbitan tristearate E 492 Sorbitan monolaurate E 493 Sorbitan mono-oleate E 494 Sorbitan monopalmitate E 495

Restriction on use.

Restricted to the use of an amount not in excess of that required in accordance with good manufacturing practice, unless otherwise specified in these Regulations.

## SCHEDULE I.

### PART II.

#### SPECIFIC PURITY CRITERIA FOR PERMITTED EMULSIFIERS AND STABILISERS.

##### E 322 Lecithins.

**Chemical Description** Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs.

The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides. **Description** Brown liquid or viscous semi-liquid or powder. **Content** Not less than 60 per cent substances insoluble in acetone. **Volatile Matter** Not more than 2 per cent determined by drying at 105°C for 1 hour. **Substances insoluble in Toluene** Not more than 0.3 per cent. **Acid Number** Not more than 35mg potassium hydroxide per gramme. **Peroxide number** Equal to or less than 10, expressed as milliequivalents per kg.

E 339 A Monosodium orthophosphate.

**Chemical Description** Monosodium monophosphate; acid monosodium monophosphate; monosodium orthophosphate; monobasic sodium phosphate;

$\text{NaH}_2\text{PO}_4$ ; the substance is available commercially in anhydrous or hydrated form with 1 or 2 molecules of water. **Description** Slightly deliquescent white powder, crystals or granules. **Content** Not less than 97 per cent  $\text{NaH}_2\text{PO}_4$  on a volatile matter-free basis. **Volatile Matter** Determined by drying at 60°C for 1 hour and then at 105°C for 4 hours — anhydrous: not more than 2 per cent. —with 1 molecule of water:

not more than 15 per cent. —with 2 molecules of water:

not more than 25 per cent. **Water-insoluble substances** Not more than 0.2 per cent of the volatile matter-free substance. **Flourides** Not more than 10 mg/kg expressed as flourine.

E 339B Disodium orthophosphate

**Chemical Description** Disodium monophosphate; secondary sodium phosphate; disodium orthophosphate; acid disodium phosphate;  $\text{Na}_2\text{HPO}_4$ . The substance is available commercially in anhydrous form or as a

hydrate with 2, 7 or 12 molecules of water. **Description**—Anhydrous: white hygroscopic powder with 2 molecules of water: white crystalline

solid,—with 7 molecules of water: granular powder or white efflorescent crystals,—with 12 molecules of water: white efflorescent powder or crystals. Content Not less than 98 per cent  $\text{Na}_2\text{HPO}_4$  on a volatile matter-free basis. Volatile Matter Determined by drying at  $60^\circ\text{C}$  for 1 hour and then at  $105^\circ\text{C}$  for 4 hours —anhydrous: not more than 5 per cent —with 1 molecule of water: not more than 21 per cent —with 7 molecules of water: not more than 50 per cent —with 12 molecules of water: not more than 61 per cent. Water-insoluble substances Not more than 0.2 per cent of the volatile matter-free substance. Flourides Not more than 10 mg/kg expressed as flourine.  
E 339C Trisodium orthophosphates.

Chemical Description Trisodium monophosphate; trisodium orthophosphate;  $\text{Na}_3\text{PO}_4$ ; the substance is available commercially in anhydrous form or as a hydrate with 1 or 12 molecules of water. Description White powder, crystals or granules. Content Not less than 97 per cent  $\text{Na}_3\text{PO}_4$  on a volatile matter-free basis. Volatile matter Determined by drying at  $105^\circ\text{C}$  for 1 hour, followed by calcination at  $800^\circ\text{C} + 25^\circ\text{C}$  for 30 minutes — —anhydrous: not more than 2 per cent —with 1 molecule of water: not more than 9 per cent —with 12 molecules of water: not more than 55 per cent. Water-insoluble substances Not more than 0.2 per cent of the volatile matter-free substance. Flourides Not more than 10 mg/kg expressed as flourine.  
E 340 A Monopotassium orthophosphate

Chemical Description Monopotassium monophosphate; acid monopotassium monophosphate;  $\text{KH}_2\text{PO}_4$ . Description Colourless crystals or white granular or crystalline powder, hygroscopic. Content Not less than 98 per cent  $\text{KH}_2\text{PO}_4$  on a volatile matter-free basis. Volatile matter Not more than 2 per cent determined by drying at  $105^\circ\text{C}$  for 4 hours. Water-insoluble substances Not more than 0.2 per cent of the volatile matter-free substance. Flourides Not more than 10 mg/kg expressed as flourine.  
E 340 B Dipotassium orthophosphate.

Chemical Description Dipotassium monophosphate; secondary potassium phosphate; acid dipotassium orthophosphate; dipotassium phosphate;  $\text{K}_2\text{HPO}_4$ . Description Colourless or white granular deliquescent substance. Content Not less than 98 per cent  $\text{K}_2\text{HPO}_4$  on a volatile matter-free basis. Volatile Matter Not more than 2 per cent determined by drying at  $105^\circ\text{C}$  for 4 hours. Water-insoluble substances Not more than 0.2 per cent of the volatile matter-free substance. Flourides Not more than 10 mg/kg expressed as flourine.  
E 340 C Tripotassium orthophosphate.

Chemical Description Tripotassium monophosphate; tripotassium orthophosphate;  $\text{K}_3\text{PO}_4$ ; the substance is available commercially in anhydrous form or hydrated form, the most common being that with 1 molecule of water of crystallization. Description White hygroscopic crystals or granules. Content Not less than 97 per cent  $\text{K}_3\text{PO}_4$  on a volatile matter-free basis. Volatile Matter Determined by drying at  $105^\circ\text{C}$  for 1 hour followed by calcination at  $800^\circ\text{C} + 25^\circ\text{C}$  for 30 minutes, —anhydrous: not more than 3 per cent —with one molecule of water: not more than 20 per cent. Water-insoluble substances Not more than 0.2 per cent of the volatile matter-free substance. Flourides Not more than 10 mg/kg expressed as flourine.



E 341 A Monocalcium orthophosphate.

**Chemical Description** Monocalcium phosphate;  $\text{CaH}_4(\text{PO}_4)_2$ ; available commercially in anhydrous form or as the monohydrate. **Description** Granular powder or white, deliquescent crystals or granules. **Calcium Content** Anhydrous: not less than 23 per cent and not more than 25 per cent expressed as CaO. with one molecule of water: not less than 22.2 per cent and not more than 24.7 per cent expressed as CaO. **Volatile matter** Anhydrous: not less than 14 per cent and not more than 15.5 per cent determined after calcination at  $800^\circ\text{C} + 25^\circ\text{C}$  for 30 minutes. With one molecule of water: not more than 0.6 per cent determined by drying at  $60^\circ\text{C}$  for 3 hours. **Flourides** Not more than 30 mg/kg expressed as flourine.

E 341B Dicalcium orthophosphate.

**Chemical Description** Diabasic calcium phosphate Dicalcium phosphate;  $\text{CaHPO}_4$  available commercially in anhydrous and dihydrate form. **Description** Impalpable white powder. **Calcium content** Anhydrous: not less than 39 per cent and not more than 42 per cent expressed as CaO. With two molecules of water: not less than 31.9 per cent and not more than 33.5 per cent expressed as CaO. **Volatile matter** Determined by calcination at  $800^\circ\text{C} + 25^\circ\text{C}$  to constant weight. Anhydrous: not less than 7 per cent and not more than 8.5 per cent. Dihydrate: not less than 24.5 per cent and not more than 26.5 per cent. **Flourides** Not more than 50 mg/kg expressed as flourine.

E 400 Alginic acid.

**Chemical Description** Linear glycuronoglycan consisting mainly of beta (1-4) linked D-mannuronic and alpha (1-4) linked L-glucuronic acid units in pyranose ring form. Hydrophillic colloidal carbohydrate extracted by the use of dilute alkali from various species of brown seaweeds. **Description** A nearly odourless, tasteless white to yellowish fibrous powder. **Content** Yields, on a volatile matter-free basis, not less than 20 per cent and not more than 23 per cent of carbon dioxide corresponding to not less than 91.0 per cent and not more than 104.5 per cent of alginic acid (equivalent weight 200). **Ash** Not more than 4 per cent on a volatile matter-free basis determined at  $600^\circ\text{C}$  after drying at  $105^\circ\text{C}$  for 4 hours. **Volatile matter** Not more than 15 per cent determined by drying at  $105^\circ\text{C}$  for 4 hours. **Acid-insoluble ash** (insoluble in approx. 3N hydrochloric acid) Not more than 2 per cent.

E 401 Sodium alginate.

**Chemical Name** Sodium salt of alginic acid. **Description** Nearly odourless, tasteless white to yellowish fibrous or granular powder. **Content** Yields, on a volatile matter-free basis, not less than 18 per cent and not more than 21 per cent of carbon dioxide corresponding to not less than 90.8 per cent and not more than 106.0 per cent of sodium alginate (equivalent weight 222). **Ash** Not less than 18.0 per cent and not more than 27.0 per cent on a volatile matter-free basis determined at  $600^\circ\text{C}$  after drying at  $105^\circ\text{C}$  for 4 hours. **Volatile matter** Not more than 15 per cent determined by drying at  $105^\circ\text{C}$  for 4 hours. **Acid-insoluble ash** (insoluble in approx. 3N hydrochloric acid) Not more than 2 per cent.

#### E 402 Potassium alginate.

**Chemical Name**Potassium salt of alginic acid.**Description**Nearly odourless, tasteless white to yellowish fibrous or granular powder.**Content Yields**, on a volatile matter-free basis, not less than 16.5 per cent and not more than 19.5 per cent of carbon dioxide corresponding to not less than 89.2 per cent and not more than 105.5 per cent of potassium alginate (equivalent weight 238).**Ash**Not less than 23 per cent and not more than 32 per cent on a volatile matter free basis determined at 600°C after drying at 105°C for 4 hours.**Volatile matter**Not more than 15 per cent determined by drying at 105°C for 4 hours.**Acid-insoluble ash** (insoluble in approx. 3N hydrochloric acid)Not more than 2 per cent.

#### E 403 Ammonium alginate

**Chemical Name**Ammonium salt of alginic acid.**Description**White to yellowish fibrous or granular powder.**Content Yields**, on a volatile matter-free basis, not less than 18 per cent and not more than 21 per cent of carbon dioxide corresponding to not less than 88.7 per cent and not more than 103.6 per cent of ammonium alginate (equivalent weight 217).**Ash**Not more than 4 per cent on a volatile matter-free basis determined at 600°C after drying at 105°C for 4 hours.**Volatile matter**Not more than 15 per cent when dried for 4 hours at 105°C.**Acid-insoluble ash** (insoluble in approx. 3N hydrochloric acid)Not more than 2 per cent.

#### E 404 Calcium alginate

**Chemical Name**Calcium salt of alginic acid.**Description**Nearly odourless, tasteless fibrous or granular powder.**Content Yields**, on a volatile matter-free basis, not less than 18 per cent and not more than 21 per cent of carbon dioxide corresponding to not less than 89.6 per cent and not more than 104.5 per cent of calcium alginate (equivalent weight 219).**Ash**Not less than 15 per cent and not more than 24 per cent on a volatile matter-free basis determined at 600°C after drying at 105°C for 4 hours.**Volatile matter**Not more than 15 per cent when dried for 4 hours at 105°C.**Acid-insoluble ash** (insoluble in approx. 3N hydrochloric acid)Not more than 2 per cent.

#### E 405 Propane-1,2-diol alginate.

**Chemical Description**Propane-1,2-diol ester of alginic acid varies in composition according to its degree of esterification and the percentages of free and neutralized carboxyl groups in the molecule.**Description**Nearly odourless and tasteless white to yellowish fibrous or granular powder.**Content Yields**, on a volatile matter-free basis, not less than 16 per cent and not more than 20 per cent of carbon dioxide.**Ash**Not more than 10 per cent on a volatile matter-free basis determined at 600°C after drying at 105°C for 4 hours.**Total propane 1,2-diol content**Not less than 15 per cent and not more than 20 per cent.**Free propane-1,2-diol content**Not more than 12 per cent.**Volatile Matter**Not more than 20 per cent when dried for 4 hours at 105°C.**Acid insoluble ash** (insoluble in approx. 3N hydrochloric acid)Not more than 2 per cent.

#### E 406 Agar.

**Chemical Description**A hydrophilic colloidal polygalactoside, about 90

per cent of the galactose molecules being of the D-form and 10 per cent of the L-form. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain marine algae of the families Gelidiaceae and Sphaerococcaceae and related red algae of the class Rhodophyceae. Description White to pale yellow powder, fibres or flakes which are either odourless, or have a slight characteristic odour and a mucilaginous taste. Ash (Total) Not more than 6.5 per cent determined at 550°C on a volatile matter-free basis. Acid insoluble ash (insoluble in approx. 3N hydrochloric acid). Not more than 0.5 per cent determined at 550°C on a volatile matter-free basis. Gelatin and Other Proteins Dissolve about 1g agar in 100ml of boiling water and allow to cool to about 50°C. To 5ml of the solution add 5ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml hot water). No turbidity appears within 10 minutes. Insoluble matter (in hot water) Not more than 1 per cent. Volatile matter Not more than 20 per cent when dried for 5 hours at 105°C. Starch and dextrins Boil 100 mg agar in 100ml of water. Cool and add a few drops of iodine solution prepared by dissolving 14g I<sub>2</sub> in a solution of 36g KI in 100ml H<sub>2</sub>O. Add 3 drops HCL and dilute to 1,000ml. No blue or red colour is produced. Water absorption Place 5g agar in a 100ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25°C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100ml graduated cylinder. Not more than 75ml water is obtained.

E 407 Carrageenan.

Chemical Description Obtained by aqueous extraction of seaweeds of GIGARTINACEAE, SOLIERIACEAE, HYPNEACHEAE, FURCELLARIACEAE and families of the class RHODOPHYCEAE (red seaweeds). No organic precipitants shall be used other than methanol, ethanol and isopropanol.

Carrageenan consists chiefly of the calcium, potassium, sodium, and magnesium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3, 6 anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded. Description Yellowish to colourless, coarse to fine powder which is practically odourless and has a mucilaginous taste. Volatile matter Not more than 12 per cent determined by drying at 105°C for 4 hours. Sulphate (expressed as SO<sub>4</sub>) Not less than 15 per cent and not more than 40 per cent on a volatile matter-free basis, expressed as SO<sub>4</sub>. Acid insoluble ash (insoluble in 10 per cent w/v hydrochloric acid) Not more than 1 per cent dry matter. Acid insoluble matter (insoluble in 1 per cent v/v sulphuric acid) Not more than 2 per cent dry matter. Ash Not less than 15 per cent and not more than 40 per cent determined at 550°C on a volatile matter-free basis. Viscosity of a 1.5 per cent solution at 75°C Not less than 5 centipoises. Isopropanol } Ethanol Not more than 1 per cent singly or in combination. Methanol Content

E 410 Locust bean gum.

Chemical Description Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be

described chemically as galactomannan. Description The ground endosperm of the seeds of the carob tree, *Ceratonia siliqua* (L.) Taub. (Fam. Leguminosae). A white to yellowish-white nearly odourless powder. Galactopyranose and Mannopyranose content Not less than 75 per cent. Insoluble matter (in 0.4N Sulphuric acid): Not more than 4 per cent after digestion for 6 hours. Ash Not more than 1.2 per cent determined at 800°C. Volatile Matter Not more than 14 per cent when dried to constant weight at 102°-105°C (3-5 hours). Protein (Nx 6.25) Not more than 7 per cent.  
E 412 Guar gum.

Chemical description Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycoside linkages, which may be described chemically as galactomannan. Description The ground endosperm of the seeds of the guar plant, *Cyamopsis tetragonolobus* (L) Taub. (Fam Leguminosae). A white to yellowish-white nearly odourless powder. Galactopyranose content Not less than 75 per cent. Insoluble matter (in 0.4N sulphuric acid) Not more than 4 per cent after digestion for 6 hours. Ash Not more than 1.5 per cent determined at 800°C. Volatile matter Not more than 14 per cent when dried to constant weight at 102°-105°C. (3-5 hours). Protein (Nx 6.25) Not more than 7 per cent.  
E 413 Tragacanth.

Chemical Description Consists mainly of high molecular weight polysaccharides composed of galactoarabans and acidic polysaccharides containing galacturonic acid groups. Description A dried gummy exudate obtained from *Astragalus gummifer* Labillardiere, or other Asiatic species of *Astragalus* (Fam. Leguminosae). Unground tragacanth occurs as flattened lamellated, frequently curved fragments or straight or spirally twisted linear pieces from 0.5 to 2.3 mm in thickness which are white to pale yellow in colour. It is odourless and has an insipid, mucilaginous taste. Powdered tragacanth is white to yellowish white in colour. Viscosity of a 1 per cent Solution at 25°C Not less than 250 centipoises. Ash Not more than 3.5 per cent at 550°C. Acid insoluble ash (insoluble in approx. 3N hydrochloric acid) Not more than 0.5 per cent at 550°C. Karaya gum Boil 1g with 20ml of water until a mucilage is formed. Add 5ml of hydrochloric acid and again boil the mixture for 5 minutes. No permanent pink or red colour develops.  
E 414 Acacia.

Chemical Description Consists mainly of high molecular weight polysaccharides and their calcium, potassium and magnesium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid. It is obtained as a dried gummy exudate from the stems and branches of *Acacia senegal* (L) Willd or of related species of *Acacia* (Fam. Leguminosae). Description Unground acacia occurs as white, yellowish-white or pale pinkish spheroidal tears of varying size or in angular fragments. It is also available commercially in the form of white or yellowish-white flakes, granules or powder. Ash Not more than 4 per cent at 550°C. Insoluble matter (in approx. 3N hydrochloric acid) Not more than 1 per cent. Volatile matter Not more than 15 per cent determined by drying at 105°C for

5 hours. Starch or Dextrin Boil a 1 in 50 solution of the gum and cool. To 5ml add one drop of iodine solution (14 g iodine in a solution of 36 g potassium iodine in 100ml water, add 3 drops hydrochloric acid and dilute to 1000ml). No bluish or reddish colour is produced. Tannin To 10ml of a 1 in 50 solution add about 0.1ml of ferric chloride solution (9g FeCl<sub>3</sub>·6H<sub>2</sub>O made up to 100ml with water). No blackish colouration or blackish precipitate is formed.

E 415 Xanthan Gum.

**Chemical Description** Xanthan gum is a high molecular weight polysaccharide gum produced by pure-culture fermentation of a carbohydrate with *Xanthomonas campestris*, purified by recovery with ethanol or isopropanol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral. **Description** Cream-coloured powder. **Content** Xanthan gum yields, on a volatile matter-free basis, not less than 4.2 per cent and not more than 5.0 per cent of carbon dioxide. **Volatile matter** Not more than 15 per cent determined by drying at 105°C for 2½ hours. **Ash** Not more than 16 per cent on a volatile matter-free basis determined at 600°C after drying at 105°C for 4 hours. **Pyruvic acid** Not less than 1.5 per cent. **Nitrogen** Not more than 1.5 per cent. **Isopropanol** Not more than 750mg/kg. **Microbiological criteria** Viable cells of *Xanthomonas campestris* shall be absent.

E 416 Karaya gum or Sterculia Gum.

The criteria in the monograph for Karaya gum contained in the Food Chemicals Codex 1972 at page 423.

E 420 (i) Sorbitol.

**Chemical Name** D-sorbitol. **Description** White hygroscopic crystalline powder, flakes or granules, having a sweet taste. **Content** Sorbitol contains not less than 98 per cent of glycitols and not less than 91 per cent of D-sorbitol, on a dry matter basis in each case. Glycitols are compounds with the structural formula CH<sub>2</sub>OH (CHOH)<sub>n</sub>CH<sub>2</sub>OH where 'n' is an integer. That part of the product which is not D-Sorbitol is composed mainly of mannitol together with small quantities of other glycitols, n < 4 and minor quantities of hydrogenated oligosaccharides. **Water** Not more than 10 per cent [Karl Fischer]. **Reducing sugars** Not more than 0.3 per cent on a dry-weight basis, expressed as dextrose. **Total sugars** Not more than 1 per cent on a dry-weight basis, expressed as dextrose. **Sulphated ash** Not more than 0.1 per cent at 800±25°C on a dry-weight basis. **Sulphate** Not more 0.01 per cent on a dry-weight basis. **Chloride** Not more than 0.005 per cent on a dry-weight basis, expressed as Cl. **Nickel** Not more than 2 mg/kg, expressed as Ni.

E 420 (ii) Sorbitol Syrup.

**Description** Clear colourless and sweet-tasting aqueous solution of sorbitol and hydrogenated oligosaccharides. That part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of other glycitols where n < 4 may be present. **Content** Not less than 69 per cent total solids and not less than 50 per cent of D-Sorbitol. **Sulphated Ash** Not more than 0.1 per cent on a dry-weight basis. **Sulphate** Not more than 0.01 per cent on a dry-weight basis. **Chloride** Not more than 0.005 per cent on a dry-weight basis. **Nickel** Not more than 2 mg/kg. **Reducing Sugars** Not more than 0.3 per cent on a dry-weight basis, expressed as dextrose.

E 421 Mannitol.

Chemical Name D-mannitol. Description White crystalline solid which is odourless and has a sweet taste. Content Not less than 98 per cent of D-mannitol (C<sub>6</sub>H<sub>14</sub>O<sub>6</sub>) on a volatile matter-free basis. Melting Range 165°C-168°C. Specific Rotation [α]<sub>D</sub> Not less than + 23.0° and not more than + 24.3°. Volatile Matter Not more than 0.3 per cent determined by drying at 105°C for 4 hours. Reducing Sugars Not more than 0.05 per cent expressed as dextrose. Chloride Not more than 0.007 per cent, expressed as Cl. Sulphate Not more than 0.01 per cent, expressed as SO<sub>4</sub>. Ash Not more than 0.1 per cent determined at 800 + 25°C. Nickel Not more than 2 mg/kg, expressed as Ni.  
E 422 Glycerol.

Chemical Name Glycerol. Description Clear, colourless hygroscopic syrupy liquid with a sweet taste accompanied by a sensation of heat to the tongue. Content Not less than 98 per cent of glycerol (C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>). Specific Gravity (25/25°C) Not less than 1.25 per cent. Refractive Index [n]<sub>D</sub> 1.471-1.474. Acrolein, Glucose and Ammonium compounds Heat a mixture of 5ml glycerol and 5ml potassium hydroxide solution (1 in 10) at 60°C for 5 minutes. It neither becomes yellow nor emits an odour of ammonia. Butanetriols Not more than 0.2 per cent. Chlorinated compounds (as Cl) Not more than 0.003 per cent. Fatty acids and esters Not more than 1 per cent calculated as butyric acid. Sulphated Ash Not more than 0.01 per cent determined at 800 + 25°C.

E 432 Polyoxyethylene (20) sorbitan monolaurate or polysorbate 20. The criteria in the monograph for polysorbate 20 contained in the Food Chemicals Codex 1972 at page 632 as amended by the Second Supplement, 1975 at page 30.

E 433 Polyoxyethylene (20) sorbitan mono-oleate or polysorbate 80. The criteria in the monograph for polysorbate 80 contained in the Food Chemicals Codex 1972 at page 637 as amended by the Second Supplement 1975 at page 30 except that the final sentence of the description shall be deleted.

E 434 Polyoxyethylene (20) sorbitan monopalmitate or polysorbate 40. The criteria in the monograph for polyoxyethylene (20) sorbitan monopalmitate contained in the Nutrition Meetings Report Series No. 35 (1964) of the United Nations' Food and Agriculture Organisation at page 135.

E 435 Polyoxyethylene (20) sorbitan monostearate or polysorbate 60. The criteria in the monograph for polysorbate 60 contained in the Food Chemicals Codex 1972 at page 634 except that the final sentence of the description shall be deleted.

E 436 Polyoxyethylene (20) sorbitan tristearate or polysorbate 65. The criteria in the monograph for polysorbate 65 contained in the Food Chemicals Codex 1972 at page 635 except that the final sentence of the description shall be deleted.

E 440 Pectin.

Chemical Description Pectin consists mainly of the partial methyl esters of polygalacturonic acid and their sodium, potassium, calcium and ammonium salts. Pectin is obtained by aqueous extraction of appropriate edible plant material, usually citrus fruits or apples. No organic precipitants shall be used other than methanol, ethanol and isopropanol. Description White, light yellow, light grey or light

brown powder. Galacturonic acid Not less than 65 per cent calculated on an ash and volatile matter-free basis after washing with acid and alcohol. Volatile matter Not more than 12 per cent after drying at 105°C for 2 hours. Acid-insoluble ash (insoluble in approx. 3N hydrochloric acid) Not more than 1 per cent. Free Methanol, Ethanol and Isopropanol content Not more than 1 per cent singly or in combination on a volatile matter-free basis. Sulphur Dioxide Residue Not more than 50 mg/kg on a volatile matter-free basis. Nitrogen content Not more than 0.5 per cent determined after washing with acid and alcohol [Kjeldahl].

E 440 Amidated Pectin.

Chemical Description Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium sodium, potassium and calcium salts. It is obtained by aqueous extraction of appropriate edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic precipitants shall be used other than methanol, ethanol and isopropanol. Description White, light yellow, light grey or light brown powder. Degree of amidation Not more than 25 per cent of total carboxyl groups. Galacturonic acid Not less than 65 per cent calculated on an ash and volatile matter-free basis determined after washing with acid and alcohol. Volatile matter Not more than 12 per cent after drying at 105°C for 2 hours. Acid-insoluble ash (insoluble in approx. 3N hydrochloric acid) Not more than 1 per cent. Free Methanol, Ethanol and Isopropanol content Not more than 1 per cent singly or in combination on a volatile matter-free basis. Sulphur Dioxide residue Not more than 50 mg/kg on a volatile matter-free basis. Nitrogen content Not more than 2.5 per cent after washing with acid and alcohol [Kjeldahl].

E 442 Ammonium phosphatides.

Description An unctuous semi-solid (at 25°C.) and consisting essentially of a mixture of the ammonium salts of phosphatidic acids derived from partially hardened rapeseed oil together with unreacted partially hardened rapeseed oil. Matter insoluble in petroleum ether (40°C-60°C) Total: Not more than 2.5 per cent Inorganic matter: not more than 0.2 per cent. pH of an aqueous extract of melted ammonium phosphatides Not less than 6.0 and not more than 8.0. Phosphorus Not less than 3.0 per cent and not more than 3.4 per cent. Ammonium nitrogen Not less than 1.2 per cent and not more than 1.5 per cent. Arsenic Not more than 5 mg/kg.

E 450 (a) (i) disodium dihydrogen diphosphate ( $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ ) or Sodium acid salt of pyrophosphoric acid.

Description White powder or grains. Content Not less than 95 per cent of  $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ . Content in  $\text{P}_2\text{O}_5$  Not less than 63.0 per cent and not more than 64.0 per cent. Loss on drying Not more than 0.5 per cent after drying for 4 hours at 105°C. pH of 1 per cent solution Not less than 2.7 and not more than 4.4. Water insoluble matter Not more than 0.6 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.

E 450 (a) (ii) Trisodium diphosphate ( $\text{Na}_3\text{HP}_2\text{O}_7$ ) or sodium pyrophosphate.

Description White powder or grains. Occurs anhydrous or as a

monohydrate. Content Not less than 95 per cent of  $\text{Na}_3\text{HP}_2\text{O}_7$  or of  $\text{Na}_3\text{HP}_2\text{O}_7\cdot\text{H}_2\text{O}$ . Content in  $\text{P}_2\text{O}_5$  Not less than 57.5 per cent and not more than 58.5 per cent for the anhydrous salt. Not less than 53.6 per cent and not more than 54.6 per cent for the monohydrate. Ph of a 1 per cent solution Not less than 6.7 and not more than 7.3. Volatile matter Not more than 0.5 per cent determined by drying at  $105^\circ\text{C}$  for 4 hours. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.

E 450 (a) (iii) Tetra Sodium diphosphate ( $\text{Na}_4\text{P}_2\text{O}_7$ ) or tetra sodium pyrophosphate.

Description White, crystalline or granular powder. Occurs anhydrous or as a decahydrate. Content Not less than 95 per cent of  $\text{Na}_4\text{P}_2\text{O}_7$ , or  $\text{Na}_4\text{P}_2\text{O}_7\cdot 10\text{H}_2\text{O}$ . Content in  $\text{P}_2\text{O}_5$  Not less than 52.5 per cent and not more than 54.0 per cent for the anhydrous salt. Not less than 31.5 per cent and not more than 32.5 per cent for the decahydrate. Loss on ignition Not more than 0.5 per cent for the anhydrous salt, not less than 38 per cent and not more than 42 per cent for the decahydrate, in both cases determined after drying at  $105^\circ\text{C}$  for 4 hours, followed by ignition at  $550^\circ\text{C}$  for 30 minutes. Ph of a 1 per cent solution Not less than 9.9 and not more than 10.7. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.

E 450 (a) (iv) tetra Potassium diphosphate ( $\text{K}_4\text{P}_2\text{O}_7$ ) or potassium pyrophosphate.

Description Colourless crystals or white, very hygroscopic powder. Content Not less than 95 per cent of  $\text{K}_4\text{P}_2\text{O}_7$ . Content in  $\text{P}_2\text{O}_5$  Not less than 42.0 per cent and not more than 43.7 per cent. Loss on ignition Not more than 2 per cent after drying for 4 hours at  $105^\circ\text{C}$  followed by ignition at  $550^\circ\text{C}$  for 30 minutes. Ph of a 1 per cent solution Not less than 10.0 and not more than 10.7. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.

E 450 (b) (i) pentasodium triphosphate ( $\text{Na}_5\text{P}_3\text{O}_{10}$ ) or sodium tripolyphosphate.

Description White, slightly hygroscopic granules or powder. Occurs anhydrous or as an hexahydrate. Content Not less than 85.0 per cent of  $\text{Na}_5\text{P}_3\text{O}_{10}$  or of  $\text{Na}_5\text{P}_3\text{O}_{10}\cdot 6\text{H}_2\text{O}$  remainder being principally other sodium phosphates (E450). Content in  $\text{P}_2\text{O}_5$  Not less than 56.0 per cent and not more than 58.0 per cent for the anhydrous salt. Not less than 43.0 per cent and not more than 45.0 per cent for the hexahydrate. Loss on Ignition For the anhydrous salt not more than 0.5 per cent and for the hexahydrate not more than 23.2 per cent in both cases determined after drying for 4 hours at  $105^\circ\text{C}$  followed by ignition at  $550^\circ\text{C}$  for 30 minutes. Ph of a 1 per cent solution Not less than 9.3 and not more than 10.1. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.

E 450 (b) (ii) pentapotassium triphosphate ( $\text{K}_5\text{P}_3\text{O}_{10}$ ).

Description White, very hygroscopic powder. Content Not less than 85 per cent of  $\text{K}_5\text{P}_3\text{O}_{10}$  after ignition at  $550^\circ\text{C}$  for 30 minutes, the remainder being principally other potassium phosphates (E450). Content in  $\text{P}_2\text{O}_5$  Not less than 46.5 per cent and not more than 48.0 per



cent. Loss on Ignition Not more than 0.5 per cent calculated on the P<sub>2</sub>O<sub>5</sub> content after drying for 4 hours at 105°C followed by ignition at 550°C for 30 minutes. pH of a 1 per cent solution Not less than 9.3 and not more than 10.1. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine.  
E 450 (c) (i) sodium polyphosphates.

Chemical Description Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula H<sub>(n-2)</sub>PO<sub>(3n+1)</sub> where 'n' is not less than 2. Description Fine white powders or crystals or colourless glassy platelets. Content in P<sub>2</sub>O<sub>5</sub> Not less than 59.5 per cent not more than 70.0 per cent calculated on the ignited basis. Loss on Ignition Not more than 0.5 per cent after drying at 105°C for 4 hours followed by ignition at 550°C for 30 minutes. pH of a 1 per cent solution Not less than 3.6 and not more than 9.0. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine. Cyclic phosphates Not more than 8 per cent.  
E 450 (c) (ii) Potassium polyphosphates.

Chemical Description Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula H<sub>(n + 2)</sub>PnO<sub>(3n + 1)</sub> where 'n' is not less than 2. Description Fine white powders or crystals or colourless glassy platelets. Content in P<sub>2</sub>O<sub>5</sub> Not less than 53.5 per cent and not more than 61.5 per cent on the ignited basis. Loss on Ignition Not more than 2 per cent after drying for 4 hours at 105°C followed by ignition at 550°C for 30 minutes. pH of a 1 per cent solution Not more than 7.8. Water insoluble matter Not more than 0.2 per cent. Flouride Not more than 10 mg/kg, expressed as flourine. Cyclic phosphates. Not more than 8 per cent.  
35 E 460 (i) Microcrystalline cellulose.

Chemical Description Purified partially depolymerised cellulose prepared by acid hydrolysis of alpha-cellulose obtained directly from fibrous plant material. It has a molecular weight of about 36,000. Description A fine white or almost white odourless powder. Volatile matter Not more than 5 per cent determined by drying to constant weight at 105°C. pH Shake about 5g with 40ml of carbon dioxide free water for 20 minutes and centrifuge. The pH of the supernatant liquid is between 5.5 and 7.0. Sulphated ash Not more than 0.1 per cent determined at 800 + 25°C. Water soluble substances Not more than 0.16 per cent. Diethyl ether extractable matter Not more than 200 mg/kg. Chloride Not more than 350 mg/kg expressed as Cl. Sulphate Not more than 600 mg/kg expressed as SO<sub>4</sub>  
E 460 (II) Powdered Cellulose.

Chemical Description Powdered cellulose is purified mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained directly from fibrous plant material. It has a molecular weight of 1.6 x 10<sup>5</sup> or greater. Description A white, odourless powder. Content Not less than 92 per cent (C<sub>12</sub>H<sub>20</sub>O<sub>10</sub>)<sub>n</sub>. Volatile matter Not more than 7 per cent determined by drying at 105°C for three hours. pH Shake about 5g with 40ml of carbondioxide-free water for 20 minutes and centrifuge. The pH of the supernatant liquid is between 5.0 and 7.5. Sulphated ash Not more than 0.3 per cent determined at 800 +

25°C. Water-soluble substances Not more than 1 per cent.  
E 461 Methylcellulose.

**Chemical Description** Obtained directly from fibrous plant material and partially etherified with methyl groups.  
**Description** A slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless granular or fibrous powder.  
**Chemical Formula** The polymers contain substituted glucose units with the following general formula:  $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ , where  $R_1$ ,  $R_2$  and  $R_3$  each may be  $-H$  or  $-CH_3$  or  $-CH_2CH_2OH$ .  
**Molecular weight** From about 20,000 to 380,000.  
**Content of substituted groups** Not less than 25 per cent and not more than 33 per cent of methoxyl groups ( $-OCH_3$ ), No more than 5 per cent of hydroxyethoxyl groups ( $-OCH_2CH_2CH_3$ ).  
**Volatile matter** Not more than 10 per cent determined by drying to constant weight at 105°C.  
**Sulphated ash** Not more than 1.5 per cent determined at 800 + 25°C.  
**pH of a 1 per cent solution** Not less than 5 and not more than 8  
E 463 Hydroxypropylcellulose.

**Chemical Description** Obtained directly from fibrous plant material and partially etherified with hydroxypropyl group.  
**Description** Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder.  
**Chemical Formula** The polymers contain substituted glucosidic units with the following general formula:  
 $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ , where  $R_1$ ,  $R_2$  and  $R_3$  each may be any one of the following:  $-H$   $-CH_2CHOHCH_3$   $-CH_2CHO(CH_2CHOHCH_3)CH_3$   $-CH_2CHO(CH_2CHOHCH_3)CH_3$   
**Molecular weight** From about 30,000 to 1,000,000.  
**Content of substituted groups** Not more than 80.5 per cent of hydroxypropoxyl groups ( $-OCH_2CHOHCH_3$ ) on a volatile matter-free basis, equivalent to not more than 4.6 hydroxypropyl groups per anhydroglucose unit.  
**pH of a 1 per cent solution** Not less than 5.0 and not more than 8.0.  
**Volatile matter** Not more than 10 per cent determined by drying to constant weight at 105°C.  
**Sulphated ash** Not more than 0.5 per cent determined at 800 + 25°C.  
E 464 Hydroxypropylmethylcellulose.

**Chemical Description** Obtained directly from fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution.  
**Description** Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder.  
**Chemical formula** The polymers contain substituted anhydroglucose units with the following general formula:  
 $C_6H_7O_2(OR_1)(OR_2)(OR_3)$  where  $R_1$ ,  $R_2$  and  $R_3$  each may be any one of the following:  $-H$   $-CH_3$   $-CH_2CHOHCH_3$   $-CH_2CHO(CH_2CHOHCH_3)CH_3$   $-CH_2CHO(CH_2CHOHCH_3)CH_3$   
**Molecular weight** From about 13,000 to 200,000.  
**Content of substituted groups** Not less than 19 per cent and not more than 30 per cent of methoxyl groups ( $OCH_3$ ) and not less than 3 per cent and not more than 12 per cent hydroxypropoxyl groups ( $OCH_2CHOHCH_3$ ) on a volatile matter-free basis.  
**pH of a 1 per cent solution** Not less than 5.0 and not more than 8.0.  
**Volatile matter** Not more than 10 per cent after drying to constant weight at 105°C.  
**Sulphated ash** Not more than 1.5 per cent for products with viscosities greater than 50cP and not more than 3.0 per cent for products with viscosities of 50cP or less, determined at 800 ± 25°C.

#### E 465 Ethylmethylcellulose.

**Chemical Description** Obtained directly from fibrous plant material and partially etherified with methyl and ethyl groups. **Description** Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless granular or fibrous powder. **Chemical Formula** The polymers contain substituted anhydroglucose units with the following general formula:

$C_6H_7O_2 (OR_1) (OR_2) (OR_3)$ , where R1, R2 and R3 each may be any one of the following: —H —CH<sub>3</sub> —CH<sub>2</sub> CH<sub>3</sub> **Molecular weight** From about 30,000 to 40,000. **Content of substituted groups** Not less than 14.5 per cent and not more than 19 per cent of ethoxyl groups (-OCH<sub>2</sub>H<sub>5</sub>) and not less than 3.5 per cent and not more than 6.5 per cent of methoxyl groups (-OCH<sub>3</sub>) on a volatile matter-free basis. **Volatile matter** Fibrous form: Not more than 15 per cent. Powdered form: not more than 10 per cent. Determined by drying to constant weight at 105°C in each case. **Sulphated ash** Not more than 0.6 per cent determined at 800 ± 25°C. **pH of a 1 per cent solution** Not less than 5 and not more than 8.

#### E 466 Carboxymethylcellulose.

**Chemical Description** The partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from fibrous plant material. **Description** Slightly hygroscopic white or slightly yellowish or greyish, odourless and tasteless, granular or fibrous powder. **Chemical formula** The polymers contain substituted glucosidic units with the following general formula:

$C_6H_7O_2 (OR_1) (OR_2) (OR_3)$ , where R1, R2 and R3 each may be any one of the following: —H —CH<sub>2</sub>COONa —CH<sub>1</sub> COOH **Molecular weight** Higher than approximately 17,000 (degree of polymerisation approximately 100). **Content** Not less than 99.5 per cent of carboxymethylcellulose calculated on a volatile matter-free basis. **Sodium Chloride and Sodium Glycolate** Not more than 0.5 per cent total and not more than 0.4 per cent of sodium glycolate. **Degree of Substitution** Not less than 0.2 and not more than 1.0 carboxymethyl groups (CH<sub>2</sub> COOH) per anhydroglucose unit. **Sodium** Not more than 9.7 per cent on a volatile matter-free basis. **Volatile matter** Not more than 12 per cent determined by drying to constant weight at 105°C. **pH of a 1 per cent solution** Not less than 6 and not more than 8.5.

#### E 470 Sodium, Potassium and Calcium salts of food fatty acids.

**Chemical Description** Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats or from distilled food fatty acids. **Description** White or creamy white light powders, flakes or semi-solids. **Unsaponifiable matter** Not more than 2 per cent. **Free fatty acids** Not more than 3 per cent estimated as oleic acid. **Free Alkali** Not more than 0.1 per cent expressed as NaOH. **Total Glycerol (combined and free)** Not more than 1 per cent. **Matter insoluble in Alcohol** Not more than 0.2 per cent (sodium and potassium salts only). **Loss on drying** Not more than 3 per cent. **Content of sodium or Potassium or Calcium** Sodium: 9 per cent to 14 per cent expressed as Na<sub>2</sub>O. Potassium: 13 per cent to 21.5 per cent expressed as K<sub>2</sub>O. Calcium: 8.5 per cent to 13 per cent expressed as CaO.

#### E 471 Mono- and diglycerides of food fatty acids\*

**Chemical Description**Mixtures of glycerol mono-, di - and tri-esters of fatty acids occurring in food fats. They may contain amounts of free fatty acids and glycerol.**Description**The product varies from a pale straw to brown oily liquid to a white or slightly off-white hard waxy solid. These solids may be in the form of flakes, powders or small beads.**Mono- and di- ester content**Not less than 70 per cent.**Free fatty acids**Not more than 3 per cent estimated as oleic acid.**Free glycerol**Not more than 7 per cent.**Total glycerol**Not less than 16 per cent and not more than 33 per cent.**Polyglycerols**Not more than 4 per cent diglycerol and not more than 1 per cent higher polyglycerols both based on total glycerol content.**Water**Not more than 2 per cent [Karl Fischer].**Sulphated ash**Not more than 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .

\*Note: These criteria are based on the product without E470.

E 472 (a) Acetic acid esters of mono- and diglycerides of fatty acids.

**Chemical Description**Esters of glycerol with acetic acid and fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free acetic acid, and free glycerides.**Description**Clear, mobile liquids to solids and white to pale yellow in colour.**Total acetic acid content**Not less than 9 per cent and not more than 32 per cent.**Free fatty acids (and acetic acid)**Not more than 3 per cent estimated as oleic acid.**Free glycerol**Not more than 2 per cent.**Total glycerol**Not less than 14 per cent and not more than 31 per cent.**Sulphated ash**Not more than 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .

E 472 (b) Lactic Acid esters of mono- and diglycerides of food fatty acids\*

**Chemical Description**Esters of glycerol with lactic acid and forming fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free lactic acid, and free glycerides.**Description**Soft to hard waxy solids.**Total lactic acid content**Not less than 13 per cent and not more than 45 per cent.**Free fatty acids**Free glycerolNot more than 3 per cent estimated as oleic acid. Not more than 2 per cent.**Total glycerol**Not less than 13 per cent and not more than 30 per cent.**Sulphated ash**Not more than 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .

\*Note: These criteria are based on the product without added E 470.

E 472 (c) Citric acid esters of mono- and diglycerides of food fatty acids.

**Chemical Description**Esters of glycerol with citric acid and fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid, and free glycerides. They may be partially or wholly neutralised with sodium hydroxide or with potassium hydroxide.**Description**Yellowish or light brown liquids to waxy solids or semi-solids.**Total citric acid content**Not less than 13 per cent and not more than 50 per cent.**Free fatty acids**Free glycerolNot more than 3 per cent estimated as oleic acid. Not more than 2 per cent.**Total glycerol**Not less than 11 per cent and not more than 29 per cent.**Sulphated ash**Not more than 0.5 per cent for the non-neutralised products and

not more than 10.0 per cent for the partially or wholly neutralised products determined at 800 25°C. pH of a 1 per cent solution Not less than 3 and not more than 7.3.

E 472 (d) Tartaric acid esters of mono- and diglycerides of food fatty acids.

Chemical Description Esters of glycerol with tartaric acid (E 334) and fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid, and free glycerides. Description Sticky viscous yellowish liquids to hard yellow waxes. Total tartaric acid content Not less than 15 per cent and not more than 50 per cent. Free fatty acids Free glycerol Not more than 3 per cent estimated as oleic acid. Not more than 2 per cent. Total glycerol Not less than 12 per cent and not more than 29 per cent. Sulphated ash Not more than 0.5 per cent determined at 800 25°C. E 472 (e) Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids.

Chemical Description Esters of glycerol with mono- and diacetyl tartaric acids (obtained from E 334 tartaric acid) and fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acid and their combinations, and free glycerides. Description Sticky viscous liquids through to fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid. Total tartaric acid content Not less than 10 per cent and not more than 40 per cent. Total acetic acid content Not less than 8 per cent and not more than 32 per cent. Free fatty acids Not more than 3 per cent estimated as oleic acid. Free glycerol Not more than 2 per cent. Total glycerol Not less than 11 per cent and not more than 28 per cent. Sulphated ash Not more than 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .

E 472 (f) Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids.

Chemical Description Esters of glycerol with acetic and tartaric acids (E 334) and fatty acids occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free acetic and tartaric acid, and free glycerides. Description Clear mobile liquids to solids and from white to pale yellow in colour. Total acetic acid Not less than 10 per cent and not more than 20 per cent. Free tartaric acid Not less than 20 per cent and not more than 40 per cent. Free acetic acid Not less than 5.5 per cent and not more than 8.5 per cent. Free tartaric acid Not more than 1 per cent. Free fatty acids Not more than 3 per cent estimated as oleic acid. Free glycerol Not more than 2 per cent. Total glycerol Not less than 12 per cent and not more than 27 per cent. Sulphated ash Not more than 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .

E 473 Sucrose esters of food fatty acids.

Chemical Description Essentially the mono- and di-esters of sucrose with fatty acids occurring in food fats. They may be prepared from sucrose and the methyl and ethyl esters of food fatty acids or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, isopropanol, isobutanol and methylethylketone may be used in their

preparation. Description Soft solids, stiff gels or white to greyish-white powders. Total Sucrose fatty acid ester content Not less than 80 per cent. Total glyceride content Not more than 20 per cent. Free sucrose content Not more than 5 per cent. Free fatty acid content Not more than 3 per cent estimated as oleic acid. Sulphated ash Not more than 2 per cent determined at  $800 \pm 25^\circ\text{C}$ . Dimethylsulphoxide content Not more than 2 mg/kg. Methanol content Not more than 10 mg/kg. Isobutanol content Not more than 10 mg/kg. Methyl ethyl ketone content Not more than 10 mg/kg. Dimethylformamide content Not more than 1 mg/kg. Total Ethyl acetate and isopropanol content Not more than 350 mg/kg singly or in combination.  
\*Note: These criteria are based on the product without E 470.  
E 474 Sucroglycerides\*

Chemical Description Produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono- and di-esters of sucrose and fatty acids together with residual mono-, di- and tri-glycerides from that fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, isobutanol and isopropanol. Description Soft solids masses, stiff gels or white to off-white powders. Total Sucrose fatty acid ester content Not less than 40 per cent and not more than 60 per cent. Total glyceride content Not less than 10 per cent and not more than 60 per cent. Free sucrose content Not more than 5 per cent. Free fatty acid content Not more than 3 per cent estimated as oleic acid. Sulphated ash Not more than 2 per cent determined at  $800 \pm 25^\circ\text{C}$ . Dimethylformamide content Not more than 1 mg/kg. Total ethyl acetate and isopropanol content Not more than 350 mg/kg singly or in combination. Methanol content Not more than 10 mg/kg. Total cyclohexane and isobutanol content Not more than 10 mg/kg singly or in combination.  
\*Note: These criteria are based on the product without E 470.  
E 475 Polyglycerol esters of non-polymerised food fatty acids\*.

Chemical Description Produced by the esterification of polyglycerol with food fats or with fatty acids occurring in food fats. The polyglycerol moiety is predominantly di-, tri-, and tetra-glycerol and contains not more than 10 per cent of polyglycerols equal to or higher than heptaglycerol. Description Yellow or light brown liquids or semi-solids. Total fatty acid ester content Not less than 90 per cent. Free fatty acids Not more than 6 per cent estimated as oleic acid. Total glycerol and polyglycerol Not less than 18 per cent and not more than 60 per cent. Free glycerol and polyglycerol Not more than 7 per cent. Sulphated ash 0.5 per cent determined at  $800 \pm 25^\circ\text{C}$ .  
\*Note: These criteria are based on the product without E 470.  
E 476 Partial polyglycerol esters of polycondensed fatty acids of castor oil.

Description A highly viscous liquid at  $25^\circ\text{C}$  being essentially a complex mixture of the partial esters and ethers of polyglycerol with linearly interesterified (polycondensed) fatty acids derived from castor oil. The polycondensed castor oil fatty acids are prepared by condensation in the absence of oxygen and have an average of about 5 fatty acid residues per molecule. The polyglycerol moiety is predominantly di-, tri- and tetra-glycerol and contains not more than

10 per cent of polyglycerols equal to or higher than heptaglycerol. Refractive index, ND 65°C Not less than 1.4630 and not more than 1.4665. Hydroxyl value Not less than 80 and not more than 100. Iodine value Not less than 72 and not more than 103 [Wijs]. Acid value Not more than 6mg KOH per g.  
E 477 Propane-1, 2-diol esters of food fatty acids\*.

**Chemical Description** Consists chiefly of mixtures of propane-1, 2-diol mono- and di-esters of fatty acids occurring in food fats. The alcohol moiety is exclusively propane-1, 2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent. **Description** Waxy white flakes, beads or solids. **Total fatty acid ester content** Not less than 85 per cent. **Free propane -1,2-diol** Not more than 5 per cent. **Dimer and trimer of Propane-1, 2-Diol**: Not more than 0.5 per cent. **Free fatty acids** Not more than 6 per cent estimated as oleic acid. **Sulphated ash** Not more than 0.5 per cent determined at 800 ± 25°C. **Total propane-1,2-diol content** Not less than 11 per cent and not more than 31 per cent.

\*Note: These criteria are based on the product without E 470.

E 479a Oxidatively polymerised soya bean oil.

**Description** A highly viscous liquid at 25°C obtained by blowing air into edible soya bean oil at a temperature not exceeding 250°C. **Combined oxidised fatty acids** Not more than 30 per cent. **Urea non-adduct content of total fatty acid methyl esters**. Not more than 42 per cent. **Refractive Index, ND40°C** Not less than 1.475 and not more than 1.485. **Saponification value** Not more than 220. **Iodine value** Not less than 75 and not more than 85 [Wijs]. **Hydroxyl value** Not less than 30 and not more than 70. **Acid value** Not more than 6mg KOH per g.  
E 479b Polyglycerol esters of dimerised fatty acids of soya bean oil.

**Description** A viscous oil obtained by the inter-esterification of polyglycerol with refined soya bean oil thermally polymerised in vacuo. The polyglycerol moiety is predominantly di-, tri- and tetra-glycerol and contains not more than 10 per centum of polyglycerols equal to or higher than heptaglycerol. **Urea non-adduct content of total fatty acid methyl esters** Not more than 65 per cent. **Saponification value** Not less than 15 per cent and not more than 175. **Iodine value** Not less than 78 and not more than 82 [Wijs]. **Hydroxyl value** Not less than 60 and not more than 70. **Acid value** Not more than 6mg KOH per g.  
E 481 Sodium Stearoyl-2-Lactylate.

**Chemical Description** A mixture of the sodium salts of stearoyl lactic acids and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present free or esterified due to their presence in the stearic acid used. **Description** Cream coloured powder or brittle solid with a characteristic odour. **Sodium content** Not less than 2.5 per cent and not more than 5 per cent. **Ester value** Not less than 90 and not more than 190mg KOH/g. **Total lactic acid (free and combined)** Not less than 15 per cent and not more than 40 per cent. **Acid value** Not less than 60 and not more than 130mg KOH/g.  
E 482 Calcium stearoyl-2-lactylate.

**Chemical Description**A mixture of calcium salts of stearyl lactic acids with minor amounts of calcium salts of other related acids manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used.**Description**White or slightly yellowish powder or brittle solid with a characteristic odour.**Calcium content**Not less than 1.0 per cent and not more than 5.2 per cent.**Ester value**Not less than 125 and not more than 190mg KOH/g.**Total lactic acid (free and combined)**Not less than 15 per cent and not more than 40 per cent.**Acid value**Not less than 50 and not more than 130 mg/KOH/g.  
E 483 Stearyl tartrate.

**Chemical Description**Produced by the esterification of tartaric acid (E 334) with stearyl alcohol, consisting chiefly of the di-ester with minor amounts of mono-ester, tartaric acid and free stearyl alcohol. Other esters may also be present due to the presence in the stearyl alcohol used of alcohols derived from food fatty acids other than stearic acid.**Description**A cream coloured unctuous solid (at 25°C).**Total ester content**Not less than 90 per cent.**Total tartaric acid content**Not less than 18 per cent and not more than 35 per cent.**Unsaponifiable matter**Not less than 77 per cent and not more than 83 per cent.**Melting range**67°C-77°C.**Ester value**Not less than 163 and not more than 180 mg KOH/G.**Iodine value**Not more than 4 (Wijs).**Acid value**Not more than 6 mg KOH/g.**Sulphated ash**Not more than 0.5 per cent determined at 800 ± 25°C.  
E 491 Sorbitan monostearate.

The criteria in the monograph for sorbitan monostearate contained in the Food Chemicals codex 1972 at page 784 except that the final sentence of the description shall be deleted.

E 492 Sorbitan tristearate.

The criteria in the monograph for sorbitan tristearate contained in the Nutrition Meetings report Series No. 35 (1964) of the United Nations' Food and Agriculture Organisation at page 108.

E 493 Sorbitan monolaurate.

The criteria in the monograph for sorbitan monolaurate contained in the British Pharmaceutical Codex 1973 at page 465.

E 494 Sorbitan mono-oleate.

The criteria in the monograph for sorbitan mono-oleate contained in the British Pharmaceutical codex 1973 at page 466.

E 495 Sorbitan monopalmitate.

The criteria in the monograph for sorbitan monopalmitate contained in the Nutrition Meetings Report Series No. 35 (1964) of the United Nations' Food and Agriculture Organisation at page 102.

## SCHEDULE 1.

### PART III.

General purity criteria applicable to permitted emulsifiers and permitted stabilisers except where otherwise provided by specific purity criteria.

Each emulsifier and stabiliser shall not contain—

( a ) a toxicologically dangerous amount of any element, in particular heavy metals;



- ( b ) more than 3 milligrams per kilogram of arsenic;
- ( c ) more than 10 milligrams per kilogram of lead;
- ( d ) more than 50 milligrams per kilogram of copper, or 25 milligrams per kilogram of zinc, or 50 milligrams per kilogram of any combination of copper and zinc.

## SCHEDULE 2.

### PART I.

#### EMULSIFIERS AND STABILISERS PERMITTED ONLY IN CERTAIN FOOD.

Specified food	Permitted emulsifier or permitted stabiliser	Milligrams per kilogram not exceeding
123(a) Dutch type rusks	Sodium, potassium and calcium salts of fatty acids	15,000 (calculated as sodium oleate, C <sub>18</sub> H <sub>33</sub> NaO <sub>2</sub> , and on the weight of the flour)
(b) The permitted emulsifiers or permitted stabilisers:—	Sodium, potassium and calcium salts of fatty acids	60,000 (calculated as sodium oleate C <sub>18</sub> H <sub>33</sub> NaO <sub>2</sub> )
	Mono- and diglycerides of fatty acids; lactic acid esters of mono- and diglycerides of fatty acids; sucrose esters of fatty acids; sucroglycerides polyglycerol esters of fatty acids; propane -1,2-diol esters of fatty acids	
(c) tin-greasing emulsions	Oxidatively polymerised soya bean oil Polyglycerol esters of dimerised fatty acids of soya bean oil	In accordance with good manufacturing practice

## SCHEDULE 2.

### PART II.

#### FOODS IN WHICH THE USE OF PERMITTED EMULSIFIERS AND PERMITTED STABILISERS IS LIMITED.

Specified food	Permitted emulsifier or permitted stabiliser	Milligrams per kilogram not exceeding
123(a) Bread	Lecithins	In accordance with good manufacturing practice
	Mono- and diglycerides of fatty acids	Lactic acid esters of mono- and diglycerides of fatty acids
	Citric acid esters of mono- and diglycerides of fatty acids	Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids
	Stearyl tartrate	Sodium stearoyl 2-lactylate
5,000	Calcium stearoyl-2-lactylate	(b) Soft cheese, whey cheese, processed cheese, cheese spread
	Lecithins	In accordance with good manufacturing practice
	Alginic acid	Sodium alginate Calcium alginate Carrageenan Locust bean gum Tragacanth Acacia Karaya gum or Sterculia gum
	Xanthan gum Guar gum	Sodium orthophosphates Sodium & Potassium polyphosphates (E 450)
(c) Cream which contains not less than 35 per cent milk-fat and which is sold as whipping cream or whipped cream	Alginic acid	3,000 singly or in combination
	Sodium alginate	TetraSodium-diphosphate or tetraSodium-pyrophosphate
	Sodium carboxymethyl-cellulose	carrageenan

Footnote: The permitted emulsifiers or permitted stabilisers mono- and diglycerides of fatty acids, lactic acid esters of mono- and diglycerides of fatty acids, citric acid esters of mono- and diglycerides of fatty acids and mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids shall, when used in bread, have a hydroxyl value of the free combined fatty acids not exceeding 2.

### **SCHEDULE 3.**

#### **LABELLING OF PERMITTED EMULSIFIERS AND PERMITTED STABILISERS.**

1. (1) Each container to which article 9 (1) relates shall bear a label on which is printed a true statement:—

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

( b ) where any other substance or substances is or are present:—

(i) of the common or usual name or an appropriate designation of each such substance;

(ii) of the proportion of each such substance in respect of which any Regulations, other than these Regulations, made under the Act contain a requirement to that effect; and

( c ) in the case of emulsifiers to which sugars have been added, the statement "standardised with sugar" shall be added to the designation on the label.

(2) The said statement shall be headed or preceded by the words "for foodstuffs (restricted use)".

(3) The container shall have on it the name and address of the person importing or the person selling the substance in the container or, if the substance is manufactured within the State, the name of the manufacturer of the substance.

2. Any statement required by the preceding paragraph—

( a ) shall be clear and legible;

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

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

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

( a ) shall be in characters of uniform colour and size (being not less than 1.5 millimetres in height for a label on a container of which the greatest dimension does not exceed 12 centimetres and not less than 3 millimetres in height for a label on a container of which the greatest dimension exceeds 12 centimetres), but so that the initial letter of any word may be taller than any other letter in the word;

( b ) shall appear on a contrasting ground, so however that where there is no ground other than such as is provided by a transparent container and the contents of that container are visible behind the letters, those contents shall be taken to be the ground for the purposes of this paragraph;

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

4. For the purposes of this Schedule—

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

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

Dated this 8th day of April, 1994.

WILLIAM O'DEA,

Minister of State at the Department of Health.

#### EXPLANATORY NOTE.

These Regulations consolidate the law on emulsifiers, stabilisers, thickeners and gelling agents. They also implement Council Directive 74/329/EEC as amended by Council Directive 78/612 on the approximation of the laws of the Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs, Council Directive 78/663/EEC as last amended by Council Directive 82/4/EEC laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs.

The Regulations prohibit the manufacture, importation, distribution or sale of food which contains any emulsifier or stabiliser other than a permitted emulsifier or stabiliser and prescribe criteria of purity for these substances. In addition, the Regulations specify that certain emulsifiers and stabilisers may be used only in particular foodstuffs and restrict other specified foods to containing only particular permitted emulsifiers and stabilisers, subject to prescribed limits in each case.

The Regulations prohibit the manufacture, importation, distribution, sale or advertisement for sale of any emulsifier or stabiliser for use as an ingredient in the preparation of food, other than a permitted emulsifier or stabiliser. Also, the Regulations prescribe labelling requirements for permitted emulsifiers and stabilisers to be sold as ingredients in the preparation of food and prohibit the labelling or advertising of any permitted emulsifier or stabiliser to be sold as an ingredient in the preparation of food which would indicate that the substance is a nutritive substitute for fat or eggs.