

1980 No. 1888 (S. 175)

FOOD AND DRUGS
COMPOSITION AND LABELLING
The Emulsifiers and Stabilisers in Food (Scotland)
Regulations 1980

Made - - - - 4th December 1980

Laid before Parliament 18th December 1980

Coming into Operation 8th January 1981

In exercise of the powers conferred on me by sections 4, 7, 26(3) and 56 of the Food and Drugs (Scotland) Act 1956(a) and of all other powers enabling me in that behalf, and after consultation with such organisations as appear to me to be representative of interests substantially affected by these regulations and after reference to the Scottish Food Hygiene Council under section 25 of the said Act (in so far as the regulations are made in exercise of the powers conferred by the said section 7), I hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Emulsifiers and Stabilisers in Food (Scotland) Regulations 1980, and shall come into operation on 8th January 1981.

Interpretation

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

“the Act” means the Food and Drugs (Scotland) Act 1956;

“appropriate designation” means, as respects any permitted emulsifier or permitted stabiliser, 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 emulsifier or permitted stabiliser to which it is applied;

“bread” has the meaning assigned to it by the Bread and Flour (Scotland) Regulations 1963(b);

“cheese spread”, “processed cheese”, “soft cheese” and “whey cheese” have the meanings respectively assigned to them by the Cheese (Scotland) Regulations 1970(c);

(a) 1956 c. 30; section 4 was amended by the European Communities Act 1972 (c. 68), section 4 and Schedule 4, paragraph 3; section 26(3) was amended by the Local Government (Scotland) Act 1973 (c. 65), section 214(2) and Schedule 27, part II, paragraphs 123, 124.

(b) S.I. 1963/1461; the relevant amending instrument is S.I. 1972/1489.

(c) S.I. 1970/108; the relevant amending instrument is S.I. 1974/1337.

“chocolate product” and “cocoa product” have the meanings respectively assigned to them by the Cocoa and Chocolate Products (Scotland) Regulations 1976(a);

“emulsifier” and “stabiliser” mean respectively any substance which is capable—

(a) in the case of an emulsifier, of aiding the formation of, and
 (b) in the case of a stabiliser, of maintaining, the uniform dispersion of two or more immiscible substances, but do not in either case include—

- (i) any natural food substance,
- (ii) any permitted antioxidant,
- (iii) any permitted artificial sweetener,
- (iv) any permitted bleaching agent,
- (v) any permitted colouring matter,
- (vi) any permitted improving agent,
- (vii) any permitted miscellaneous additive,
- (viii) any permitted preservative,
- (ix) any permitted solvent,
- (x) caseins and caseinates
- (xi) proteins, protein concentrates and protein hydrolysates,
- (xii) starches, whether modified or not,
- (xiii) normal straight chain fatty acids derived from food fats;

“flour” has the meaning assigned to it by the Bread and Flour (Scotland) Regulations 1963;

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

“Food Chemicals Codex 1972” and “First Supplement 1974” mean respectively the second edition of the Food Chemicals Codex published in 1972 and the First Supplement to that edition published in 1974, in each case, by the National Academy of Sciences, Washington DC, United States of America;

“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 antioxidant” means any antioxidant in so far as its use is permitted by the Antioxidants in Food (Scotland) Regulations 1978(b);

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

“permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour (Scotland) Regulations 1963;

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

(a) S.I. 1976/914.

(b) S.I. 1978/492, amended by S.I. 1980/1886.

(c) S.I. 1969/1848.

(d) S.I. 1973/1310; relevant amending instruments are S.I. 1975/1595, 1976/2232, 1979/107.

“permitted emulsifier” and “permitted stabiliser” mean respectively any emulsifier and any stabiliser specified in Part I of Schedule 1 which complies with the specific purity criteria in relation to that emulsifier or stabiliser specified or 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, or any mixture of two or more such emulsifiers or stabilisers or emulsifiers and stabilisers;

“permitted improving agent” means any improving agent in so far as its use is permitted by the Bread and Flour (Scotland) Regulations 1963;

“permitted miscellaneous additive” means any acid, anti-caking agent, anti-foaming agent, base, buffer, firming agent, glazing agent, humectant, liquid freezant, packaging gas, propellant, release agent or sequestrant in so far as its use is, in each case, permitted by the Miscellaneous Additives in Food (Scotland) Regulations 1980(a);

“permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food (Scotland) Regulations 1979(b);

“permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food (Scotland) Regulations 1968(c);

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

“soft drink” has the meaning assigned to it by the Soft Drinks (Scotland) Regulations 1964(d);

“specified food” means any food of a description specified in column 1 of Part I or Part II of Schedule 2;

“specified sugar product” has the meaning assigned to it by the Specified Sugar Products (Scotland) Regulations 1976(e);

“statutory maximum” in relation to a fine on summary conviction, means the prescribed sum within the meaning of section 289B of the Criminal Procedure (Scotland) Act 1975(f) (which at the making of these regulations was £1,000).

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

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

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

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

(a) S.I. 1980/1889.

(b) S.I. 1979/1073, amended by S.I. 1980/1232.

(c) S.I. 1968/263, amended by S.I. 1980/1887.

(d) S.I. 1964/767, to which there are amendments not relevant to these regulations.

(e) S.I. 1976/946.

(f) 1975 c. 21, amended by Schedule 11 to the Criminal Law Act 1977 (c. 45).

Exemptions

3. The provisions of these regulations shall not apply to food having any emulsifier or stabiliser in it or on it or to any emulsifier or stabiliser which, in each case, is intended at the time of sale or importation, as the case may be, for exportation to any place outside the United Kingdom.

Sale, etc. of food containing emulsifiers or stabilisers

4.—(1) Subject to the provisions of this regulation, no food sold or imported shall have in it or on it any added emulsifier or added stabiliser other than a permitted emulsifier or permitted stabiliser.

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

Provided that any specified food described in column 1 of that Part of that Schedule may have in it or on it any permitted emulsifier or permitted stabiliser of the description and in the proportion specified in relation thereto in columns 2 and 3 respectively of that Part of that Schedule.

(3) Save as hereinafter provided, no specified food described in column 1 of Part II of Schedule 2, sold or imported shall have in it or on it any added permitted emulsifier or added permitted stabiliser.

Provided that any specified food described in column 1 of Part II of Schedule 2 may, subject to the provisions of paragraph 1 of that Part have in it or on it any permitted emulsifier or permitted stabiliser of the description and in the proportion specified in relation thereto in columns 2 and 3 respectively of that Part of that Schedule.

(4) Nothing in the two preceding paragraphs shall prohibit the presence in or on any food, which has in it or on it any specified food, 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 two preceding paragraphs:

Provided that where, by reason of the use of a tin-greasing emulsion in its preparation, any food has present in it or on it—

- (a) the permitted emulsifier oxidatively polymerised soya bean oil, that permitted emulsifier shall be present in a proportion not exceeding 50 milligrams per kilogram;
- (b) 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 paragraph (3) of this regulation 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 paragraph 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 as such, shall contain any emulsifier or stabiliser.

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

Sale, advertisement and labelling of emulsifiers and stabilisers

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

(2) No person shall sell any permitted emulsifier or any permitted stabiliser (including any such permitted emulsifier or permitted stabiliser 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 which complies with the requirements of Schedule 3.

6. No person shall—

(a) give with any permitted emulsifier or permitted stabiliser sold by him for use as an ingredient in the preparation of food any label, whether attached to or borne on the container or not, or display with any permitted emulsifier or permitted stabiliser offered or exposed by him for sale for such use any ticket or notice, or

(b) publish, or be a party to the publication of, 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 that emulsifier or stabiliser is a substitute for fat or eggs.

Condemnation of food

7. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell or import, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

Penalties

8. If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence against these regulations and shall be liable—

(a) on summary conviction to—

a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months, or both; or

(b) on conviction on indictment to—

a fine or to imprisonment for a term not exceeding one year, or both.

Enforcement

9. Each regional and islands council shall enforce and execute the provisions of these regulations within their area, but nothing in these regulations shall entitle a regional council to enforce or execute the provisions of section 9 of the Act.

Defences

10.—(1) In any proceedings for an offence against these regulations in relation to the publication of an advertisement, it shall be a defence for the accused to prove that, being a person whose business it is to publish or arrange

for the publication of advertisements, he received the advertisement for publication in the ordinary course of business and did not himself make, or cause to be made, any material alteration in the substance of that advertisement.

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

Application of various sections of the Act

11.—(1) Sections 41(2) and (5) (proceedings), 42(1), (2) and (3) (evidence of certificates of analysis), 44 (power of a court to require analysis by the Government Chemist), 46(2) (conditions under which a warranty may be pleaded as a defence) and 47 (offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken under the Act included references to proceedings, or a prosecution as the case may be, taken for an offence against these regulations and in addition as if—

(a) in the case of section 44(1) of the Act, the reference therein to section 41(5) of the Act included a reference to said section 41(5) as applied by these regulations; and

(b) in the case of section 47(1) and (2) of the Act, the references therein to an offence against the Act included references to an offence against these regulations.

(2) Section 41(4) of the Act shall apply for the purposes of these regulations as if the reference therein to section 47 of the Act included a reference to said section 47 as supplied by these regulations.

Revocations

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

George Younger,
One of Her Majesty's Principal
Secretaries of State.

New St. Andrew's House,
Edinburgh.
4th December 1980.

Regulation 2(1)

SCHEDULE 1

PART I

PERMITTED EMULSIFIERS AND PERMITTED STABILISERS

Column 1	Column 2
Name of Emulsifier or Stabiliser	Serial Number
Lecithins	E 322
Ammonium phosphatides	—
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	E 414
Pectin	E 440(a)
Amidated pectin	E 440(b)
Pectin extract	—
Ghatti gum	—
Karaya gum	—
Xanthan gum	—
Microcrystalline cellulose	E 460
Methylcellulose	E 461
Hydroxypropylcellulose	E 463
Hydroxypropylmethylcellulose	E 464
Ethylmethylcellulose	E 465
Carboxymethylcellulose, sodium salt	E 466

Column 1	Column 2
Name of Emulsifier or Stabiliser	Serial Number
Sodium, potassium and calcium salts of fatty acids	E 470
Mono- and di-glycerides of fatty acids	E 471
Acetic acid esters of mono- and di-glycerides of fatty acids	E 472(a)
Lactic acid esters of mono- and di-glycerides of fatty acids	E 472(b)
Citric acid esters of mono- and di-glycerides of fatty acids	E 472(c)
Mono- and di-acetyltartaric acid esters of mono- and di-glycerides of fatty acids	E 472(e)
Sucrose esters of fatty acids	E 473
Sucroglycerides	E 474
Polyglycerol esters of fatty acids	E 475
Polyglycerol esters of polycondensed fatty acids of castor oil ...	—
Polyglycerol esters of dimerised fatty acids of soya bean oil	—
Oxidatively polymerised soya bean oil	—
Propane-1,2-diol esters of fatty acids	E 477
Lactylated fatty acid esters of glycerol and propane-1,2-diol ...	—
Sodium stearoyl -2-lactylate	E 481
Calcium stearoyl -2-lactylate	E 482
Stearyl tartrate	E 483
Polyoxyethylene (8) stearate	—
Polyoxyethylene (40) stearate	—
Polyoxyethylene (20) sorbitan monostearate	—
Polyoxyethylene (20) sorbitan tristearate	—
Polyoxyethylene (20) sorbitan monopalmitate	—
Polyoxyethylene (20) sorbitan monolaurate	—
Polyoxyethylene (20) sorbitan mono-oleate	—
Sorbitan monostearate	—
Sorbitan tristearate	—
Sorbitan monopalmitate	—
Sorbitan monolaurate	—

Column 1	Column 2
Name of Emulsifier or Stabiliser	Serial Number
Sorbitan mono-oleate	—
Diocetyl sodium sulphosuccinate	—
Extract of Quillaia	—

PART II

SPECIFIC PURITY CRITERIA FOR PERMITTED EMULSIFIERS AND
PERMITTED STABILISERS*E 322 Lecithins*

The specific purity criteria for lecithins contained in Council Directive 78/664/EEC(a).

Ammonium phosphatides

Description	Ammonium phosphatides exist as an unctuous semi-solid (at 25°C). They consist 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 centum. Inorganic matter: Not more than 0.2 per centum.
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 centum and not more than 3.4 per centum.
Ammonium nitrogen	Not less than 1.2 per centum and not more than 1.5 per centum.
Arsenic	Not more than 5 mg. per kg.

E 400 Alginic acid

The specific purity criteria for alginic acid contained in Council Directive 78/663/EEC(b).

E 401 Sodium alginate

The specific purity criteria for sodium alginate contained in Council Directive 78/663/EEC.

E 402 Potassium alginate

The specific purity criteria for potassium alginate contained in Council Directive 78/663/EEC.

(a) O.J. No. L223, 14.8.78, p. 30.

(b) O.J. No. L223, 14.8.78, p. 7.

E 403 Ammonium alginate

The specific purity criteria for ammonium alginate contained in Council Directive 78/663/EEC.

E 404 Calcium alginate

The specific purity criteria for calcium alginate contained in Council Directive 78/663/EEC.

E 405 Propane-1,2-diol alginate

Synonym Propylene glycol alginate.

The specific purity criteria for propane-1,2-diol alginate contained in Council Directive 78/663/EEC.

E 406 Agar

The specific purity criteria for agar contained in Council Directive 78/663/EEC.

E 407 Carrageenan

The specific purity criteria for carrageenan contained in Council Directive 78/663/EEC.

E 410 Locust bean gum

Synonym Carob gum.

The specific purity criteria for locust bean gum contained in Council Directive 78/663/EEC.

E 412 Guar gum

The specific purity criteria for guar gum contained in Council Directive 78/663/EEC.

E 413 Tragacanth

The specific purity criteria for tragacanth contained in Council Directive 78/663/EEC.

E 414 Acacia

Synonym Gum arabic.

The specific purity criteria for acacia contained in Council Directive 78/663/EEC.

E 440(a) Pectin

The specific purity for pectin contained in Council Directive 78/663/EEC.

E 440(b) Amidated pectin

The specific purity criteria for amidated pectin contained in Council Directive 78/663/EEC.

Pectin extract

Description	Pectin extract is obtained by extraction of dried apple pomace, citrus peel, or a mixture of both, with dilute acid followed by partial neutralisation with sodium or potassium salts and concentration by evaporation. It may be in the form of a buff to brownish viscous solution (liquid pectin) or in the form of dry brown flakes or powder.
Content	Not more than 20 per centum of total solids and not less than 1·3 per centum of galacturonic acid for the liquid form; not less than 6·5 per centum of galacturonic acid for the dry form.

Reducing sugars	Not more than 12 per centum for the liquid form and not more than 75 per centum for the dry form.																
Sulphate	Not more than 3 per centum for the liquid form and not more than 30 per centum for the dry form, in both cases expressed as Na ₂ SO ₄ .																
Acid-insoluble ash	Not more than 1 per centum.																
<i>Ghatti gum</i>																	
Description	Ghatti gum is an off-white to buff powder. It is a complex high molecular weight polysaccharide derived from the gum exuded from the stem of the tree <i>Anogeissus latifolia</i> . On acid hydrolysis the gum yields L-arabinose, D-galactose, D-mannose, D-xylose and D-glucuronic acid.																
Solubility	Completely soluble in five parts of water forming a very viscous mucilage. Insoluble in ethanol.																
Identification	Precipitates from ghatti gum solutions are characterised as follows: <table border="0" style="margin-left: 2em;"> <thead> <tr> <th style="text-align: left;"><i>Reagent</i></th> <th style="text-align: left;"><i>Precipitate</i></th> </tr> </thead> <tbody> <tr> <td>Ethanol (90 per centum aqueous solution)</td> <td>Fine, flocculent, non-adherent</td> </tr> <tr> <td>Tannic acid (10 per centum aqueous solution)</td> <td>Precipitate (distinction from Acacia)</td> </tr> <tr> <td>Lead acetate (20 per centum aqueous solution)</td> <td>None (distinction from Amrad and other gums)</td> </tr> <tr> <td>Lead subacetate solution (Basic lead acetate)</td> <td>Translucent, flocculent</td> </tr> <tr> <td>Potassium hydroxide (10 per centum aqueous solution)</td> <td>None</td> </tr> <tr> <td>Ferric chloride (5 per centum aqueous solution)</td> <td>None (absence of tannin)</td> </tr> <tr> <td><i>di</i>Sodium tetraborate (4 per centum aqueous solution)</td> <td>None</td> </tr> </tbody> </table>	<i>Reagent</i>	<i>Precipitate</i>	Ethanol (90 per centum aqueous solution)	Fine, flocculent, non-adherent	Tannic acid (10 per centum aqueous solution)	Precipitate (distinction from Acacia)	Lead acetate (20 per centum aqueous solution)	None (distinction from Amrad and other gums)	Lead subacetate solution (Basic lead acetate)	Translucent, flocculent	Potassium hydroxide (10 per centum aqueous solution)	None	Ferric chloride (5 per centum aqueous solution)	None (absence of tannin)	<i>di</i> Sodium tetraborate (4 per centum aqueous solution)	None
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<i>di</i> Sodium tetraborate (4 per centum aqueous solution)	None																
Moisture	Not more than 14 per centum (Karl Fischer).																
Ash	Total: Not more than 3 per centum on a moisture-free basis. Acid insoluble: Not more than 0.35 per centum on a moisture-free basis (using approximately 2N HCl).																
Starch or dextrans	Addition of a few drops of iodine solution to an aqueous solution of ghatti gum shall not produce a blue or reddish colouration.																

Karaya gum

Synonym Sterculia gum

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

Xanthan gum

The criteria in the monograph for xanthan gum contained in the Food Chemicals Codex 1972 at page 856 with the additional requirements that viable cells of *Xanth-*

omonas campestris shall be absent and that the nitrogen content shall be not more than 1.5 per centum.

E 460 Microcrystalline cellulose

The specific purity criteria for microcrystalline cellulose contained in Council Directive 78/663/EEC.

E 461 Methylcellulose

The specific purity criteria for methylcellulose contained in Council Directive 78/663/EEC.

E 463 Hydroxypropylcellulose

The specific purity criteria for hydroxypropylcellulose contained in Council Directive 78/663/EEC.

E 464 Hydroxypropylmethylcellulose

The specific purity criteria for hydroxypropylmethylcellulose contained in Council Directive 78/663/EEC.

E 465 Ethylmethylcellulose

Synonym Methylethylcellulose

The specific purity criteria for ethylmethylcellulose contained in Council Directive 78/663/EEC.

E 466 Carboxymethylcellulose, sodium salt

Synonym Sodium carboxymethylcellulose

The specific purity criteria for carboxymethylcellulose contained in Council Directive 78/663/EEC.

E 470 Sodium, potassium and calcium salts of fatty acids

The specific purity criteria for sodium, potassium and calcium salts of fatty acids contained in Council Directive 78/663/EEC.

E 471 Mono- and di-glycerides of fatty acids

The specific purity criteria for mono- and di-glycerides of fatty acids contained in Council Directive 78/663/EEC.

E 472(a) Acetic acid esters of mono- and di-glycerides of fatty acids

Synonym Acetylated mono- and di-glycerides

The specific purity criteria for acetic acid esters of mono- and di-glycerides of fatty acids contained in Council Directive 78/663/EEC.

E 472(b) Lactic acid esters of mono- and di-glycerides of fatty acids

Synonyms Lactylated mono- and di-glycerides
Lactoglycerides

The specific purity criteria for lactic acid esters of mono- and di-glycerides of fatty acids contained in Council Directive 78/663/EEC.

E 472(c) Citric acid esters of mono- and di-glycerides of fatty acids

Synonym Citroglycerides

The specific purity criteria for citric acid esters of mono- and di-glycerides of food fatty acids contained in Council Directive 78/663/EEC.

E 472(e) Mono- and diacetyltartaric acid esters of mono- and di-glycerides of fatty acids

Synonym Mono- and di-acetyltartaric acid esters of mono- and di-glycerides.

The specific purity criteria for mono- and di-acetyltartaric acid esters of mono- and di-glycerides of fatty acids contained in Council Directive 78/663/EEC.

E 473 Sucrose esters of fatty acids

The specific purity criteria for sucrose esters of fatty acids contained in Council Directive 78/663/EEC.

E 474 Sucroglycerides

The specific purity criteria for sucroglycerides contained in Council Directive 78/663/EEC.

E 475 Polyglycerol esters of fatty acids

The specific purity criteria for polyglycerol esters of non-polymerised fatty acids contained in Council Directive 78/663/EEC.

Polyglycerol esters of polycondensed fatty acids of castor oil

Synonym	Polyglycerol polyricinoleate
Description	The polyglycerol esters of polycondensed fatty acids of castor oil exist as a highly viscous liquid (at 25°C.). They are 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 centum of polyglycerols equal to or higher than heptaglycerol.
Refractive index, $n_D^{65^\circ\text{C}}$	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 6 mg. KOH per g.

Polyglycerol esters of dimerised fatty acids of soya bean oil

Description	Polyglycerol esters of dimerised fatty acids of soya bean oil exist as a viscous oil obtained by the interesterification 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 centum.
Saponification value	Not less than 158 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 6 mg. KOH per g.
<i>Oxidatively polymerised soya bean oil</i>	
Description	Oxidatively polymerised soya bean oil is a highly viscous liquid (at 25°C.). It is 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 centum.
Urea non-adduct content of total fatty acid methyl esters	Not more than 42 per centum.
Refractive index, $n_D^{40^\circ C}$	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 6 mg. KOH per g.

E 477 Propane-1,2-diol esters of fatty acids

Synonym Propylene glycol esters of fatty acids

The specific purity criteria for propane-1,2-diol esters of fatty acids contained in Council Directive 78/663/EEC.

Lactylated fatty acid esters of glycerol and propane-1,2-diol

Description	Lactylated fatty acid esters of glycerol and propane-1,2-diol occur as off-white to light caramel coloured flakes obtained by reacting hardened vegetable oils or hardened animal fats (iodine values less than 2) firstly with propane-1,2-diol and then with lactic acid.
Combined glycerol	Not more than 6 per centum.
Combined propane-1,2-diol	Not more than 14 per centum.
Combined lactic acid	Not more than 18 per centum.
Saponification value	Not less than 230 and not more than 250.
Matter soluble in water	Not more than 5 per centum.
Acid value	Not more than 12 mg. KOH per g.

E 481 Sodium stearoyl-2-lactylate

The specific purity criteria for sodium stearoyl-2-lactylate contained in Council Directive 78/663/EEC.

E 482 Calcium stearoyl-2-lactylate

The specific purity criteria for calcium stearoyl-2-lactylate contained in Council Directive 78/663/EEC.

E 483 Stearyl tartrate

The specific purity criteria for stearyl tartrate contained in Council Directive 78/663/EEC.

Polyoxyethylene (8) stearate

The criteria in the monograph for polyoxyethylene (8) stearate contained in the Nutrition Meetings Report Series No. 35 (1964) of the United Nations Food and Agriculture Organization at page 118.

Polyoxyethylene (40) stearate

The criteria in the monograph for polyoxyethylene (40) stearate contained in the Nutrition Meetings Report Series No. 35 (1964) of the United Nations Food and Agriculture Organization at page 127.

Polyoxyethylene (20) sorbitan monostearate

Synonym 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 (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

Polyoxyethylene (20) sorbitan tristearate

Synonym 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 (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

Polyoxyethylene (20) sorbitan monopalmitate

Synonym 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 Organization at page 135.

Polyoxyethylene (20) sorbitan monolaurate

Synonym Polysorbate 20.

The criteria in the monograph for polysorbate 20 contained in the Food Chemicals Codex 1972 at page 632.

Polyoxyethylene (20) sorbitan mono-oleate

Synonym Polysorbate 80.

The criteria in the monograph for polysorbate 80 contained in the Food Chemicals Codex 1972 at page 637 except that the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

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 (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

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 Organization at page 108.

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 Organization at page 102.

Sorbitan monolaurate

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

Sorbitan mono-oleate

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

Diethyl sodium sulphosuccinate

The criteria in the monograph for diethyl sodium sulphosuccinate contained in the Food Chemicals Codex 1972 at page 256 as amended by the First Supplement, 1974 at page 16 except that the requirement for residue on ignition shall be calculated on a dry matter basis and that for the method of assay there shall be substituted the method of V. W. Reid, G. F. Longman and E. Heinerth contained in *Tenside, Zeitschrift für Physik, Chemie und Anwendung Grenzflächenaktiver Stoffe*, published by Carl Hanser, Munich, Federal Republic of Germany, 1967, volume 4, part 9 at page 302.

Extract of Quillaia

The aqueous extract of the product complying with the monograph for Quillaia or for powdered Quillaia, in each case, contained in the British Pharmacopoeia 1973 at page 406.

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

Regulation 4

SCHEDULE 2

PART I

EMULSIFIERS AND STABILISERS PERMITTED ONLY IN CERTAIN FOODS

Column 1	Column 2	Column 3
Specified food	Permitted emulsifier or permitted stabiliser	Milligrams per kilogram Not exceeding—
(a) Soft drinks	Extract of Quillaia	200 (of the dry matter content of the extract)
(b) Dutch type rusks	Sodium, potassium and calcium salts of fatty acids	15,000 (calculated as sodium oleate, $C_{18}H_{33}NaO_2$ and on the weight of the flour)
(c) The permitted emulsifiers or permitted stabilisers:—Mono- and di-glycerides of fatty acids; lactic acid esters of mono- and di-glycerides of fatty acids; sucrose esters of fatty acids; sucroglycerides; polyglycerol esters of fatty acids; propane-1, 2-diol esters of fatty acids	Sodium, potassium and calcium salts of fatty acids	60,000 (calculated as sodium oleate, $C_{18}H_{33}NaO_2$)
(d) Tin-greasing emulsions	Oxidatively polymerised soya bean oil Polyglycerol esters of dimerised fatty acids of soya bean oil	In accordance with good manufacturing practice

Regulation 5(2)

SCHEDULE 3

LABELLING OF PERMITTED EMULSIFIERS AND PERMITTED STABILISERS

1.—(1) Each container to which regulation 5(2) relates shall bear a label on which is printed a true statement, specifying—

- (a) in respect of each permitted emulsifier or permitted stabiliser present, the serial number, if any, as specified in relation thereto in column 2 of Part I of Schedule 1, and the common or usual name or an appropriate designation of that permitted emulsifier or permitted stabiliser;
- (b) in respect of each permitted emulsifier or permitted stabiliser present to which any specified sugar product has been added for the purpose of standardisation, the declaration “standardised with sugar” or “standardised with sugars” as the case may be; and
- (c) where any other substance or substances is or are present,—
 - (i) the common or usual name or an appropriate designation of each such substance, and
 - (ii) 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.

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

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

4. For the purposes of this Schedule—

- (a) the height of any lower case letter shall be taken to be the x height thereof, disregarding any ascender or descender thereof;
- (b) any requirement that figures or letters shall be of uniform height, colour or size, shall be construed as being subject to the saving that any inconsiderable variation in height, colour or size, as the case may be, may be disregarded.

SCHEDULE 4

Regulation 12

Regulations revoked	References	Extent of revocation
The Emulsifiers and Stabilisers in Food (Scotland) Regulations 1975.	S.I. 1975/1597.	All the regulations.
The Cocoa and Chocolate Products (Scotland) Regulations 1976.	S.I. 1976/914.	Regulation 22.
The Emulsifiers and Stabilisers in Food (Scotland) Amendment Regulations 1976.	S.I. 1976/1911.	All the regulations.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations re-enact with amendments the Emulsifiers and Stabilisers in Food (Scotland) Regulations 1975, as amended, and come into operation on 8th January 1981.

The 1975 Regulations, as amended, implemented Council Directive No. 74/329/EEC (O.J. No. L189, 12.7.74, p. 1) on the approximation of the laws of the Member States relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs.

These Regulations implement in part Council Directive No. 78/612/EEC (O.J. No. L197, 22.7.78, p. 22) amending for the first time Directive 74/329/EEC, Council Directive No. 78/663/EEC (O.J. No. L223, 14.8.78, p. 7) laying down specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs and Council Directive No. 78/664/EEC (O.J. No. L223, 14.8.78, p. 30) laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption.

The Regulations—

- (a) specify permitted emulsifiers and permitted stabilisers and prescribe purity criteria for those emulsifiers and stabilisers (Regulation 2 and Schedule 1);
- (b) prohibit the sale and the importation of food which has in it or on it any added emulsifier or stabiliser other than a permitted emulsifier or permitted stabiliser (Regulation 4(1));
- (c) restrict to certain specified foods and within prescribed limits the use of certain permitted emulsifiers and permitted stabilisers (Regulation 4(2) and Schedule 2, part I);
- (d) restrict the permitted emulsifiers and permitted stabilisers that may be used in other specified foods and limit the quantity in which they may be used (Regulation 4(3) and Schedule 2, Part II);
- (e) permit, with exceptions, food which has in it or on it any food specified in Schedule 2 to have in it or on it any permitted emulsifier or permitted stabiliser of the description specified for, and in the amount appropriate to the quantity of, that specified food (Regulation 4(4));
- (f) permit bread to have in it or on it up to a prescribed limit any permitted emulsifier or permitted stabiliser which is present in the bread by reason

of the use of any tin-greasing emulsion in the preparation of the bread (Regulation 4(5));

- (g) prohibit the use of any emulsifier or stabiliser in flour intended for sale as such (Regulation 4(6));
- (h) prohibit the sale, the importation and the advertisement for sale of any emulsifier or stabiliser, other than a permitted emulsifier or permitted stabiliser, for use as an ingredient in the preparation of food (Regulation 5(1));
- (i) prescribe labelling requirements for permitted emulsifiers and permitted stabilisers sold for use as ingredients in the preparation of food (Regulation 5(2) and Schedule 3); and
- (j) prohibit the labelling and the advertisement of any permitted emulsifier or permitted stabiliser for sale for use as an ingredient in the preparation of food with any words, device or description calculated to indicate that the emulsifier or stabiliser is a substitute for fat or eggs (Regulation 6).

The Regulations do not apply to any emulsifier or stabiliser, or to any food having in it or on it any emulsifier or stabiliser, which is intended for export (Regulation 3).

The principal changes effected by the Regulations are:—

- (a) the deletion from the list of permitted emulsifiers and permitted stabilisers in Part I of Schedule 1 of furcellaran (E 408) which is now covered by the new specific purity criteria for the permitted emulsifier or stabiliser carragenan (E 407), the deletion of ethylcellulose (E 462) and the consequent removal of specific purity criteria from Part II of Schedule 1;
- (b) the replacement of the entry relating to pectins (E 440) in Part I of Schedule 1 by entries for pectin (E 440(a)), amidated pectin (E 440(b)) and pectin extract;
- (c) the replacement of the entry in Part I of Schedule 1 relating to diacetyltartaric acid esters of mono- and di-glycerides of fatty acids (E 472(e)) by an entry for mono- and di-acetyltartaric acid esters of mono- and di-glycerides of fatty acids (E 472(e)) and consequent amendments to Part II of Schedule 1 and Part II of Schedule 2;
- (d) the replacement in appropriate cases of the specific purity criteria for permitted emulsifiers and permitted stabilisers in Part II of Schedule 1 by the specific purity criteria laid down in Council Directive No. 78/663/EEC and Council Directive No. 78/664/EEC;
- (e) the insertion in Part II of Schedule 1 of specific purity criteria for pectin extract; and
- (f) the insertion in Schedule 3 of a new labelling requirement for permitted emulsifiers and permitted stabilisers to which a specified sugar product has been added for the purpose of standardisation.

The Food Chemicals Codex 1972 and First Supplement, 1974, referred to in Regulation 2(1) and Part II of Schedule 1, may be consulted by prior arrangement with the Librarian, University Library, Glasgow, G12 8QE (telephone 041-334 2122). The journal *Tenside* 1967, volume 4, part 9, referred to in Part II of Schedule 1, may be inspected at the British Library Lending Division, Boston Spa, Wetherby, West Yorkshire, LS23 7BQ (Telephone Boston Spa 843434) or at the Science Museum Library, London SW7 5NH (telephone 01-589 3456).

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