COUNCIL DIRECTIVE

of 25 July 1978

laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs

(78/663/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (1), as last amended by Directive 78/612/EEC (2), and in particular Article 7 (1) thereof,

Having regard to the proposal from the Commission,

Whereas under Article 6 of Directive 74/329/EEC emulsifiers, stabilizers, thickeners and gelling agents must satisfy specific criteria of purity established in accordance with Article 7 (1) of that Directive,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The specific criteria of purity referred to in Article 6 (1) (b) of Directive 74/329/EEC are given in the Annex to this Directive.

Article 2

As regards the substances referred to in the Annex under numbers E 474 and E 477, the Council may, acting unanimously on a proposal from the Commission, decide on any necessary amendments by 31 December 1981 following an enquiry by the Commission.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months after the notification of this Directive. They shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1978.

For the Council
The President
H. J. ROHR

⁽¹⁾ OJ No L 189, 12. 7. 1974, p. 1.

⁽²⁾ OJ No L 197, 22. 7. 1978, p. 22.

ANNEX

SPECIFIC CRITERIA OF PURITY FOR EMULSIFIERS, STABILIZERS, THICKENERS AND GELLING AGENTS FOR USE IN FOODSTUFFS

General observations

- (a) Where interpretation of the criteria set out below requires the definition of certain technical details, reference should be made to the methods of analysis established pursuant to Article 7 (2) of Directive 74/329/EEC.
- (b) Unless otherwise stated, the quantities and percentages shall be calculated in terms of weight of the product as such.
- (c) The specific criteria of purity applicable to substances E 322, E 339 (i), (ii) and (iii), E 340 (i), (ii) and (iii) and E 341 (i) and (iii) are laid down by Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption (1). The regime applicable to hydrolysed lecithins is set out in the same Directive.

E 341 — (iii) Tricalcium orthophosphate

Chemical description — tricalcium diorthophosphate; Ca₃ (PO₄)₂,

— hydroxyapatite; Ca₅ (PO₄)₃OH.

Appearance Impalpable white powder.

Content Not less than 90 % expressed as Ca₃ (PO₄)₂ after calcination at 800 ±

25 °C to constant weight.

Volatile matter Not more than 10 % determined by calcination at 800 ± 25 °C to

constant weight.

Fluoride Not more than 50 mg/kg expressed as fluorine.

E 400 — Alginic acid

Chemical description Linear glycuronoglycan consisting mainly of beta (1-4) linked D-man-

nuronic and alpha (1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of di-

lute alkali from various species of brown seaweeds.

Description Nearly odourless, tasteless white to yellowish fibrous powder.

Content Yields, on a volatile matter-free basis, not less than 20 % and not

more than 23 % of carbon dioxide corresponding to not less than $91\cdot0$ % and not more than $104\cdot5$ % of alginic acid (equivalent weight

200).

Ash Not more than 4 % on a volatile matter-free basis determined at

600 °C after drying at 105 °C for four hours.

⁽¹⁾ See page 30 of this Official Journal.

Insoluble matter (using dilute

NaOH)

Not more than 0.5 %.

Volatile matter

Not more than 15 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

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 % and not more than 21 % of carbon dioxide corresponding to not less than 90.8 % and not more than 106.0 % of sodium alginate (equivalent

weight 222).

Ash

Not less than 18·0 % and not more than 27·0 % on a volatile matter-free basis determined at 600 °C after drying at 105 °C for four hours.

Insoluble matter (in dilute

NaOH)

Not more than 0.5.

Volatile matter

Not more than 15 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

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 % and not more than 19.5 % of carbon dioxide corresponding to not less than 89.2 % and not more than 105.5 % of potassium alginate (equivalent

weight 238).

Ash

Not less than 23 % and not more than 32 % on a volatile matter-free basis determined at 600 °C after drying at 105 °C for four hours. '

Insoluble matter (in dilute

NaOH)

Not more than 0.5 %.

Volatile matter

Not more than 15 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

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 % and not more than 21 % of carbon dioxide corresponding to not less than 88.7 % and not more than 103.6 % of ammonium alginate (equivalent weight 217)

ent weight 217).

Ash

Not more than 4 % on a volatile matter-free basis determined at

600 °C after drying at 105 °C for four hours.

Insoluble matter (in dilute

NaOH)

Not more than 0.5 %.

Volatile matter

Not more than 15 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

E 404 — Calcium alginate

Chemical name

Calcium 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 % and not more than 21 % of carbon dioxide corresponding to not less than 89.6 % and not more than 104.5 % of calcium alginate (equivalent

weight 219).

Ash

Not less than 15 % and not more than 24 % on a volatile matter-free basis determined at 600 °C after drying at 105 °C for four hours.

Insoluble matter (in dilute NaOH using sodium poly-

phosphate E 450 (c))

Not more than 0.5 %.

Volatile matter

Not more than 15 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

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 percentage of free and neu-

tralized 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 % and not

more than 20 % of carbon dioxide.

Ash

Not more than 10 % on a volatile matter-free basis determined at 600 °C after drying at 105 °C for four hours.

Total propane-1,2-diol con-

tent

Not less than 15 % and not more than 36 %.

Free propane-1,2-diol con-

tent

Not more than 12 %.

Insoluble matter (in dilute

NaOH)

Not more than 0.5 %.

Volatile matter

Not more than 20 % determined by drying at 105 °C for four hours.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 %.

E 406 — Agar

Chemical description

A hydrophilic colloidal polygalactoside, about 90 % of the galactose molecules being of the D-form and 10 % of the L-form. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralized 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

It occurs as white to pale yellow powder, fibres or flakes and is either odourless, or has a slight characteristic odour and a mucilaginous

taste

Ash

Not more than 6.5 % determined at 550 °C on a volatile matter-free basis.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 % determined at 550 °C on a volatile matter-free basis.

Gelatin and other proteins

Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool to about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes.

Insoluble matter (in hot water)

Not more than 1 %.

Volatile matter

Not more than 20 % determined by drying at 105 °C for five hours.

Starch and dextrins

Boil 100 mg of agar in 100 ml of water. Cool and add a few drops of iodine solution (14 g I_2 in a solution of 36 g KI in 100 ml H_2O , add three drops of HCl and dilute to 1 000 ml). No blue or red colour is produced.

Water absorption

Place 5 g of agar in a 100 ml 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 100 ml graduated cylinder. Not more than 75 ml of water is obtained.

E 407 — Carrageenan

Chemical description

Carrageenan is obtained by aqueous extraction of seaweeds of Gigartinaceae, Solieriaceae, Hypneaceae and Furcellariaceae, families of the class Rhodophyceae (red seaweeds). No organic precipitants shall be used other than methanol, ethanol and isopropanol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium 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 % determined by drying at 105 °C for four hours.

Sulphate

Not less than 15 % and not more than 40 % on a volatile matter-free

basis, expressed as SO₄.

Acid-insoluble ash (insoluble in approximately 1 % v/v sulphuric acid)

Not more than 2 % on a volatile matter-free basis.

Ash

Not less than 15 % and not more than 40 % determined at 550 °C on

a volatile matter-free basis.

Methanol, ethanol, isopro-

panol content

Not more than 1 % singly or in combination.

Viscosity of a 1.5 % solution

at 75 °C

Not less than five centipoises.

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 chemi-

cally as galactomannan.

Description

Locust bean gum is the ground endosperm of the seeds of the carob tree, Cerationia siliqua (L.) Taub. (Fam. Leguminosae). It is a white to

yellowish-white, nearly odourless powder.

Galactomannan content

Not less than 75 %.

Insoluble matter (in 0.4 N

sulphuric acid)

Not more than 4 % after digestion for six hours.

Ash

Not more than 1.2 % determined at 800 °C.

Volatile matter

Not more than 14 % determined by drying to constant weight at 102

to 105 °C (three to five hours).

Protein (N \times 6.25)

Not more than 7 %.

E 412 — Guar gum

Chemical description Consists mainly of a high molecular weight hydrocolloidal polysac-

charide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemi-

cally as galactomannan.

Description Guar gum is the ground endosperm of the seeds of the guar plant,

Cyamopsis tetragonolobus (L.) Taub. (Fam. Leguminosae). It is a

white to yellowish-white, nearly odourless powder.

Galactomannan content Not less than 75 %.

Insoluble matter (in 0.4 N

sulphuric acid)

Not more than 4 % after digestion for six hours.

Ash Not more than 1.5 % determined at 800 °C.

Volatile matter Not more than 14 % determined by drying to constant weight at 102

to 105 °C (three to five hours).

Protein $(N \times 6.25)$ Not more than 7 %.

E 413 — Tragacanth

Chemical description Consists mainly of high molecular weight polysaccharides composed of

galacto-arabans and acidic polysaccharides containing galacturonic

acid groups.

Description Tragacanth is 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 2.5 mm in thickness. It is 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 % solution

at 25 °C

Not less than 250 centipoises.

Ash

Not more than 3.5 % determined at 550 °C.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 % determined at 550 °C.

Karaya gum

Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five 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 sizes 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 % determined at 550 °C.

Acid-insoluble ash (insoluble in approximately 3 N hydro-

chloric acid)

Not more than 0.5 % determined at 550 °C.

Insoluble matter (in approximately 3 N hydrochloric

acid)

Not more than 1 %.

Volatile matter

Not more than 15 % determined by drying at 105 °C for five hours.

Starch or dextrin

Boil a 1 in 50 solution of the gum and cool. To 5 ml add one drop of iodine solution (14 g of iodine in a solution of 36 g of potassium iodide in 100 ml of water, add three drops of hydrochloric acid and dilute to 1 000 ml). No bluish or reddish colour is produced.

Tannin

To 10 ml of a 1 in 50 solution add about 0.1 ml of ferric chloride solution (9 g FeCl₃ · 6H₂O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed.

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 % of glycitols and not less than 91 % of D-sorbitol, on a dry-matter basis in each case. Glycitols are compounds with the structural formula CH₂OH (CHOH)_n CH₂OH 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, where $n \le 4$, and minor quantities of hydrogenated oligosaccharides.

Water

Not more than 1 % (Karl Fischer).

Reducing sugars

Not more than 0.3 % on a dryweight basis, expressed as dextrose.

Total sugars

Not more than 1 % on a dryweight basis, expressed as dextrose.

Sulphated ash

Not more than 0.1 % at 800 ± 25 °C on a dryweight basis.

Sulphate Chloride Not more than 0.01 % on a dryweight basis, expressed as SO₄. Not more than 0.005 % on a dryweight 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-crystallizing) or mannitol. Minor quantities of glycitols where $n \le 4$ may be present. Glycitols are compounds with the structural formula CH_2OH (CHOH)_n CH_2OH , where 'n' is an integer.

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Not less than 69 % total solids and not less than 50 % of D-sorbitol.

Reducing sugars

Not more than 0.3 % on a dryweight basis, expressed as dextrose.

Sulphated ash

Not more than 0.1 % on a dryweight basis (after ignition at 800 ±

25 °C).

Sulphate

Content

Not more than 0.01 % on a dryweight basis, expressed as SO₄.

Chloride

Not more than 0.005 % on a dryweight basis, expressed as Cl.

Nickel

Not more than 2 mg/kg, expressed as Ni.

E 421 — Mannitol

Chemical name

D-mannitol.

Description

White crystalline solid which is odourless and has a sweet taste.

Content

Not less than 98 % of D-mannitol (C₆H₁₄O₆) on a volatile matter-free

basis.

Melting range

165 to 169 °C.

Specific rotation $[\alpha]_D^{25}$

Not less than +23.0° and not more than +24.3°.

Volatile matter

Not more than 0.3 % determined by drying at 105 °C for four hours.

Reducing sugars

Not more than 0.05 %, expressed as dextrose.

Sulphate

Not more than 0.01 %, expressed as SO₄.

Chloride

Not more than 0.007 %, expressed as Cl.

Ash

Not more than 0.1 % determined at 800 \pm 25 °C.

Nickel

Not more than 2 mg/kg, expressed as Ni.

E 422 — Glycerol

Description

Clear, colourless hygroscopic syrupy liquid with a sweet taste accom-

panied by a sensation of heat to the tongue.

Content

Not less than 98 % of glycerol (C₃H₈O₃).

Specific gravity (25/25 °C)

Not less than 1.257.

Refractive index [n] D

1.471 to 1.474.

Acrolein, glucose and ammonium compounds

Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide

solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow

nor emits an odour of ammonia.

Butanetriols

Not more than 0.2 %.

Chlorinated compounds

(expressed as Cl)

Not more than 0.003 %.

Fatty acids and esters

Not more than 0.1 % calculated as butyric acid.

Sulphated ash

Not more than 0.01 % determined at 800 \pm 25 °C.

E 440 (a) — 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 % calculated on an ash and volatile matter-free basis

after washing with acid and alcohol.

Volatile matter

Not more than 12 % after drying at 105 °C for two hours.

Acid-insoluble ash (insoluble

in approximately 3 N hydrochloric acid)

Not more than 1 %.

Free methanol, ethanol and

isopropanol content

Not more than 1 %, 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 % determined after washing with acid and alcohol

(kjeldahl).

E 440 (b) — 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 % of total carboxyl groups.

Galacturonic acid

Not less than 65 % calculated on an ash and volatile matter-free basis

determined after washing with acid and alcohol.

Volatile matter

Not more than 12 % after drying at 105 °C for two hours.

Acid-insoluble ash (insoluble

in approximately 3 N hydrochloric acid)

Not more than 1 %.

Free methanol, ethanol and

isopropanol content

Not more than 1 %, 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 % after washing with acid and alcohol (kjeldahl).

E 450 (a) — (i) Disodium dihydrogen diphosphate

Description

White powder or grains.

Content

Not less than 95.0 % of Na₂H₂P₂O₇.

Content in P2O5

Not less than 63.0 % and not more than 64.0 %.

Volatile mater

Not more than 0.5 % determined by drying at 105 °C for four hours.

pH of 1 % solution

Not less than 3.7 and not more than 4.4.

Water insoluble matter

Not more than 0.6 %.

Fluoride

Not more than 10 mg/kg expressed as fluorine.

E 450 (a) — (ii) Trisodium diphosphate

Description

White powder or grains. Occurs anhydrous or as a monohydrate.

Content

Not less than 95.0 % of Na₃HP₂O₇ or of Na₃HP₂O₇ · H₂O.

Content in P2O5

Not less than 57.5 % and not more than 58.5 % for the anhydrous salt. Not less than 53.6 % and not more than 54.6 % for the

monohydrate.

pH of a 1 % solution

Not less than 6.7 and not more than 7.3.

Volatile matter

Not more than 0.5 % determined by drying at 105 °C for four hours.

Water insoluble matter

Not more than 0.2 %.

Fluoride

Not more than 10 mg/kg expressed as fluorine.

E 450 (a) — (iii) Tetrasodium diphosphate

Description

White, crystalline or granular powder. Occurs anhydrous or as a

decahydrate.

Content

Not less than 95.0 % of $Na_4P_2O_7$ or of $Na_4P_2O_7 \cdot 10H_2O$.

Content in P₂O₅ Not less than 52.5 % and not more than 54.0 % for the anhydrous

salt.

Not less than 31.5 % and not more than 32.5 % for the decahydrate.

Loss on ignition Not more than 0.5 % for the anhydrous salt, not less than 38 % and

not more than 42 % for the decahydrate, in both cases determined after drying at 105 °C for four hours, followed by ignition at 550 °C

for 30 minutes.

pH of a 1 % solution Not less than 9.9 and not more than 10.7.

Water insoluble matter Not more than 0.2 %.

Fluoride Not more than 10 mg/kg expressed as fluorine.

E 450 (a) — (iv) Tetrapotassium diphosphate

Description Colourless crystals or white, very hygroscopic powder.

Content Not less than 95.0 % of K₄P₂O₇.

Content in P_2O_5 Not less than 42.0 % and not more than 43.7 %.

Loss on ignition Not more than 2 % after drying at 105 °C for four hours followed by

ignition at 550 °C for 30 minutes.

pH of a 1 % solution Not less than 10·0 and not more than 10·7.

Water insoluble matter Not more than 0.2 %.

Fluoride (expressed as F) Not more than 10 mg/kg.

E 450 (b) — (i) Pentasodium triphosphate

Description White, slightly hygroscopic granules or powder. Occurs anhydrous or

as a hexahydrate.

Content Not less than 85.0 % of Na₅P₃O₁₀ or of Na₅P₃O₁₀ · 6H₂O, the re-

mainder being principally other sodium phosphates (E 450).

Content in P_2O_5 Not less than 56.0 % and not more than 58.0 % for the anhydrous

salt.

Not less than 43.0 % and not more than 45.0 % for the hexahydrate.

Loss on ignition Not more than 0.5 % for the anhydrous salt and not more than

23.5 % for the hexahydrate, in both cases determined after drying at 105 °C for four hours followed by ignition at 550 °C for 30 minutes.

pH of a 1 % solution Not less than 9.3 and not more than 10.1.

Water insoluble matter Not more than 0.2 %.

Fluoride (expressed as F) Not more than 10 mg/kg.

E 450 (b) — (ii) Pentapotassium triphosphate

Description White, very hygroscopic powder.

Content Not less than 85.0 % of K₅P₃O₁₀, the remainder being principally

other potassium phosphates (E 450).

Content in P_2O_5 Not less than 46.5 % and not more than 48.0 %.

Loss on ignition Not more than 0.5 % calculated on the P₂O₅ content after drying at

105 °C for four hours, followed by ignition at 550 °C for 30 minutes.

pH of a 1 % solution Not less than 9.3 and not more than 10.1.

Water insoluble matter Not more than 2 %.

Fluoride (expressed as F) Not more than 10 mg/kg.

E 450 (c) — (i) Sodium polyphosphates

Chemical description Heterogenous mixtures of sodium salts of linear condensed polyphos-

phoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where 'n' is not less

than 2.

Description Fine white powders or crystals or colourless glassy platelets.

Content in P₂O₅ Not less than 59.5 % and not more than 70.0 %, calculated on the

ignited basis.

Loss on ignition Not more than 0.5 % after drying at 105 °C for four hours followed

by ignition at 550 °C for 30 minutes.

pH of a 1 % solution Not less than 3.6 and not more than 9.0.

Water insoluble matter Not more than 0.2 %.

Fluoride Not more than 10 mg/kg expressed as fluorine.

Cyclic phosphates Not more than 8 %.

E 450 (c) — (ii) Potassium polyphosphates

Chemical description Heterogenous mixtures of potassium salts of linear condensed

polyphosphoric acids of general formula $H_{(n+2)} P_n O_{(3n+1)}$ where 'n' is

not less than 2.

Description Fine white powders or crystals or colourless glassy platelets.

Content in P_2O_5 Not less than 53.5 % and not more than 61.5 %, calculated on the

ignited basis.

Loss on ignition Not more than 2 % after drying at 105 °C for four hours followed by

ignition at 550 °C for 30 minutes.

pH of a 1 % solution Not more than 7.8 (1).

Water insoluble matter Not more than 0.2 % (1).

Fluoride Not more than 10 mg/kg expressed as fluorine.

Cyclic phosphates Not more than 8 %.

⁽¹⁾ A special method of analysis is required to determine this.

E 460 — Microcrystalline cellulose

Chemical description Microcrystalline cellulose is purified partially depolymerized 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 % determined by drying to constant weight at

105 °C.

pH Shake about 5 g with 40 ml of carbon dioxide-free water for 20

minutes and centrifuge. The pH of the supernatant liquid is between

5.5 and 7.

Sulphated ash Not more than 0.1 % determined at $800 \pm 25 \degree$ C.

Water soluble substances Not more

Not more than 0·16 %.

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 SO₄.

E 461 — Methylcellulose

Chemical description Methylcellulose is cellulose obtained directly from fibrous plant ma-

terial and partially etherified with methyl 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 fol-

lowing general formula:

 $C_6H_7O_2(OR_1)$ (OR₂) (OR₃) where

R₁, R₂, R₃ each may be

— H,

— CH₃, or

— CH₂ CH₂ OH.

Molecular weight From about 20 000 to 380 000.

Content of substituted

groups

Not less than 25 % and not more than 33 % of methoxyl groups

(-OCH₃). Not more than 5 % of hydroxyethoxyl groups

(-OCH₂CH₂OH).

Volatile matter Not more than 10 % determined by drying to constant weight at

105 °C.

Sulphated ash - Not more than 1.5 % determined at 800 ± 25 °C.

pH of a 1 % solution Not less than 5 and not more than 8.

E 463 — Hydroxypropylcellulose

Chemical description

Hydroxypropylcellulose is cellulose obtained directly from fibrous plant material and partially etherified with hydroxypropyl 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 fol-

lowing general formula:

 $C_6H_7O_2$ (OR₁) (OR₂) (OR₃) where

R₁, R₂, R₃ each may be any one of the following:

-- H,

- CH2CHOHCH3,

- CH₂CHO (CH₂CHOHCH₃) CH₃,

- CH₂CHO [CH₂CHO(CH₂CHOHCH₃)CH₃] CH₃.

Molecular weight

From about 30 000 to 1 000 000.

Content of substituted

groups

Not more than 80.5 % of hydroxypropoxyl groups (-OCH₂CHOHCH₃) on a volatile matter-free basis, equivalent to not

more than 4.6 hydroxypropyl groups per anhydroglucose unit.

pH of a 1 % solution

Not less than 5.0 and not more than 8.0.

Volatile matter

Not more than 10 % determined by drying to constant weight at

105 °C.

Sulphated ash

Not more than 0.5 % determined at 800 \pm 25 °C.

E 464 — Hydroxypropylmethylcellulose

Chemical description

Hydroxypropylmethylcellulose is cellulose 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 fol-

lowing general formula:

 $C_6H_7O_2(OR_1)$ (OR₂) (OR₃) where

R₁, R₂ and R₃ each may be any one of the following:

-- H,

— CH₃,

- CH2CHOHCH3,

— CH₂CHO(CH₂CHOHCH₃)CH₃,

— CH₂CHO [CH₂CHO(CH₂CHOHCH₃)CH₃] CH₃.

Molecular weight

From about 13 000 to 200 000.

Content of substituted

groups

Not less than 19 % and not more than 30 % of methoxyl groups

(-OCH₃) and not less than 3 % and not more than 12 % hydroxy-propoxyl groups (-OCH₂CHOHCH₃) on a volatile matter-free basis.

pH of a 1 % solution

Not less than 5.0 and not more than 8.0.

Volatile matter

Not more than 10 % determined by drying to constant weight at

105 °C.

Sulphated ash

Not more than 1.5 % for products with viscosities greater than 50 cP

and not more than 3.0 % for products with viscosities of 50 cP or less,

determined at 800 \pm 25 °C.

E 465 — Ethylmethylcellulose

Chemical description Ethylmethylcellulose is cellulose 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.

lowing general formula:

 $C_6H_7O_2(OR_1)$ (OR₂) (OR₃) where

R₁, R₂ and R₃ each may be any one of the following:

— Н, — СН₃,

— CH₂CH₃.

Molecular weight From about 30 000 to 40 000.

Content of substituted

groups Not less than 14.5 % and not more than 19.0 % of ethoxyl groups

(-OC₂H₅) and not less than 3.5 % and not more than 6.5 % of

methoxyl groups (-OCH₃) on a volatile matter-free basis.

Volatile matter Fibrous form: not more than 15 %. Powdered form: not more than

10 %. Determined by drying to constant weight at 105 °C in each case.

Sulphated ash Not more than 0.6 % determined at 800 ± 25 °C.

pH of a 1 % solution Not less than 5 and not more than 8.

E 466 — Carboxymethylcellulose

Chemical description Carboxymethylcellulose is 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.

lowing general formula:

 $C_6H_7O_2(OR_1)$ (OR₂) (OR₃) where

R₁, R₂ and R₃ each may be any one of the following:

— H,

— CH₂COONa, — CH₂COOH.

Molecular weight From

From about 17 000 to 1 500 000.

Content Not less than 99.5 % of carboxymethylcellulose calculated on a

volatile matter-free basis.

Sodium chloride and sodium

glycolate

Not more than 0.5 % total, and not more than 0.4 % of sodium

glycolate.

Degree of substitution Not less than 0.2 and not more than 1.0 carboxymethyl groups

(-CH₂COOH) per anhydroglucose unit.

Sodium

Not more than 9.7 % on a volatile matter-free basis.

Volatile matter

Not more than 12 % determined by drying to constant weight at

105 °C.

pH of a 1 % solution

Not less than 6 and not more than 8.5.

E 470 — Sodium, potassium and calcium salts of 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 %.

Free fatty acids

Not more than 3 % estimated as oleic acid.

Total glycerol (combined and

free)

Not more than 10 %.

Free alkali

Not more than 0.1 % expressed as NaOH.

Matter insoluble in alcohol

Not more than 0.2 % (sodium and potassium salts only).

Volatile matter

Not more than 3 %.

Content of sodium, or potas-

sium, or calcium

Sodium

Not less than 9.0 % and not more than 14.0 % expressed as Na₂O.

Potassium

Not less than 13.0 % and not more than 21.5 % expressed as K_2O .

Calcium

Not less than 8.5 % and not more than 13.0 % expressed as CaO.

E 471 — Mono- and diglycerides of fatty acids

Chemical description

Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and tri-esters of fatty acids occurring in food fats. They

may contain small amounts of free fatty acids and glycerol.

Description

The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the

form of flakes, powders or small beads.

Mono- and di- ester content

Not less than 70 %.

Free fatty acids

Not more than 3 % estimated as oleic acid.

Free glycerol

Not more than 7 %.

Total glycerol

Not less than 16 % and not more than 33 %.

Polyglycerols Not more than 4 % diglycerol and not more than 1 % higher poly-

glycerols both based on total glycerol content.

Water Not more than 2 % (Karl Fischer).

Sulphated ash Not more than 0.5 % determined at 800 ± 25 °C.

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

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, from white to pale yellow in colour.

Total acetic acid content Not less than 9 % and not more than 32 %.

Free fatty acids (and acetic

acid) Not more than 3 % estimated as oleic acid.

Free glycerol Not more than 2 %.

Total glycerol Not less than 14 % and not more than 31 %.

Sulphated ash Not more than 0.5 % determined at $800 \pm 25 \%$.

E 472 (b) — Lactic acid esters of mono- and diglycerides of fatty acids

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 % and not more than 45 %.

Free fatty acids Not more than 3 % estimated as oleic acid.

Free glycerol Not more than 2 %.

Total glycerol Not less than 13 % and not more than 30 %.

Sulphated ash Not more than 0.5 % determined at 800 ± 25 °C.

Note: These criteria are based on the product without 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 oils

and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralized with sodium hydroxide or with potassium hydrox-

ide.

Description Yellowish or light brown liquids to waxy solids or semi-solids.

Total citric acid content Not less than 13 % and not more than 50 %.

Free fatty acids Not more than 3 % estimated as oleic acid.

Free glycerol Not more than 2 %.

Total glycerol Not less than 11 % and not more than 29 %.

Sulphated ash Not more than 0.5 % for the non-neutralized products and not more

than 10.0 % for the partially or wholly neutralized products deter-

mined at 800 ± 25 °C.

pH of a 1 % 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 % and not more than 50 %.

Free fatty acids Not more than 3 % estimated as oleic acid.

Free glycerol Not more than 2 %.

Total glycerol Not less than 12 % and not more than 29 %.

Sulphated ash Not more than 0.5 % 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 acids and their combinations, and free glycerides.

Description Sticky viscous liquids through a fat-like consistency to yellow waxes

which hydrolyse in moist air to liberate acetic acid.

Total tartaric acid content Not less than 10 % and not more than 40 %.

Total acetic acid content

Not less than 8 % and not more than 32 %.

Free fatty acids

Not more than 3 % estimated as oleic acid.

Free glycerol

Not more than 2 %.

Total glycerol

Not less than 11 % and not more than 28 %.

Sulphated ash

Not more than 0.5 % determined at 800 \pm 25 °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 (E 334) acids and fatty acids

occurring in food fats. They may contain small amounts of free glycerol, free fatty acids, free acetic and tartaric acids, and free

glycerides.

Description Clear mobile liquids to solids, from white to pale yellow in colour.

Total acetic acid Not less than 10 % and not more than 20 %.

Total tartaric acid Not less than 20 % and not more than 40 %.

Free acetic acid Not less than 5.5 % and not more than 8.5 %.

Free tartaric acid Not more than 1 %.

Free fatty acids Not more than 3 % estimated as oleic acid.

Free glycerol Not more than 2 %.

Total glycerol Not less than 12 % and not more than 27 %.

Sulphated ash Not more than 0.5 % determined at 800 ± 25 °C.

E 473 — Sucrose esters of fatty acids

Chemical description Essentially the mono- and di-esters of sucrose with fatty acids occur-

ring in food fats. They may be prepared from sucrose and the methyl and ethyl esters of food fatty acids or by extraction from sucro-glycerides. No organic solvents shall be used in their preparation other

than dimethylformamide, ethyl acetate and isopropanol.

Description Soft solids, stiff gels or white to greyish-white powders.

Total sucrose fatty acid ester

content

Not less than 80 %.

Total glyceride content

Not more than 20 %.

Free sucrose content

Not more than 5 %.

Free fatty acid content

Not more than 3 % estimated as oleic acid.

Sulphated ash

Not more than 2 % determined at 800 \pm 25 °C.

Dimethylformamide content

Not more than 1 mg/kg.

Methanol content

Not more than 10 mg/kg.

Total ethyl acetate and iso-

propanol 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 Sucroglycerides are 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 dimethylformamide, ethyl acetate and isopropanol.

Description Soft solid masses, stiff gels or white to off-white powders.

Total sucrose fatty acid ester

content

Not less than 40 % and not more than 60 %.

Total glyceride content

Not less than 40 % and not more than 60 %.

Free sucrose content

Not more than 5 %.

Free fatty acid content

Not more than 3 % estimated as oleic acid.

Sulphated ash

Not more than 2 % determined at 800 \pm 25 °C.

Dimethylformamide content

Not more than 1 mg/kg.

Methanol content

Not more than 10 mg/kg.

Total ethyl acetate and iso-

propanol content

Not more than 350 mg/kg singly or in combination.

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

E 475 — Polyglycerol esters of non-polymerized fatty acids

Chemical description Polyglycerol esters of fatty acids are 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 % 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 %.

Free fatty acids Not more than 6 % estimated as oleic acid.

Total glycerol and poly-

glycerol

Not less than 18 % and not more than 60 %.

Free glycerol and poly-

glycerol

Not more than 7 %.

Sulphated ash

Not more than 0.5 % determined at 800 ± 25 °C.

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

E 477 — Propane-1,2-diol esters of 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 %.

Free propane-1,2-diol Not more than 5 %.

Dimer and trimer of pro-

pane-1,2-diol Not more than 0.4 %.

Free fatty acids Not more than 6 % estimated as oleic acid.

Sulphated ash Not more than 0.5 % determined at 800 ± 25 °C.

Total propane-1,2 Not less than 11 % and not more than 31 %.

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

E 481 — Sodium stearoyl-2-lactylate

Chemical description A mixture of the sodium salts of stearoyl lactylic 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 % and not more than 5 %.

Ester value Not less than 90 and not more than 190 mg KOH/g.

Total lactic acid (free and

combined) Not less than 15 % and not more than 40 %.

Acid value Not less than 60 and not more than 130 mg KOH/g.

E 482 — Calcium stearoyl-2-lactylate

Chemical description A mixture of calcium salts of stearoyl lactylic 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 character-

istic odour.

Calcium content Not less than 1.0 % and not more than 5.2 %.

Ester value Not less than 125 and not more than 190 mg KOH/g.

Total lactic acid (free and

combined)

Not less than 15 % and not more than 40 %.

Acid value Not less than 50 and not more than 130 mg KOH/g.

E 483 — Stearyl tartrate

Chemical description Stearyl tartrate is produced by the esterification of tartaric acid

(E 334) with stearyl alcohol. It consists chiefly of the di-ester with minor amounts of mono-ester, tartaric acid and 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 Cream coloured unctuous solid (at 25 °C).

Total ester content Not less than 90 %.

Total tartaric acid content Not less than 18 % and not more than 35 %.

Unsaponifiable matter Not less than 77 % and not more than 83 %.

Melting range 67 to 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 % determined at 800 ± 25 °C.