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# Official Journal of the European Communities

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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(Acts whose publication is not obligatory)

# COUNCIL

#### COUNCIL DECISION

#### of 25 July 1978

# amending Fifth Decision 76/539/EEC on the equivalence of seed produced in third countries

#### (78/661/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

plants (<sup>7</sup>), as last amended by Directive 78/388/EEC (<sup>8</sup>), and in particular Article 15 (1) (b) thereof,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 66/400/EEC of 14 June 1966 on the marketing of beet seed (<sup>1</sup>), as last amended by Directive 78/55/EEC (<sup>2</sup>), and in particular Article 16 (1) (b) thereof,

Having regard to Council Directive 66/401/EEC) of 14 June 1966 on the marketing of fodder plant seed (<sup>3</sup>), as last amended by Directive 78/386/EEC (<sup>4</sup>), and in particular Article 16 (1) (b) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (<sup>5</sup>), as last amended by Directive 78/387/EEC (<sup>6</sup>), and in particular Article 16 (1) (b) thereof,

Having regard to Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre

- <sup>(5)</sup> OJ No 125, 11. 7. 1966, p. 2309/66.
- (<sup>6</sup>) OJ No L 113, 25. 4. 1978, p. 13.

Having regard to the proposal from the Commission,

Whereas in Decision 76/539/EEC (9), as amended by Decision 77/659/EEC (10), the Council declared that seed of certain species produced in 20 third countries is equivalent to corresponding seed produced in the Community;

Whereas for certain species this declaration of equivalence relates also to New Zealand;

Whereas in the meantime it has been established that there are rules on seed control for a range of plant species also in Cyprus and the German Democratic Republic;

Whereas an examination of the rules of the abovementioned countries and of the manner in which they are applied has shown that the conditions governing certain seed harvested and controlled in these countries afford the same assurances as regards the seed's characteristics,

<sup>(1)</sup> OJ No 125, 11. 7. 1966, p. 2290/66.

<sup>(&</sup>lt;sup>2</sup>) OJ No L 16, 20. 1. 1978, p. 23.

<sup>(&</sup>lt;sup>3</sup>) OJ No 125, 11. 7. 1966, p. 2298/66.

<sup>(&</sup>lt;sup>4</sup>) OJ No L 113, 25. 4. 1978, p. 1.

<sup>(&</sup>lt;sup>7</sup>) OJ No L 169, 10. 7. 1969, p. 3.

<sup>(&</sup>lt;sup>8</sup>) OJ No L 113, 25. 4. 1978, p. 20.

<sup>(&</sup>lt;sup>9</sup>) OJ No L 162, 23. 6. 1976, p. 10.

<sup>(&</sup>lt;sup>10</sup>) OJ No L 271, 22. 10. 1977, p. 12.

identity, examination, marking and control, as do the conditions applicable to seed harvested and controlled within the Community;

Whereas Cyprus and the German Democratic Republic should therefore also be granted equivalence and the existing equivalence for New Zealand be extended to sugar beet and linseed;

Whereas, moreover, the special conditions set out in the Annex to Decision 76/539/EEC must be adapted to the particular circumstances of the abovementioned countries;

Whereas this Decision does not affect the Protocol on German internal trade and connected problems,

HAS ADOPTED THIS DECISION:

#### Article 1

With effect from 1 July 1978, the entries set out in the Annex to Decision 76/539/EEC shall be amended as follows:

- (a) reference No 7 shall be supplemented by the text set out in the Annex hereto;
- (b) reference Nos 21 and 22 given in the Annex hereto shall be added.

#### Article 2

The special conditions in the Annex to Decision 76/539/EEC shall be amended as follows:

- 1. The following shall be substituted for point 4:
  - '4. In the case of certified seed or certified seed of the first generation, the basic seed, and, in the case of certified seed of the second and subsequent generations, the certified seed of the preceding generation or generations:
    - (a) shall have been officially controlled or certified in a third country which has been granted equivalence in the same way for the same species or within the Community, or
    - (b) shall have been officially certified within the Community.'
- 2. The following shall be added after point 4:
  - '4A. In the case of basic seed, the seed of the preceding generation shall have been officially controlled within the Community in accordance with the provisions applicable for the certification of basic seed.'
- 3. The following shall be added after point 13:
  - '14. The seed shall have been produced on a holding directly supervised by the State.'

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 25 July 1978.

For the Council The President H. J. ROHR 7

<b>.</b>				Cate	egories:	
No	Country	Authority	Species	in the country	in the Community	Special conditions
1	2	3	4	5	6	7
7	New Zealand (NZ)	Ministry of Agriculture and Fisheries	– Sugar beet – Linseed	<ul> <li>Certified seed</li> <li>Basic seed</li> <li>Certified seed, 1st generation</li> </ul>	<ul> <li>Certified seed</li> <li>Basic seed</li> <li>Certified seed, 1st generation</li> </ul>	1, 3, 4(b), 6, 8, 9, 10 1, 3, 5, 8, 9, 10 1, 3, 4(a), 5, 8, 9, 10
21	Cyprus (CY)	Ministry of Agriculture and Natural Resources Department of Agriculture, Nicosia	Fodder kale	<ul> <li>Basic seed</li> <li>Certified seed</li> </ul>	<ul> <li>Basic seed</li> <li>Certified seed</li> </ul>	1, 3, 4A, 5, 8, 9, 10, 14 1, 3, 4(b), 5, 8, 9, 10, 14
22	German Democratic Republic (DDR)	Amt für Standardisierung, Meßwesen und Warenprüfung, Berlin	<ul> <li>Beet</li> <li>Grass and legume species subject to national rules on varietal control</li> <li>Swede, fodder kale, fodder radish</li> <li>Cereals, except canary grass, rice and maize</li> <li>Oil and fibre plants subject to national rules on varietal control</li> </ul>	<ul> <li>Basic seed</li> <li>Certified seed</li> <li>Basic seed</li> <li>Certified seed, 1st generation</li> <li>Certified seed, 2nd and later genera- tions</li> <li>Basic seed</li> <li>Certified seed</li> <li>Certified seed, 1st generation</li> <li>Certified seed, 2nd generation (except rye)</li> <li>Basic seed</li> <li>Certified seed, 1st generation</li> </ul>	<ul> <li>Basic seed</li> <li>Certified seed</li> <li>Basic seed</li> <li>Certified seed 1st generation</li> <li>Certified seed, subsequent generations</li> <li>Basic seed</li> <li>Certified seed</li> <li>Certified seed, 1st generation</li> <li>Certified seed, 2nd generation (except rye)</li> <li>Basic seed</li> <li>Certified seed, 1st generation</li> </ul>	1, 3, 6, 8, 9, 10 1, 3, 4(a), 6, 8, 9, 10 1, 3, 5, 8, 9, 10 1, 3, 4(a), 5, 8, 9, 10 1, 3, 5, 8, 9, 10 1, 3, 5, 8, 9, 10 1, 3, 4(a), 5, 8, 9, 10 1, 3, 4(a), 5, 8, 9, 10

ANNEX

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#### 14. 8. 78

#### **COUNCIL DECISION**

#### of 25 July 1978

#### amending Fifth Decision 76/538/EEC on the equivalence of field inspections carried out in third countries on seed-producing crops

#### (78/662/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Whereas for certain species this declaration of equivalence relates also to New Zealand;

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 66/400/EEC of 14 June 1966 on the marketing of beet seed (<sup>1</sup>), as last amended by Directive 78/55/EEC (<sup>2</sup>), and in particular Article 16 (1) (a) thereof,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (<sup>3</sup>), as last amended by Directive 78/386/EEC (<sup>4</sup>), and in particular Article 16 (1) (a) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (<sup>5</sup>), as last amended by Directive 78/387/EEC (<sup>6</sup>), and in particular Article 16 (1) (a) thereof,

Having regard to Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre plants (<sup>7</sup>), as last amended by Directive 78/388/EEC (<sup>8</sup>), and in particular Article 15 (1) (a) thereof,

Having regard to the proposal from the Commission,

Whereas in Decision 76/538/EEC (9), as amended by Decision 77/658/EEC (10), the Council declared that field inspections carried out in 20 third countries on seed-producing crops of certain species satisfy the conditions laid down in the Community Directives;

- (<sup>1</sup>) OJ No 125, 11. 7. 1966, p. 2290/66.
- (<sup>2</sup>) OJ No L 16, 20. 1. 1978, p. 23.
- (<sup>3</sup>) OJ No 125, 11. 7. 1966, p. 2298/66.
- (<sup>4</sup>) OJ No L 113, 25. 4. 1978, p. 1.
- (<sup>5</sup>) OJ No 125, 11. 7. 1966, p. 2309/66.
- (<sup>6</sup>) OJ No L 113, 25. 4. 1978, p. 13.
- (<sup>7</sup>) OJ No L 169, 10. 7. 1969, p. 3.
- (<sup>8</sup>) OJ No L 113, 25. 4. 1978, p. 20.
- (<sup>9</sup>) OJ No L 162, 23. 6. 1976, p. 1.
- (<sup>10</sup>) OJ No L 271, 22. 10. 1977, p. 9.

Whereas in the meantime it has been established that there are rules on seed control for a range of plant species also in Cyprus and the German Democratic Republic which provide for official field inspection car-

ried out during the period of seed production;

Whereas an examination of the rules of the abovementioned countries and of the manner in which they are applied has shown that the prescribed field inspections satisfy the conditions laid down in Annex I to each of the abovementioned Directives;

Whereas Cyprus and the German Democratic Republic should therefore also be granted equivalence and the existing equivalence for New Zealand be extended to sugar beet and to linseed;

Whereas, moreover, the special conditions set out in the Annex to Decision 76/538/EEC must be adapted to the particular circumstances of the abovementioned countries;

Whereas this Decision does not affect the Protocol on German internal trade and connected problems,

HAS ADOPTED THIS DECISION:

#### Article 1

With effect from 1 July 1978, the entries set out in the Annex to Decision 76/538/EEC shall be amended as follows:

- (a) reference no 7 shall be supplemented by the text set out in the Annex hereto;
- (b) reference Nos 21 and 22 given in the Annex hereto shall be added.

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Article 2	Article 3	
	This Decision is addressed to the M	Member States.
The following shall be added to the special conditate the Annex to Decision 76/538/EEC:	Done at Brussels, 25 July 1978.	
	For	the Council
'7. The seed shall have been produced on a h	olding	be President
directly supervised by the State.'	ł	I. J. ROHR

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Reference No	Country	Authority	Species	Special conditions
1	2	3	4	5
7	New Zealand (NZ)	Ministry of Agriculture and Fisheries	— Sugar beet — Linseed	1,3,5,6 1,3,4,5
21	Cyprus (CY)	Ministry of Agriculture and Natural Resources Department of Agriculture, Nicosia	Fodder kale	1,3,4,5,7
22	German Democratic Republic (DDR)	Amt für Standardisierung, Meßwesen und Warenprüfung, Berlin	<ul> <li>Beet</li> <li>Grass and legume species subject to national rules on varietal control</li> <li>Swede, fodder kale, fodder radish</li> <li>Cereals, except canary grass, rice and maize</li> <li>Oil and fibre plants subject to national rules on varietal control</li> </ul>	1,3,5,6 1,3,4,5 1,3,4,5 1,3,4,5 1,3,4,5

#### ANNEX

#### 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 (<sup>1</sup>), as last amended by Directive 78/612/EEC (<sup>2</sup>), 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,

### 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.

#### 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. Done at Brussels, 25 July 1978.

For the Council The President H. J. ROHR

HAS ADOPTED THIS DIRECTIVE:

(<sup>1</sup>) OJ No L 189, 12. 7. 1974, p. 1.
(<sup>2</sup>) 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 (ii) 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 (<sup>1</sup>). The regime applicable to hydrolysed lecithins is set out in the same Directive.

#### E 341 — (iii) Tricalcium orthophosphate

Chemical description	— tricalcium diorthophosphate; $Ca_3 (PO_4)_2$ , — hydroxyapatite; $Ca_5 (PO_4)_3OH$ .
Appearance	Impalpable white powder.
Content	Not less than 90 % expressed as Ca <sub>3</sub> (PO <sub>4</sub> ) <sub>2</sub> after calcination at 800 $\pm$ 25 °C to constant weight.
Volatile matter	Not more than 10 % determined by calcination at 800 $\pm$ 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 $91.0$ % and not more than $104.5$ % of alginic acid (equivalent weight 200).
Ash	Not more than 4 % on a volatile matter-free basis determined at $600 ^{\circ}$ C after drying at 105 °C for four hours.

<sup>(1)</sup> See page 30 of this Official Journal.

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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 hydrochloric 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 %
contraction actual	Not more than 0.5 /0,

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# 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).
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.

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Onic	fai journal of the European Communities
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 es- terified with sulphuric acid which is neutralized by calcium, mag- nesium, potassium or sodium. It is extracted from certain marine algae of the families <i>Gelidiaceae</i> and <i>Sphaerococcaceae</i> and related red algae of the class <i>Rhodophyceae</i> .
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 trinitro- phenol 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.

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# E 407 — Carrageenan

Chemical description	Carrageenan is obtained by aqueous extraction of seaweeds of Gigar- tinaceae, 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 $SO_4$ .
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 polysac- charide, 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
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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

Description

Consists mainly of high molecular weight polysaccharides composed of galacto-arabans and acidic polysaccharides containing galacturonic acid groups.

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

Ash

Not more than 3.5 % determined at 550 °C.

Not less than 250 centipoises.

Acid-insoluble ash (insoluble in approximately 3 N hydrochloric acid)

Karaya gum

Not more than 0.5 % determined at 550 °C.

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).

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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 approx- imately 3 N hydrochloric	Number of the second seco
acia)	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 FeCl <sub>3</sub> $\cdot$ 6H <sub>2</sub> O made up to 100 ml with water). No black-ish 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 $CH_2OH$ (CHOH) <sub>n</sub> $CH_2OH$ 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 $\pm$ 25 °C on a dryweight basis.
Sulphate	Not more than 0.01 % on a dryweight basis, expressed as $SO_4$ .
Chloride	Not more than $0.005$ % on a dryweight basis, expressed as Cl.
Nickel	Not more than 2 mg/kg, expressed as Ni.

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E 420 — (ii) Sorbitol syrup

Description

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Clear, colourless and sweet-tasting aqueous solution of sorbitol and hydrogenated oligosaccharides. That part of the product which is not

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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  $n \leq 4$  may be present. 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.

Content	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 $\pm$ 25 °C).
Sulphate	Not more than 0.01 % on a dryweight basis, expressed as $SO_4$ .
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 ( $C_6H_{14}O_6$ ) on a volatile matter-free basis.
Melting range	165 to 169 °C.
Specific rotation $\left[ \alpha \right] \frac{25}{D}$	Not less than $+23.0^{\circ}$ and not more than $+24.3^{\circ}$ .
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 $SO_4$ .
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 ( $C_3H_8O_3$ ).
Specific gravity (25/25 °C)	Not less than 1.257.
Refractive index $\begin{bmatrix} n \end{bmatrix} \begin{bmatrix} 20 \\ D \end{bmatrix}$	1.471 to 1.474.

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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 $^{\circ}$ 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, potas- sium and calcium salts. It is obtained by aqueous extraction of ap- propriate edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic pre- cipitants 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.

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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 $Na_2H_2P_2O_7$ .
Content in $P_2O_5$	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 $Na_3HP_2O_7$ or of $Na_3HP_2O_7 \cdot H_2O$ .
Content in P <sub>2</sub> O <sub>5</sub>	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 <sub>4</sub> P <sub>2</sub> O <sub>7</sub> or of Na <sub>4</sub> P <sub>2</sub> O <sub>7</sub> $\cdot$ 10H <sub>2</sub> O.

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Content in $P_2O_5$	Not less than $52.5$ % and not more than $54.0$ % for the anhydron salt.	18
	Not less than $31.5$ % and not more than $32.5$ % for the decahydrat	e.
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 determine after drying at 105 °C for four hours, followed by ignition at 550 ° for 30 minutes.	ıd :d C
pH of a 1 % solution	on Not less than 9.9 and not more than 10.7.	
Water insoluble ma	Not more than 0.2 %.	
Fluoride	Not more than 10 mg/kg expressed as fluorine.	

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# E 450 (a) — (iv) Tetrapotassium diphosphate

Description	Colourless crystals or white, very hygroscopic powder.
Content	Not less than $95.0 \%$ of $K_4P_2O_7$ .
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 $Na_5P_3O_{10}$ or of $Na_5P_3O_{10} \cdot 6H_2O$ , the remainder being principally other sodium phosphates (E 450).
Content in P <sub>2</sub> O <sub>5</sub>	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

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Description

White, very hygroscopic powder.

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	Content	Not less than $85.0$ % of $K_5P_3O_{10}$ , the remainder being principall other potassium phosphates (E 450).	ly
	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 $P_2O_5$ content after drying a 105 °C for four hours, followed by ignition at 550 °C for 30 minutes	1t 5.
	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.	

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# E 450 (c) — (i) Sodium polyphosphates

Chemical description	Heterogenous mixtures of sodium salts of linear condensed polyphosphoric 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 $P_2O_5$	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 <sub>2</sub> O <sub>5</sub>	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 $0.2 \%$ ( <sup>1</sup> ).
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.

#### 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. Not more than 5 % determined by drying to constant weight at Volatile matter 105 °C. Shake about 5 g with 40 ml of carbon dioxide-free water for 20 pН 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 °C. Water soluble substances 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 SO<sub>4</sub>.

#### E 461 — Methylcellulose

E 460 — Microcrystalline cellulose

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:
	$C_6H_7O_2(OR_1)$ (OR <sub>2</sub> ) (OR <sub>3</sub> ) where
	$R_1, R_2, R_3$ each may be
	— H,
	$- CH_3$ , or
	- CH <sub>2</sub> CH <sub>2</sub> 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 (-OCH <sub>3</sub> ). Not more than 5 % of hydroxyethoxyl groups (-OCH <sub>2</sub> CH <sub>2</sub> OH).
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 $\pm$ 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.

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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 <sub>1</sub> ) (OR <sub>2</sub> ) (OR <sub>3</sub> ) where
	<ul> <li>R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> each may be any one of the following:</li> <li>H,</li> <li>CH<sub>2</sub>CHOHCH<sub>3</sub>,</li> <li>CH<sub>2</sub>CHO (CH<sub>2</sub>CHOHCH<sub>3</sub>) CH<sub>3</sub>,</li> <li>CH<sub>2</sub>CHO [CH<sub>2</sub>CHO(CH<sub>2</sub>CHOHCH<sub>3</sub>)CH<sub>3</sub>] CH<sub>3</sub>.</li> </ul>
Molecular weight	From about 30 000 to 1 000 000.
Content of substituted groups	Not more than $80.5$ % of hydroxypropoxyl groups (-OCH <sub>2</sub> CHOHCH <sub>3</sub> ) 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:
	$C_6H_7O_2(OR_1)$ (OR <sub>2</sub> ) (OR <sub>3</sub> ) where
	$R_1$ , $R_2$ and $R_3$ each may be any one of the following:
	— H,
	— CH <sub>3</sub> ,
	- CH <sub>2</sub> CHOHCH <sub>3</sub> ,
	— $CH_2CHO(CH_2CHOHCH_3)CH_3$ ,
	— $CH_2CHO [CH_2CHO(CH_2CHOHCH_3)CH_3] CH_3.$
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 (-OCH <sub>3</sub> ) and not less than 3 % and not more than 12 % hydroxy- propoxyl groups (-OCH <sub>2</sub> CHOHCH <sub>3</sub> ) 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.

## Ethylmethylcellulose is cellulose obtained directly from fibrous plant Chemical description material and partially etherified with methyl and ethyl groups. Slightly hygroscopic white or slightly yellowish or greyish odourless Description and tasteless, granular or fibrous powder. The polymers contain substituted anhydroglucose units with the fol-Chemical formula lowing general formula: $C_6H_7O_2(OR_1)$ (OR<sub>2</sub>) (OR<sub>3</sub>) where $R_1$ , $R_2$ and $R_3$ each may be any one of the following: — Н, — CH<sub>3</sub>, - CH<sub>2</sub>CH<sub>3</sub>. From about 30 000 to 40 000. Molecular weight Content of substituted Not less than 14.5 % and not more than 19.0 % of ethoxyl groups groups (-OC<sub>2</sub>H<sub>5</sub>) and not less than 3.5 % and not more than 6.5 % of methoxyl groups (-OCH<sub>3</sub>) 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. Not more than 0.6 % determined at 800 $\pm$ 25 °C. Sulphated ash pH of a 1 % solution Not less than 5 and not more than 8.

#### E 466 — Carboxymethylcellulose

E 465 — Ethylmethylcellulose

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.
Chemical formula	The polymers contain substituted anhydroglucose units with the fol- lowing general formula:
	$C_6H_7O_2(OR_1)$ (OR <sub>2</sub> ) (OR <sub>3</sub> ) where
	$R_1$ , $R_2$ and $R_3$ each may be any one of the following: — H,
	$- CH_2 COONa$ ,
	— $CH_2COOH$ .
Molecular weight	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 (-CH <sub>2</sub> COOH) per anhydroglucose unit.

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	Sodium	Not more than 9.7 % on a volatile matter-free basis.	
	Volatile matter	Not more than 12 % determined by drying to constant weig 105 °C.	ght at
	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 $Na_2O$ .
	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 %.
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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 $\pm$ 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 °C.

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

Chemical description	Esters of glycerol with lactic acid and 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 % 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 $\pm$ 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 determined at 800 $\pm$ 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 $\pm$ 25 °C.

# E 472 (e) - Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids

Chemical des	cription	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 tar- taric 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 tartaria	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 $\pm$ 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.

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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 prep- aration 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 %.

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#### Sulphated ash

Not more than 0.5 % determined at 800  $\pm$  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 $\pm$ 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

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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 $\pm$ 25 °C.

#### **COUNCIL DIRECTIVE**

#### of 25 July 1978

laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption

#### (78/664/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

#### HAS ADOPTED THIS DIRECTIVE:

# Article 1

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidants authorized for use in foodstuffs intended for human consumption (<sup>1</sup>), as last amended by Directive 78/143/EEC (<sup>2</sup>), and in particular Article 5 (1) thereof,

Having regard to the proposal from the Commission,

Whereas, pursuant to Article 4 of Directive 70/357/EEC, antioxidants must comply with specific criteria of purity laid down in accordance with Article 5 (1) thereof;

Whereas specific criteria of purity should be laid down for the antioxidants listed in Parts I to III and points 4 to 7 of Part IV of the Annex to Directive 70/357/EEC, on the understanding that certain of these criteria have already been laid down in Directive 65/66/EEC (<sup>3</sup>), as last amended by Directive 76/463/EEC (<sup>4</sup>), and in Directive 78/663/EEC (<sup>5</sup>);

Whereas this Directive lays down no specific criteria of purity for ethyl alcohol covered by point 4 of Part IV of the Annex to Directive 70/357/EEC, and this substance will be considered in greater detail when rules of a general nature governing solvents are drawn up in the future;

Whereas for economic and technological reasons in certain Member States, provision should be made for the Member States to retain their existing national arrangements concerning specific criteria of purity concerning DL-tartaric acid and salts thereof, hydrolysed lecithins, and the aldehyde content of propylene glycol, of Directive 70/357/EEC are set out in the Annex to this Directive.

#### Article 2

1. This Directive does not affect national measures in existence at the time of its notification under which specific criteria of purity are set for:

(a) DL-tartaric acid and salts thereof;

(b) hydrolysed lecithins;

(c) the aldehyde content of propylene glycol.

2. The Council, acting unanimously on a proposal from the Commission, shall decide before 1 January 1982 on the criteria of purity referred to in paragraph 1 (a) and (b).

#### 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 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 J. ERTL

The specific criteria of purity referred to in Article 5 (1)

<sup>14. 8. 78</sup> 

<sup>(&</sup>lt;sup>1</sup>) OJ No L 157, 18. 7. 1970, p. 31.

<sup>(&</sup>lt;sup>2</sup>) OJ No L 44, 15. 2. 1978, p. 18.

<sup>(&</sup>lt;sup>3</sup>) OJ No 22, 9. 2. 1965, p. 373/65.

<sup>(&</sup>lt;sup>4</sup>) OJ No L 126, 14. 5. 1976, p. 33.

<sup>(&</sup>lt;sup>5</sup>) See page 4 of this Official Journal.

#### ANNEX

#### SPECIFIC CRITERIA OF PURITY FOR ANTIOXIDANTS WHICH MAY BE USED IN FOOD-STUFFS INTENDED FOR HUMAN CONSUMPTION

#### General remarks

- (a) Except where otherwise stated, the quantities and percentages shall be calculated by mass on the basis of the anhydrous form of the substance.
- (b) Where the substance in question is not anhydrous at the outset and where 'volatile matter' is involved, the latter shall include all moisture, including water of crystallization.
- (c) Where the drying temperature and time are not stated, the latter shall be understood to mean 'to constant weight' and the former shall be 105 °C.
- (d) Where the interpretation of the criteria set out below require that certain technical data such as 'vacuum' data be defined, the methods of analysis established pursuant to Article 5 (2) of the Directive concerning antioxidants shall be referred to.
- (e) Where the concentration of a solution is given, this shall be taken to mean mass/volume except where otherwise stated.
- (f) Temperatures shall always be stated in degrees centigrade (Celsius).
- (g) The specific criteria of purity applicable to substances E 220 to E 224, E 226 and E 270 are laid down by Directive 65/66/EEC.
- (h) The specific criteria of purity applicable to sorbitol, glycerol and to substance E 472 (c) are laid down by Council Directive 78/663/EEC.

Chemical description	(+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; C <sub>6</sub> H <sub>8</sub> O <sub>6</sub> .
Appearance	White or pale yellow crystalline powder.
Melting range	189 to 193 °C with slight decomposition.
Content	Not less than 99 % $C_6H_8O_6$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha] \frac{20}{D} = + 20.5 \text{ to } + 21.5^{\circ} \text{ (C} = 10 \% \text{ aqueous).}$
Volatile matter	Not more than $0.4$ % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0.1 % on a volatile matter-free basis determined by calcination at 800 $\pm$ 25 °C.
pН	2.4 to 2.8 in 2 % aqueous solution.

## E 300 — L-ascorbic acid

E 301 — Sodium L-ascorbate

Chemical description

Sodium salt of (+)-L-ascorbic acid; 3-oxo-L-gulofuranolactone; sodium enolate;  $C_6H_7O_6Na$ .

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Appearance	White or pale yellow crystalline powder.
Content	Not less than 99 % $C_6H_7O_6Na$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha] \frac{20}{D} = +103 \text{ to } + 106^{\circ} \text{ (C} = 5 \% \text{ aqueous).}$
Volatile matter	Not more than $0.3$ % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
pН	6.0 to $8.0$ in 10 % aqueous solution.

#### E 302 — Calcium L-ascorbate

Chemical description	Calcium salt of (+)-L-ascorbic acid; $(C_6H_7O_6)_2Ca \cdot 2H_2O$ .
Appearance	White or very pale grey crystalline powder.
Content	Not less than 99 % $(C_6H_7O_6)_2Ca \cdot 2H_2O$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha] \frac{20}{D} = +95 \text{ to } +97^{\circ} \text{ (C} = 5\% \text{ aqueous)}.$
Volatile matter	Not more than $0.3 \%$ ( <sup>1</sup> ) determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
рН	6.0 to $7.5$ in 10 % aqueous solution.

#### E 303 — 5,6-Diacetyl-L-ascorbic acid

Chemical description	Ascorbyl diacetate, derivative of (+)-L-ascorbic acid; $C_{10}H_{12}O_8$ .
Appearance	White or pale yellow crystalline powder.
Melting range	155 to 158 °C.
Content	Not less than 99 % $C_{10}H_{12}O_8$ on a volatile matter-free basis.
Specific optical rotatory power	$[\alpha] \frac{20}{D} = -77 \text{ to } -79^{\circ} \text{ (C = 2 \% in methanol).}$
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide.
Sulphated ash	Not more than 0.1 % of the volatile matter-free substance determined by calcination at 800 $\pm$ 25 °C.

#### E 304 — 6-Palmitoyl-L-ascorbic acid

Chemical description

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Ascorbyl palmitate; derivative of (+)-L-ascorbic acid; L-ascorbyl palmitate; 6-0-palmitoyl-3-oxo-L-gulofuranolactone.

<sup>(1)</sup> This percentage value does not relate to the water of crystallization but to the atmospheric water vapour (moisture in the substance) determined under these conditions.

Appearance	Impalpable white or yellowish-white powder or yellowish-white crystals.
Content	Not less than 98 % $C_{22}H_{38}O_7$ on a volatile matter-free basis.
Melting range	111 to 113 °C (changes to viscous state without completely melting).
Specific optical rotatory	$[\alpha] \frac{20}{D} = +21 \text{ to } +24^{\circ} (C = 5 \% \text{ in methanol}).$
Volatile matter	Not more than 1 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pent-oxide.
Sulphated ash	Not more than 0.2 % of the volatile matter-free substance after calcination at 800 $\pm$ 25 °C.

# E 306 - Tocopherol-rich extracts of natural origin

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Chemical description	Mixed tocopherols concentrate obtained from edible vegetable oils or their derivatives.
Appearance	Clear, viscous, red to brownish-red oil.
Content	Not less than 34 % total tocopherols (1).
Relative density d $\frac{20}{4}$	Not less than $0.928$ and not more than $0.951$ (1).
Free fatty acids	Not more than 3 % expressed in terms of oleic acid (1).

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# E 307 — Synthetic alpha-tocopherol

Chemical description	Synthetic dl- $\alpha$ -tocopherol; 2,5,7,8-tetramethyl-2-(4',8',12'-trimethyl-tridecyl)-6-chromanol; C <sub>29</sub> H <sub>50</sub> O <sub>2</sub> .
Appearance	Clear, viscous, yellowish oil which darkens on exposure to air or light.
Content	Not less than 96 % $C_{29}H_{50}O_2$ ( <sup>1</sup> ).
Refractive index $n \frac{20}{D}$	Not less than 1.503 and not more than 1.507 (1).
Relative density $d \frac{20}{4}$	Not less than 0.947 and not more than 0.958 (1).
Specific absorption $E = \frac{1 \%}{1 cm}$ in ethanol	Absorption at 292 nm: E $\begin{pmatrix} 1 & \% \\ 1 & cm \end{pmatrix}$ (292 nm): not less than 72 and not more than 76. Absorption at 255 nm: E $\begin{pmatrix} 1 & \% \\ 1 & cm \end{pmatrix}$ (255 nm): not less than 60 and not
Sulphated ash	More than 8.0. Not more than 0.1 % after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).

<sup>(1)</sup> These criteria apply to the product as it is.

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Chemical description	Synthetic dl- $\gamma$ -tocopherol, 2,7,8-trimethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol; C <sub>28</sub> H <sub>48</sub> O <sub>2</sub> .
Appearance	Clear, viscous, pale yellow oil which darkens on exposure to air or light.
Content	Not less than 97 % $C_{28}H_{48}O_2$ ( <sup>1</sup> ).
Refractive index n <sup>20</sup> D	Not less than 1.503 and not more than 1.507 (1).
Relative density $d \frac{20}{4}$	Not less than $0.948$ and not more than $0.959$ ( <sup>1</sup> ).
Specific absorption E $\frac{1 \%}{1 cm}$ in ethanol	Absorption at 298 nm: E $\begin{array}{c} 1 \ \% \\ 1 \ cm \end{array}$ (298 nm): not less than 91 and not more than 97.
	Absorption at 257 nm: E $\frac{1 \%}{1 \text{ cm}}$ (257 nm): not less than 5.0 and not more than 8.0.
Sulphated ash	Not more than 0.1 % after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).

#### . E 309 — Synthetic delta-tocopherol

E 308 — Synthetic gamma-tocopherol

Chemical description	Synthetic dl- $\delta$ -tocopherol; 2,8-dimethyl-2-(4',8',12'-trimethyltri- decyl)-6-chromanol; C <sub>28</sub> H <sub>48</sub> O <sub>2</sub> .
Appearance	Clear, viscous, pale yellowish or orange oil which darkens on expo- sure to air or light.
Content	Not less than 97 % $C_{27}H_{46}O_2$ ( <sup>1</sup> ).
Refractive index $n \frac{20}{D}$	Not less 1.500 and not more than 1.504 (1).
Relative density d 20 4	Not less than $0.952$ and not more than $0.962$ ( <sup>1</sup> ).
Specific absorption E 1 % in ethanol 1 cm	Absorption at 298 nm: E $1\%$ (298 nm): not less than 89 and not more than 95. $1 \text{ cm}$
	Absorption at 257 nm: E $\begin{array}{c} 1 \% \\ 1 \text{ cm} \end{array}$ (257 nm): not less than 3.0 and not more than 6.0.
Sulphated ash	Not more than 0.1 % after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).
E 310 — Propyl gallate	

Chemical descriptionPropyl gallate; n-propyl ester of 3,4,5-trihydroxybenzoic acid;<br/> $C_{10}H_{12}O_5$ .AppearanceWhite or pale cream crystalline powder.

<sup>(1)</sup> These criteria apply to the product as it is.

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Content	Not less than 99 % $C_{10}H_{12}O_5$ on a volatile matter-free basis.
Melting range	146 to 150 °C after drying at 110 °C for four hours.
Specific absorption E 1 % in ethanol 1 cm	Absorption at 275 nm: E $\frac{1 \%}{1 \text{ cm}}$ (275 nm): not less than 485 and not more than 505.
Volatile matter	Not more than $1.0$ % determined by drying at 110 °C for four hours.
Sulphated ash	Not more than 0.05 % of the volatile matter-free substances after calcination at 800 $\pm$ 25 °C.
Free acids	Not more than $0.5$ % expressed as gallic acid (8.506 mg gallic acid corresponding to 1 ml 0.05 N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

E 311 — Octyl gallate

Chemical description	Octyl gallate; n-octyl ester of 3,4,5-trihydroxybenzoic acid, $C_{15}H_{22}O_5$ .
Appearance	White or very pale yellowish crystalline powder.
Melting range	99 to 102.5 °C after drying at 90 °C for six hours.
Content	Not less than 98.5 % $C_{15}H_{22}O_5$ on a volatile matter-free basis.
Specific absorption E 1 % in ethanol 1 cm	Absorption at 275 nm: E $\frac{1\%}{1 \text{ cm}}$ (275 nm): not less than 375 and not more than 390.
Volatile matter	Not more than 0.5 % determined by drying at 90 °C for six hours.
Sulphated ash	Not more than 0.05 % of the volatile matter-free substance after calcination at 800 $\pm$ 25 °C.
Free acids	Not more than $0.5$ % expressed as gallic acid (8.506 mg gallic acid corresponding to 1 ml $0.05$ N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

E 312 — Dodecyl gallate	
Chemical description	Dodecyl gallate; lauryl gallate; n-dodecyl ester of 3,4,5-trihydroxy- benzoic acid; $C_{19}H_{30}O_5$ .
Appearance	White or pale cream crystalline powder.
Melting range	95 to 98 °C after drying at 90 °C for six hours.
Content	Not less than 98.5 % $C_{19}H_{30}O_5$ on a volatile matter-free basis.

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Specific absorption E 1 % in ethanol 1 cm	Absorption at 275 nm: E $\frac{1 \%}{1 \text{ cm}}$ (275 nm): not less than 300 and not more than 325.
Volatile matter	Not more than $0.5$ % determined by drying at 90 °C for six hours.
Sulphated ash	Not more than 0.05 % of the volatile matter-free substance after cal- cination at 800 $\pm$ 25 °C.
Free acids	Not more than $0.5$ % expressed as gallic acid (8.506 mg gallic acid corresponding to 1 ml 0.05 N sodium hydroxide).
Chlorinated organic compounds	Not more than 100 mg/kg expressed as chlorine.

# E 320 — Butylated hydroxyanisole (BHA)

Chemical description	Mixture of 3- and 2-tertiarybutyl-4-hydroxyanisole; 2- and 3-ter- tiarybutyl-4-methoxy-phenol; $C_{11}H_{16}O_2$ .
Appearance	White or pale yellowish powder or large crystals with waxy appear- ance and slight aromatic smell.
Content	Not less than $98.5 \% C_{11}H_{16}O_2$ and not less than $85 \%$ of the 3-tertiary+butyl-4-hydroxyanisole isomer ( <sup>1</sup> ).
Specific absorption $E = \frac{1 \%}{1 cm}$ in ethanol	Absorption at 290 nm: E $\frac{1 \%}{1 \text{ cm}}$ (290 nm): not less than 190 and not more than 210.
	Absorption at 228 nm: E $\frac{1 \%}{1 \text{ cm}}$ (228 nm): not less than 326 and not more than 345.
4-hydroxyanisole content	Not more than $0.5$ %.
Sulphated ash	Not more than 0.05 % after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).

# E 321 — Butylated hydroxy toluene (BHT)

Chemical description	2,6-ditert-butyl-p-cresol; 4-methyl-2,6-ditert-butyl phenol; $C_{15}H_{24}O$ .
Appearance	White crystalline or powdery crystalline substance.
Content	Not less than 99 % $C_{15}H_{24}O$ .
Melting range	69 to 70 °C.
Specific absorption E $\frac{1 \%}{1 cm}$ in ethanol	Absorption at 278 nm: E $\frac{1 \%}{1 \text{ cm}}$ (278 nm): not less than 81 and not more than 88.
Sulphated ash	Not more than 0.005 % after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).

<sup>(1)</sup> These criteria apply to the product as it is.

## E 322 — Lecithins

Description	Lecithins are mixtures or fractions of phosphatides obtained by physi- cal procedures from animal or vegetable foodstuffs. The lecithins may be slightly bleached in aqueous medium by means of hydrogen per- oxide. This oxidation must not chemically modify the lecithin phos- phatides.
Appearance	Brown liquid or viscous semi-liquid or powder.
Content	Not less than 60 % substances insoluble in acetone (1).
Volatile matter	Not more than 2 % determined by drying at 105 °C for one hour $(^1)$ .
Substances insoluble in to- luene	Not more than $0.3 \% (1)$ .
Acid number	Not more than 35 mg of potassium hydroxide per gram $(^1)$ .
Peroxide number	Equal to or less than 10, expressed as milliequivalents per kilogram.

## E 325 — Sodium lactate

Chemical description	Sodium salt of lactic acid; C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> Na.
Appearance	White hygroscopic mass. Solutions are practically colourless and odourless.
Description	The substance is usually available commercially in the form of an aqueous solution containing 50 to 80 % mass/mass of anhydrous sodium lactate.
Content	Not less than 98 % $C_3H_5O_3Na$ after drying.
Acidity	Not more than $0.5$ % after drying expressed as lactic acid.
Reducing substances	No reduction of Fehling's solution.

# E 326 — Potassium lactate

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Chemical description	Potassium salt of lactic acid; C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> K.
Description	The substance is usually available commercially in the form of an aque- ous, slightly syrupy, clear, almost odourless solution containing about 60 % mass/mass of anhydrous potassium lactate.
Content	Not less than 98 % C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> K after drying.
Acidity	Not more than $0.5$ % after drying expressed as lactic acid.
Reducing substances	No reduction of Fehling's solution.

(1) These criteria apply to the product as it is.

E 327 — Calcium lactate	
Chemical description	Calcium salt of lactic acid; calcium dilactate; $(C_3H_5O_2)_2C_3$ ; also available commercially in hydrated forms (one, three or four-and-a-half molecules of water).
Appearance	Almost odourless, white crystalline powder or granules.
Content	Not less than 98 % $(C_3H_5O_3)_2C_3$ on a volatile matter-free basis.
Volatile matter	<ul> <li>Determined by drying at 120 °C for four hours:</li> <li>anhydrous: not more than 3 %,</li> <li>with one molecule of water: not more than 8 %,</li> <li>with three molecules of water: not more than 20 %,</li> <li>with four-and-a-half molecules of water: not more than 27 %.</li> </ul>
Acidity	Not more than $0.5$ % of the dry matter expressed as lactic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.
Reducing substances	No reduction of Fehling's solution.

E 330 — Citric acid

Chemical description	2-hydroxy-1,2,3-propane tricarboxylic acid; $C_6H_8O_7$ ; available commercially in anhydrous or monohydrate form.
Appearance	Colourless or translucent crystalline solid or white crystalline powder.
Content	Not less than $99.5 \% C_6 H_8 O_7$ after drying.
Volatile matter	Anhydrous: not more than $0.5$ %.
	Monohydrate: not more than 8.8 %.
Oxalates	Not more than $0.05$ %, expressed as oxalic acid, after drying.
Sulphated ash	Not more than 0.05 % of the dry matter after calcination at 800 $\pm$ 25 °C.
Sulphuric acid test	1 g sample dissolved in 10 ml 95 % sulphuric acid and heated for 60 minutes at 90° shall not show a darker colouration than a solution containing 0.5 part of a $CoCl_2 \cdot 6H_2O$ solution (59.5 mg/ml) and 4.5 parts of a $FeCl_3 \cdot 6H_2O$ solution (45.0 mg/ml).

E 331 — Sodium citrates	
(i) Monosodium citrate	
Chemical description	Monosodium salt of citric acid; $C_6H_5O_7H_2N_3$ ; in anhydrous form or as the monohydrate.
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7H_2Na$ on a volatile matter-free basis.

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	Volatile matter	Determined by drying at 120 °C for two hours:	
		— anhydrous: not more than $1.0$ %,	
		— monohydrate: not more than $8.8$ %.	
	Oxalates	Not more than 0.05 % expressed as oxalic acid.	
,	pН	Determined in a 1 % solution, not less than $3.5$ and not more than $3.8$ .	

(ii) Disodium citrate	
Chemical description	Disodium salt of citric acid with one-and-a-half molecules of water; $C_6H_5O_7HNa_2$ , 1.5 $H_2O$ .
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7HNa_2$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 180 °C for two hours, not more than 13 %.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
pН	Determined in a 1 % solution, not less than $4.9$ and not more than $5.2$ .

(iii) Trisodium citrate	
Chemical description	Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form; $C_6H_5O_7Na_3$ .
Appearance	Crystalline white powder or colourless crystals.
Content	Not less than 99 % $C_6H_5O_7Na_3$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 180 °C for two hours:
	— anhydrous: not more than 1.0 %,
	— dihydrate: not more than 13.5 %,
	- pentahydrate: not more than 30.3 %.
Oxalates	Not more than 0.05 % expressed as oxalic acid.
рН	Determined in a 1 % solution, not less than 7.0 and not more than $9.0$ .

E 332 — Potassium citrates

(i) Monopotassium citrate

Chemical description

.

Anhydrous monopotassium salt of citric acid; C<sub>6</sub>H<sub>5</sub>O<sub>7</sub>H<sub>2</sub>K.

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Appearance	White, hygroscopic, granular powder or transparent crystals.
Content	Not less than 99 % $C_6H_5O_7H_2K$ on a volatile matter-free basis.
Volatile matter	Not more than 1 % determined by drying at 120 °C for four hours.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
pH	Determined in a 1 % solution, not less than $3.5$ and not more than $3.8$ .

(ii) Tripotassium citrate	
Chemical description	Monohydrated tripotassium salt of citric acid; $C_6H_5O_7K_3$ , 1 $H_2O$ .
Appearance	White hygroscopic granular powder or transparent crystals.
Content	Not less than 99 % $C_6H_5O_7K_3$ on a volatile matter-free basis.
Volatile matter	Not more than 6 % determined by drying at 180 °C for four hours.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
рН	Determined in a 1 % solution, not less than $7.0$ and not more than $9.0$ .

E 333 — Calcium citrates	
(i) Monocalcium citrate	
Chemical description	Monohydrate monocalcium salt of citric acid; $(C_6H_5O_7)_2$ H <sub>4</sub> Ca, 1 H <sub>2</sub> O.
Appearance	Fine white powder.
Content	Not less than 97.5 % $(C_6H_5O_7)_2$ H <sub>4</sub> Ca on a volatile matter-free basis.
Volatile matter	Not more than 7 % determined by drying at 120 °C for four hours.
Carbonates	Dissolving 1 g of calcium: citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

(ii) Dicalcium citrate

Chemical description

Trihydrated dicalcium salt of citric acid; (C<sub>6</sub>H<sub>5</sub>O<sub>7</sub>)<sub>2</sub> H<sub>2</sub>Ca<sub>2</sub>, 3 H<sub>2</sub>O.

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Appearance	Fine white powder.
Content	Not less than 97.5 % $(C_6H_5O_7)_2$ H <sub>2</sub> Ca <sub>2</sub> on a volatile matter-free basis.
Volatile matter	Not more than 20 % determined by drying at 120 °C for four hours.
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

(iii) Tricalcium citrate	
Chemical description	Tetrahydrated tricalcium salt of citric acid; (C <sub>6</sub> H <sub>5</sub> O <sub>7</sub> ) <sub>2</sub> Ca <sub>3</sub> , 4 H <sub>2</sub> O.
Appearance	Fine white powder.
Content	Not less than 97.5 % $(C_6H_5O_7)_2$ Ca <sub>3</sub> on a volatile matter-free basis.
Volatile matter	Not more than 14 % determined by drying at 150 °C for four hours.
Carbonates	Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

E 334 — Tartaric acid

Chemical description	L-(+)-tartaric acid; 2,3-dihydroxysuccinic acid; $C_4H_6O_6$ .
Appearance	Colourless or translucent crystalline solid or white crystalline powder.
Content	Not less than $99.5 \% C_4H_6O_6$ .
Volatile matter	Not more than 0.5 %.
Sulphated ash	Not more than 0.1 % of the dry matter after calcination at 800 $\pm$ 25 °C.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.
Melting range	168 to 170 °C.
Specific optical rotatory power	$[\alpha] \frac{20}{D}$ from + 11.5 to + 13.5° (C = 20 % aqueous).

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E 335 — Sodium tartrates		
(i) Monosodium tartrate		
Chemical description	Monohydrated monosodium salt of L-(+)-tartaric acid; $C_4H_4O_6H$ Na, $H_2O$ .	
Description	Transparent, colourless crystals.	
Content	Not less than 99 % $C_4H_4O_6$ H Na on a volatile matter-free basis.	
Volatile matter	Not more than 10 % determined by drying at 105 °C for four hours.	
Oxalates	Not more than $0.05$ % expressed as oxalic acid.	

(ii) Disodium tartrate	
Chemical description	Dihydrated disodium salt of L-(+)-tartaric acid, $C_4H_4O_6$ Na <sub>2</sub> , 2 H <sub>2</sub> O.
Description	Transparent, colourless crystals.
Content	Not less than 99 % $C_4H_4O_6$ Na <sub>2</sub> on a volatile matter-free basis.
Volatile matter	Not more than 17 % determined by drying at 150 °C for four hours.
Oxalates	Not more than $0.05$ % expressed as oxalic acid.

#### E 336 — Potassium tartrates

(i) Monopotassium tartrate		
Chemical description	Anhydrous monopotassium salt of L-(+)-tartaric acid; $C_4H_4O_6$ HK.	
Description	White crystalline or granulated powder.	
Content	Not less than 98 % $C_4H_4O_6$ HK on a volatile matter-free basis.	
Volatile matter	Not more than 1 % determined by drying at 105 °C for four hours.	
Oxalates	Not more than $0.05$ % expressed as oxalic acid.	

(ii) Dipotassium tartrate		
Chemical description	Dipotassium salt with half a molecule of water of L-(+)-tartaric acid; $C_4H_4O_6$ K <sub>2</sub> , $\frac{1}{2}$ H <sub>2</sub> O.	
Description	White crystalline or granulated powder.	

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	Content	Not less than 99 % $C_4H_4O_6K_2$ on a volatile matter-free basis.	
	Volatile matter	Not more than 4 % determined by drying at 150 °C for four hours.	
	Oxalates	Not more than $0.05$ % expressed as oxalic acid.	

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# E 337 — Potassium sodium tartrate

Chemical description	Derivate of L-(+)-tartaric acid; potassium sodium L (+) tartrate; Available commercially in the form of potassium sodium tartrate with four molecules of water of crystallization; $C_4H_4O_6K$ Na, 4 H <sub>2</sub> O.	
Description	Colourless crystals or white crystalline powder.	
Content	Not less than 99 % $C_4H_4O_6K$ Na on a volatile matter-free basis.	
Volatile matter	Not more than 21 % determined by drying at 150 °C for three hours.	
Oxalates	Not more than 0.05 % expressed as oxalic acid.	

# E 338 — Orthophosphoric acid

Chemical description	Orthophosphoric acid H <sub>3</sub> PO <sub>4</sub> in concentrated aqueous solution.
Appearance	Clear, colourless, viscous liquid.
Content	Not less than 85 % $H_3PO_4$ ( <sup>1</sup> ).
Chlorides	Not more than 200 mg/kg expressed as chlorine (1).
Nitrates	Not more than 5 mg/kg expressed as NaNO <sub>3</sub> ( <sup>1</sup> ).
Sulphates	Not more than 1 500 mg/kg expressed as CaSO <sub>4</sub> ( <sup>1</sup> ).
Fluorides	Not more than 10 mg/kg expressed as fluorine (1).
Volatile acids	Not more than 10 mg/kg expressed as acetic acid (1).

#### E 339 — Sodium orthophosphates

# (i) Monosodium orthophosphate

Chemical description	Monosodium monophosphate; acid monosodium monophosphate; monosodium orthophosphate; monobasic sodium phosphate; Na $H_2PO_4$ .
	The substance is available commercially in anhydrous or hydrated form with one or two molecules of water.
Appearance	Slightly deliquescent white powder, crystals or granules.
Content	Not less than 97 % Na $H_2PO_4$ on a volatile matter-free basis.

<sup>(1)</sup> These criteria apply to the product as it is.

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# Official Journal of the European Communities

Volatile matter	Determined by drying at 60 °C for one hour and then at 105 °C for four hours:
	- anhydrous: not more than 2 %,
	— with one molecule of water: not more than 15 %,
	— with two molecules of water: not more than 25 %.
Water insoluble substances	Not more than $0.2$ % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

# (ii) Disodium orthophosphate

Chemical description	Disodium monophosphate; secondary sodium phosphate; disodium orthophosphate; acid disodium phosphate; Na <sub>2</sub> H PO <sub>4</sub> .
	The substance is available commercially in anhydrous form or as a hydrate with two, seven or 12 molecules of water.
Appearance	Anhydrous: white hygroscopic powder.
	With two molecules of water: white crystalline solid.
	With seven molecules of water: granular powder or white efflorescent crystals.
	With 12 molecules of water: white efflorescent powder or crystals.
Content	Not less than 98 % $Na_2H PO_4$ on a volatile matter-free basis.
Volatile matter	Determined by drying at 60 °C for one hour and at 105 °C for four hours:
	— anhydrous: not more than 5 %,
	— with one molecule of water: not more than 21 %,
	— with seven molecules of water: not more than 50 %,
	— with 12 molecules of water: not more than 61 %.
Water insoluble substances	Not more than $0.2$ % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

# (iii) Trisodium orthophosphates

Chemical description	Trisodium monophosphate; trisodium orthophosphate; Na <sub>3</sub> PO <sub>4</sub> .	
	The substance is available commercially in anhydrous form or as a hydrate with one or 12 molecules of water.	
Appearance	White powder, crystals or granules.	
Content	Not less than 97 % $Na_3PO_4$ on a volatile matter-free basis.	
Volatile matter	Determined by drying at 105 °C for one hour, followed by calcination at 800 $\pm$ 25 °C for 30 minutes:	
	— anhydrous: not more than 2 %,	
	— with one molecule of water: not more than 9 %,	
	— with 12 molecules of water: not more than 55 %.	

Water insoluble substancesNot more than 0.2 % of the volatile matter-free substance.FluoridesNot more than 10 mg/kg expressed as fluorine.

#### E 340 — Potassium orthophosphates

(i) Monopotassium orthophosphate

Chemical description	Monopotassium monophosphate; acid monopotassium monophosphate; $KH_2PO_4$ .
Appearance	Colourless crystals or white granular or crystalline powder, hygroscopic.
Content	Not less than 98 % $KH_2PO_4$ on a volatile matter-free basis.
Volatile matter	Not more than 2 % determined by drying at 105 °C for four hours.
Water insoluble substances	Not more than $0.2$ % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

#### (ii) Dipotassium orthophosphate

Chemical description	Dipotassium monophosphate; secondary potassium phosphate; acid dipotassium orthophosphate; dipotassium phosphate; K <sub>2</sub> H PO <sub>4</sub> .
Appearance	Colourless or white granular deliquescent substance.
Content	Not less than 98 % $K_2H$ PO <sub>4</sub> on a volatile matter-free basis.
Volatile matter	Not more than 2 % determined by drying at 105 °C for four hours.
Water insoluble substances	Not more than $0.2$ % of the volatile matter-free substance.
Fluorides	Not more than 10 mg/kg expressed as fluorine.

#### (iii) Tripotassium orthophosphate

Chemical description	Tripotassium monophosphate; tripotassium orthophosphate; K <sub>3</sub> PO <sub>4</sub> .	
	The substance is available commercially in anhydrous form or hy- drated form, the most common being that with one molecule of water of crystallization.	
Appearance	White hygroscopic crystals or granules.	
Content	Not less than 97 % $K_3PO_4$ on a volatile matter-free basis.	
Volatile matter	Determined by drying at 105 °C for one hour followed by calcination at 800 $\pm$ 25 °C for 30 minutes:	
	— anhydrous: not more than 3 %,	
	— with one molecule of water: not more than 20 %.	

Water insoluble substances Not more than 0.2 % of the volatile matter-free substance.

Fluorides

Not more than 10 mg/kg expressed as fluorine.

#### E 341 -- Calcium orthophosphates

# (i) Monocalcium orthophosphate

Chemical description	Monocalcium phosphate; $CaH_4(PO_4)_2$ . Available commercially in anhydrous form or as the monohydrate.
Appearance	Granular powder or white, deliquescent crystals or granules.
Calcium content	Anhydrous: not less than 23 % and not more than 25 % expressed as CaO (1).
	With one molecule of water: not less than $22 \cdot 2$ % and not more than $24 \cdot 7$ % expressed as CaO ( <sup>1</sup> ).
Volatile matter	Anhydrous: not less than 14 % and not more than $15.5$ % determined after calcination at 800 $\pm$ 25 °C for 30 minutes.
	With one molecule of water: not more than $0.6$ % determined by drying at 60 °C for three hours.
Fluorides	Not more than 30 mg/kg expressed as fluorine.

# (ii) Dicalcium orthophosphate

Chemical description	Dibasic calcium phosphate; dicalcium phosphate; Ca H PO <sub>4</sub> . Available commercially in anhydrous and dihydrate form.	
Appearance	Impalpable white powder.	
Calcium content	Anhydrous: not less than 39 % and not more than 42 % expressed as CaO (1).	
	With two molecules of water: not less than $31.9$ % and not more than $33.5$ % expressed as CaO ( <sup>1</sup> ).	
Volatile matter	Determined by calcination at 800 $\pm$ 25 °C to constant weight.	
· · ·	Anhydrous: not less than 7 % and not more than $8.5$ %.	
	Dihydrate: not less than $24.5$ % and not more than $26.5$ %.	
Fluorides	Not more than 50 mg/kg expressed as fluorine.	

<sup>(1)</sup> These criteria apply to the product as it is.

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#### Propylene glycol (1,2-propanediol)

Chemical description	Propane-1,2-diol; 1,2-dihydroxypropane; methyl glycol; $C_3H_8O_2$ .
Appearance	Clear, colourless, almost odourless, viscous, hygroscopic liquid with a slightly bitter-sweet flavour.
Content	Not less than 98.5 % by weight propane-1,2-diol (1).
Distillation range	Not less than 185 °C and not more than 189 °C.
Relative density $d = \frac{20}{4}$	Not less than 1.035 and not more than 1.037.
Refractive index $n \frac{20}{D}$	Not less than 1.431 and not more than 1.433.
Sulphated ash	Not more than 0.07 % of the dry matter after calcination at 800 $\pm$ 25 °C ( <sup>1</sup> ).
Total content of dimer, trimer and higher polymers of propane-1,2-diol	Not more than $0.1 \% (^1)$ .
Propane-1,3-diol content	Not more than 100 mg/kg ( <sup>1</sup> ).
Chlorinated organic com- pounds	Not more than 1 mg/kg expressed as chlorine (1).

(1) These criteria apply to the product as it is.

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# COMMISSION

#### COMMISSION DIRECTIVE

#### of 14 July 1978

adapting to technical progress Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against pollution of the air by gases from positive ignition engines installed in motor vehicles

(78/665/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers  $(^1)$ , as amended by the Act of Accession, and in particular Articles 11, 12 and 13 thereof,

Having regard to Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against pollution of the air by gases from positive-ignition engines of motor vehicles (<sup>2</sup>), as amended by the Act of Accession, and in particular Article 5 thereof,

Whereas the first European Community programme of action on the environment approved on 22 November 1973 provides that Directives may be amended in order to take account of the most recent scientific progress and more specifically as regards the pollution of air by gases from spark-ignition engines;

Whereas the maximum permissible limits for carbon monoxide and unburnt hydrocarbons emitted by sparkignition engines fitted to motor vehicles were laid down in Directive 70/220/EEC; whereas these limits were initially reduced by Council Directive 74/290/EEC of 28 May 1974 (<sup>3</sup>), and permissible limits for nitrogen oxide emissions were added by Commission Directive 77/102/EEC of 30 November 1976 (<sup>4</sup>);

Whereas the requirements relating to the protection of public health and the environment require a further short term reduction in these limits; whereas the technical advances made in engine design now enable a reduction of this type to be made without running counter to Community policy aims in other fields and in particular that of the rational use of energy;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives aimed at the Removal of Technical Barriers to Trade in the Motor-Vehicle Sector,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annexes I, II, III, V and VII to Directive 70/220/EEC, as amended by Directive 74/290/EEC and by Directive 77/102/EEC, are hereby amended in accordance with the Annex to this Directive.

<sup>&</sup>lt;sup>(1)</sup> OJ No L 42, 23. 2. 1970, p. 1.

<sup>(&</sup>lt;sup>2</sup>) OJ No L 76, 6. 4. 1970, p. 1.

<sup>(&</sup>lt;sup>3</sup>) OJ No L 159, 15. 6. 1974, p. 61.

<sup>(&</sup>lt;sup>4</sup>) OJ No L 32, 3. 2. 1977, p. 32.

#### Article 2

1. From 1 April 1979, the Member States shall neither, on grounds relating to air pollution by gases from an engine:

- refuse to grant EEC type-approval, or to issue the documents referred to in the last indent of Article 10 (1) of Directive 70/156/EEC, or to grant national type-approval of a type of motor vehicle, nor
- prohibit the entry into service of such vehicles,

where the level of gaseous pollutants emitted from this type of motor vehicle or from such vehicles meets the requirements of Directive 70/220/EEC, as last amended by this Directive.

2. From 1 October 1979, Member States:

- --- shall no longer issue the document provided for in the last indent of Article 10 (1) of Directive 70/156/EEC in respect of a type of motor vehicle which emits gaseous pollutants at levels which do not meet the requirements of Directive 70/220/EEC, as last amended by this Directive,
- -- may refuse national type-approval of a type of motor vehicle which emits gaseous pollutants at

levels which do not meet the requirements of Directive 70/220/EEC, as last amended by this Directive.

3. From 1 October 1981, Member States may prohibit the entry into service of vehicles which emit gaseous pollutants at levels which do not meet the requirements of Directive 70/220/EEC, as last amended by this Directive.

4. Before 1 January 1979, Member States shall put into force the provisions required in order to comply with this Directive and shall forthwith inform the Commission thereof.

#### Article 3

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1978.

For the Commission

Étienne DAVIGNON

Member of the Commission

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#### ANNEX

#### AMENDMENTS TO THE ANNEXES TO DIRECTIVE 70/220/EEC, AS AMENDED BY DIRECTIVES 74/290/EEC AND 77/102/EEC

#### I. General provisions relating to units of measurement

The provisions of Directive 70/220/EEC shall be aligned with Directive 71/354/EEC, as last amended by Directive 76/770/EEC, relating to units of measurement.

In the Annexes to Directive 70/220/EEC:

- the words 'reference weight' and 'maximum weight' shall be replaced by the words 'reference mass' and 'maximum mass';
- the pressure values indicated in millimetres of mercury and in millimetres water gauge shall be replaced by the values indicated in millibars in accordance with the formula:
  - -1 mm Hg = 1.33322 mbar,
  - $-1 \text{ mm } H_2O = 0.0980665 \text{ mbar};$
- the power values shall be indicated in kilowatts instead of horsepower or chevaux vapeur in accordance with the formula:
  - -1 CV = 0.735498 kW,
  - -1 hp = 0.7457 kW.

#### II. Individual provisions

#### ANNEX I

#### DEFINITIONS, APPLICATION FOR EEC TYPE-APPROVAL AND TEST SPECIFICATIONS

- Point 1.2 to read:
- '1.2. Reference mass

"Reference mass" means the mass of the vehicle in running order less the uniform mass of the driver of 75 kg and increased by a uniform mass of 100 kg."

Add a new point 1.2.1 as follows:

"Mass of the vehicle in running order" means the mass defined under point 2.6 of Annex I to Directive 70/156/EEC."

Reference mass (kilograms)	Mass of carbon monoxide (grams per test)	Mass of hydrocarbons (grams per test)	Mass of nitrogen oxides expressed in No2 equivalent (grams per test)
RW	LI	L2	L3
<b>RW</b> < 750	65	6.0	8-5
$750 < RW \leq 850$	71	6.3	8.5
$850 < RW \le 1020$	76	6.5	8.5
$1\ 020\ < RW \le\ 1\ 250$	87	7.1	10.2
$1\ 250\ < RW \le\ 1\ 470$	99	7.6	11.9
$1  470  < \mathbf{RW} \le  1  700$	110	8.1	12.3
$1\ 700\ < RW \le\ 1\ 930$	121	8.6	12.8
$1 930 < RW \le 2 150$	132	9.1	13.2
$2  150  < \mathbf{RW}$	143	9.6	13.6

In point 3.2.1.1.4 the table shall be replaced by the following:

Point 3.2.1.1.4.1 to read:

'3.2.1.1.4.1. However, until 1 October 1981, for type-approval in respect of emissions of vehicles of category  $M_1$  equipped with automatic transmissions, the limits L3 for nitrogen-oxide emissions given in the table in point 3.2.1.1.4 shall be multiplied by the factor 1.25.

Concerning vehicles other than those of category  $M_1$ , the limits for nitrogen-oxide emissions remain those given in point 3.2.1.1.4 of Directive 77/102/EEC, multiplied by the factor 1.25.'

Point 3.2.1.2.2 to read:

'3.2.1.2.2. The carbon monoxide content by volume of the exhaust gases emitted with the engine idling must not exceed 3.5 %. When a check is made in accordance with the provisions of Annex IV, under operating conditions not in conformity with the standards recommended by the manufacturer (configuration of the adjustment components), the maximum content measured by volume shall not exceed 4.5 %.'

Point 4.2.2 'Ratio E' shall be as follows: 'E  $\leq 8$  %'.

Point 4.2.3 'Ratio E' shall be as follows: 'E > 8 % and E  $\leq$  13 %'.

In point 5.1.1.1 the table shall be replaced by the following:

Reference mass (kilograms) RW	Mass of carbon monoxide (grams per test) L1	Mass of hydrocarbons (grams per test) 1.2	Mass of nitrogen oxides expressed in NO2 equivalent (grams per test) L3
≤ 750	78	7.8	10.2
$750 < RW \leq 850$	85	8.2	10.2
$850 < RW \le 1.020$	91	8.5	10.2
$1\ 020\ < RW \le\ 1\ 250$	104	9.2	12.2
$1\ 250\ < RW \le\ 1\ 470$	119	9.9	14.3
$1\;470\;< RW \leq\;1\;700$	132	10.5	14.8
$1\ 700\ < RW \le\ 1\ 930$	145	11.2	15.4
$1930 \ < RW \le \ 2150$	158	11.8	15.8
2  150  < RW	172	12.5	16.3

'5.1.1.1.1. For vehicles of category  $M_1$  equipped with automatic transmissions which have been granted type-approval in respect of emissions before 1 October 1981, the limits L3 for nitrogen-oxide emissions given in the table in point 5.1.1.1 of this Directive shall be multiplied by the factor 1.25.

Concerning vehicles other than those of category  $M_1$ , the limits for nitrogen-oxide emissions remain those given in point 5.1.1.1 of Directive 77/102/EEC, multiplied by the factor 1.25.'

#### ANNEX II

# ESSENTIAL CHARACTERISTICS OF THE ENGINE AND INFORMATION CONCERNING THE CONDUCT OF TESTS

Add the following new items:

'3.2.1.3.6. Idling system. Description of settings and relevant requirements in order to comply with point 3.2.1.2.2 of Annex I (configuration of adjustment components).'

'8.1.1. Carbon monoxide content by volume in the exhaust gas, with the engine idling ... % (manufacturer's standard).'

#### ANNEX III

#### TYPE 1 TEST

To point 1.3.1 add the following sentence:

'The second, third and fourth gears may also be used when the driving instructions recommend starting in second gear on level ground, or when first gear is therein defined as a gear reserved for cross-country driving, crawling or towing.'

To point 2.1.4 add the following sentence:

'This requirement also applies, in particular, to the settings for idling (rotational speed and carbon monoxide content of the exhaust gases), for the automatic choke and for the exhaust-gas cleaning system.'

#### Point 2.1.5 to read:

'2.1.5. The intake system of the vehicle tested shall be fitted, beyond the throttle, with a connection making it possible to measure accurately the vacuum in the intake pipe.'

- Point 2.1.7 (new) to read:
- <sup>(2.1.7.</sup> Vehicles designed to operate with catalytic convertors shall be tested with the catalyst removed although these devices may be fitted to vehicles produced to the type approved.'

#### Point 3.2.4 to read:

'3.2.4. A cooling condenser shall be installed between the tail pipe and the inlet valve to the bag or bags, so that the temperature of the gases at the condenser outlet is not reduced below 5 °C. The cooling system should be such as to avoid any condensed water entrainment by the gases flowing through it, and the humidity of the gases in the collecting bag or bags must be less than 90 % at 20 °C.'

In point 3.2.5, for the last sentence, read:

'The volume of the section of the sampling tube leading into the bag shall be less than  $0.03 \text{ m}^3$ .'

Point 4.1.2 to read:

'4.1.2. The brake is adjusted in the following way:'

The existing points 4.1.2, 4.1.3 and 4.1.4 become points 4.1.2.1, 4.1.2.2 and 4.1.2.3.

Point 4.1.2.4 (new) to read:

'4.1.2.4. Other methods of measuring the power necessary for propelling the vehicle (e.g. driveline torque measurement, deceleration measurement, etc.) will also be permitted.'

Point 4.1.2.5 (new) to read:

'4.1.2.5. The brake can only be adjusted on the basis of road tests if the conditions of air pressure and temperature, on the road and at the location of the dynamometer bench, do not differ by more than  $\pm$  15 mbar and  $\pm$  8 °C.'

Point 4.1.3 (new) to read:

'4.1.3. If the preceding method is not applicable, the bench is regulated in order to absorb the power exerted by the driving wheels at a constant speed of 50 km/h in accordance with the provisions of the table in point 4.2. This power is determined according to the method indicated in Annex VII.'

Point 4.1.3.1 (new) to read:

'4.1.3.1. In the case of vehicles other than those of category  $M_1$ , vehicles with a reference mass of more than 1 700 kg, or vehicles all of whose wheels are driven, the power values given in

the table shall be multiplied by the factor 1.3.'

In point 4.2 the table shall be replaced by the following:

Reference mass (RW) of vehicle (kilograms)	Equivalent inertias (kilograms)	Power absorbed by the dynamometer (kilowatts)
≤ 750	680	1.8
$750 < RW \leq 850$	800	2.0
$850 < RW \le 1020$	910	2.2
$1\ 020\ < RW \le\ 1\ 250$	1 130	2.4
$1\ 250\ < RW\ \le\ 1\ 470$	1 360	2.7
$1 \ 470 \ < RW \ \le \ 1 \ 700$	1 590	2.9
$1\ 700\ < RW\ \le\ 1\ 930$	1 810	3.1
$1 930 < RW \leq 2 150$	2 040	3.3
$2 \ 150 \ < RW \ \le \ 2 \ 380$	2 270	3.5
$2 380 < RW \le 2 610$	2 270	3.6
2 610 <rw< td=""><td>2 270</td><td>3.7</td></rw<>	2 270	3.7

To point 4.4 add the following sentence:

'For vehicles with a reference mass of more than 1 700 kg whose engine is fitted with a device for the dilution of exhaust gases (an air pump, for example), a back-pressure not exceeding 10 mbar is allowed.'

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#### ANNEX V

#### TYPE III TEST

In point 2.2 the table shall be replaced by the following:

Condition No	Vehicle speed (km/h)	Weighting factor	Power absorbed by brake
1	Idling	0.25	Nil
2	$50 \pm 2$	0.25	That corresponding to the setting for type-I test
3	$50 \pm 2$	0.50	That for condition No 2, multiplied by the factor 1.7

Delète point 2.3.

Point 2.4: Re-number as 2.3.

A new Annex VII as follows is added:

#### 'ANNEX VII

#### METHOD OF CALIBRATING THE DYNAMOMETER

1.	This Annex describes the method to be used to determine the relationship between the indicated power of the dynamometer and the actual power absorbed by the dynamometer.
	The actual power absorbed by the dynamometer $(P_a)$ is the power absorbed by the brake, plus the power absorbed due to friction within the dynamometer, but not the power loss due to the friction between the tyre and roller.
2.	This method disregards the variations in the internal friction of the roller(s), which are due to the load applied by the vehicle.
3.	According to this method the power absorbed is determined on the basis of the deceler- ation times of the roller(s). The difference between the deceleration time of the driven roller and that of the free roller can be disregarded in the case of two-roller dyna- mometers, i.e. the time to be taken into consideration is that of the driven roller.
4.	The following procedure will be used:
4.1.	Use a flywheel or any other means of simulating the inertia of the mass of the vehicle. Select for this purpose the inertial mass with which the dynamometer is most commonly used.
4.2.	Bring the dynamometer up to speed by placing the vehicle on the rollers, or by any other method.
4.3.	A fifth wheel, revolution counter or any other suitable device may be used to measure the speed(s) of the roller(s).
4.4.	Bring the roller(s) to a speed of 50 km/h and apply a suitable power to the dynamometer in accordance with the table in point 4.2 of Annex III.

- 4.5. Note the power indicated  $(P_i)$ .
- 4.6. Bring the roller(s) to a speed of at least 60 km/h.
- 4.7. Disengage the device used to bring the dynamometer up to speed (there must be no vehicle on the roller(s)).
- 4.8. Note the times taken for the speed of the roller(s) to decrease from 55 to 45 km/h.
- 4.9. The power  $P_a$  is to be calculated using the formula:

$$P_{a} = \frac{M_{1} \cdot (V_{1}^{2} - V_{2}^{2})}{2\,000 \cdot t} = \frac{0.03857 \cdot M_{1}}{t}$$

where:

t

- $P_a$  = power absorbed by the dynamometer in kW,
- $M_1$  = equivalent inertia of the driven roller in kg,
- $V_1$  = initial speed in m/s (55 km/h = 15.28 m/s),
- $V_2$  = final speed in m/s (45 km/h = 12.50 m/s),
  - = time needed by the roller(s) to slow down from 55 to 45 km/h.
- 4.10. Repeat operations 4.4 to 4.9 a sufficient number of times to cover the range of powers set out in Annexes III and V.
- 4.11. Diagram showing the indicated power as a function of the power absorbed at 50 km/h.



Power absorbed  $(P_a)$  at 50 km/h, in kW'

The existing Annex VII becomes Annex VIII.

#### ANNEX VIII

The title to read:

#### 'MODEL

# Annex to the EEC vehicle type-approval certificate concerning pollution of the air by gases from positive-ignition engines

Articles 4 (2) and 10 of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers)

Having regard to the modifications in accordance with Directive 78/665/EEC'

Point 5 to read:

Delete point 5.1.

Point 7.3 to read:

'7.3. Transmission ratio:

I ransmission ratio:
— first gear
— second gear
— third gear
Final drive ratio
Tyres:
— dimensions
— dynamic rolling circumference