SCHEDULE 5 Regulations 2(1) and 11(5)

Purity Criteria

Each miscellaneous additive for which specific purity criteria are specified or referred to below shall not contain—

(a) more than 3 milligrams per kilogram of arsenic;

(b) more than 10 milligrams per kilogram of lead;

(c) more than 50 milligrams per kilogram of copper, or 25 milligrams per kilogram of zinc or 50 milligrams per kilogram of any combination of copper and zinc;

except in so far as those specific purity criteria provide otherwise or in the case of E 957 Thaumatin.

E 170(i) Calcium carbonate

E 170(i)

Description	Fine white microcrystalline or amorphous powder
Content	Not less than 97 per centum of $CaCO_3$ on a volatile matter-free basis
Volatile matter	Not more than 1 per centum (determined by drying at 105°C to constant weight)
Matter insoluble in hydrochloric acid	Shall comply with the requirement for aluminium, iron, phosphate and matter insoluble in hydrochloric acid in the monograph for chalk in the British Pharmacopoeia 1973 at page 93
Arsenic	Not more than 5 mg per kg.
Lead	Not more than 20 mg per kg.
Other inorganic impurities	Not more than 100 mg per kg of any of the following substances, namely antimony, copper, chromium, zinc or barium sulphate, or more than 200 mg per kg of any combination of those substances.

E 200 Sorbic acid

E 200

E 202 Potassium sorbate

E 202

E 203 Calcium sorbate

E 203

E 210 Benzoic acid

E 210

E 211 Sodium benzoate

E 211

E 212 Potassium benzoate

E 212

E 213 Calcium benzoate

E 213

E 214 Ethyl *p*-hydroxybenzoate

E 214

Synonyms	Ethyl 4-hydroxybenzoate
	Ethyl ester of *p*-hydroxybenzoic acid

E 215 Sodium ethyl *p*-hydroxybenzoate

E 215

Synonyms	Ethyl 4-hydroxybenzoate, sodium salt
	Sodium ethyl *para*-hydroxybenzoate

E 216 Propyl *p*-hydroxybenzoate

E 216

Synonyms	Propyl 4-hydroxybenzoate
	Propyl *para*-hydroxybenzoate *n*-propyl *p*-hydroxybenzoate

E 217 Sodium propyl *p*-hydroxybenzoate

E 217

Synonyms	Propyl 4-hydroxybenzoate, sodium salt
	Sodium propyl *para*-hydroxybenzoate
	Sodium *n*-propyl *p*-hydroxybenzoate

E 218 Methyl *p*-hydroxybenzoate

E 218

Synonyms	Methyl 4-hydroxybenzoate Methyl *para*-hydroxybenzoate

E 219 Sodium methyl *p*-hydroxybenzoate

E 219

Synonyms	Methyl 4-hydroxybenzoate, sodium salt Sodium methyl *para*-hydroxybenzoate

E 220 Sulphur dioxide

E 220

E 221 Sodium sulphite (anhydrous or heptahydrate)

E 221

E 222 Sodium hydrogen sulphite

E 222

Synonym	Acid sodium sulphite

E 223 Sodium metabisulphite

the appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 67/428/EEC and Council Directive 76/463/EEC.

E 224 Potassium metabisulphite

E 224

The appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 67/428/EEC.

E 226 Calcium sulphite

E 226

E 227 Calcium hydrogen sulphite

the appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 76/463/EEC.

E 228 Potassium hydrogen sulphite

E 228

Synonyms	Potassium bisulhite Potassium acid sulphite

The appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 86/604/EEC(**1**).

E 230 Biphenyl, diphenyl

E 230

E 231 Orthophenyl phenol

E 231

Synonym	2-Hydroxybiphenyl

E 232 Sodium orthophenyl phenol

E 232

Synonyms	Sodium biphenyl-2-yl-oxide Sodium orthophenylphenate

E 233 Thiabendazole

E 233

Synonyms	2-(Thiazol-4-yl) benzimidazole 2-(4-thiazolyl) benzimidazole

The appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 76/463/EEC.

E 234 Nisin

E 234

The criteria in the monograph for nisin contained in the Nutrition Meetings Report Series No. 45A (1969) of the United Nations' Food and Agriculture Organisation at page 53.

E 239 Hexamethylene tetramine

E 239

(**1**) O.J. No. L352, 13.12.86, p. 45

Synonym	Hexamine

E 249 Potassium nitrite

the appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 76/463/EEC.

In the case of:—

E 250 Sodium nitrite

E 250

E 251 Sodium nitrate

E 251

E 252 Potassium nitrate

the appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 67/428/EEC and Council Directive 76/463/EEC.

In the case of:—

E 260 Acetic acid

E 260

E 261 Potassium acetate

the appropriate specific purity criteria contained in Council Directive 65/66/EEC.

E 262(i) Sodium acetate

E 262(i)

Sodium acetate, anhydrous

The criteria in the monograph for sodium acetate, anhydrous contained in the Food Chemicals Codex 1972 at page 718.

Sodium acetate

The criteria in the monograph for sodium acetate contained in the Food Chemicals Codex 1972 at page 717 except that the alkalinity shall be not more than 0.1 per centum (as sodium carbonate, Na_2CO_3).

In the case of:—

E 262(ii) Sodium diacetate

E 262(ii)

Synonym	Sodium hydrogen diacetate

E 263 Calcium acetate

the appropriate specific purity criteria contained in Council Directive 65/66/EEC.

E 270 Lactic acid

E 270

The specific purity criteria for lactic acid contained in Council Directive 65/66/EEC.

E 280 Propionic acid

E 280

E 281 Sodium propionate

E 281

E 282 Calcium propionate

the appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 67/428/EEC and Council Directive 76/463/EEC.

E 283 Potassium propionate

E 283

The appropriate specific purity criteria contained in Council Directive 65/66/EEC as amended by Council Directive 76/463/EEC.

E 290 Carbon dioxide

E 290

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

E 296 Malic acid

E 296

DL-Malic acid

The criteria in the monograph for malic acid contained in the Food Chemicals Codex 1972 at page 484 as amended by the Second Supplement to that Codex at page 27, except that the melting range shall be 130°C to 132°C (corrected) and that the method for determining the melting range shall be that specified or a method of equivalent accuracy.

L-Malic Acid

Description	White or nearly white crystalline powder or granules
Content Melting range	Not less than 99 per centum of $C_4H_6O_5$. 99°C to 101°C.
Specific rotation [α] 20°C D	Not less than –2.4° and not more than –2.2° using a solution containing 8.5g L-malic and in 100 ml water.
Malic acid Fumaric acid Residue on ignition Water insoluble matter	Shall comply with the limits given in the }monograph for malic acid in the Food Chemicals Codex 1972 at page 484.

E 297 Fumaric acid

E 297

The criteria in the monograph for fumaric acid contained in the Food Chemicals Codex 1972 at page 331.

E 300 Ascorbic acid

E 300

E 301 Sodium ascorbate

E 301

E 302 Calcium ascorbate

E 302

E 304 Fatty acid esters of ascorbic acid

E 304

E 304(i) Ascorbyl palmitate

E 304(i)

E 306 Tocopherol-rich extract

E 306

E 307 Alpha-tocopherol

E 307

E 308 Gamma-tocopherol

E 308

E 309 Delta-tocopherol

E 309

E 310 Propyl gallate

E 310

E 311 Octyl gallate

E 311

E 312 Dodecyl gallate

E 312

E 320 Butylated hydroxyanisole (BHA)

E 320

E 321 Butylated hydroxytoluene (BHT)

the appropriate specific purity criteria contained in Council Directive 78/664/EEC(**2**).

E 322 Lecithins

The specific purity criteria for lecithins contained in Council Directive 78/664/EEC as amended by Article 1.2 of Council Directive 82/712/EEC(**3**).

In the case of:—

E 325 Sodium lactate

E 325

E 326 Potassium lactate

E 326

E 327 Calcium lactate

E 327

E 330 Citric acid

E 330

(**2**) O.J. No. L223, 14.8.78, p. 30
(**3**) O.J. No. L297, 23.10.82, p. 31

E 331(i) Monosodium citrate

E 331(i)

Synonym	Sodium dihydrogen citrate

E 331(ii) Disodium citrate

E 331(ii)

E 331(iii) Trisodium citrate

E 331(iii)

E 332(i) Monopotassium citrate

E 332(i)

Synonym	Potassium dihydrogen citrate

E 332(ii) Tripotassium citrate

E 332(ii)

E 333(i) Monocalcium citrate

E 333(i)

E 333(ii) Dicalcium citrate

E 333(ii)

E 333(iii) Tricalcium citrate

E 333(iii)

E 334 L-(+)-Tartaric acid

E 334

E 335(i) Monosodium L-(+)-tartrate

E 335(i)

E 335(ii) Disodium L-(+)-tartrate

E 335(ii)

E 336(i) Monopotassium L-(+)-tartrate

E 336(i)

E336(ii) Dipotassium L-(+)-tartrate

E336(ii)

E 337 Sodium potassium L-(+)-tartrate

E 337

Synonym	Potassium sodium tartrate

E 338 Phosphoric acid

E 338

Synonym	Orthophosphoric acid

E 339(i) Monosodium phosphate

E 339(i)

Synonym	Monosodium orthophosphate

E 339(ii) Disodium phosphate

E 339(ii)

Synonym	Disodium orthophosphate Disodium hydrogen orthophosphate

E 339(iii) Trisodium phosphate

E 339(iii)

Synonym	Trisodium orthophosphate

E 340(i) Monopotassium phosphate

E 340(i)

Synonyms	Monodipotassium orthophosphate Potassium dihydrogen orthophosphate

E 340(ii) Dipotassium phosphate

E 340(ii)

Synonyms	Dipotassium orthophosphate Dipotassium hydrogen orthophosphate

E 340(iii) Tripotassium phosphate

E 340(iii)

Synonym	Tripotassium orthophosphate

E 341(i) Monocalcium phosphate

E 341(i).

Synonyms	Monocalcium orthophosphate Calcium tetrahydrogen diorthophosphate

E 341(ii) Dicalcium phosphate

E 341(ii).

Synonyms	Dicalcium orthophosphate Calcium hydrogen orthophosphate

E 340(iii) Tricalcium phosphate

E 340(iii).

Synonyms	Tricalcium orthophosphate Tricalcium diorthophosphate

the appropriate specific purity criteria contained in Council Directive 78/664/EEC.

E 350(i) Sodium malate

E 350(i)

Description	Colourless or almost colourless aqueous solution. Sodium malate may be derived from either DL-malic acid or L-malic acid.
Content	Not less than 59.5 per centum of $C_4H_4O_5Na_2$.
Maleic acid	Not more than 0.05 per centum calculated on the $C_4H_4O_5Na_2$ content.

E 350(ii) Sodium hydrogen malate

E 350(ii)

Description	White odourless powder. Sodium hydrogen malate may be derived from either DL-malic acid or L-malic acid.
Content	Not less than 99 per centum of $C_4H_5O_5Na$ on a volatile matter-free basis.

Volatile matter	Not more than 2 per centum (determined by drying at 110°C for 3 hours)
Maleic acid	Not more than 0.05 per centum.

E 351 Potassium malate

E 351

Description	Colourless or almost colourless aqueous solution. Potassium malate may be derived from either DL-malic acid or L-malic acid.
Content	Not less than 59.5 per centum of $C_4H_4O_5K_2$
Maleic acid	Not more than 0.05 per centum calculated on the $C_4H_4O_5K_2$ content.

E 352(i) Calcium malate

E 352(i)

Description	White odourless powder. Calcium malate may be derived from either DL-malic acid or L-malic acid
Content	Not less than 97.5 per centum of $C_4H_4O_5Ca$ on a volatile matter-free basis.
Volatile matter	Not more than 2 per centum (determined by drying at 110°C for 3 hours)
Maleic acid	Not more than 0.05 per centum.
Fluoride	Not more than 30 mg per kg on a volatile matter-free basis

E 352(ii) Calcium hydrogen malate

E 352(ii)

Description	White odourless powder. Calcium hydrogen malate may be derived from either DL-malic acid or L-malic acid
Content	Not less than 97.5 per centum of $(C_4H_5O_5)_2Ca$ on a volatile matter-free basis.
Volatile matter	Not more than 2 per centum (determined by drying at 110°C for 3 hours)
Maleic acid	Not more than 0.05 per centum.
Fluoride	Not more than 30 mg per kg on a volatile matter-free basis

E 353 Metatartaric acid

E 353

Description	White or yellow powder which consists chiefly of a mixture of polyesters obtained by the controlled dehydration of L-(+)-tartaric acid together with unchanged L-(+)-tartaric acid.
Specific absorption 1 per centum E 1 cm	Not more than 1.5×10^{-2} at 430 nm. (determined using a filtered aqueous solution).
Identification	Place 5 to 10 mg of sample in a test tube. Add 2 ml sulphuric acid (about 94 per centum H_2SO_4) plus two drops of resorcinol reagent (2 g. resorcinol dissolved in 100 ml water plus 0.5 ml sulphuric acid) and heat to 150°C. An intense violet colour is produced.
Content	Not less than the equivalent of 105 per centum of tartaric acid ($C_4H_6O_6$). The esterified tartaric acid content shall be not less than 27 per centum and not more than 38 per centum of the tartaric acid equivalent when determined by the following method: Add three drops of bromothymol blue indicator (0.04 per centum weight/volume solution of bromothymol blue in 95 per centum volume/volume ethanol) to 50 ml of freshly prepared 2 per centum weight/volume cold aqueous solution of metatartaric acid. Titrate with N aqueous sodium hydroxide solution to a blue-green colour (T_1ml.). Add a further 20 ml of N aqueous sodium hydroxide solution and leave for 2 hours at room temperature. Titrate with N aqueous sulphuric acid solution (T_2ml). Calculations: Tartaric acid equivalent per centum $= 7.5\ (T_1 + 20 - T_2)$ Esterfied tartaric acid per centum $= \frac{100\ (20 - T_2)}{T_1 = 20 - T_2}$
Specific rotation [α] 20°C D	Not less than + 12.5° and not more than + 13.5° (using a filtered 10 per centum weight/volume aqueous solution).

Matter insoluble in water (at about 20°C)	Not more than 2.5 per centum (insoluble matter weighed after drying for 3 hours at 70°C in a vacuum oven).
Pyruvic acid	Not more than 0.5 per centum.

E 355 Adipic acid

E 355

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

E 363 Succinic acid

E 363

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

E 380 Triammonium citrate

E 380

Synonym	Ammonium citrate

The criteria in the monograph for ammonium citrate contained in the British Pharmaceutical Codex 1973 at page 830.

E 385 Calcium disodium ethylenediamine — N N N'N' — tetra-acetate

E 385

Synonym	Sodium calciumedate

The criteria in the monograph for sodium calciumedetate contained in the British Pharmacopoeia 1973 at page 425.

E 400 Alginic acid

E 400

E 401 Sodium alginate

E 401

E 402 Potassium alginate

E 402

E 403 Ammonium alginate

E 403

E 404 Calcium alginate

E 404

E 405 Propane-1,2-diol alginate

E 405

Synonym	Propylene glycol alginate

E 406 Agar

E 406

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

E 407 Carrageenan

E 407

The specific purity criteria for carrageenan contained in Council Directive 78/663/EEC, as amended by Article 1 of Commission Directive 90/612/EEC(**4**).

E 410 Locust bean gum

E 410

Synonym	Carob gum

E 412 Guar gum

E 412

E 413 Tragacanth

E 413

E 414 Acacia

E 414

Synonym	Gum arabic

E 415 Xanthan gum

E 415

The specific purity criteria for xanthan gum contained in Council Directive 78/663/EEC, as amended by Article 1.2(b) of Council Directive 82/504/EEC.

(**4**) O.J. No. L326, 24.11.90, p. 58

E 416 Karaya gum

E 416

Synonym	Sterculia gum

The criteria in the monograph for karaya gum contained in the Food Chemicals Codex 1981 at page 157.

E 420(i) Sorbitol

E 420(i)

E 420(ii) Sorbitol syrup

E 420(ii)

E 421 Mannitol

the appropriate specific purity criteria contained in Commission Directive 95/31/EC(**5**).

E 422 Glycerol

E 422

As set out in the Annex to Council Directive 78/663/EEC.

E 432 Polyoxyethylene (20) sorbitan monolaurate

E 432

Synonym	Polysorbate 20

The criteria in the monograph for polysorbate 20 contained in the Food Chemicals Codex 1981 at page 234.

E 433 Polyoxyethylene (20) sorbitan monooleate

E 433

Synonym	Polysorbate 80

The criteria in the monograph for polysorbate 80 contained in the Food Chemicals Codex 1981 at page 236 except that the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

E 434 Polyoxyethylene (20) sorbitan monopalmitate

E 434

(**5**) O.J. No. L178, 28.7.95, p. 1

Synonym	Polysorbate 40

The criteria in the monograph for polyoxyethylene (20) sorbitan monopalmitate contained in the Food and Nutrition Paper No. 4 (1978) of the United Nations' Food and Agriculture Organisation at page 278.

E 435 Polyoxyethylene (20) sorbitan monostearate

E 435

Synonym	Polysorbate 60

The criteria in the monograph for polysorbate 60 contained in the Food Chemicals Codex 1981 at page 235 except that the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

E 436 Polyoxyethylene (20) sorbitan tristearate

E 436

Synonym	Polysorbate 65

The criteria in the monograph for polysorbate 65 contained in the Food Chemicals Codex 1981 at page 235 except that the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

E 440(i) Pectin

E 440(i)

E 440(ii) Amidated pectin

the appropriate specific purity criteria contained in Council Directive 78/663/EEC.

E 442 Ammonium phosphatides

E 442

Description	Ammonium phosphatides exist as an unctuous semi-solid (at 25°C). They consist essentially of a mixture of the ammonium salts of phosphatidic acids derived from partially hardened rapeseed oil together with unreacted partially hardened rape-seed oil.
Matter insoluble in petroleum ether (40°C-60°C)	Total: Not more than 2.5 per centum. Inorganic matter: not more than 0.2 per centum.
pH of an aqueous extract of melted ammonium phosphatides	Not less than 6.0 and not more than 8.0
Phosphorus	Not less than 3.0 per centum and not more than 3.4 per centum.

Ammonium nitrogen	Not less than 1.2 per centum and not more than 1.5 per centum.
Arsenic	Not more than 5 mg per kg.

E 450(i) Disodium diphosphate

E 450(i)

E 450(ii) Trisodium diphosphate

E 450(ii)

E 450(iii) Tetrasodium diphosphate

E 450(iii)

E 450(v) Tetrapotassium diphosphate

the appropriate specific purity criteria contained in Council Directive 78/663/EEC.

E 450(vi) Dicalcium diphosphate

E 450(vi)

Synonyms	Dicalcium pyrophosphate Calcium pyrophosphate
The criteria in the monograph for calcium pyrophosphate contained in the Food Chemicals Codex 1972 at page 153.	

E 451(i) Pentasodium triphosphate

E 451(i)

E 451(ii) Pentapotassium triphosphate

E 451(ii)

E 452(i) Sodium polyphosphate

E 452(i)

E 452(ii) Potassium polyphosphate

the appropriate specific purity criteria contained in Council Directive 78/663/EEC.

E 452(iv) Calcium polyphosphates

E 452(iv)

Description	Calcium polyphosphates exist as a fine white powder or crystals or colourless glassy platelets. They are reproducible heterogeneous

	mixtures of calcium salts of condensed polyphosphoric acids of general formula: $H(n+2)P_nO(3n+1)$ where n shall be not less than 2
Content (expressed as P_2O_5)	Not less than 50 per centum and not more 71 per centum of an anhydrous basis.
pH (1 per centum aqueous solution)	For water soluble phosphates only: not less than 4.0 and not more than 9.0.
Cyclic phosphate	Not more than 8 per centum calculated on the P_2O_5 content.
Fluoride	Not more than 15 mg per kg calculated on the P_2O_5 content.

E 460(i) Microcrystalline cellulose

E 460(i)

The specific purity criteria for microcrystalline cellulose contained in Council Directive 78/663/EEC, as amended by Article 1.2(c) of Council Directive 82/504/EEC.

E 460(ii) Powdered cellulose

E 460(ii)

Synonym	Alpha-cellulose

The criteria in the monograph for cellulose, powdered, contained in the Food Chemicals Codex 1981 at page 80. Additionally the level of lead present shall not exceed 1 mg per kg.

E 461 Methylcellulose

E 461

E 463 Hydroxypropylcellulose

E 463

E 464 Hydroxypropylmethylcellulose

E 464

E 465 Ethylmethylcellulose

E 465

Synonym	Methylethylcellulose

E 466 Carboxymethylcellulose

E 466

Synonym	Sodium carboyxmethylcellulose

The specific purity criteria for carboxymethylcellulose contained in Council Directive 78/663/EEC, as amended by Article 1 of Commission Directive 90/612/EEC.

E 470a Sodium, potassium and calcium salts of fatty acids

E 470a

E 471 Mono- and diglycerides of fatty acids

E 471

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

E 472(a)

Synonym	Acetylated mono- and diglycerides

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

E 472(b).

Synonyms	Lactylated mono- and diglycerides
	Lactoglycerides

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

E 472(c)

Synonym	Citroglycerides

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

E 472(d)

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

E 472(e)

Synonym	Mono- and diacetyl tartaric acid esters of mono-and diglycerides

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

the appropriate specific purity criteria contained in Council Directive 78/663/EEC.

E 473 Sucrose esters of fatty acids

E 473

The specific purity criteria for sucrose esters of fatty acids contained in Council Directive 78/663/EEC, as amended by Article 1 of Commission Directive 90/612/EEC and Article 1 of Commission Directive 92/4/EEC(**6**).

E 474 Sucroglycerides

E 474

The specific purity criteria for sucroglycerides contained in Council Directive 78/663/EEC, as amended by Article 1.2(e) of Council Directive 82/504/EEC.

E 475 Polyglycerol esters of fatty acids

E 475

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

E 476 Polyglycerol polyricinoleate

E 476

Synonym of castor oil.	Polyglycerol esters of polycondensed fatty acids
Description	The polyglycerol esters of polycondensed fatty acids of castor oil exist as a highly viscous liquid (at 25°C). They are essentially a complex mixture of the partial esters and ethers of polyglycerol with linearly interesterified (polycondensed) fatty acids derived from castor oil. The polycondensed castor oil fatty acids are prepared by condensation in the absence of oxygen and have an average of about 5 fatty acid residues per molecule. The polyglycerol moiety is predominantly di-, tri- and tetra-glycerol and contains not more than 10 per centum of polyglycerols equal to or higher than heptaglycerol.
Refractive index, $m^{65}D°C$	Not less than 1.4630 and not more than 1.4665.
Hydroxyl value	Not less than 80 and not more than 100.
Iodine value	Not less than 72 and not more than 103 (Wijs).
Acid value	Not more than 6 mg KOH per g.

(**6**) O.J. No. L55, 29.2.92, p. 96

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

E 477

Synonym	Propylene glycol esters of fatty acids.

The specific purity criteria for propane-1,2-diol esters of fatty acids contained in Council Directive 78/663/EEC, as amended by Article 1.2(f) of Council Directive 82/504/EEC.

E 481 Sodium stearoyl-2-lactylate

E 481

E 482 Calcium stearoyl-2-lactylate

E 482

E 483 Stearyl tartrate

the appropriate specific purity criteria contained in Council Directive 78/663/EEC.

E 491 Sorbitan monostearate

E 491

The criteria in the monograph for sorbitan monostearate contained in the Food Chemicals Codex 1981 at page 307 except that the final sentence of the description (requirement to conform to the regulations of the federal Food and Drug Administration pertaining to specifications for fats or fatty acids derived from edible sources) shall be deleted.

E 492 Sorbitan tristearate

E 492

The criteria in the monograph for sorbitan tristearate contained in the Food and Nutrition Paper No. 4 (1978) of the United Nations' Food and Agriculture Organisation at page 297.

E 493 Sorbitan monolaurate

E 493

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

E 494 Sorbitan monooleate

E 494

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

E 495 Sorbitan monopalmitate

E 495

The criteria in the monograph for sorbitan monopalmitate contained in the Food and Nutrition Paper No. 4 (1978) of the United Nations' Food and Agriculture Organisation at page 293.

E 500(i) Sodium carbonate

E 500(i)

Description	Colourless crystals or white granular or crystalline powder. The anhydrous salt is hygroscopic and the decahydrate is efflorescent.
Content	Not less than 98 per centum of Na_2CO_2 on a volatile matter-free basis.
Volatile matter	Not more than: 2 per centum for the non-hydrated substance; 15 per centum for the monohydrate; 65 per centum for the decahydrate; (determined by the method for loss on drying in the monograph for sodium carbonate in the Food Chemicals Codex 1972 at page 731.)
Matter insoluble in dilute ammonia solution	Not more than 0.12 per centum on a volatile matter-free basis, determined by the following method: Boil 5 g of hydrated sodium carbonate, or 2.5 g of anhydrous sodium carbonate, with 50 ml of water and 10 ml of dilute ammonia solution (about 10 per centum NH_3). Filter and wash the residue with water, then ignite to constant weight.
Sulphate	Not more than 0.4 per centum on a volatile matter-free basis.
Chloride	Not more than 0.4 per centum on a volatile matter-free basis
Iron	Not more than 40 mg per kg on a volatile matter-free basis.

E 500(ii) Sodium hydrogen carbonate

E 500(ii)

Synonym	Sodium bicarbonate

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

E 500(iii) Sodium sesquicarbonate

E 500(iii)

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

E 501(i) Potassium carbonate

E 501(i)

Description	The anhydrous form is a white granular powder. The hydrated form consists of small white translucent crystals or granules.
Content	Not less than 98 per centum K_2CO_3 on a volatile matter-free basis.
Volatile matter	Not more than: 2 per centum for the non-hydrated substance; 18 per centum for the hydrated substance; (determined by drying at 180°C for 4 hours)

E 501(ii) Potassium hydrogen carbonate

E 501(ii)

Synonym	Potassium bicarbonate

The criteria in the monograph for potassium bicarbonate contained in the Food Chemicals Codex 1972 at page 642.

E 503(i) Ammonium carbonate

E 503(i)

The criteria in the monograph for ammonium carbonate contained in the Food Chemicals Codex 1972 at page 45.

E 503(ii) Ammonium hydrogen carbonate

E 503(ii)

Synonym	Ammonium bicarbonate

The criteria in the monograph for ammonium bicarbonate contained in the Food Chemicals Codex 1972 at page 44.

E 504 Magnesium carbonates

E 504

Magnesium carbonate, heavy

The criteria in the monograph for heavy magnesium carbonate contained in the European Pharmacopoeia Vol. 1, 1969 at page 322.

Magnesium carbonate, light

The criteria in the monograph for light magnesium carbonate contained in the European Pharmacopoeia Vol. 1, 1969 at page 321.

E 507 Hydrochloric acid

E 507

The criteria in the monograph for concentrated hydrochloric acid contained in the European Pharmacopoeia Vol. II, 1971 at page 145.

E 508 Potassium chloride

E 508

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

E 509 Calcium chloride

E 509

Calcium chloride, anhydrous

The criteria in the monograph for calcium chloride, anhydrous contained in the Food Chemicals Codex 1972 at page 124.

Calcium chloride

Description	The dihydrate consists of deliquescent white odourless fragments or granules. The hexahydrate consists of deliquescent colourless and odourless crystals.
Content	Not less than:

	98 per centum of $CaCl_2$. $2H_2O$ for the dihydrate; 97 per centum of $CaCl_2$. $6H_2O$ for the hexahydrate.
Magnesium and alkali salts	Not more than 2 per centum, determined by the method in the monograph for calcium chloride contained in the Food Chemicals Codex 1972 at page 123 except that the weight of the residue shall not exceed 10 mg.
Fluoride	Not more than 40 mg per kg on an anhydrous basis.

E 513 Sulphuric acid

E 513

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

E 514(i) Sodium sulphate

E 514(i)

The criteria in the monograph for sodium sulphate contained in the Food Chemicals Codex 1972 at page 775.

E 515(i) Potassium sulphate

E 515(i)

The criteria in the monograph for potassium sulphate contained in the Food Chemicals Codex 1972 at page 670.

E 516 Calcium sulphate

E 516

The criteria in the monograph for calcium sulphate contained in the Food Chemicals Codex 1972 at page 163.

E 522 Aluminium potassium sulphate

E 522

Synonyms	Potassium aluminium sulphate Potash alum.

The criteria in the monograph for alum contained in the European Pharmacopoeia Vol. 1, 1969 at page 243.

E 524 Sodium hydroxide

E 524

The criteria in the monograph for sodium hydroxide contained in the Food Chemicals Codex 1972 at page 743.

E 525 Potassium hydroxide

E 525

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

E 526 Calcium hydroxide

E 526

Description	Soft white powder.
Solubility	1 g dissolves in 630 ml of water at 25°C, and in 1300 ml of boiling water. Soluble in glycerol and in a saturated solution of sucrose. Insoluble in ethanol.
Content	Not less than 92 per centum of $Ca(OH)_2$.
Matter insoluble in dilute Hydrochloric acid (about 10 per centum weight/ volume HCL)	Not more than 0.5 per centum.
Magnesium and alkali salts	Not more than 6 per centum, determined by the method in the monograph for calcium hydroxide contained in the Food Chemicals Codex 1972 at page 131 except that the weight of the residue shall not exceed 15 mg.
Carbonate	When 2 g of calcium hydroxide is mixed with 50 ml of water and an excess of dilute hydrochloric acid (approximately 2N) is added, no more than a slight effervescence is produced.
Sulphate	Not more than 0.35 per centum.
Fluoride	Not more than 50 mg per kg.

E 527 Ammonium hydroxide

E 527

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

E 528 Magnesium hydroxide

E 528

The criteria in the monograph for magnesium hydroxide contained in the British Pharmaceutical Codex 1973 at page 277.

E 529 Calcium oxide

E 529

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

E 530 Magnesium oxide

E 530

Magnesium oxide, heavy

Description	White fine odourless powder.
Solubility	Practically insoluble in water. Soluble in dilute acids with, at most, slight effervescence.
Apparent volume	20 g of heavy magnesium oxide occupies a volume of about 50 ml.
Content	Not less than 98 per centum of MgO calculated with reference to the ignited substance and determined by the assay method contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol. I, 1969 at page 319.
Loss on ignition	Not more than 5 per centum (determined by ignition at 900°C to 950°C to constant weight).
Matter soluble in water	Not more than 2 per centum, determined by the method for soluble substances contained in the monograph for light magnesium oxide in the European Pharmacopoeia Vol. I, 1969 at page 319.
Matter insoluble in acetic acid	Not more than 0.1 per centum when determined by the following method: Dissolve 5 g heavy magnesium oxide in a mixture of 70 ml acetic acid (see *Note 1*) and 30 ml water. Heat to boiling for 2 minutes, cool and dilute to 100 ml with dilute acetic acid (see *Note 2*). Filter through a sintered glass filter. Any residue, after washing with water, drying

	and ignition at 600°C, shall weigh not more than 5 mg.
Sulphate	Not more than 0.75 per centum.
Chloride	Not more than 0.07 per centum.
Calcium	Not more than 2 per centum.
Iron	Not more than 0.1 per centum.
Arsenic	Not more than 4 mg per kg.
Heavy metals	Not more than 40 mg per kg.

Note 1:

Acetic acid: contains not less than 29 per centum weight/volume and not more than 31 per centum weight/volume of $C_2H_4O_2$. Dilute 30 g glacial acetic acid (98 per centum weight/volume $C_2H_4O_2$) to 100 ml with water.

Note 2:

Dilute acetic acid: contains not less than 11.5 per centum weight/volume and not more than 12.5 per centum weight/volume of $C_2H_4O_2$. Dilute 12 g or 11.7 ml glacial acetic acid (98 per centum weight/volume $C_2H_4O_2$) to 100 ml with water and, if necessary, adjust the concentration of the solution.

Magnesium oxide, light

The criteria in the monograph for light magnesium oxide contained in the European Pharmacopoeia Vol I, 1969 at page 319.

E 535 Sodium ferrocyanide

E 535

Synonyms	Sodium hexacyanoferrate (II)

The criteria in the monograph for sodium ferrocyanide contained in the Food Chemicals Codex 1972 at page 741.

E 536 Potassium ferrocyanide

E 536

Synonym	Potassium hexacyanoferrate (II)
Description	Odourless lemon yellow crystals.
Solubility	Soluble in water and in acetone. Insoluble in ethanol, in ether and in hydrocarbons.
Content	Not less than 98 per centum of $K_4Fe(CN)_6.3H_2O$.
Free moisture	Not more than 1 per centum (determined by the method for free moisture in the monograph

	for sodium ferrocyanide in the Food Chemicals Codex 1972 at page 741).
Chloride	Not more than 0.1 per centum.
Sulphate	Not more than 0.1 per centum.

E 541 Sodium aluminium phosphate, acidic

E 541

The criteria in the monograph for sodium aluminium phosphate, acidic contained in the Food Chemicals Codex 1972 at page 722.

E 551 Silicon dioxide

E 551

Synonym	Silica, chemically prepared.
Description	Silica aerogel is a whie fluffy powdered or granular microcellular silica. Hydrated silica is a precipitated hydrated silicon dioxide occurring as a fine white amorphous powder or as beads or granules.
Content	Silica aerogel: not less than 90 per centum of SiO_2. Hydrated silica: not less than 91 per centum of SiO_2 on a volatile matter-free basis.
Volatile matter	Hydrated silica: not more than 7 per centum (determined by drying at 105°C for 2 hours).
Loss on ignition	Not more than 13 per centum (determined by ignition at 1000°C to constant weight).
Soluble ionisable salts (expressed as Na_2SO_4)	Not more than 5 per centum.

E 552 Calcium silicate

E 552

Description	White to off-white free-flowing powder.
Solubility	Insoluble in water. Forms a gel with mineral acids.
Content:	
(expressed as SiO_2)	Not less than 72 per centum and not more than 78 per centum on a volatile matter-free basis.
(expressed as CaO)	Not less than 16 per centum and not more than 21 per centum on a volatile matter-free basis.

(expressed as Na_2O)	Not less than 2 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter	Not more than 6 per centum (determined by drying at 105°C for 2 hours).
Loss on ignition	Not less than 7 per centum and not more than 14 per centum (determined by ignition at 1000°C to constant weight).

E 553a(i) Magnesium silicate

E 553a(i)

The criteria in the monograph for magnesium silicate contained in the Food Chemicals Codex 1972 at page 479.

E 553a(ii) Magnesium trisilicate

E 553a(ii)

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

E 553b Talc

E 553b

Description	Talc is a native hydrous magnesium silicate sometimes containing a small proportion of aluminium silicate

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

E 554 Sodium aluminium silicate

E 554

Synonyms	Aluminium sodum silicate. Sodium aluminosilicate. Sodium silicoaluminate.
Description	Fine white amorphous powder or beads.
Content:	
(expressed as SiO_2)	Not less than 70 per centum and not more than 80 per centum on a volatile matter-free basis.

(expressed as Al_2O_3)	Not less than 8 per centum and not more than 11 per centum on a volatile matter-free basis.
(expressed as Na_2O)	Not less than 5 per centum and not more than 10 per centum on a volatile matter-free basis.
Volatile matter	Not more than 8 per centum (determined by drying at 105°C for 2 hours)
Loss on ignition	Not less than 10 per centum and not more than 14 per centum (determined by ignition at 1000°C to constant weight).

E 556 Calcium aluminium silicate

E 556

Synonyms	Aluminium calcium silicate. Calcium aluminosilicate. Calcium silicoaluminate.
Description	Fine white free-flowing powder.
Content:	
(expressed as SiO_2)	Not less than 44 per centum and not more than 50 per centum on a volatile matter-free basis.
(expressed as Al_2O_3)	Not less than 3 per centum and not more than 5 per centum on a volatile matter-free basis.
(expressed as CaO)	Not less than 32 per centum and not more than 38 per centum on a volatile matter-free basis.
(expressed as Na_2O)	Not less than 0.5 per centum and not more than 4 per centum on a volatile matter-free basis.
Volatile matter	Not more than 10 per centum (determined by drying at 105°C for 2 hours).
Loss on ignition	Not less than 14 per centum and not more than 18 per centum (determined by ignition at 1000°C to constant weight).

E 559 Aluminium silicate (Kaolin)

E 559

Kaolin, heavy

The criteria in the monograph for heavy kaolin contained in the British Pharmaccopoeia 1968 at page 538 as amended by the 1969 Addendum at page 54.

Kaolin, light

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

E 575 Glucono-delta-lactone

E 575

Synonym	*D-Glucono-l,5-lactone*

The criteria in the monograph for glucono *delta*-lactone contained in the Food Chemicals Codex 1972 at page 346.

E 576 Sodium gluconate

E 576

The criteria in the monograph for sodium gluconate contained in the Food Chemicals Codex 1972 at page 742.

E 577 Potassium gluconate

E 577

Description	White free-flowing powder.
Solubility	Freely soluble in water. Practically insoluble in ethanol and in ether.
Content	Not less than 97 per centum of $C_6H_{11}O_7K$ on a volatile matter-free basis.
Volatile matter	Not more than 3 per centum (determined by drying in a vacuum at 105°C for 4 hours).
Reducing substances (expressed as glucose)	Not more than 0.5 per centum.

E 578 Calcium gluconate

E 578

The criteria in the monograph for calcium gluconate contained in the Food Chemicals Codex 1972 at page 129.

E 621 Monosodium glutamate

E 621

Synonyms	Sodium hydrogen L-glutamate. Sodium glutamate. Glutamic acid, sodium salt.

Formula	$C_5H_8NNaO_4.H_2O$ (molecular weight 187.13).

The criteria in the monograph for monosodium L-glutamate contained in the Food Chemicals Codex 1981 at page 203.

E 627 Disodium guanylate

E 627

Synonyms	Guanosine 5' -(disodium phosphate) Sodium 5'-guanylate. Disodium guanosine 5'-monophosphate.
Formula	$C_{10}H_{12}N_5Na_2O_8P.xH_2O$ (molecular weight (anhydrous) 407.20).

The criteria in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105.

E 631 Disodium inosinate

E 631

Synonyms	Inosine 5'-(disodium phosphate) Sodium 5'-inosate. Disodium inosine 5'-monophosphate.
Formula	$C_{10}H_{11}N_4Na_2O_8P.xH_2O$ (molecular weight (anhydrous) 392.19).

The criteria in the monograph for disodium inosinate contained in the Food Chemicals Codex 1981 at page 106.

E 635 Disodium 5' -ribonucleotides

E 635

Description	White or nearly white crystalline powder consisting of a mixture of guanosine 5' -(disodium phosphate) and inosine 5' -(disodium phosphate) in approximately equal proportions. Soluble in water, practically insoluble in ethanol.
Content	Not less than 97% and not more than 102% of $C_{10}H_{12}N_5Na_2O_8P$ and $C_{10}H_{11}N_4Na_2O_8P$, and not less than 47% and not more than 53% of $C_{10}H_{12}N_5Na_2O_8P$ or of $C_{10}H_{11}N_4Na_2O_8P$, in every case calculated on an anhydrous basis.
Moisture	Not less than 22% and not more than 26% (Karl Fischer).
pH (5% aqueous solution)	Not less than 7.0 and not more than 8.5.

Ammonium salts	Place 100 mg of sample in a test tube. Add 50 mg magnesium oxide plus 1 ml of water. Heat on a water bath for 5 minutes; the vapour evolved does not affect the colour of moist litmus paper.
Amino acids	Place 5 ml of a 0.1% (weight/volume) solution in a test tube. Add 1 ml of a 2% (weight/volume) solution of ninhydrin and heat for 3 minutes; no blue colour is produced.
Other nucleotides	The paper chromatogram obtained when sodium 5' -ribonucleotide is analysed using the procedure described for “other nucleotides” in the monograph for disodium guanylate contained in the Food Chemicals Codex 1981 at page 105 shall show no spots other than those for guanosine 5' -(disodium phosphate) and inosine 5' -(disodium phosphate).

E 640 Glycine

E 640

The criteria in the monograph for glycine contained in the Food Chemicals Codex 1972 at page 359.

E 900 Dimethylpolysiloxane

E 900

Synonym	Dimethyl silicone.
Appearance	Clear colourless odourless liquid free from extraneous matter.
Solubility	Insoluble in water. Soluble in most aliphatic and aromatic hydrocarbon solvents.
Volatile matter	Not more than 2 per centum (determined by drying at 200°C for 4 hours).
Identification	Shall comply with the identification tests in the monograph for dimethicone in the British Pharmaceutical Codex 1973 at page 168.
Acidity	Shall comply with the requirement for acidity in the monograph for dimethicone in the British Pharmaceutical Codex 1973 at page 168.
Total silicon	Not less than 37.3 and not more than 38.5 per centum.
Refractive index n 25°C D	Not less than 1.400 and not more than 1.405.

Viscosity (25°C)	Not less than 300 and not more than 1050 centistokes.
Relative density d 20°C 4°C	Not less than 0.960 and not more than 0.980.

E 901 Beeswax, white and yellow

E 901

Beeswax, white

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

Beeswax, yellow

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

E 903 Carnauba wax

E 903

The criteria in the monograph for carnauba wax contained in the Food Chemicals Codex 1972 at page 170.

E 904 Shellac

E 904

The standard for machine-made shellac contained in British Standard 3722:1964.

E 941 Nitrogen

E 941

The standard for nitrogen type 2 contained in British Standard 4366:1968.

E 942 Nitrous oxide

E 942

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

E 948 Oxygen

E 948

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

E 950 Acesulfame potassium

E 950

E 951 Aspartame

E 951

E 953 Isomalt

E 953

E 957 Thaumatin

E 957

E 959 Neohesperidine DC

E 959

E 965(i) Maltitol

E 965(i)

E 965(ii) Maltitol syrup

E 965(ii)

E 966 Lactitol

E 966

Xylitol

the appropriate specific purity criteria contained in Commission Directive 95/31/EEC.

E 999 Extract of Quillaia

E 999

The aqueous extract of the product complying with the monograph for Quillaia or for powdered Quillaia, in each case, contained in the British Pharmacopoeia 1980, at page 382.

E 1200 Polydextrose

E 1200

Description	Polydextrose is an off-white to light tan coloured, water-soluble powder. It consists of a randomly bonded condensation polymer

	produced by the reaction of D-glucose with sorbitol and citric acid. Free acid groups may be neutralised with potassium hydroxide.
Content	Not less than 90% of polymer on an ash-free and water-free basis.
Free glucose	Not more than 4% of an ash-free and water-free basis.
Free 1,6 anhydro-D-glucose	Not more than 4% on an ash-free and water-free basis.
Free sorbital	Not more than 2% on an ash-free and water-free basis.
Water	Not more than 4% (Karl Fischer).
pH (10% aqueous solution)	Not less than 2.5 and not more than 3.5 (not less than 5.0 and not more than 6.0 for the neutralised product).
Sulphated ash	Not more than 0.3% (not more than 3.0% for the neutralised product).
Arsenic	Not more than 1 mg/kg.
Lead	Not more than 1 mg/kg.

Propane-1,2-diol (propylene glycol)

As set out in the Annex to Council Directive 78/663/EEC.