

L.N. 171 of 2011

**FOOD SAFETY ACT
(CAP. 449)**

Permitted Food Additives (Amendment) Regulations, 2011

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister for Health, the Elderly and Community Care, has made the following regulations:-

1. (1) The title of these regulations is the Permitted Food Additives (Amendment) Regulations, 2011, and they shall be read and construed as one with the Permitted Food Additives Regulations 2005, hereinafter referred to as “the principal regulations”.

Citation and commencement.

L.N. 54 of 2005.

(2) These regulations shall be deemed to have come into force on the 31st March 2011.

2. (1) Regulations 4 and 10 implement the provisions of Commission Directive 2010/67/EU of 20 October 2010 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

Scope.

(2) Regulations 3 and 5 to 9 implement the provisions of Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners.

3. For regulation 1.4 of the principal regulations, there shall be substituted the following:-

Amends regulation 1 of the principal regulations.

“1.4 These regulations implement the provisions of Directive 95/2/EC of the European Parliament and of the Council of the 20th February, 1995 on food additives other than colours and sweeteners, as amended by the following Directives:

- Directive 96/85/EC of the European Parliament and of the Council of the 19th December 1996

- Directive 98/72/EC of the European Parliament and of the Council of the 15th October 1998

- Directive 2001/5/EC of the European Parliament and of the Council of the 12th February 2001

- Directive 2003/52/EC of the European Parliament and of the Council of the 18th June 2003

- Directive 2003/114/EC of the European Parliament and of the Council of the 22nd December 2003

- Directive 2006/52/EC of the European Parliament and of the Council of the 5th July 2006

- Commission Directive 2010/69/EU of the 22nd October 2010.”.

- Commission Directive 2008/84/EC of the 27th August 2008 laying down specific purity criteria on food additives other than colours and sweeteners, as amended by the following Directives:

- Commission Directive 2009/10/EC of the 13th February 2009

- Commission Directive 2010/67/EU of the 20th October 2010.”.

Amends regulation
5 of the principal
regulations.

4. For regulation 5.1 of the principal regulations there shall be substituted the following:

“5.1 The additives permitted for use by these regulations shall satisfy the purity criteria laid down by Commission Directive 2008/84/EC, as amended by Directives 2009/10/EC and 2010/67/EU. A list of the food additives for which

purity criteria have been established is given in the Seventh Schedule.”.

5. The Second Schedule for the principal regulations shall be amended as follows:

Amends the Second Schedule to the principal regulations.

(a) For the row “Pre-packed preparations of fresh minced meat”, there shall be substituted the following:-

“Pre-packed preparations of fresh minced meat	E 261 Potassium acetate	<i>quantum satis</i>
	E 262i Sodium acetate	
	E 262ii Sodium hydrogen acetate	
	E 300 Ascorbic acid	
	E 301 Sodium ascorbate	
	E 302 Calcium ascorbate	
	E 325 Sodium lactate	
	E 326 Potassium lactate	
	E 330 Citric acid	
	E 331 Sodium citrates	
	E 332 Potassium citrates	
	E 333 Calcium citrates	

”; and

(b) at the end of the Schedule, there shall be added the following entry:-

“Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %	E 406 Agar	<i>quantum satis</i>
	E 407 Carrageenan	
	E 410 Locust bean gum	
	E 412 Guar gum	
	E 415 Xanthan gum	
	E 440 Pectins	

	E 460 Cellulose E 466 Carboxy methyl cellulose E 471 Mono- and diglycerides of fatty acids E 1404 Oxidised starch E 1410 Monostarch phosphate E 1412 Distarch phosphate E 1413 Phosphated distarch phosphate E 1414 Acetylated distarch phosphate E 1420 Acetylated starch E 1422 Acetylated distarch adipate E 1440 Hydroxyl propyl starch E 1442 Hydroxy propyl distarch phosphate E 1450 Starch sodium octenyl succinate E 1451 Acetylated oxidised starch	
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6. The Third Schedule to the principal regulations shall be amended as follows:

Amends the Third Schedule to the principal regulations.

(a) at the end of Part A, there shall be added the following entries:-

“Seaweed-based fish analogue products	1 000	500				
Beer in kegs containing more than 0,5 % added fermentable sugar and/or fruit juices	200	200		400		

or concentrates						
Unpeeled fresh citrus fruit (surface treatment only)	20			1 000 in the product ready for consumption'		
Food supplements as defined in the Food Supplements Regulations, 2003, (L.N. 239 of 2003), supplied in dried form containing preparations of vitamin A and of combinations of vitamin A and D						

”;

(b) at the end of Part B, there shall be added the following rows:-

“Blueberries (<i>Vaccinium corymbosum</i> only)	10
Cinnamon (<i>Cinnamomum ceylanicum</i> only)	150”;

(c) in Part C, for the row for the additive E 234, there shall be substituted the following:-

“E 234	Nisin (*)	Semolina and tapioca puddings and similar products	3 mg/kg
		Ripened cheese and processed cheese	12,5 mg/kg
		Clotted cream	10 mg/kg
		<i>Mascarpone</i>	10 mg/kg
		Pasteurised liquid egg (white, yolk or whole egg)	6,25 mg/l
(*) This substance may be present in certain cheeses as a result of fermentation process.”;			

(d) in Part C, for the row for the additive E 242, there shall be substituted the following:-

“E 242	Dimethyl dicarbonate	Non-alcoholic flavoured drinks	250 mg/l ingoing amount, residues not detectable
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		Alcohol-free wine	
		Liquid-tea concentrate	
		Cider, perry, fruit wines Alcohol-reduced wine	250 mg/l ingoing amount, residues not detectable
		Wine-based drinks and products covered by Regulation (EEC) No 1601/91	

”; and

- (e) in Part D, the following row shall be inserted after the row for additive E 316:-

“E 392	Extracts of rosemary	Vegetable oils (excluding virgin oils and olive oils) and fat where content of polyunsaturated fatty acids is higher than 15 % w/w of the total fatty acid, for the use in non heat treated food products	30 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Fish oils and algal oil	50 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Lard, beef, poultry, sheep and porcine fat Fats and oils for the professional manufacture of heat-treated foodstuffs Frying oil and frying fat, excluding olive oil and olive pomace oil	

		Snack foods (snack based on cereals, potatoes or starch)	
		Sauces	100 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Fine bakery wares	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Food supplements as defined in L.N. 239 of 2003	400 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated potatoes Egg products Chewing gum	200 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Milk powder for vending machines Seasoning and condiments Processed nuts	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Dehydrated soups and broths	50 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated meat	150 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Meat and fish products, excluding dehydrated meat and dried sausage	150 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis

		Dried sausage	100 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Flavourings	1 000 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dried milk for the manufacturing of ice cream	30 mg/kg (expressed as the sum of carnosol and carnosic acid)".

7. The Fourth Schedule to the principal regulations shall be amended as follows:

Amends the Fourth
Schedule to the
principal regulations.

(a) in the entry concerning additives E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452, the following row shall be inserted after the row concerning 'vegetable protein drinks':-

		"Whey protein containing sport drinks	4 g/kg";
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(b) the following entry shall be inserted before the entry concerning additives E 432, E 433, E 434, E 435 and E 436:-

“E 427	Cassia gum	Edible ices	2 500mg/kg
		Fermented milk products with the exception of unflavoured live fermented milk products	
		Dairy-based dessert and similar products	
		Filling, topping and coating for fine bakery wares and dessert	
		Processed cheese	
		Sauces and salads dressing	
		Dehydrated soups and broths	
		Heat-treated meat products	1 500 mg/kg”;

- (c) in the entry for E 901, E 902, and E 904, in the third column, under the use ‘As glazing agent only for’, the following entry shall be added:-

		“— Pre-packed wafers containing ice cream (only for E 901)	<i>quantum satis</i> ”;
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- (d) in the entry for E 901, E 902, and E 904, in the third column, below the use as “Peaches and pineapples (surface treatment only)”, the following entry shall be added:-

		“Flavourings in non-alcoholic flavoured drinks (only for E 901)	0,2 g/kg in the flavoured drinks”;
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- (e) the following entry shall be inserted after the entry concerning the additive E 959:-

“E 961	Neotame	Water-based flavoured drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		“Snacks”: certain flavours of ready-to-eat, pre- packed, dry, savoury starch products and coated nuts	2 mg/kg as flavour enhancer
		Starch-based confectionery, energy-reduced or with no added sugar	3 mg/kg as flavour enhancer
		Breath-freshening micro-sweets, with no added sugar	3 mg/kg as flavour enhancer
		Strongly flavoured throat pastilles with no added sugar	3 mg/kg as flavour enhancer
		Chewing gum with added sugar	3 mg/kg as flavour enhancer
		Energy-reduced jams, jellies and marmalades	2 mg/kg as flavour enhancer
		Sauces	2 mg/kg as flavour enhancer
		Food supplements as defined in L.N. 239 of 2003, supplied in a liquid	2 mg/kg as flavour enhancer

		form	
		Food supplements as defined in L.N. 239 of 2003, supplied in a solid form	2 mg/kg as flavour enhancer
		Food supplements as defined in L.N. 239 of 2003, based on vitamins and/or mineral elements and supplied in a syrup-type or non-chewable form	2 mg/kg as flavour enhancer”;

- (f) the following entry shall be inserted after the entry concerning additive E 1202:-

“E 1203	Polyvinyl alcohol	Food supplements as defined in L.N. 239 of 2003, in capsule and tablet form	18 g/kg
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”; and

- (g) after the entry concerning the additive E 1202, for the entry concerning the food additive E 1505, there shall be substituted the following:-

“E 1505	Triethyl citrate	Food supplements as defined in L.N. 239 of 2003, in capsule and tablet form	3.5 g/kg
		Dried egg white	<i>quantum satis</i> ”.

Amends the Fifth Schedule to the principal regulations.

8. In the Fifth Schedule to the principal regulations, for, the entry concerning the additive ‘Polyethyleneglycol 6000’, there shall be substituted the following:-

“E 1521	Polyethylene glycol	Sweeteners”.
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9. In Part 3 of the Sixth Schedule to the principal regulations, the following entry shall be added after the entry concerning additive E 526:-

Amends the Sixth Schedule to the principal regulations.

“E 920	L-cysteine	Biscuits for infants and young children	1 g/kg”.
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10. For the Seventh Schedule to the principal regulations, there shall be substituted the following:-

Substitutes the Seventh Schedule to the principal regulations.

“SEVENTH SCHEDULE

Purity Criteria

Purity criteria for the following additives are prescribed in Annex I of Commission Directive 2008/84/EC (OJ L 253, 20.9.2008, p. 1-175), as amended by Commission Directive 2009/10/EC (OJ L 44, 14.2.2009, p. 62-78) and Commission Directive 2010/67/EU (OJ L 277, 21.10.2010, p. 17-26).

- E 170 (i) Calcium carbonate
- E 200 Sorbic acid
- E 202 Potassium sorbate
- E 203 Calcium sorbate
- E 210 Benzoic acid
- E 211 Sodium benzoate
- E 212 Potassium benzoate
- E 213 Calcium benzoate
- E 214 Ethyl p-Hydroxybenzoate
- E 215 Sodium ethyl p-hydroxybenzoate
- E 218 Methyl p-Hydroxybenzoate
- E 219 Sodium Methyl p-Hydroxybenzoate
- E 220 Sulphur dioxide
- E 221 Sodium sulphite
- E 222 Sodium bisulphate
- E 223 Sodium metabisulphite
- E 224 Potassium metabisulphite
- E 226 Calcium sulphite

- E 227 Calcium bisulphite
- E 228 Potassium bisulphite
- E 231 Ortophenylphenol
- E 232 Sodium ortophenylphenol
- E 234 Nisin
- E 235 Natamycin
- E 239 Hexamethylene tetramine
- E 242 Dimethyl dicarbonate
- E 249 Potassium nitrite
- E 250 Sodium nitrite
- E 251 Sodium nitrate
 - 1. Solid sodium nitrate
 - 2. Liquid sodium nitrate
- E 252 Potassium nitrate
- E 260 Acetic acid
- E 261 Potassium acetate
- E 262 (i) Sodium acetate
- E 262 (ii) Sodium diacetate
- E 263 Calcium acetate
- E 270 Lactic acid
- E 280 Propionic acid
- E 281 Sodium propionate
- E 282 Calcium propionate
- E 283 Potassium propionate
- E 284 Boric acid
- E 285 Sodium tetraborate (borax)
- E 290 Carbon dioxide
- E 296 Malic acid
- E 297 Fumaric acid
- E 300 Ascorbic acid
- E 301 Sodium ascorbate
- E 302 Calcium ascorbate
- E 304 (i) Ascorbyl palmitate
- E 304 (ii) Ascorbyl stearate
- E 306 Tocopherol-rich extract
- E 307 Alpha-tocopherol
- E 308 Gamma-tocopherol
- E 309 Delta-tocopherol
- E 310 Propyl gallate
- E 311 Octyl gallate
- E 312 Dodecyl gallate
- E 315 Erythorbic acid
- E 316 Sodium erythorbate
- E 319 Tertiary-butylhydroquinone (TBHQ)
- E 320 Butylated hydroxyanisole (BHA)
- E 321 Butylated hydroxytoluene (BHT)

- E 322 Lecithins
- E 325 Sodium lactate
- E 326 Potassium lactate
- E 327 Calcium lactate
- E 330 Citric acid
- E 331 (i) Monosodium citrate
- E 331 (ii) Disodium citrate
- E 331 (iii) Trisodium citrate
- E 332 (i) Monopotassium citrate
- E 332 (ii) Tripotassium citrate
- E 333 (i) Monocalcium citrate
- E 333 (ii) Dicalcium citrate
- E 333 (iii) Tricalcium citrate
- E 334 L (+) – Tartaric acid
- E 335 (i) Monosodium tartrate
- E 335 (ii) Disodium tartrate
- E 336 (i) Monopotassium tartrate
- E 336 (ii) Dipotassium tartrate
- E 337 Potassium sodium tartrate
- E 338 Phosphoric acid
- E 339 (i) Monosodium phosphate
- E 339 (ii) Disodium phosphate
- E 340 (i) Monopotassium phosphate
- E 340 (ii) Dipotassium phosphate
- E 340 (iii) Tripotassium phosphate
- E 341 (i) Monocalcium phosphate
- E 341 (ii) Dicalcium phosphate
- E 341 (iii) Tricalcium phosphate
- E 343 (i) Monomagnesium phosphate
- E 343 (ii) Dimagnesium phosphate
- E 350 (i) Sodium malate
- E 350 (ii) Sodium hydrogen malate
- E 351 Potassium malate
- E 352 (i) Calcium malate
- E 352 (ii) Calcium hydrogen malate
- E 353 Metatartaric acid
- E 354 Calcium tartrate
- E 355 Adipic acid
- E 356 Sodium adipate
- E 357 Potassium adipate
- E 363 Succinic acid
- E 380 Triammonium citrate
- E 385 Calcium disodium ethylenediaminetetraacetate
- E 392 Extracts of Rosemary
- E 400 Alginic acid
- E 401 Sodium alginate

- E 402 Potassium alginate
- E 403 Ammonium alginate
- E 404 Calcium alginate
- E 405 Propane-1,2-diol alginate
- E 406 Agar
- E 407 Carrageenan
- E 407a Processed eucheuma seaweed
- E 410 Locust bean gum
- E 412 Guar gum
- E 413 Tragacanth
- E 414 Acacia gum
- E 415 Xanthan gum
- E 416 Karaya-gum
- E 417 Tara gum
- E 418 Gellan gum
- E 420 (i) Sorbitol
- E 420 (ii) Sorbitol syrup
- E 421 Mannitol
- E 422 Glycerol
- E 425 (i) Konjac gum
- E 425 (ii) Konjac glucomannan
- E 426 Soybean hemicellulose
- E 427 Cassia gum
- E 431 Polyoxyethylene (40) stearate
- E 432 Polyoxyethylene sorbitan monolaurate (polysorbate 20)
- E 433 Polyoxyethylene sorbitan monooleate (polysorbate 80)
- E 434 Polyoxyethylene sorbitan monopalmitate (polysorbate 40)
- E 435 Polyoxyethylene sorbitan monostearate (polysorbate 60)
- E 436 Polyoxyethylene sorbitan tristearate (polysorbate 65)
- E 440 (i) Pectin
- E 440 (ii) Amidated pectin
- E 442 Ammonium phosphatides
- E 444 Sucrose acetate isobutyrate
- E 445 Glycerol esters of wood rosin
- E 450 (i) Disodium diphosphate
- E 450 (ii) Trisodium diphosphate
- E 450 (iii) Tetrasodium diphosphate
- E 450 (v) Tetrapotassium diphosphate
- E 450 (vi) Dicalcium diphosphate
- E 450 (vii) Calcium dihydrogen diphosphate
- E 451 (i) Pentasodium triphosphate
- E 451 (ii) Pentapotassium triphosphate
- E 452 (i) Sodium polyphosphate
 - 1. Soluble polyphosphate
 - 2. Insoluble polyphosphate
- E 452 (ii) Potassium polyphosphate

- E 452 (iii) Sodium calcium polyphosphate
- E 452 (iv) Calcium polyphosphate
- E 459 Beta-cyclodextrin
- E 460 (i) Microcrystalline cellulose
- E 460 (ii) Powdered cellulose
- E 461 Methyl cellulose
- E 462 Ethyl cellulose
- E 463 Hydroxypropyl cellulose
- E 464 Hydroxypropyl methyl cellulose
- E 465 Ethyl methyl cellulose
- E 466 Sodium carboxy methyl cellulose
- E 468 Cross-linked sodium carboxymethylcellulose
- E 469 Enzymatically hydrolysed carboxymethylcellulose
- E 470a Sodium, Potassium and Calcium salts of fatty acids
- E 470b Magnesium salts of fatty acids
- E 471 Mono- and diglycerides of fatty acids
- E 472a Acetic acid esters of mono- and diglycerides of fatty acids
- E 472b Lactic acid esters of mono- and diglycerides of fatty acids
- E 472c Citric acid esters of mono- and diglycerides of fatty acids
- E 472d Tartaric acid esters of mono- and diglycerides of fatty acids
- E 472e Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids
- E 472f Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
- E 473 Sucrose esters of fatty acids
- E 474 Sucroglycerides
- E 475 Polyglycerol esters of fatty acids
- E 476 Polyglycerol polyricinoleate
- E 477 Propane-1,2-diol esters of fatty acids
- E 479b Thermally oxidized soya bean oil interacted with mono- and diglycerides of fatty acids
- E 481 Sodium stearoyl-2-lactylate
- E 482 Calcium stearoyl-2-lactylate
- E 483 Stearyl tartrate
- E 491 Sorbitan monostearate
- E 492 Sorbitan tristearate
- E 493 Sorbitan monolaurate
- E 494 Sorbitan monooleate
- E 495 Sorbitan monopalmitate
- E 500 (i) Sodium carbonate
- E 500 (iii) Sodium sequicarbonate
- E 501 (i) Potassium carbonate
- E 501 (ii) Potassium hydrogen carbonate
- E 503 (i) Ammonium carbonate
- E 503 (ii) Ammonium hydrogen carbonate
- E 504 (i) Magnesium carbonate
- E 504 (ii) Magnesium hydroxide carbonate
- E 507 Hydrochloric acid

- E 508 Potassium chloride
- E 509 Calcium chloride
- E 511 Magnesium chloride
- E 512 Stannous chloride
- E 513 Sulphuric acid
- E 514 (i) Sodium sulphate
- E 514 (ii) Sodium hydrogen sulphate
- E 515 (i) Potassium sulphate
- E 515 (ii) Potassium hydrogen sulphate
- E 516 Calcium sulphate
- E 517 Ammonium sulphate
- E 520 Aluminium sulphate
- E 521 Aluminium sodium sulphate
- E 522 Aluminium potassium sulphate
- E 523 Aluminium ammonium sulphate
- E 524 Sodium hydroxide
- E 525 Potassium hydroxide
- E 526 Calcium hydroxide
- E 527 Ammonium hydroxide
- E 528 Magnesium hydroxide
- E 529 Calcium oxide
- E 530 Magnesium oxide
- E 535 Sodium ferrocyanide
- E 536 Potassium ferrocyanide
- E 538 Calcium ferrocyanide
- E 541 Sodium aluminium phosphate, acidic
- E 551 Silicon dioxide
- E 553a (i) Magnesium silicate
- E 553a (ii) Magnesium trisilicate
- E 553b Talc
- E 554 Sodium aluminium silicate
- E 555 Potassium aluminium silicate
- E 556 Calcium aluminium silicate
- E 558 Bentonite
- E 559 Aluminium silicate (Kaolin)
- E 570 Fatty acids
- E 574 Glucono-delta-lactone
- E 576 Sodium gluconate
- E 577 Potassium gluconate
- E 578 Calcium gluconate
- E 579 Ferrous gluconate
- E 585 Ferrous lactate
- E 586 4-Hexylresorcinol
- E 620 Glutamic acid
- E 621 Monosodium glutamate
- E 622 Monopotassium glutamate

E 623 Calcium diglutamate
E 624 Monoammonium glutamate
E 625 Magnesium diglutamate
E 626 Guanylic acid
E 627 Disodium guanylate
E 628 Dipotassium guanylate
E 629 Calcium guanylate
E 630 Inosinic acid
E 631 Disodium inosinate
E 632 Dipotassium inosinate
E 633 Calcium inosinate
E 634 Calcium 5'-ribonucleotide
E 635 Disodium 5'-ribonucleotide
E 640 Glycine and its sodium salt
E 650 Zinc acetate
E 900 Dimethyl polysiloxane
E 901 Beeswax
E 902 Candelilla wax
E 903 Carnauba wax
E 904 Shellac
E 905 Microcrystalline wax
E 907 Hydrogenated poly-1-decene
E 912 Montan acid esters
E 914 Oxidised polyethylene wax
E 920 L-cysteine
E 927b Carbamide
E 938 Argon
E 939 Helium
E 941 Nitrogen
E 942 Nitrous oxide
E 943a Butane
E 943b Isobutane
E 944 Propane
E 948 Oxygen
E 949 Hydrogen
E 950 Acesulfame K
E 951 Aspartame
E 953 Isomalt
E 957 Thaumatin
E 959 Neohesperidine dihydrochalcone
E 965(i) Maltitol
E 965(ii) Maltitol syrup
E 966 Lactitol
E 967 Xylitol
E 999 Quillaia extract
E 1103 Invertase

VERŻJONI ELETTRONIKA

