

## I

(Acts whose publication is obligatory)

**COMMISSION DIRECTIVE 2001/30/EC****of 2 May 2001****amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>(1)</sup>, as amended by Directive 94/34/EC of the European Parliament and of the Council<sup>(2)</sup> and in particular Article 3(3)(a) thereof,

After consulting Scientific Committee on Food,

Whereas:

- (1) It is necessary to establish purity criteria for all additives other than colours and sweeteners mentioned in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners<sup>(3)</sup>, as last amended by Directive 2001/5/EC<sup>(4)</sup>.
- (2) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners<sup>(5)</sup>, as last amended by Directive 2000/63/EC<sup>(6)</sup> set out purity criteria for a number of food additives. This Directive should now be completed with purity criteria for the remaining food additives mentioned in Directive 95/2/EC.
- (3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 96/77/EC is hereby amended as follows:

In the Annex, the text of the Annex to this Directive shall be added.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 June 2002 at the latest. They shall forthwith inform the Commission thereof.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Products put on the market or labelled before 1 June 2002 which do not comply with this Directive may be marketed until stocks are exhausted.

*Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 2 May 2001.

*For the Commission*

David BYRNE

*Member of the Commission*

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 27.

<sup>(2)</sup> OJ L 237, 10.9.1994, p. 1.

<sup>(3)</sup> OJ L 61, 18.3.1995, p. 1.

<sup>(4)</sup> OJ L 55, 24.2.2001, p. 59.

<sup>(5)</sup> OJ L 339, 30.12.1996, p. 1.

<sup>(6)</sup> OJ L 227, 30.10.2000, p. 1.

## ANNEX

**E 170 (i) CALCIUM CARBONATE**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs <sup>(1)</sup>.

<sup>(1)</sup> OJ L 226, 22.9.1995, p. 13.

**E 353 METATARTARIC ACID****Synonyms**

Ditartaric acid

**Definition***Chemical name*

Metatartaric acid

*Chemical formula* $C_4H_6O_6$ *Assay*

Not less than 99,5 %

*Description*

Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel

**Identification**

A.

Very soluble in water and ethanol.

B.

Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulfuric acid and 2 drops of sulpho-resorcinol reagent. When heated to 150 °C, an intense violet coloration appears

**Purity**

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

**E 354 CALCIUM TARTRATE****Synonyms**

L-Calcium tartrate

**Definition***Chemical name*

Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate

*Chemical formula* $C_4H_4CaO_6 \cdot 2H_2O$ *Molecular weight*

224,18

*Assay*

Not less than 98,0 %

*Description*

Fine crystalline powder with a white or off-white colour

**Identification**

A. Slightly soluble in water. Solubility approximately 0,01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids

B. Specific rotation $[\alpha]^{20}_D$	+7,0° to +7,4° (0,1 % in a 1N de HCl solution)
C. pH of a 5 % slurry	Between 6,0 and 9,0
<b>Purity</b>	
Sulphates (as H <sub>2</sub> SO <sub>4</sub> )	Not more than 1 g/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

**E 356 SODIUM ADIPATE****Definition**

<i>Chemical name</i>	Sodium adipate
<b>EINECS</b>	231-293-5
<i>Chemical formula</i>	C <sub>6</sub> H <sub>8</sub> Na <sub>2</sub> O <sub>4</sub>
<i>Molecular weight</i>	190,11
<i>Assay</i>	Content not less than 99,0 % (on anhydrous basis)
<i>Description</i>	White odourless crystals or crystalline powder

**Identification**

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium	

**Purity**

Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

**E 357 POTASSIUM ADIPATE****Definition**

<i>Chemical name</i>	Potassium adipate
<b>EINECS</b>	242-838-1
<i>Chemical formula</i>	C <sub>6</sub> H <sub>8</sub> K <sub>2</sub> O <sub>4</sub>
<i>Molecular weight</i>	222,32
<i>Assay</i>	Content not less than 99,0 % (on anhydrous basis)
<i>Description</i>	White odourless crystals or crystalline powder

**Identification**

A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium	

**Purity**

Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

**E 420(i) SORBITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs <sup>(1)</sup>.

**E 420(ii) SORBITOL SYRUP**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 421 MANNITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

<sup>(1)</sup> OJ L 178, 28.7.1995, p. 1.

**E 425(i) KONJAC GUM****Definition**

	Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant <i>Amorphophallus konjac</i> . The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by $\beta(1-4)$ -glycosidic bonds. Shorter side chains are attached through $\beta(1-3)$ -glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units.
Molecular weight	The main component, glucomannan, has an average molecular weight of 200 000 to 2 000 000
Assay	Not less than 75 % carbohydrate
Description	A white to cream to light tan powder

**Identification**

A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0
B. Gel formation	Add 5 ml of a 4 % sodium borate solution to a 1 % solution of the sample in a test tube, and shake vigorously. A gel forms
C. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
D. Viscosity (1 % solution)	Not less than 3 kgm <sup>-1</sup> s <sup>-1</sup> at 25 °C

**Purity**

Loss on drying	Not more than 12 % (105 °C, 5 h)
Starch	Not more than 3 %
Protein	Not more than 3 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,1 %
Total ash	Not more than 5,0 % (800 °C, 3 to 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

**E 425(ii) KONJAC GLUCOMANNAN****Definition**

Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ratio of 1,6:1,0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated

Molecular weight	500 000 to 2 000 000
Assay	Total dietary fibre: not less than 95 % on a dry weight basis
Description	White to slightly brownish fine particle size, free flowing and odourless powder

**Identification**

A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation
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B. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
C. Viscosity (1 % solution)	Not less than 20 kgm <sup>-1</sup> s <sup>-1</sup> at 25 °C
<b>Purity</b>	
Loss on drying	Not more than 8 % (105 °C, 3h)
Starch	Not more than 1 %
Protein	Not more than 1,5 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,5 %
Sulphite (as SO <sub>2</sub> )	Not more than 4 mg/kg
Chloride	Not more than 0,02 %
50 % Alcohol-soluble	Not more than 2,0 % material
Total ash	Not more than 2,0 % (800 °C, 3 to 4h)
Lead	Not more than 1 mg/kg
<i>Salmonella</i> spp.	Absent in 12,5 g
<i>E. coli</i>	Absent in 5 g

**E 504(ii) MAGNESIUM HYDROXIDE CARBONATE**

<b>Synonyms</b>	Magnesium hydrogen carbonate, magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide
<b>Definition</b>	
<i>Chemical name</i>	Magnesium carbonate hydroxide hydrated
<b>EINECS</b>	235-192-7
<i>Chemical formula</i>	4MgCO <sub>3</sub> Mg(OH) <sub>2</sub> 5H <sub>2</sub> O
<i>Molecular weight</i>	485
<i>Assay</i>	Mg content not less than 40,0 % and not more than 45,0 % calculated as MgO
<i>Description</i>	Light, white friable mass or bulky white powder
<b>Identification</b>	
A. Positive tests for magnesium and for carbonate	
B. Solubility	Practically insoluble in water. Insoluble in ethanol

**Purity**

Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1,0 %
Calcium	Not more than 1,0 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 10 mg/kg
Mercury	Not more than 1 mg/kg

**E 553b TALC****Synonyms**

Talcum

**Definition**

Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite

*Chemical name*

Magnesium hydrogen metasilicate

**EINECS**

238-877-9

*Chemical formula* $\text{Mg}_3(\text{Si}_4\text{O}_{10})(\text{OH})_2$ *Molecular weight*

379,22

*Description*

Light, homogeneous, white or almost white powder, greasy to the touch

**Identification**

## A. IR absorption

Characteristic peaks at 3 677, 1 018 and 669  $\text{cm}^{-1}$ 

## B. X-ray diffraction

Peaks at 9,34 / 4,66 / 3,12 Å

## C. Solubility

Insoluble in water and ethanol

**Purity**

Loss on drying	Not more than 0,5 % (105 °C, 1h)
Acid-soluble matter	Not more than 6 %
Water-soluble matter	Not more than 0,2 %
Acid-soluble iron	Not detectable
Arsenic	Not more than 10 mg/kg
Lead	Not more than 5 mg/kg

**E 554 SODIUM ALUMINIUM SILICATE****Synonyms**

Sodium silicoaluminate, sodium aluminosilicate, aluminium sodium silicate

**Definition***Chemical name*

Sodium aluminium silicate

*Assay*

Content on the anhydrous basis:

— as  $\text{SiO}_2$  not less than 66,0 % and not more than 88,0 %— as  $\text{Al}_2\text{O}_3$  not less than 5,0 % and not more than 15,0 %*Description*

Fine white amorphous powder or beads

**Identification**

A. Positive tests for sodium, for aluminium and for silicate

B. pH of a 5 % slurry

Between 6,5 and 11,5

**Purity**

Loss on drying

Not more than 8,0 % (105 °C, 2h)

Loss on ignition

Not less than 5,0 % and not more than 11,0 % on the anhydrous basis (1 000 °C, constant weight)

Sodium

Not less than 5 % and not more than 8,5 % (as  $\text{Na}_2\text{O}$ ) on the anhydrous basis

Arsenic

Not more than 3 mg/kg

Lead

Not more than 5 mg/kg

Mercury

Not more than 1 mg/kg

**E 555 POTASSIUM ALUMINIUM SILICATE****Synonyms**

Mica

**Definition**

Natural mica consists of mainly potassium aluminium silicate (muscovite)

**EINECS**

310-127-6

*Chemical name*

Potassium aluminium silicate

*Chemical formulae* $\text{KAl}_2[\text{AlSi}_3\text{O}_{10}](\text{OH})_2$ *Molecular weight*

398

*Assay*

Content not less than 98 %

*Description*

Light grey to white crystalline platelets or powder

**Identification**

A. Solubility

Insoluble in water, diluted acids and alkali and organic solvents

**Purity**

Loss on drying

Not more than 0,5 % (105 °C, 2h)

Antimony

Not more than 20 mg/kg

Zinc

Not more than 25 mg/kg



Barium	Not more than 25 mg/kg
Chromium	Not more than 100 mg/kg
Copper	Not more than 25 mg/kg
Nickel	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Lead	Not more than 10 mg/kg

**E 556 CALCIUM ALUMINIUM SILICATE****Synonyms**

Calcium aluminosilicate, calcium silicoaluminate, aluminium calcium silicate

**Definition***Chemical name*

Calcium aluminium silicate

*Assay*

Content on the anhydrous basis:

- as  $\text{SiO}_2$  not less than 44,0 % and not more than 50,0 %
- as  $\text{Al}_2\text{O}_3$  not less than 3,0 % and not more than 5,0 %
- as CaO not less than 32,0 % and not more than 38,0 %

*Description*

Fine white, free-flowing powder

**Identification**

A. Positive tests for calcium, for aluminium and for silicate

**Purity**

## Loss on drying

Not more than 10,0 % (105 °C, 2h)

## Loss on ignition

Not less than 14,0 % and not more than 18,0 on the anhydrous basis (1 000 °C, constant weight)

## Fluoride

Not more than 50 mg/kg

## Arsenic

Not more than 3 mg/kg

## Lead

Not more than 10 mg/kg

## Mercury

Not more than 1 mg/kg

**E 558 BENTONITE****Definition**

Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms were naturally replaced by other atoms such as magnesium and iron. Calcium and sodium ions are trapped between the mineral layers. There are four common types of bentonite: natural sodium bentonite, natural calcium bentonite, sodium-activated bentonite and acid-activated bentonite

**EINECS**

215-108-5

*Chemical formula* $(\text{Al, Mg})_8(\text{Si}_4\text{O}_{10})_4(\text{OH})_8 \cdot 12\text{H}_2\text{O}$ *Molecular weight*

819

*Assay*

Montmorillonite content not less than 80 %

*Description*

Very fine, yellowish or greyish white powder or granules. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties)

**Identification**

A. Methylene blue test

B. X-Ray diffraction

Characteristic peaks at 12,5/15 Å

C. IR absorption

Peaks at 428/470/530/1 110-1 020/3 750 — 3 400  $\text{cm}^{-1}$ **Purity**

Loss on drying

Not more than 15,0 % (105 °C, 2h)

Arsenic

Not more than 2 mg/kg

Lead

Not more than 20 mg/kg

**E 559 ALUMINIUM SILICATE (KAOLIN)****Synonyms**

Kaolin, light or heavy

**Definition**

Aluminium silicate hydrous (kaolin) is a purified white plastic clay composed of kaolinite, potassium aluminium silicate, feldspar and quartz. Processing should not include calcination

**EINECS**

215-286-4 (kaolinite)

*Chemical formula* $\text{Al}_2\text{Si}_2\text{O}_5(\text{OH})_4$  (kaolinite)*Molecular weight*

264

*Assay*

Content not less than 90 % (sum of silica and alumina, after ignition)

Silica ( $\text{SiO}_2$ ) Between 45 % and 55 %Alumina ( $\text{Al}_2\text{O}_3$ ) Between 30 % and 39 %*Description*

Fine, white or greyish white, unctuous powder. Kaolin is made up of loose aggregations of randomly oriented stacks of kaolinite flakes or of individual hexagonal flakes

**Identification**

A. Positive tests for alumina and for silicate

B. X-ray diffraction:

characteristic peaks at 7,18 / 3,58 / 2,38 / 1,78 Å

C. IR absorption:

peaks at 3 700 and 3 620  $\text{cm}^{-1}$

**Purity**

Loss on ignition	Between 10 and 14 % (1 000 °C, constant weight)
Water soluble matter	Not more than 0,3 %
Acid soluble matter	Not more than 2,0 %
Iron	Not more than 5 %
Potassium oxide (K <sub>2</sub> O)	Not more than 5 %
Carbon	Not more than 0,5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

**E 620 GLUTAMIC ACID****Synonyms**

L-Glutamic acid, L-α-aminoglutaric acid

**Definition**

*Chemical name* L-Glutamic acid, L-2-amino-pentanedioic acid

**EINECS**

200-293-7

*Chemical formula*

C<sub>5</sub>H<sub>9</sub>NO<sub>4</sub>

*Molecular weight*

147,13

*Assay*

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

*Description*

White crystals or crystalline powder

**Identification**

A. Positive test for glutamic acid by thin layer chromatography

B. Specific rotation [α]<sub>D</sub><sup>20</sup>

Between + 31,5° and + 32,2°  
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

C. pH of a saturated solution

Between 3,0 and 3,5

**Purity**

Loss on drying	Not more than 0,2 % (80 °C, 3h)
Sulphated ash	Not more than 0,2 %
Chloride	Not more than 0,2 %
Pyrrolidone carboxylic acid	Not more than 0,2 %
Lead	Not more than 2 mg/kg

**E 621 MONOSODIUM GLUTAMATE****Synonyms**

Sodium glutamate, MSG

**Definition***Chemical name*

Monosodium L-glutamate monohydrate

**EINECS**

205-538-1

*Chemical formula* $C_5H_8NaNO_4 \cdot H_2O$ *Molecular weight*

187,13

*Assay*

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

*Description*

White, practically odourless crystals or crystalline powder

**Identification**

A. Positive test for sodium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation  $[\alpha]_D^{20}$ Between + 24,8° and + 25,3°  
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

D. pH of a 5 % solution

Between 6,7 and 7,2

**Purity**

Loss on drying

Not more than 0,5 % (98 °C, 5h)

Chloride

Not more than 0,2 %

Pyrrolidone carboxylic acid

Not more than 0,2 %

Lead

Not more than 2 mg/kg

**E 622 MONOPOTASSIUM GLUTAMATE****Synonyms**

Potassium glutamate, MPG

**Definition***Chemical name*

Monopotassium L-glutamate monohydrate

**EINECS**

243-094-0

*Chemical formula* $C_5H_8KNO_4 \cdot H_2O$ *Molecular weight*

203,24

*Assay*

Content not less than 99,0 % and not more than 101,0 % on the anhydrous basis

*Description*

White, practically odourless crystals or crystalline powder

**Identification**

- A. Positive test for potassium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation  $[\alpha]_D^{20}$
- D. pH of a 2 % solution

Between + 22,5° and + 24,0°  
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

Between 6,7 and 7,3

**Purity**

- Loss on drying
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 0,2 % (80 °C, 5h)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

**E 623 CALCIUM DIGLUTAMATE****Synonyms**

Calcium glutamate

**Definition**

*Chemical name*

Monocalcium di-L-glutamate

**EINECS**

242-905-5

*Chemical formula*

$C_{10}H_{16}CaN_2O_8 \cdot x H_2O$  (x = 0, 1, 2 or 4)

*Molecular weight*

332,32 (anhydrous)

*Assay*

Content not less than 98,0 % and not more than 102,0 % on the anhydrous basis

*Description*

White, practically odourless crystals or crystalline powder

**Identification**

- A. Positive test for calcium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation  $[\alpha]_D^{20}$

Between + 27,4 and + 29,2 (for calcium diglutamate with x = 4) (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

**Purity**

- Water
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 19,0 % (for calcium diglutamate with x = 4) (Karl Fischer)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

**E 624 MONOAMMONIUM GLUTAMATE****Synonyms**

Ammonium glutamate

**Definition***Chemical name*

Monoammonium L-glutamate monohydrate

**EINECS**

231-447-1

*Chemical formula* $C_5H_{12}N_2O_4 \cdot H_2O$ *Molecular weight*

182,18

*Assay*

Content not less than 99,0 % and not more 101,0 % on the anhydrous basis

*Description*

White, practically odourless crystals or crystalline powder

**Identification**

A. Positive test for ammonium

B. Positive test for glutamic acid by thin-layer chromatography

C. Specific rotation  $[\alpha]_D^{20}$ Between + 25,4° and + 26,4°  
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

D. pH of a 5 % solution

Between 6,0 and 7,0

**Purity**

Loss on drying

Not more than 0,5 % (50 °C, 4h)

Sulphated ash

Not more than 0,1 %

Pyrrolidone carboxylic acid

Not more than 0,2 %

Lead

Not more than 2 mg/kg

**E 625 MAGNESIUM DIGLUTAMATE****Synonyms**

Magnesium glutamate

**Definition***Chemical name*

Monomagnesium di-L-glutamate tetrahydrate

**EINECS**

242-413-0

*Chemical formula* $C_{10}H_{16}MgN_2O_8 \cdot 4H_2O$ *Molecular weight*

388,62

*Assay*

Content not less than 95,0 % and not more than 105,0 % on the anhydrous basis

*Description*

Odourless, white or off-white crystals or powder

**Identification**

- A. Positive test for magnesium
- B. Positive test for glutamic acid by thin-layer chromatography
- C. Specific rotation  $[\alpha]_D^{20}$
- D. pH of a 10 % solution

Between + 23,8° and + 24,4°  
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)

Between 6,4 and 7,5

**Purity**

- Water
- Chloride
- Pyrrolidone carboxylic acid
- Lead

Not more than 24 % (Karl Fischer)

Not more than 0,2 %

Not more than 0,2 %

Not more than 2 mg/kg

**E 626 GUANYLIC ACID****Synonyms**

Guanylic acid

**Definition**

*Chemical name*

Guanosine-5'-monophosphoric acid

**EINECS**

201-598-8

*Chemical formula*

$C_{10}H_{14}N_5O_8P$

*Molecular weight*

363,22

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, colourless or white crystals or white crystalline powder

**Identification**

- A. Positive test for ribose and for organic phosphate
- B. pH of a 0,25 % solution
- C. Spectrometry:

Between 1,5 and 2,5

maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

**Purity**

- Loss on drying
- Other nucleotides
- Lead

Not more than 1,5 % (120 °C, 4h)

Not detectable by thin-layer chromatography

Not more than 2 mg/kg

**E 627 DISODIUM GUANYLATE****Synonyms**

Sodium guanylate, sodium 5'-guanylate

**Definition**

<i>Chemical name</i>	Disodium guanosine-5'-monophosphate
<b>EINECS</b>	221-849-5
<i>Chemical formula</i>	$C_{10}H_{12}N_5Na_2O_8P \cdot x H_2O$ (x = ca. 7)
<i>Molecular weight</i>	407,19 (anhydrous)
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder

**Identification**

A. Positive test for ribose, for organic phosphate, and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

**Purity**

Loss on drying	Not more than 25 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

**E 628 DIPOTASSIUM GUANYLATE****Synonyms**

Potassium guanylate, potassium 5'-guanylate

**Definition**

<i>Chemical name</i>	Dipotassium guanosine-5'-monophosphate
<b>EINECS</b>	226-914-1
<i>Chemical formula</i>	$C_{10}H_{12}K_2N_5O_8P$
<i>Molecular weight</i>	439,40
<i>Assay</i>	Content not less than 97,0 % on the anhydrous basis
<i>Description</i>	Odourless, colourless or white crystals or white crystalline powder

**Identification**

A. Positive test for ribose, for organic phosphate, and for potassium	
B. pH of a 5 % solution	Between 7,0 and 8,5
C. Spectrometry:	maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

**Purity**

Loss on drying	Not more than 5 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg



**E 629 CALCIUM GUANYLATE****Synonyms**

Calcium 5'-guanylate

**Definition***Chemical name*

Calcium guanosine-5'-monophosphate

*Chemical formula* $C_{10}H_{12}CaN_5O_8P \cdot nH_2O$ *Molecular weight*

401,20 (anhydrous)

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, white or off-white crystals or powder

**Identification**

A. Positive test for ribose, for organic phosphate, and for calcium

B. pH of a 0,05 % solution

Between 7,0 and 8,0

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 256 nm

**Purity**

Loss on drying

Not more than 23,0 % (120 °C, 4h)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

**E 630 INOSINIC ACID****Synonyms**

5'-Inosinic acid

**Definition***Chemical name*

Inosine-5'-monophosphoric acid

**EINECS**

205-045-1

*Chemical formula* $C_{10}H_{13}N_4O_8P$ *Molecular weight*

348,21

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, colourless or white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate

B. pH of a 5 % solution

Between 1,0 and 2,0

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

**Purity**

Loss on drying	Not more than 3,0 % (120 °C, 4h)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

**E 631 DISODIUM INOSINATE****Synonyms**

Sodium inosinate, sodium 5'-inosinate

**Definition***Chemical name*

Disodium inosine-5'-monophosphate

**EINECS**

225-146-4

*Chemical formula* $C_{10}H_{11}N_4Na_2O_8P \cdot H_2O$ *Molecular weight*

392,17 (anhydrous)

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, colourless or white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for sodium

B. pH of a 5 % solution

Between 7,0 and 8,5

C. Spectrometry:

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

**Purity**

Water	Not more than 28,5 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

**E 632 DIPOTASSIUM INOSINATE****Synonyms**

Potassium inosinate, potassium 5'-inosinate

**Definition***Chemical name*

Dipotassium inosine-5'-monophosphate

**EINECS**

243-652-3

*Chemical formula* $C_{10}H_{11}K_2N_4O_8P$ *Molecular weight*

424,39

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, colourless or white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for potassium

B. pH of a 5 % solution

C. Spectrometry:

Between 7,0 and 8,5

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

**Purity**

Water

Not more than 10,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

**E 633 CALCIUM INOSINATE****Synonyms**

Calcium 5'-inosinate

**Definition**

*Chemical name*

Calcium inosine-5'-monophosphate

*Chemical formula*

$C_{10}H_{11}CaN_4O_8P \cdot nH_2O$

*Molecular weight*

386,19 (anhydrous)

*Assay*

Content not less than 97,0 % on the anhydrous basis

*Description*

Odourless, colourless or white crystals or powder

**Identification**

A. Positive test for ribose, and for organic phosphate and for calcium

B. pH of a 0,05 % solution

C. Spectrometry:

Between 7,0 and 8,0

maximum absorption of a 20 mg/l solution in 0,01N HCl at 250 nm

**Purity**

Water

Not more than 23,0 % (Karl Fischer)

Other nucleotides

Not detectable by thin-layer chromatography

Lead

Not more than 2 mg/kg

**E 634 CALCIUM 5'-RIBONUCLEOTIDE****Definition**

*Chemical name*

Calcium 5'-ribonucleotide is essentially a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate

*Chemical formula*

$C_{10}H_{11}N_4CaO_8P \cdot nH_2O$  y

$C_{10}H_{12}N_5CaO_8P \cdot nH_2O$

Assay	Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis
Description	Odourless, white or nearly white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and for organic phosphate and for calcium	
B. pH of a 0,05 % solution	Between 7,0 and 8,0
<b>Purity</b>	
Water	Not more than 23,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

**E 635 DISODIUM 5'-RIBONUCLEOTIDE**

<b>Synonyms</b>	Sodium 5'-ribonucleotide
<b>Definition</b>	
Chemical name	Disodium 5'-ribonucleotide is essentially a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate
Chemical formula	$C_{10}H_{11}N_4O_8P \cdot nH_2O$ and $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$
Assay	Content of both major components not less than 97,0 %, and of each component not less than 47,0 % and not more than 53 %, in every case on the anhydrous basis
Description	Odourless, white or nearly white crystals or powder
<b>Identification</b>	
A. Positive test for ribose, and for organic phosphate and for sodium	
B. pH of a 5 % solution	Between 7,0 and 8,5
<b>Purity</b>	
Water	Not more than 26,0 % (Karl Fischer)
Other nucleotides	Not detectable by thin-layer chromatography
Lead	Not more than 2 mg/kg

**E 905 MICROCRYSTALLINE WAX**

<b>Synonyms</b>	Petroleum wax
<b>Definition</b>	Microcrystalline wax is a refined mixture of solid, saturated hydrocarbons, mainly branched paraffin, obtained from petroleum
Description	White to amber, odourless wax

**Identification**

A. Solubility

Insoluble in water, very slightly soluble in ethanol

B. Refractive Index

 $n_D^{100}$  1,434-1,448**Purity**

Molecular weight

Average not less than 500

Viscosity at 100 °C

Not less than  $1,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$ 

Residue on ignition

Not more than 0,1 %

Carbon number at 5 %  
distillation point

Not more than 5 % of molecules with carbon number less than 25

Colour

Passes test

Sulphur

Not more than 0,4 %

Arsenic

Not more than 3 mg/kg

Lead

Not more than 3 mg/kg

Polycyclic aromatic compounds

The polycyclic aromatic hydrocarbons, obtained by extraction with dimethyl sulfoxide, shall meet the following ultraviolet absorbency limits:

nm	Maximum absorbance per cm path length
280-289	0,15
290-299	0,12
300-359	0,08
360-400	0,02

**E 912 MONTAN ACID ESTERS****Definition**

Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol

*Chemical name*

Montan acid esters

*Description*

Almost white to yellowish flakes, powder, granules or pellets

**Identification**

A. Density (20 °C)

Between 0,98 and 1,05

B. Drop point

Greater than 77 °C

**Purity**

Acid value

Not more than 40

Glycerol

Not more than 1 % (by gas chromatography)

Other polyols

Not more than 1 % (by gas chromatography)

Other wax types	Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)
Arsenic	Not more than 2 mg/kg
Chromium	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

**E 914 OXIDISED POLYETHYLENE WAX****Definition**

Polar reaction products from mild oxidation of polyethylene

*Chemical name*

Oxidised polyethylene

*Description*

Almost white flakes, powder, granules or pellets

**Identification**

A. Density (20 °C)

Between 0,92 and 1,05

B. Drop point

Greater than 95 °C

**Purity**

Acid value

Not more than 70

Viscosity at 120 °C

Not less than  $8,1 \cdot 10^{-5} \text{ m}^2\text{s}^{-1}$ 

Other wax types

Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)

Oxygen

Not more than 9,5 %

Chromium

Not more than 5 mg/kg

Lead

Not more than 2 mg/kg

**E 950 ACESULFAME K**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 951 ASPARTAME**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 953 ISOMALT**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC, as amended by Directive 98/66/EC, laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 957 THAUMATIN**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 959 NEOHESPERIDINE DIHYDROCHALCONE**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 965(i) MALTITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 965(ii) MALTITOL SYRUP**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 966 LACTITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

**E 967 XYLITOL**

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

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