Commission Directive 2009/10/EC of 13 February 2009 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance) (repealed)

COMMISSION DIRECTIVE 2009/10/EC

of 13 February 2009

amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance) (repealed)

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[(1)], and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food (SCF) and the European Food Safety Authority (EFSA),

Whereas:

(1) Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners[(2)] sets out the purity criteria for the additives mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[(3)].

(2) The European Food Safety Authority (hereinafter EFSA) concluded in its opinion of 20 October 2006[(4)] that nisin produced through a modified production process using a sugar-based medium is equivalent with respect to health protection to the one produced by the original milk-based medium process. On the basis of that opinion, the existing specifications for E234 nisin should be amended in order to adapt the definition and the purity criteria set out for that additive.

(3) Formaldehyde is used as a preservative during the manufacture of alginic acid, alginate salts and esters of alginic acid. It has been reported that residual formaldehyde, up to 50 mg/kg, may be present in the final gelling additives. At the request of the Commission, EFSA assessed the safety in use of formaldehyde as a preservative during the manufacture and preparation of food additives[(5)]. EFSA in its opinion of 30 November 2006 concluded that the estimated exposure to gelling additives containing residual formaldehyde at the level of 50 mg/kg of additive would be of no safety concern. Therefore the existing purity criteria for E400 alginic acid, E401 sodium alginate, E402 potassium alginate, E403 ammonium alginate, E404 calcium alginate, and E405 propane-1,2-diol alginate should be amended in such a way that the maximum level of formaldehyde is set at 50 mg/kg.

(4) Formaldehyde is not currently used in the processing of seaweeds for the production of E407 carrageenan and E407a processed eucheuma seaweed. However, it may be naturally occurring in marine algae and be consequently present as an impurity in the finished product. It is therefore appropriate to fix a maximum level of adventitious presence of the above substance in those food additives.

(5) Guar gum is authorised as a food additive for use in foodstuffs by Directive 95/2/EC. In particular, it is used as thickener, emulsifier, and stabiliser. A request to use a partially depolymerised guar gum as a food additive, produced from native guar gum by one of the three manufacturing processes consisting of heat treatment, acid hydrolysis or alkaline oxidation, was submitted to the Commission. EFSA assessed the safety in use of that additive and, in its opinion of 4 July 2007[(6)], estimated that partially depolymerised guar gum has been shown to be very similar to native guar gum with respect to the composition of the final product. It also concluded that partially depolymerised guar gum is of no safety concern for its use as thickener, emulsifier or stabiliser. However, in the same opinion, EFSA recommended that the specifications for E412 guar gum should be adjusted to take into account the increased level of salts and the possible presence of undesirable by-products that may result from the manufacturing process. On the basis of the recommendations issued by EFSA, the specifications of guar gum should be amended.

(6) It is necessary to adopt specifications for E504(i) magnesium carbonate authorised as a food additive for use in foodstuffs through Directive 95/2/EC.

(7) On the basis of data provided by the European Lime Association, it appears that the manufacturing of lime products from available raw materials does not permit them to comply with the existing purity criteria set for E526 calcium hydroxide and E529 calcium oxide, as regards the level of magnesium and alkali salts. Taking into account that magnesium salts are of no safety concern and the specifications as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA), it is appropriate to adjust the levels of magnesium and alkali salts for E526 calcium hydroxide and E529 calcium oxide to the lowest achievable values, which remain lower or equal to the levels set by JECFA.

(8) In addition, it is necessary to take into account the specifications as set out in the Codex Alimentarius drafted by JECFA with regard to the level of lead for E526 calcium hydroxide and E529 calcium oxide. However, due to the natural high background of lead contained in the raw material (calcium carbonate) extracted in some Member States, and from which those additives are derived, it appears difficult to align the level of lead contained in those food additives with the upper limit of lead set by JECFA. Therefore the current level of lead should be reduced to the lowest achievable threshold.

(9) E 901 beeswax is authorised as a food additive in Directive 95/2/EC. EFSA in its opinion of 27 November 2007[(7)] confirmed the safety in use of this food additive. However, it also indicated that the presence of lead should be restricted to the lowest possible level. Taking into account the revised specifications for beeswax as set out in the Codex Alimentarius as drafted by JECFA, it is appropriate to amend the existing purity criteria for E901 beeswax in order to lower the maximum permitted level of lead.

(10) Highly refined waxes deriving from synthetic hydrocarbon feedstock (synthetic waxes) and from petroleum based feedstock were jointly evaluated by the Scientific Committee on Food (hereinafter SCF)[8] and an opinion on mineral and synthetic hydrocarbons was issued on 22 September 1995. The SCF considered that sufficient data had been provided to allocate a full group ADI (acceptable daily intake), covering both types of waxes, i.e. waxes deriving from petroleum based or synthetic hydrocarbon feed stocks. When purity criteria for E905 microcrystalline wax were established, the synthetic hydrocarbon waxes were omitted and not included in the specifications. The Commission considers it therefore necessary to amend the purity criteria for E905 microcrystalline wax in order to also cover waxes derived from synthetic hydrocarbon feedstocks.

(11) E230 (biphenyl) and E233 (thiabendazole) are no longer permitted as food additives in the EU legislation. These substances have been removed respectively by Directive 2003/114/EC and Directive 98/72/EC. Consequently, the Annex I to Directive 2008/84/EC should be updated accordingly and the specifications to E230 and E233 should be withdrawn.

(12) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the JECFA. In particular where appropriate, the specific purity criteria need to be adapted to reflect the limits for individual heavy metals of interest.

(13) Directive 2008/84/EC should therefore be amended accordingly.

(14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1 U.K.

The Annex I to Directive 2008/84/EC is amended in accordance with the Annex to this Directive.

Article 2 U.K.

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 13 February 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3 U.K.

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4 U.K.

This Directive is addressed to the Member States.

Done at Brussels, 13 February 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX U.K.

The Annex I to Directive 2008/84/EC is amended as follows:

1. The text concerning E 234 nisin is replaced by the following:

E 234 NISIN

Definition	Nisin consists of several closely related polypeptides produced during the fermentation of a milk or sugar medium by certain natural strains of *Lactococcus lactis subsp.lactis*
Einecs	215-807-5
Chemical formula	$C_{143}H_{230}N_{42}O_{37}S_7$
Molecular weight	3 354,12
Assay	Nisin concentrate contains not less than 900 units per mg in a mixture of non-fat milk proteins or fermented solids and a minimum sodium chloride content of 50 %
Description	White powder
Purity	
Loss on drying	Not more than 3 % when dried to constant weight at 102 °C to 103 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

2. The text concerning E 400 alginic acid is replaced by the following:

E 400 ALGINIC ACID

Definition	Linear glycuronoglycan consisting mainly of β-(1-4) linked D-mannuronic and α-(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds (*Phaeophyceae*)
Einecs	232-680-1
Chemical formula	$(C_6H_8O_6)_n$
Molecular weight	10 000-600 000 (typical average)

Assay		Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO_2), equivalent to not less than 91 % and not more than 104,5 % of alginic acid $(C_6H_8O_6)_n$ (calculated on equivalent weight basis of 200)
Description		Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless
Identification		
A.	Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B.	Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum
C.	Ammonium sulphate precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch
D.	Colour reaction	Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes, a cherry-red colour develops that finally becomes deep purple
Purity		
pH of a 3 % suspension		Between 2,0 and 3,5
Loss on drying		Not more than 15 % (105 °C, 4 hours)
Sulphated ash		Not more than 8 % on the anhydrous basis

Sodium hydroxide (1 M solution)	Not more than 2 % on the anhydrous basis insoluble matter
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

3. The text concerning E 401 sodium alginate is replaced by the following:

E 401 SODIUM ALGINATE

Definition	
Chemical name	Sodium salt of alginic acid
Chemical formula	$(C_6H_7NaO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for sodium and alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram

Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

4. The text concerning E 402 potassium alginate is replaced by the following:

E 402 POTASSIUM ALGINATE

Definition	
Chemical name	Potassium salt of alginic acid
Chemical formula	$(C_6H_7KO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16,5 % and not more than 19,5 % of carbon dioxide corresponding to not less than 89,2 % and not more than 105,5 % of potassium alginate (calculated on an equivalent weight basis of 238)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for potassium and for alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

5. The text concerning E 403 ammonium alginate is replaced by the following:

E 403 AMMONIUM ALGINATE

Definition	
Chemical name	Ammonium salt of alginic acid
Chemical formula	$(C_6H_{11}NO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88,7 % and not more than 103,6 % ammonium alginate (calculated on an equivalent weight basis of 217)
Description	White to yellowish fibrous or granular powder
Identification	
Positive test for ammonium and alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 7 % on the dried basis
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

6. The text concerning E 404 calcium alginate is replaced by the following:

E 404 CALCIUM ALGINATE

Synonyms	Calcium salt of alginate
Definition	
Chemical name	Calcium salt of alginic acid
Chemical formula	$(C_6H_7Ca_{1/2}O_6)_n$

Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for calcium and alginic acid	
Purity	
Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

7. The text concerning E 405 propane-1,2-diol alginate is replaced by the following:

E 405 PROPANE-1,2-DIOL ALGINATE

Synonyms	Hydroxypropyl alginate 1,2-propanediol ester of alginic acid Propylene glycol alginate
Definition	
Chemical name	Propane-1,2-diol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule
Chemical formula	$(C_9H_{14}O_7)_n$ (esterified)
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO_2 of carbon dioxide

Description	Nearly odourless, white to yellowish brown fibrous or granular powder
Identification	
Positive test for 1,2-propanediol and alginic acid after hydrolysis	
Purity	
Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

8. The text concerning E 407 carrageenan is replaced by the following:

E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from *Eucheuma* spp.) Iridophycan (from *Iridaea* spp.) Hypnean (from *Hypnea* spp.) Furcellaran or Danish agar (from *Furcellaria fastigiata*) Carrageenan (from *Chondrus* and *Gigartina* spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of *Gigartinaceae, Solieriaceae, Hypneaeceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan

	consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg
Einecs	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

9. The text concerning E 407a processed eucheuma seaweed is replaced by the following:

E 407A PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg.
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)

Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Absent in 5 g
Salmonella spp.	Absent in 10 g

10. The text concerning E 412 guar gum is replaced by the following:

E 412 GUAR GUM

Synonyms	Gum cyamopsis Guar flour
Definition	Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, *Cyamopsis tetragonolobur* (L.) Taub. (family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alkaline oxidative treatment for viscosity adjustment.
Einecs	232-536-0
Molecular weight	Consists mainly of a high molecular weight hydrocolloidal polysaccharide (50 000-8 000 000)

Assay	Galactomannan content not less than 75 %
Description	A white to yellowish-white, nearly odourless powder
Identification	
A. Positive tests for galactose and for mannose	
B. Solubility	Soluble in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 5,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein (N × 6,25)	Not more than 10 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution (no blue colour is produced)
Organic peroxides	Not more than 0,7 meq active oxygen/kg sample
Furfural	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

11. After the entry E 503(ii), the following text concerning E 504(i) is added:

E 504(I) MAGNESIUM CARBONATE

Synonyms	Hydromagnesite
Definition	Magnesium carbonate is a basic hydrated or a monohydrated magnesium carbonate or a mixture of the two
Chemical name	Magnesium carbonate
Chemical formula	$MgCO_3.nH_2O$
Einecs	208-915-9
Assay	Not less than 24 % and not more than 26,4 % of Mg

Description	Odourless, light, white friable masses or as a bulky white powder
Identification	
A. Solubility	Practically insoluble both in water or ethanol
B. Positive tests for magnesium and for carbonate	
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1 %
Calcium	Not more than 0,4 %
Arsenic	Not more than 4 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

12. The text concerning E 526 calcium hydroxide is replaced by the following:

E 526 CALCIUM HYDROXIDE

Synonyms	Slaked lime, hydrated lime
Definition	
Chemical name	Calcium hydroxide
Einecs	215-137-3
Chemical formula	$Ca(OH)_2$
Molecular weight	74,09
Assay	Content not less than 92 %
Description	White powder
Identification	
A. Positive tests for alkali and for calcium	
B. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Acid insoluble ash	Not more than 1,0 %
Magnesium and alkali salts	Not more than 2,7 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg

Lead	Not more than 6 mg/kg

13. The text concerning E 529 calcium oxide is replaced by the following:

E 529 CALCIUM OXIDE

Synonyms	Burnt lime
Definition	
Chemical name	Calcium oxide
Einecs	215-138-9
Chemical formula	CaO
Molecular weight	56,08
Assay	Content not less than 95 % on the ignited basis
Description	Odourless, hard, white or greyish white masses of granules, or white to greyish powder
Identification	
A. Positive test for alkali and for calcium	
B. Heat is generated on moistening the sample in water	
C. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Loss on ignition	Not more than 10 % (ca. 800 °C to constant weight)
Acid insoluble matter	Not more than 1 %
Barium	Not more than 300 mg/kg
Magnesium and alkali salts	Not more than 3,6 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 7 mg/kg

14. The text concerning E 901 beeswax is replaced by the following:

E 901 BEESWAX

Synonyms	White wax, yellow wax
Definition	Yellow beeswax is the wax obtained by melting the walls of the honeycomb

	made by the honey bee, *Apis mellifera L.*, with hot water and removing foreign matter White beeswax is obtained by bleaching yellow beeswax
Einecs	232-383-7 (beeswax)
Description	Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour
Identification	
A. Melting range	Between 62 °C and 65 °C
B. Specific gravity	About 0,96
C. Solubility	Insoluble in water Sparingly soluble in alcohol Very soluble in chloroform and ether
Purity	
Acid value	Not less than 17 and not more than 24
Saponification value	87-104
Peroxide value	Not more than 5
Glycerol and other polyols	Not more than 0,5 % (as glycerol)
Ceresin, paraffins and certain other waxes	Absent
Fats, Japan wax, rosin and soaps	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

15. The text concerning E 905 microcrystalline wax is replaced by the following:

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax, hydrocarbon wax, Fischer-Tropsch wax, synthetic wax, synthetic paraffin
Definition	Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks
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 Alternative: n_D^{120} 1,426-1,440
Purity	
Molecular weight	Average not less than 500
Viscosity	Not less than $1,1 \times 10^{-5}$ m^2 s^{-1} at 100 °C Alternative: Not less than $0,8 \times 10^{-5}$ m^2 s^{-1} at 120 °C, if solid at 100 °C
Residue on ignition	Not more than 0,1 wt %
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 wt %
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

Alternative, if solid at 100 °C
PAC method as per 21 CFR& 175.250; Absorbency at 290 nm in decahydronaphthalene at 88 °C: Not exceeding 0,01

16. The text concerning E 230 and E 233 is deleted.

(**1**) OJ L 40, 11.2.1989, p. 27.

(**2**) OJ L 253, 20.9.2008, p. 1.

(**3**) OJ L 61, 18.3.1995, p. 1.

(**4**) http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej314b_nisin.html

(**5**) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to use of formaldehyde as a preservative during the manufacture and preparation of food additives; Question No EFSA Q-2005-032.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620766610.htm

(**6**) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food on a request from the Commission related to an application on the use of partially depolymerised guar gum as a food additive; Question No EFSA-Q-2006-122.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178638739757.htm

(**7**) Beeswax (E 901) as a glazing agent and as carrier for flavours; Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC); Question No EFSA-Q-2006-021.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178672652158.htm

(**8**) http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_37.pdf