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EUROPEAN COMMISSION

Brussels,

**Draft**

**COMMISSION DIRECTIVE**

**of [...]**

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

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## COMMISSION DIRECTIVE

of [...]

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union

Having regard to Regulation 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives and in particular art.30.5 thereof<sup>1</sup>,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

- (1) Commission Directive 2008/84/EC<sup>2</sup> of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners 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<sup>3</sup>.
- (2) Regulation 1333/2008 provides under Art.30.4 that Specifications of the food additives covered under paragraphs 1 to 3 of this Article which include also additives authorised under Directive 95/2/EC shall be adopted, in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], at the moment those food additives are entered in the Annexes in accordance with those paragraphs.
- (3) Since the lists are not yet been established and in order to ensure the modification of the annexes of Directive 95/2/EC pursuant to art. 31 are effective and that additives so authorised are in accordance with safe conditions of use, Directive 2008/84/EC should therefore be amended.
- (4) The entry related to Carbon dioxide (E 290) should be revised with respect to the concentration level of “oil content” to take into account Codex Alimentarius specifications drafted by the Joint Expert Committee on Food Additives (JECFA) and the documents of International Organisation for Standardization (ISO) (e.g. ISO 6141).
- (5) The European Food Safety Authority (hereinafter "the Authority") assessed the information on the safety of extracts of rosemary when used as an antioxidant in

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 253, 20.9.2008, p. 1.

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

foodstuffs. Extracts of rosemary are derived from *Rosmarinus officinalis L.* and contain several compounds which exert antioxidative functions (mainly phenolic acids, flavonoids, diterpenoids and triterpenes). It is considered appropriate to adopt specifications for extracts of rosemary which is authorised as a new food additive for use in foodstuffs under Directive 95/2/EC and assigned E 392 as E number. Few types of production process are described, using solvent extraction (ethanolic, acetone and hexane) and supercritical carbon dioxide extraction.

- (6) Soybean hemicellulose (E 426) was evaluated by the Scientific Committee on Food in 2003<sup>4</sup> and is currently authorised within the EU under Directive 95/2/EC. A new variety of soybean hemicellulose is now produced and complies with all specifications set out in Directive 2008/84/EC for E 426 except that ethanol is technologically needed as precipitant for purifying the extract solution of that new variety of soybean hemicellulose. In consequence, the final E 426, which feature differs from a spray dried white powder, may also contain some ethanol as a residue at the maximum concentration of 2%. Ethanol is authorised by Directive 2009/32/EC as extraction solvent during the processing of raw materials, of foodstuffs, of food components, or of food ingredients, in compliance with good manufacturing practice.
- (7) The Authority assessed the information on the safety of cassia gum as a new food additive acting as gelling agent and thickener and expressed its opinion on 26 September 2006<sup>5</sup>. The Authority found the use of cassia gum as indicated under the conditions specified of no safety concern. It is therefore appropriate to adopt specifications for that new food additive which is assigned E number 427.
- (8) The entry related to hydroxypropyl cellulose E 463 should be modified in order to correct an error of the specifications in relation to the assay. Instead of “Content not less than 80,5 % of hydroxypropoxyl groups”, it should be read “Content not more than 80,5 % of hydroxypropoxyl groups”. It is therefore appropriate to update the current specifications.
- (9) The entry related to hydrogen (E 949) should be corrected so that the concentration levels indicated in the assay and purity sections can be compatible. Consequently, the concentration of nitrogen should be corrected.
- (10) The Authority assessed the information on the safety of new food additive, polyvinyl alcohol (PVA), as a film-coating agent for food supplements and expressed its opinion on 5 December 2005<sup>6</sup>. The Authority found the use of PVA of no safety concern in the coating of food supplement that are in the form of capsules and tablets. It is therefore appropriate to adopt specifications for polyvinyl alcohol which is assigned E number 1203, and which is authorised as a food additive under Directive 95/2/EC.

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<sup>4</sup> Opinion of the Scientific Committee on Food on Soybean Hemicellulose expressed on 4 April 2003 (SCF/CS/ADD/EMU/185 Final).

<sup>5</sup> Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to an application on the use of cassia gum as a food additive, The EFSA Journal (2006) 389, 1-16.

<sup>6</sup> Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyvinyl alcohol as a coating agent for food supplement, The EFSA Journal (2005) 294, 1-15.

- (11) The Authority assessed the information on the safety of six grades of polyethylene glycols (PEG 400, PEG 3000, PEG 3350, PEG 4000, PEG 6000, PEG 8000) as film coating agents for use in food supplement products and expressed its opinion on 28 November 2006<sup>7</sup>. The Authority found the use of those grades of polyethylene glycol as glazing agent in film-coating formulations of no safety concern for food supplement tablets and capsules under the intended conditions of use. All those grades of polyethylene glycols have been assigned a new E number, namely E 1521. It is therefore appropriate to adopt specifications for those six grades of polyethylene glycols and gather them under a single entry. Consequently, it is necessary to update the current specifications already established in Directive 2008/84/EC for polyethylene glycol 6000.
- (12) The Authority assessed the safety of an enzyme preparation based on thrombin with fibrinogen isolated from bovine and/or porcine blood plasma as a food additive for recombining food and concluded in its opinion on 26 April 2005<sup>8</sup> that such use of the enzyme preparation when produced as outlined in the opinion is of no safety concern. It is therefore appropriate to adopt specifications for the two components thrombin and fibrinogen of that enzyme preparation.
- (13) 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.
- (14) Directive 2008/84/EC should therefore be amended accordingly.
- (15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

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

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<sup>7</sup> Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyethylene glycol (PEG) as a film coating agent for use in food supplement products, The EFSA Journal (2006) 414, 1-22.

<sup>8</sup> 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 the use of an enzyme preparation based on thrombin:fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food. The EFSA Journal (2005) 214, 1-8.

## *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [...] 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*

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

## *Article 4*

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the Commission on behalf of the President  
Mr Dalli Member of the Commission

## ANNEX

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

1. In the section on Carbon dioxide (E290) the subentry on “oil content” is replaced by the following

Oil content	Not more than 5 mg/kg
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2. After section on additive E 385, the following section on Extracts of rosemary (E 392) is inserted:

<b>E 392 Extracts of rosemary</b>	
<b>GENERAL SPECIFICATION</b>	
<b>Synonym</b>	Extract of rosemary leaf (antioxidant)
<b>Definition</b>	Extracts of rosemary contain several components, which have been proven to exert antioxidative functions. These components belong mainly to the classes of phenolic acids, flavonoids, diterpenoids. Besides the antioxidant compounds, the extracts can also contain triterpenes and organic solvent extractable material specifically defined in the following specification.
EINECS	283-291-9
Chemical name	Rosemary extract ( <i>Rosmarinus officinalis</i> )
<b>Description</b>	Rosemary leaf extract antioxidant is prepared by extraction of the leaves of <i>Rosmarinus officinalis</i> using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised.
<b>Identification</b>	
Reference antioxidative compounds: phenolic diterpenes	Carnosic acid (C <sub>20</sub> H <sub>28</sub> O <sub>4</sub> ) and Carnosol (C <sub>20</sub> H <sub>26</sub> O <sub>4</sub> ) (which comprise not less than 90% of the total phenolic diterpenes)
Reference key volatiles	Borneol, Bornyl Acetate, Camphor, 1,8-Cineol, Verbenone
Density	> 0.25 g/ml
Solubility	Insoluble in water
<b>Purity:</b>	
Loss on Drying	< 5%

Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
<b>1 - Extracts of rosemary produced from dried rosemary leaves by acetone extraction.</b>	
<b>Description</b>	
	Extracts of rosemary are produced from dried rosemary leaves by acetone extraction, filtration, purification and solvent evaporation, followed by drying and sieving to obtain a fine powder or a liquid.
<b>Identification</b>	
Content of reference antioxidative compounds	≥ 10 % w/w, expressed as the total of carnosic acid and carnosol
<i>Antioxidant / Volatiles – Ratio</i>	(Total % w/w of carnosic acid / carnosol) ≥ 15 (% w/w of reference key volatiles) * (* as a percentage of total volatiles in the extract, measured by Gas Chromatography - Mass Spectrometry Detection, "GC-MSD" ))
Residual Solvents	Acetone : Not more than 500 mg/kg
<b>2 – Extracts of rosemary prepared by extraction of dried rosemary leaves by means of supercritical carbon dioxide.</b>	
Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer.	
<b>Identification</b>	
Content of reference antioxidative compounds	≥13 % w/w, expressed as the total of carnosic acid and carnosol
<i>Antioxidant / Volatiles – Ratio</i>	(Total % w/w of carnosic acid / carnosol) ≥ 15 (% w/w of reference key volatiles) * (* as a percentage of total volatiles in the extract, measured by Gas Chromatography - Mass Spectrometry Detection, "GC-MSD" ))
Residual Solvents	Ethanol: not more than 2%
<b>3 – Extracts of rosemary prepared from a deodorised ethanolic extract of rosemary.</b>	
Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary. The extract may be further purified, for example by treatment with active carbon and/or molecular distillation. They may be suspended in suitable and approved carriers or spray dried.	

<b>Identification</b>	
Content of reference antioxidative compounds	≥5 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant / Volatiles – Ratio	(Total % w/w of carnosic acid / carnosol) ≥ 15 (% w/w of reference key volatiles) * (* as a percentage of total volatiles in the extract, measured by Gas Chromatography - Mass Spectrometry Detection, "GC-MSD" ))
Residual Solvents	Ethanol : not more than 500 mg/kg
<b>4 - Extracts of rosemary decolourised and deodorised extracts obtained by a two-step extraction using hexane and ethanol.</b>	
Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary, undergone a hexane extraction. The extract may be further purified, for example by treatment with active carbon and/or molecular distillation. They may be suspended in suitable and approved carriers or spray dried.	
<i>Identification:</i>	
Content of reference antioxidative compounds	≥5 % w/w, expressed as the total of carnosic acid and carnosol
<i>Antioxidant / Volatiles – Ratio</i>	(Total % w/w of carnosic acid / carnosol) ≥ 15 (% w/w of reference key volatiles) * (* as a percentage of total volatiles in the extract, measured by Gas Chromatography - Mass Spectrometry Detection, "GC-MSD" ))
Residual solvents	Hexane : not more than 25 mg/kg Ethanol : not more than 500 mg/kg

3. In the section on Soybean Hemicellulose (E426), entries on "Definition" and "Description" are replaced by the following:

Definition	Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from natural strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol
Description	Free flowing white or yellowish white powder

In the entry on "Purity" of the section on Soybean Hemicellulose (E426), the following subentry is added:

Ethanol	Not more than 2%
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4. After the section on additive E 426, the following section on Cassia gum (E 427) is inserted::

<b>E 427 Cassia gum</b>	
<b>Synonyms</b>	
<b>Definition</b>	<p>Cassia gum is the ground purified endosperm of the seeds of <i>Cassia tora</i> and <i>Cassia obtusifoli</i> (<i>Leguminosae</i>) containing less than 0.05 % of <i>Cassia occidentalis</i>. It consists mainly of high molecular weight polysaccharides composed primarily of a linear chain of 1,4-<math>\beta</math>-D-mannopyranose units with 1,6 linked <math>\alpha</math>-D-galactopyranose units. The ratio of mannose to galactose is about 5:1.</p> <p>In the manufacture the seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with isopropanol.</p>
Assay	Not less than 75% of Galactomannan
<b>Description</b>	Pale yellow to off-white, odourless powder
<b>Identification</b>	
Solubility	Insoluble in ethanol. Disperses well in cold water forming a colloidal solution.
Gel formation with borate	To an aqueous dispersion of the sample add sufficient sodium borate TS to raise the pH to above 9; a gel is formed.
Gel formation with xanthan gum	<p>Weigh 1.5 g of the sample and 1.5 g of xanthan gum and blend them. Add this blend with (rapid stirring) into 300 ml water at 80° in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60° during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h.</p> <p>A firm, viscoelastic gel forms after the temperature drops below 40°, but no such gel forms in a 1% control solution of cassia gum or xanthan gum alone prepared in a similar manner.</p>
Viscosity	Less than 500 mPa (25 °C, 2h, 1% solution) corresponding to an average molecular weight of 200 000-300 000 D
<b>Purity</b>	
Acid insoluble matter	Not more than 2.0%
pH	5.5-8 (1% aqueous solution)
Crude fat	Not more than 1%

Proteins	Not more than 7 %
Total ash	Not more than 1.2%
Loss on drying	Not more than 12 % (5h, 105 °C)
Total Anthraquinones	Not more than 0.5 mg/kg(detection limit)
Solvent residues	Not more than 750 mg/kg Isopropyl alcohol
Lead	Not more than 1 mg/kg
<b>Microbiological criteria</b>	
Total plate count	Not more than 5 000 colony forming unit per gram
Yeast and mould	Not more than 100 colony forming unit per gram
Salmonella	Absent in 25g
E Coli	Absent in 1g

5. In the section on hydroxypropyl cellulose (E463) the subentry on “Assay” is replaced by the following

Assay	Content not <b>more</b> than 80,5 % of hydroxypropoxyl groups (-OCH <sub>2</sub> CHOHCH <sub>3</sub> ) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
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6. In the entry on “Purity” of the section on hydrogen (E949) the subentry on "Nitrogen" is replaced by the following:

Nitrogen	Not more than 0.07 % v/v
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7. After the section on additive E 1201, the following section is inserted:

<b>E 1203 Polyvinyl Alcohol</b>	
<b>Synonyms</b>	Vinyl alcohol polymer, PVOH
<b>Definition</b>	Polyvinyl alcohol is a synthetic resin prepared by the polymerization of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerization and the degree of hydrolysis.
Chemical name	Ethenol homopolymer
Chemical formula	(C <sub>2</sub> H <sub>3</sub> OR) <sub>n</sub> where R = H or COCH <sub>3</sub>

<b>Description</b>	Odourless, tasteless, translucent, white or cream-coloured granular powder
<b>Identification</b>	
Solubility	Soluble in water ; sparingly soluble in ethanol
Precipitation reaction	Dissolve 0.25g of the sample in 5 ml of water with warming and let the solution cool to room temperature. The addition of 10 ml of ethanol to this solution leads to a white, turbid or flocculent precipitate.
Colour reaction	Dissolve 0.01g of the sample in 100 ml of water with warming and let the solution cool to room temperature. A blue colour is produced when adding (to 5 ml solution) one drop of iodine TS and a few drops of boric acid solution  Dissolve 0.5g of the sample in 10 ml of water with warming and let the solution cool to room temperature. A dark red to blue colour is produced after adding one drop of iodine TS to 5 ml of solution.
Viscosity	4.8 to 5.8 mPa (4% solution at 20°C) corresponding to an average molecular weight of 26000-30000 D
<b>Purity</b>	
Water insoluble matter	Not more than 0.1%
Ester Value	Between 125 and 153 mg KOH/g
Degree of hydrolysis	86.5 to 89.0%
Acid value	Not more than 3.0
Solvent residues	Not more than 1.0 % Methanol, 1.0 % Methyl acetate,
pH	5.0 to 6.5 (4% solution)
Loss on drying	Not more than 5.0 % (105°C, 3H)
Residue in ignition	Not more than 1.0%
Lead	Not more than 2.0 mg/kg

8. The section on “polyethylene glycol 6000” is replaced by the following:

<b>E 1521 Polyethylene glycols</b>	
<b>Synonyms</b>	PEG, Macrogol, Polyethylene oxyde

<b>Definition</b>	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight.
Chemical name	alpha-Hydro-omega-hydroxypoly (oxy-1,2-ethanediol)
Chemical formula	$\text{HOCH}_2 - (\text{CH}_2 - \text{O} - \text{CH}_2)_n - \text{CH}_2\text{OH}$
Average Molecular weight	380 to 9000 D
Assay	PEG 400 : Not less than 95% and not more than 105 % PEG 3000 : Not less than 90% and not more than 110 % PEG 3350 : Not less than 90% and not more than 110 % PEG 4000 : Not less than 90% and not more than 110 % PEG 6000 : Not less than 90% and not more than 110 % PEG 8000 : Not less than 87.5% and not more than 112.5 %
<b>Description</b>	PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid  PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance
<b>Identification</b>	
Melting point	PEG 400 : 4-8°C PEG 3000 : 50-56°C PEG 3350 : 53-57°C PEG 4000 : 53-59°C PEG 6000 : 55-61°C PEG 8000 : 55-62°C
Viscosity	PEG 400 : 0.105 to 0.130 mPa.s at 20 °C PEG 3000 : 0.075 to 0.100 mPa.s at 20 °C PEG 3350 : 0.083 to 0.120 mPa.s at 20 °C PEG 4000 : 0.11 to 0.17 mPa.s at 20 °C PEG 6000 : 0.20 to 0.27 mPa.s at 20 °C PEG 8000 : 0.26 to 0.51 mPa.s at 20 °C For polyethylene glycols having a average molecular weight greater than 400, the viscosity is determined on a 50 per cent m/m solution of the candidate substance in water
Solubility	PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils PEG 3000 and PEG 3350 : very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils PEG 4000, PEG 6000 and PEG 8000 : very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils.

<b>Purity</b>	
Acidity or alkalinity	Dissolve 5.0 g in 50 ml of carbon dioxide-free water and add 0.15 ml of bromothymol blue solution . The solution is yellow or green. Not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to blue.
Hydroxyl value	PEG 400 : 264-300 PEG 3000 : 34-42 PEG 3350 : 30-38 PEG 4000 : 25-32 PEG 6000 : 16-22 PEG 8000 : 12-16
Sulphated ash	Not more than 0.2%
1,4-Dioxane	Not more than 10 mg/kg
Ethylene oxide	Not more than 0.2 mg/kg
Ethylene glycol and diethylene glycol	Total not more than 0.25% °w/w individually or in combination
Lead	Not more than 1 mg/kg

9. After the section on additive E 1521, the following section is added:

<b>Thrombin</b>	
Definition	
<b>Synonyms</b>	Fibrinogenase; thrombase; thrombofort; topical; thrombin-C; tropostasin; activated blood-coagulation factor II; blood-coagulation factor IIa; factor IIa; E thrombin; $\beta$ -thrombin; $\gamma$ -thrombin
<b>Definition</b>	<p>Thrombin (EC 3.4.21.5) is a serine proteinase involved in the final step of blood coagulation. This enzyme consists of two chains and has an apparent molecular mass of about 36.5 kDa and an isoelectric point of 7.5. Thrombin has a highly specific proteolytic activity, cleaving only arginine-glycine peptide bonds such as those found in fibrinogen, which is cleaved into fibrin.</p> <p>Thrombin and fibrinogen are isolated from bovine and/or porcine blood plasma.</p> <p>The enzyme thrombin is used in a preparation with fibrinogen as the substrate which are mixed together just before use.</p>
Enzyme Commission No	3.4.21.5
<b>Description</b>	Colourless solution with a neutral smell.
<b>Identification</b>	
Density	1,04 kg/l
pH	Between 6 and 9
<b>Purity</b>	
Ash	Not more than 7%
Water	92-94 % (w/w)
Lead	Not more than 0.1 mg/kg
<b>Microbiological criteria</b>	
Total bacterial count	Not more than 100 000 colony forming unit per gram
Salmonella sp	Absent in 25g
Enterobacteriaceae	Not more than 1000 colony forming unit per gram
Staphylococcus aureus	Not more than 1000 colony forming unit per gram

Moulds	Not more than 1000 colony forming unit per gram
Yeasts	Not more than 100 colony forming unit per gram
Total coliforms	Not more than 30 colony forming unit per gram
<b>Fibrinogen</b>	
<b>Definition</b>	Fibrinogen is a plasma protein which can be used for the cross linking of the amino acids lysine and glutamine
<b>Description</b>	Viscous orange / red solution
<b>Identification</b>	
Density	1,04 kg/l
pH	7-9
<b>Purity</b>	
Fat	0.3 % (w/w)
Proteins	9.5 % (w/w) including Fibrinogen (5% (w/w))
Citrate	0.5 % (w/w)
water	86 – 90% (w/w)
Arsenic	Not more than 0.2 mg/kg
Lead	Not more than 0.1 mg/kg
<b>Microbiological criteria</b>	
Total bacterial count	Not more than 100 000 colony forming unit per gram
Salmonella sp	Absent in 25g
Enterobacteriaceae	Not more than 1000 colony forming unit per gram
Staphylococcus aureus	Not more than 1000 colony forming unit per gram
Moulds	Not more than 1000 colony forming unit per gram
Yeasts	Not more than 100 colony forming unit per gram
E coli	Absent in 25g

Total coliforms	Not more than 30 colony forming unit per gram
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