Non-legislative acts

REGULATIONS


(1) Text with EEA relevance

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.
II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (1), and in particular Articles 14 and 30(4) thereof, and Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (2), and in particular Article 7(5) thereof,

Whereas:

(1) Specifications relating to origin, purity criteria and any other necessary information should be adopted for food additives listed in the Union lists in Annex II and III to Regulation (EC) No 1333/2008.

(2) To that end, specifications previously developed for food additives in Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs (3), Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners (4) and Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs (5) should be updated and taken over to this Regulation. As a consequence, those Directives should be repealed.

(3) It is necessary to take into account the specifications and analytical techniques as set out in the Codex Alimentarius drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA).

(4) The European Food Safety Authority (hereinafter ‘the Authority’) expressed its opinion on the safety of basic methacrylate copolymer (6) as a glazing agent. That food additive has subsequently been authorised on the basis of specific uses and has been allocated the number E 1205. Therefore specifications should be adopted for that food additive.

(5) Food colours ethyl ester of beta-apo-8’-carotenic acid (E 160 f), and brown FK (E 154), as well as the aluminium containing carrier bentonite (E 558) are not used anymore according to information submitted by food manufacturers. Therefore, current specifications for those food additives should not be taken over to this Regulation.

(6) On 10 February 2010 the Authority expressed an opinion on the safety of sucrose esters of fatty acids (E 473) prepared from vinyl esters of fatty acids (7). Current specifications should be adapted accordingly in particular by reducing maximum limits for impurities of safety concern.

(7) Specific purity criteria currently applicable should be adapted by reducing maximum limits for individual heavy metals of interest where feasible and where the JECFA limits are lower than those currently in force. Pursuant to that approach maximum limits for the contaminant 4-methylimidazole in ammonia caramel (E 150 c), sulphated ash in beta-carotene (E 160 a (i)), and magnesium and alkali salts in calcium carbonate (E 170), should be lowered. That approach should be departed from only for additives trisodium citrate (E 331 (iii)) (lead content), carrageenan (E 407) and

(6) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of Basic Methacrylate Copolymer as a food additive on request from the European Commission. EFSA Journal 2010; 8(2):1513.
(7) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings on request from the European Commission. EFSA Journal 2010; 8(3):1512.
Some food additives are currently listed under various Union provisions, reflecting JECFA limits, would not be technically feasible. The contribution to the total intake of those two contaminants (lead and cadmium) in those three individual food additives is not considered to be significant. On the contrary for phosphates (E 338-E 452) new significantly lower values, compared to the ones indicated by JECFA, should be established due to new developments of the manufacturing processes, by taking into account the recent recommendations of the Authority on a reduction of the intake of arsenic, especially in the inorganic form (1). In addition, a new provision on arsenic for glutamic acid (E 620) should be introduced for safety reasons. The total balance of those adaptations benefits the consumers as maximum limits for heavy metals are becoming stricter in general and in most of the food additives. Detailed information on the production process and starting materials of a food additive should be included in the specifications to facilitate any future decision pursuant to Article 12 of Regulation (EC) No 1333/2008.

Specifications should not make reference to organoleptic tests related to the taste as it cannot be expected by the control authorities to take the risk to taste a chemical substance.

Specifications should not make reference to classes as there is no added value in this reference.

Specifications should not make reference to the general parameter 'Heavy metals' as this parameter does not relate with toxicity, but rather with a generic analytical method. Parameters related to individual heavy metals are toxicity related and are included in the specifications.

Some food additives are currently listed under various names (carboxy methyl cellulose (E 466), cross-linked sodium carboxymethylcellulose (E 468), enzymatically hydrolysed carboxymethylcellulose (E 469) and beeswax, white and yellow (E 901)) in various provisions of Directive 95/2/EC of the European Parliament and of the Council (2). Therefore the specifications established by this Regulation should refer to those various names.

Current provisions on Polycyclic Aromatic Hydrocarbons (PAHs) are too generic and not relevant to safety and should be replaced by maximum limits for individual PAHs of concern for food additives vegetable carbon (E 153) and microcrystalline wax (E 905). Similar maximum limits should be established for formaldehyde in carageenan (E 407) and processed eucheuma seaweed (E 407 a), for particular microbiological criteria in agar (E 406) and for Salmonella spp. content in mannitol (E 421 (ii)) manufactured by fermentation.

The use of propan-2-ol (isopropanol, isopropyl alcohol) should be allowed for manufacturing the additives curcumin (E 100) and paprika extract (E 160 c), in line with JECFA specifications, as this particular use has been considered safe by the Authority (3). The use of ethanol in replacement of propan-2-ol in the manufacturing of gellan gum (E 418) should be permitted where the final product still complies with all other specifications and ethanol is considered to be of less safety concern.

The percentage of the colouring principle in cochineal, carminic acid, carmines (E 120) should be specified, as maximum limits are to apply to quantities of that principle.

The solid form of lactic acid (E 270) should also be included in the specifications, as it can now be manufactured in the solid form and there is no safety concern.

The current temperature value in loss on drying for monosodium citrate (E 331 (i)), anhydrous form should be adjusted as under the currently listed conditions the substance decomposes. Drying conditions for trisodium citrate (E 331 (iii)) should also be adjusted to improve the reproducibility of the method.

The current specific absorption value for alphatocopherol (E 307) should be corrected and the sublimation point for sorbic acid (E 200) should be replaced by a 'solubility test' as the former is not relevant. The specification of bacterial sources for the manufacturing of nisin (E 234) and natamycin (E 235) should be updated according to the current taxonomic nomenclature.

As new innovative manufacturing techniques resulting in less contaminated food additives are now available, the presence of aluminium in food additives should be restricted. In order to enhance legal certainty and non-discrimination it is appropriate to provide the manufacturers of food additives with a transitional period to adapt gradually to those restrictions.

(1) EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Arsenic in Food. EFSA Journal 2009; 7(10):1351.
(3) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of curcumin (E 100) as a food additive. EFSA Journal 2010; 8(9):1679.
(20) Maximum limits for aluminium should be established for food additives where relevant, and particularly for calcium phosphates (E 341(i)-(iii)) intended to be used in food for infants and young children (1), according to the relevant opinion of Scientific Committee on Food expressed on 7 June 1996 (2). In this framework a maximum limit for aluminium in calcium citrate (E 333) should also be established.

(21) The maximum limits for aluminium in calcium phosphates (E 341(i)-(iii)), disodium dihydrogen diphosphate (E 450(ii)) and calcium dihydrogen diphosphate (E 450(vii)) should be in accordance with the opinion of the Authority of 22 May 2008 (3). Current limits should be reduced, where this is technically feasible, and where the contribution to the total aluminium intake is significant. In this framework aluminium lakes of individual food colours should be authorised only if technically needed.

(22) Provisions on maximum limits for aluminium in dicalcium phosphate (E 341(iii)), tricalcium phosphate (E 341(iii)) and calcium dihydrogen diphosphate (E 450(viii)) should not cause any disruption of the market, due to a possible lack of supplies.

(23) According to Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (4), maximum limits should be set for the contaminant pentachlorophenol in guar gum (E 412).

(24) According to recital 48 of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (5) Member States are requested to examine other foodstuffs than the ones included in that Regulation for the occurrence of contaminant 3-MCPD in order to consider the need to set maximum levels for that substance. French authorities have submitted data on high concentrations of 3-MCPD in the food additive glycerol (E 422) and the average use level of this food additive in various food categories. Maximum limits for 3-MCPD in this particular food additive should be set in order to avoid contamination of the final food at a higher than permissible level, taking into account the dilution factor.

(25) Due to the development of analytical methods certain current specifications should be updated. The current limit value ‘not detectable’ is linked to the evolution of analytical methodologies and should be replaced by a specific number for additives acid esters of mono- and diglycerides (E 472 a-i), polyglycerol esters of fatty acids (E 475) and propane-1,2-diol esters of fatty acids (E 477).

(26) Specifications relating to the manufacturing procedure should be updated for citric acid esters of mono- and diglycerides of fatty acids (E 472 c), as the use of alkaline bases is replaced today by the use of their milder acting salts.

(27) The current criterion ‘free fatty acids’ for additives citric acid esters of mono- and diglycerides of fatty acids (E 472 c) and mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e) is not appropriate. It should be replaced by the criterion ‘acid value’ as the latter expresses better the titrimetric estimation of the free acidic groups. This is in accordance with the 71st report on food additives from JECFA (6) where such change was adopted for mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e).

(28) The current erroneous description of additive magnesium oxide (E 530) should be corrected according to information submitted by the manufacturers, in order to bring it in line with the Pharmacopoeia Europea (7). The current maximum value for the reducing matter in additive gluconic acid (E 574) should also be updated as this limit is not technically feasible. For the estimation of the water content of xylitol (E 967) the current method based on ‘loss on drying’, should be replaced by a more appropriate method.

(29) Some current specifications for additive candelilla wax (E 902) should not be taken over to this Regulation since they are erratic. For calcium dihydrogen diphosphate (E 450(viii)) the current entry concerning P₂O₅ content should be corrected.

(30) In the current entry ‘assay’ for thaumatin (E 957) a calculation factor should be corrected. That factor is to be used in the Kjeldahl method for the estimation of the total content of the substance based on the measurement of nitrogen. The calculation factor should be updated according to the relevant published literature for thaumatin (E 957).

(31) The Authority evaluated the safety of steviol glycosides, as a sweetener and expressed its opinion of 10 March 2010 (8). The use of steviol glycosides, which have been

7) EP 7.0 volume 2, p. 2415-2416.
8) EFSA Panel on Food Additives and Nutrient Sources (ANS); Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive. EFSA Journal (2010); 8(4):1537.
allocated number E 960, has subsequently been permitted on the basis of well defined conditions of use. Therefore specifications should be adopted for this food additive.

(32) Due to a taxonomic change, current specifications for source materials (yeasts) used in the manufacturing of erythritol (E 968) should be updated.

(33) For quillaia extract (E 999) the current specification relating to the pH range should be adjusted in order to bring it in line with JECFA.

(34) The combination of citric acid and phosphoric acid (which are currently both individually authorised for use in the manufacturing of additive polydextrose (E 1200)), should be allowed, where the final product still complies with the purity specifications, as it improves yields and results to more controllable reaction kinetics. There is no safety concern involved in such amendment.

(35) Unlike for small molecules, the molecular mass of a polymer is not one unique value. A given polymer may have a distribution of molecules with different masses. The distribution may depend on the way the polymer is produced. Polymer physical properties and behaviors are related to the mass and to the distribution of molecules with a certain mass in the mixture. A group of mathematical models describe the mixture in different ways in order to clarify the distribution of molecules in the mixture. Among the different models available, it is recommended in scientific literature to use the weight average molecular weight (Mw) to describe polymers. The specifications for polyvinylpyrrolidone (E 1201) should be adjusted accordingly.

(36) The criterion ‘Distillation range’ referred to in current specifications for propane-1,2 diol (E 1520) leads to contradictory conclusions compared to results from the assay. That criterion should therefore be corrected and renamed into ‘Distillation test’.

(37) The measures provided for in this Regulation 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 REGULATION:

Article 1

Specifications for food additives

Specifications for food additives including colours and sweeteners listed in Annex II and III to Regulation (EC) No 1333/2008 are laid down in the Annex to this Regulation.

Article 2

Repeals

Directives 2008/60/EC, 2008/84/EC and 2008/128/EC are repealed with effect from 1 December 2012.

Article 3

Transitional measures

Foodstuffs containing food additives that have been lawfully placed on the market before 1 December 2012, but do not comply with this Regulation, may continue to be marketed until stocks are exhausted.

Article 4

Entry into force

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

It shall apply from 1 December 2012.

However, the specifications laid down in the Annex for additives steviol glycosides (E 960) and basic methacrylate copolymer (E 1205) shall apply from the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in the Member States.

Done at Brussels, 9 March 2012.

For the Commission

The President

José Manuel BARROSO
Annex

Note: Ethylene oxide may not be used for sterilising purposes in food additives.

**Aluminium lakes for use in colours only where explicitly stated.**

**Definition:** Aluminium lakes are prepared by reacting colours complying with the purity criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulphate or chloride with sodium or calcium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted alumina may also be present in the finished product.

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCl insoluble matter</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>NaOH insoluble matter</td>
<td>Not more than 0.5 %, for E 127 erythrosine only</td>
</tr>
<tr>
<td>Ether extractable matter</td>
<td>Not more than 0.2 % (under neutral conditions)</td>
</tr>
</tbody>
</table>

Specific purity criteria for the corresponding colours are applicable.

**E 100 CURCUMIN**

**Synonyms**

CI Natural Yellow 3; Turmeric Yellow; Diferoyl Methane

**Definition**

Curcumin is obtained by solvent extraction of turmeric i.e. the ground rhizomes of strains of Curcuma longa L. In order to obtain a concentrated curcumin powder, the extract is purified by crystallization. The product consists essentially of curcumin; i.e. the colouring principle (1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-dien-3,5-dione) and its two desmethoxy derivatives in varying proportions. Minor amounts of oils and resins naturally occurring in turmeric may be present.

Curcumin is also used as the aluminium lake; the aluminium content is less than 30 %.

Only the following solvents may be used in the extraction: ethylacetate, acetone, carbon dioxide, dichloromethane, n-butanol, methanol, ethanol, hexane, propan-2-ol.

**Colour Index No**

75300

**Einccs**

207-280-5

**Chemical name**

I 1,7-Bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione
II 1-(4-Hydroxyphenyl)-7-(4-hydroxy-3-methoxy-phenyl)-hepta-1,6-diene-3,5-dione
III 1,7-Bis(4-hydroxyphenyl)hepta-1,6-diene-3,5-dione

**Chemical formula**

| I  | C₂₁H₂₀O₆ |
| II | C₂₀H₁₈O₅ |
| III| C₁₉H₁₈O₄ |

**Molecular weight**

| I  | 368.39 |
| II | 338.39 |
| III| 308.39 |

**Assay**

Content not less than 90 % total colouring matters

E₁₅ % 1 607 at ca. 426 nm in ethanol

**Description**

Orange-yellow crystalline powder
Identification

Spectrometry
Maximum in ethanol at ca. 426 nm

Melting range
179 °C-182 °C

Purity

Solvent residues

Ethylacetate
Acetone
n-butanol
Methanol
Ethanol
Hexane
Propan-2-ol

Not more than 50 mg/kg, singly or in combination

Dichloromethane: not more than 10 mg/kg

Arsenic
Not more than 3 mg/kg

Lead
Not more than 10 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

**E 101 (i) RIBOFLAVIN**

Synonyms
Lactoflavin;

Definition

Colour Index No
201-507-1

Einecs
7,8-Dimethyl-10-(D-ribo-2,3,4,5-tetrahydroxypentyl)benzo@pteridine-2,4(3H,10H)-dione; 7,8-dimethyl-10-(1'-D-ribityl)isoalloxazine

Chemical formula
C_{17}H_{20}N_{4}O_{6}

Molecular weight
376.37

Assay
Content not less than 98 % on the anhydrous basis

E_{1%} 328 at ca. 444 nm in aqueous solution

Description
Yellow to orange-yellow crystalline powder, with slight odour
Identification

Spectrometry The ratio $A_{375}/A_{267}$ is between 0.31 and 0.33 in aqueous solution

The ratio $A_{444}/A_{267}$ is between 0.36 and 0.39

Maximum in water at ca. 375 nm

Specific rotation $[\alpha]_{D}^{20}$ between $-115^\circ$ and $-140^\circ$ in a 0.05 N sodium hydroxide solution

Purity

Loss on drying Not more than 1.5 % (105 °C, 4 hours)

Sulphated ash Not more than 0.1 %

Primary aromatic amines Not more than 100 mg/kg (calculated as aniline)

Arsenic Not more than 3 mg/kg

Lead Not more than 2 mg/kg

Mercury Not more than 1 mg/kg

Cadmium Not more than 1 mg/kg

E 101 (ii) RIBOFLAVIN-5'-PHOSPHATE

Synonyms Riboflavin-5'-phosphate sodium

Definition These specifications apply to riboflavin 5'-phosphate together with minor amounts of free riboflavin and riboflavin diphosphate.

Colour Index No

Einecs 204-988-6

Chemical name Monosodium(2R,3R,4S)-5-(3'-10'-dihydro-7',8'-dimethyl-2',4'-dioxo-10'-benzoyl]pteridinyl)-2,3,4-trihydroxypentyl phosphate; monosodium salt of 5'-monophosphate ester of riboflavin

Chemical formula For the dihydrate form: $C_{17}H_{20}N_{4}NaO_{9}P \cdot 2H_{2}O$

For the anhydrous form: $C_{17}H_{20}N_{4}NaO_{9}P$

Molecular weight 514.36

Assay Content not less than 95 % total colouring matters calculated as $C_{17}H_{20}N_{4}NaO_{9}P \cdot 2H_{2}O$

$E_{1\%}^{1cm}$ 250 at ca. 375 nm in aqueous solution
**Description**

Yellow to orange crystalline hygroscopic powder, with slight odour.

**Identification**

- **Spectrometry**
  - The ratio $A_{375}/A_{267}$ is between 0.30 and 0.34 in aqueous solution.
  - The ratio $A_{444}/A_{267}$ is between 0.35 and 0.40.

- Maximum in water at ca. 375 nm.

- **Specific rotation**
  - $[\alpha]_{D}^{20}$ between +38° and +42° in a 5 molar HCl solution.

**Purity**

- **Loss on drying**
  - Not more than 8% (100°C, 5 hours in vacuum over $P_2O_5$) for the dihydrate form.

- **Sulphated ash**
  - Not more than 25%.

- **Inorganic phosphate**
  - Not more than 1.0% (calculated as $PO_4$ on the anhydrous basis).

- **Subsidiary colouring matters**
  - Riboflavin (free): Not more than 6%.
  - Riboflavine diphosphate: Not more than 6%.

- **Primary aromatic amines**
  - Not more than 70 mg/kg (calculated as aniline).

- **Arsenic**
  - Not more than 3 mg/kg.

- **Lead**
  - Not more than 2 mg/kg.

- **Mercury**
  - Not more than 1 mg/kg.

- **Cadmium**
  - Not more than 1 mg/kg.

**E 102 TARTRAZINE**

**Synonyms**

CI Food Yellow 4

**Definition**

Tartrazine is prepared from 4-amino-benzene-sulphonic acid, which is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is then coupled with 4,5-dihydro-5-oxo-1-(4-sulphon phenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt. Tartrazine consists essentially of trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-1H-pyrazole-3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Tartrazine is described as the sodium salt. The calcium and the potassium salt are also permitted.

**Colour Index No**

19140

**Einecs**

217-699-5

**Chemical name**

Trisodium-5-hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-1H-pyrazole-3-carboxylate.
<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>( \text{C}_{16}\text{H}_9\text{N}_4\text{Na}_3\text{O}_9\text{S}_2 )</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>534.37</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 85 % total colouring matters calculated as the sodium salt</td>
</tr>
<tr>
<td></td>
<td>( E_{1%}^{1\text{cm}} 530 ) at ca. 426 nm in aqueous solution</td>
</tr>
<tr>
<td>Description</td>
<td>Light orange powder or granules</td>
</tr>
<tr>
<td>Appearance of the aqueous solution</td>
<td>Yellow</td>
</tr>
<tr>
<td>Identification</td>
<td>Spectrometry Maximum in water at ca. 426 nm</td>
</tr>
<tr>
<td>Purity</td>
<td>Water insoluble matter Not more than 0.2 %</td>
</tr>
<tr>
<td></td>
<td>Subsidiary colouring matters Not more than 1.0 %</td>
</tr>
<tr>
<td></td>
<td>Organic compounds other than colouring matters:</td>
</tr>
<tr>
<td></td>
<td>4-hydrazinobenzene sulfonic acid</td>
</tr>
<tr>
<td></td>
<td>4-aminobenzene-1-sulfonic acid</td>
</tr>
<tr>
<td></td>
<td>5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid</td>
</tr>
<tr>
<td></td>
<td>4,4'-diazooaminodibenzene sulfonic acid</td>
</tr>
<tr>
<td></td>
<td>Tetrahydroxysuccinic acid</td>
</tr>
<tr>
<td></td>
<td>Total not more than 0.5 %</td>
</tr>
<tr>
<td></td>
<td>Unsulfonated primary aromatic amines Not more than 0.01 % (calculated as aniline)</td>
</tr>
<tr>
<td></td>
<td>Ether extractable matter Not more than 0.2 % under neutral conditions</td>
</tr>
<tr>
<td></td>
<td>Arsenic Not more than 3 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Lead Not more than 2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mercury Not more than 1 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Cadmium Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

*Aluminium lakes of this colour may be used.*
## E 104 QUINOLINE YELLOW

### Synonyms

| CI Food Yellow 13 |

### Definition

Quinoline Yellow is prepared by sulfonating 2-(2-quinolyl) indan-1,3-dione or a mixture containing about two thirds 2-(2-quinolyl)indane-1,3-dione and one third 2-(2-(6-methylquinolyl))indane-1,3-dione. Quinoline Yellow consists essentially of sodium salts of a mixture of disulfonates (principally), monosulfonates and trisulfonates of the above compound and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Quinoline Yellow is described as the sodium salt. The calcium and the potassium salt are also permitted.

### Colour Index No

| 47005 |

### Einecs

| 305-897-5 |

### Chemical name

The disodium salts of the disulfonates of 2-(2-quinolyl) indan-1,3-dione (principal component)

### Chemical formula

\[ C_{18}H_9NNa_2O_8S_2 \] (principal component)

### Molecular weight

| 477.38 (principal component) |

### Assay

Content not less than 70 % total colouring matters calculated as the sodium salt

Quinoline Yellow shall have the following composition:

- Of the total colouring matters present:
  - not less than 80 % shall be disodium 2-(2-quinolyl) indan-1,3-dione-disulfonates
  - not more than 15 % shall be sodium 2-(2-quinolyl) indan-1,3-dione-monosulfonates
  - not more than 7.0 % shall be trisodium 2-(2-quinolyl) indan-1,3-dione-trisulfonate

### Description

Yellow powder or granules

### Appearance of the aqueous solution

Yellow

### Identification

- **Spectrometry**: Maximum in aqueous acetic acid solution of pH 5 at ca. 411 nm

### Purity

| Water insoluble matter |

Not more than 0.2 %

| Subsidiary colouring matters |

Not more than 4.0 %

| Organic compounds other than colouring matters: |

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-methylquinoline</td>
<td>Total not more than 0.5 %</td>
</tr>
<tr>
<td>2-methylquinoline-sulfonic acid</td>
<td></td>
</tr>
<tr>
<td>Phthalic acid</td>
<td></td>
</tr>
<tr>
<td>2,6-dimethyl quinoline</td>
<td></td>
</tr>
<tr>
<td>2,6-dimethyl quinoline sulfonic acid</td>
<td></td>
</tr>
<tr>
<td>2-(2-quinolyl)indan-1,3-dione</td>
<td>Not more than 4 mg/kg</td>
</tr>
<tr>
<td>Unsulfonated primary aromatic amines</td>
<td>Not more than 0.01 % (calculated as aniline)</td>
</tr>
<tr>
<td>Ether extractable matter</td>
<td>Not more than 0.2 % under neutral conditions</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

*Aluminium lakes of this colour may be used.*

### E 110 SUNSET YELLOW FCF

**Synonyms**
CI Food Yellow 3; Orange Yellow S

**Definition**
Sunset Yellow FCF consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Sunset Yellow FCF is manufactured by diazotizing 4-aminobenzenesulphonic acid using hydrochloric acid and sodium nitrite or sulphuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulphonic acid. The dye is isolated as the sodium salt and dried.

Sunset Yellow FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.

**Colour Index No**
15985

**Einacs**
220-491-7

**Chemical name**
Disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate

**Chemical formula**
\( C_{14}H_{10}N_2Na_2O_6S_2 \)

**Molecular weight**
452.37

**Assay**
Content not less than 85 % total colouring matters calculated as the sodium salt

**\( E_{1%}^{1cm} \) at ca. 485 nm in aqueous solution at pH 7**
555

**Description**
Orange-red powder or granules

**Appearance of the aqueous solution**
Orange
Identification

Spectrometry

Maximum in water at ca. 485 nm at pH 7

Purity

Water insoluble matter

Not more than 0.2 %

Subsidiary colouring matters

Not more than 5.0 %

1-(Phenylazo)-2-naphthalenol (Sudan I)

Not more than 0.5 mg/kg

Organic compounds other than colouring matters:

- 4-aminobenzene-1-sulfonic acid
- 3-hydroxynaphthalene-2,7-disulfonic acid
- 6-hydroxynaphthalene-2-sulfonic acid
- 7-hydroxynaphthalene-1,3-disulfonic acid
- 4,4′-diazoaminodi(benzene sulfonic acid)
- 6,6′-oxydi(naphthalene-2-sulfonic acid)

Total not more than 0.5 %

Unsulfonated primary aromatic amines

Not more than 0.01 % (calculated as aniline)

Ether extractable matter

Not more than 0.2 % under neutral conditions

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 120 COchineal, Carminic Acid, Carmines

Synonyms

CI Natural Red 4

Definition

Carmines and carminic acid are obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect Dactylopius coccus Costa.

The colouring principle is carminic acid.

Aluminium lakes of carminic acid (carmines) can be formed in which aluminium and carminic acid are thought to be present in the molar ratio 1:2.
In commercial products the colouring principle is present in association with ammonium, calcium, potassium or sodium cations, singly or in combination, and these cations may also be present in excess.

Commercial products may also contain proteinaceous material derived from the source insect, and may also contain free carminate or a small residue of unbound aluminium cations.

| Colour Index No | 75470 |
| Chemical name | 7-β-D-glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxoan-thracene-2-carboxylic acid (carminic acid); carmine is the hydrated aluminium chelate of this acid |
| Chemical formula | C_{22}H_{20}O_{13} (carminic acid) |
| Molecular weight | 492.39 (carminic acid) |
| Assay | Content not less than 2.0 % carminic acid in the extracts containing carminic acid; not less than 50 % carminic acid in the chelates. |

**Description**

Red to dark red, friable, solid or powder. Cochineal extract is generally a dark red liquid but can also be dried as a powder.

**Identification**

- **Spectrometry**
  - Maximum in aqueous ammonia solution at ca. 518 nm
  - Maximum in dilute hydrochloric solution at ca. 494 nm for carminic acid
  - $E_{1\%}^{1cm}$ 139 at peak around 494 nm in dilute hydrochloric acid for carminic acid

**Purity**

- **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

*Aluminium lakes of this colour may be used.*

---

**E 122 AZORUBINE, CARMOISINE**

**Synonyms**

CI Food Red 3

**Definition**

Azorubine consists essentially of disodium 4-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Azorubine is described as the sodium salt. The calcium and the potassium salt are also permitted.

<p>| Colour Index No | 14720 |</p>
<table>
<thead>
<tr>
<th><strong>EINECS</strong></th>
<th>222-657-4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical name</strong></td>
<td>Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo)naphthalene-1-sulfonate</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>C$<em>{20}$H$</em>{12}$N$_2$Na$_2$O$_7$S$_2$</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>502.44</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 85 % total colouring matters, calculated as the sodium salt $E_{1%}^\text{vis}$ 510 at ca. 516 nm in aqueous solution</td>
</tr>
</tbody>
</table>

**Description**

Appearance of the aqueous solution

Red to maroon powder or granules

**Identification**

Spectrometry

Maximum in water at ca. 516 nm

**Purity**

Water insoluble matter

Not more than 0.2 %

Subsidiary colouring matters

Not more than 1 %

Organic compounds other than colouring matters:

\[
\begin{align*}
4\text{-aminonaphthalene-1-sulfonic acid} \\
4\text{-hydroxynaphthalene-1-sulfonic acid} \\
\end{align*}
\]

Total not more than 0.5 %

Unsulfonated primary aromatic amines

Not more than 0.01 % (calculated as aniline)

Ether extractable matter

Not more than 0.2 % under neutral conditions

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

**Aluminium lakes of this colour may be used.**

**E 123 AMARANTH**

**Synonyms**

CI Food Red 9

**Definition**

Amaranth consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo)naphthalene-3,6-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Amaranth is manufactured by coupling 4-amino-1-naphthalenesulphonic acid with 3-hydroxy-2,7-naphthalenedisulphonic acid.
Amaranth is described as the sodium salt. The calcium and the potassium salt are also permitted.

| Colour Index No | 16185 |
| Einacs         | 213-022-2 |
| Chemical name  | Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo)naphthalene-3,6-disulfonate |
| Chemical formula | C_{20}H_{11}N_{2}Na_{3}O_{10}S_{3} |
| Molecular weight | 604.48 |
| Assay          | Content not less than 85 % total colouring matters, calculated as the sodium salt. $E_{1\%}^{1\text{cm}}$ 440 at ca. 520 nm in aqueous solution |

**Description**

Reddish-brown powder or granules

**Appearance of the aqueous solution**

Red

**Identification**

Spectrometry Maximum in water at ca. 520 nm

**Purity**

- Water insoluble matter: Not more than 0.2 %
- Subsidiary colouring matters: Not more than 3.0 %
- Organic compounds other than colouring matters:
  - 4-aminonaphthalene-1-sulfonic acid
  - 3-hydroxynaphthalene-2,7-disulfonic acid
  - 6-hydroxynaphthalene-2-sulfonic acid
  - 7-hydroxynaphthalene-1,3-disulfonic acid
  - 7-hydroxynaphthalene-1,3-6-trisulfonic acid Total not more than 0.5 %
- Unsulfonated primary aromatic amines: Not more than 0.01 % (calculated as aniline)
- Ether extractable matter: Not more than 0.2 % under neutral conditions
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg

*Aluminium lakes of this colour may be used.*
**E 124 PONCEAU 4R, COCHINEAL RED A**

**Synonyms**
CI Food Red 7; New Coccine

**Definition**
Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Ponceau 4R is manufactured by coupling diazotized naphthionic acid to G acid (2-naphthol-6,8-disulphonic acid) and converting the coupling product to the trisodium salt.

Ponceau 4R is described as the sodium salt. The calcium and the potassium salt are also permitted.

**Colour Index No**
16255

**Einecs**
220-036-2

**Chemical name**
Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate

**Chemical formula**
C_{20}H_{11}N_{2}Na_{3}O_{10}S_{3}

**Molecular weight**
604.48

**Assay**
Content not less than 80 % total colouring matters, calculated as the sodium salt.

E_{1%}^{1cm} 430 at ca. 505 nm in aqueous solution

**Description**
Reddish powder or granules

**Appearance of the aqueous solution**
Red

**Identification**

**Spectrometry**
Maximum in water at ca. 505 nm

**Purity**

**Water insoluble matter**
Not more than 0.2 %

**Subsidiary colouring matters**
Not more than 1.0 %

**Organic compounds other than colouring matters:**

- 4-aminonaphthalene-1-sulfonic acid
- 7-hydroxynaphthalene-1,3-disulfonic acid
- 3-hydroxynaphthalene-2,7-disulfonic acid
- 6-hydroxynaphthalene-2-sulfonic acid
- 7-hydroxynaphthalene-1,3-6-trisulfonic acid

Unsulfonated primary aromatic amines
Not more than 0.01 % (calculated as aniline)
Ether extractable matter | Not more than 0.2 % under neutral conditions
Arsenic | Not more than 3 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 127 ERYTHROSINE

Synonyms
CI Food Red 14

Definition
Erythrosine consists essentially of disodium 2-{2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl} benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulphate as the principal uncoloured components. Erythrosine is manufactured by iodination of fluorescein, the condensation product of resorcinol and phthalic anhydride.

Erythrosine is described as the sodium salt. The calcium and the potassium salt are also permitted.

Colour Index No | 45430
Einecs | 240-474-8
Chemical name | Disodium 2-{2,4,5,7-tetraiodo-3-oxido-6-oxoxanthen-9-yl}benzoate monohydrate
Chemical formula | C_{20}H_{14}I_{4}Na_{2}O_{5}H_{2}O
Molecular weight | 897.88
Assay
Content not less than 87 % total colouring matters, calculated as the anhydrous sodium salt
E_{1%}^{1\text{cm}} 1 100 at ca. 526 nm in aqueous solution at pH 7

Description
Red powder or granules.

Appearance of the aqueous solution
Red

Identification
Spectrometry
Maximum in water at ca. 526 nm at pH 7

Purity
Inorganic iodides | Not more than 0.1 % (calculated as sodium iodide)
Water insoluble matter | Not more than 0.2 %
Subsidiary colouring matters (except fluorescein) | Not more than 4.0 %
Fluorescein | Not more than 20 mg/kg
<table>
<thead>
<tr>
<th>Organic compounds other than colouring matters:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tri-iodoresorcinol</td>
</tr>
<tr>
<td>2-(2,4-dihydroxy-3,5-diodobenzoyl) benzoic acid</td>
</tr>
<tr>
<td>Ether extractable matter</td>
</tr>
<tr>
<td>From a solution of pH from 7 through 8, not more than 0.2 %</td>
</tr>
<tr>
<td>Arsenic</td>
</tr>
<tr>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
</tr>
<tr>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
</tr>
<tr>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
</tr>
<tr>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Aluminium Lakes of this colour may be used.**

### E 129 ALLURA RED AC

**Synonyms**

Cl Food Red 17

**Definition**

Allura Red AC consists essentially of disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Allura Red AC is manufactured by coupling diazotized 5-amino-4-methoxy-2-toluenesulphonic acid with 6-hydroxy-2-naphthalene sulphonic acid. Allura Red AC is described as the sodium salt. The calcium and the potassium salt are also permitted.

**Colour Index No**

16035

**Einecs**

247-368-0

**Chemical name**

Disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonatophenylazo) naphthalene-6-sulfonate

**Chemical formula**

C\textsubscript{18}H\textsubscript{14}N\textsubscript{2}Na\textsubscript{2}O\textsubscript{8}S\textsubscript{2}

**Molecular weight**

496.42

**Assay**

Content not less than 85 % total colouring matters, calculated as the sodium salt

$E_{1%}^{1\text{cm}}$ 540 at ca. 504 nm in aqueous solution at pH 7

**Description**

Dark red powder or granules

**Appearance of the aqueous solution**

Red

**Identification**

**Spectrometry**

Maximum in water at ca. 504 nm
## Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Subsidiary colouring matters</td>
<td>Not more than 3.0 %</td>
</tr>
<tr>
<td>Organic compounds other than colouring matters:</td>
<td></td>
</tr>
<tr>
<td>6-hydroxy-2-naphthalene sulfonic acid, sodium salt</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>4-amino-5-methoxy-2-methyl-benzene sulfonic acid</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>6,6-oxybis (2-naphthalene sulfonic acid) disodium salt</td>
<td>Not more than 1.0 %</td>
</tr>
<tr>
<td>Unsulfonated primary aromatic amines</td>
<td>Not more than 0.01 % (calculated as aniline)</td>
</tr>
<tr>
<td>Ether extractable matter</td>
<td>From a solution of pH 7, not more than 0.2 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

*Aluminium lakes of this colour may be used.*

## E 131 PATENT BLUE V

### Synonyms

CI Food Blue 5

### Definition

Patent Blue V consists essentially of the calcium or sodium compound of [4-α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene] 2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with sodium chloride and/or sodium sulphate and/or calcium sulphate as the principal uncoloured components.

The potassium salt is also permitted.

### Colour Index No

42051

### EINECS

222-573-8

### Chemical name

The calcium or sodium compound of [4-α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene] 2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt

### Chemical formula

Calcium compound: $C_{27}H_{31}N_2O_7S_2Ca_{1/2}$

Sodium compound: $C_{27}H_{31}N_2O_7S_2Na$

### Molecular weight

Calcium compound: 579.72

Sodium compound: 582.67
Assay

Content not less than 85% total colouring matters, calculated as the sodium salt

$E_{\text{1cm}}^{\text{0.000}} = 2000$ at ca. 638 nm in aqueous solution at pH 5

Description

Dark blue powder or granules

Appearance of the aqueous solution

Blue

Identification

Spectrometry

Maximum in water at 638 nm at pH 5

Purity

Water insoluble matter

Not more than 0.2%

Subsidiary colouring matters

Not more than 2.0%

Organic compounds other than colouring matters:

- 3-hydroxy benzaldehyde
- 3-hydroxy benzoic acid
- 3-hydroxy-4-sulfobenzoic acid
- N,N-diethylamino benzene sulfonic acid

Total not more than 0.5%

Leuco base

Not more than 4.0%

Unsulfonated primary aromatic amines

Not more than 0.01% (calculated as aniline)

Ether extractable matter

From a solution of pH 5 not more than 0.2%

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 132 INDIGOTINE, INDIGO CARMINE

Synonyms

CI Food Blue 1

Definition

Indigotine consists essentially of a mixture of disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,5′-disulfonate, and disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.
Indigotine is described as the sodium salt. The calcium and the potassium salt are also permitted.

Indigo carmine is obtained by sulphonation of indigo. This is accomplished by heating indigo (or indigo paste) in the presence of sulphuric acid. The dye is isolated and subjected to purification procedures.

<table>
<thead>
<tr>
<th>Colour Index No</th>
<th>73015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>212-728-8</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,5′-disulfonate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{16}H_{8}N_{2}Na_{2}O_{8}S_{2}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>466.36</td>
</tr>
</tbody>
</table>

Assay

Content not less than 85 % total colouring matters, calculated as the sodium salt; disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 18 %

$E_{1%1cm}^{1%} 480$ at ca. 610 nm in aqueous solution

**Description**

Dark-blue powder or granules

**Appearance of the aqueous solution**

Blue

**Identification**

Spectrometry  
Maximum in water at ca. 610 nm

**Purity**

Water insoluble matter  
Not more than 0.2 %

Subsidiary colouring matters  
Excluding disodium 3,3′-dioxo-2,2′-bi-indolylidene-5,7′-disulfonate: not more than 1.0 %

Organic compounds other than colouring matters:

- Isatin-5-sulfonic acid
- 5-sulfoanthranilic acid

Total not more than 0.5 %

Anthranilic acid

Unsulfonated primary aromatic amines  
Not more than 0.01 % (calculated as aniline)

Ether extractable matter  
Not more than 0.2 % under neutral conditions

Arsenic  
Not more than 3 mg/kg

Lead  
Not more than 2 mg/kg
Mercury  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

---

**E 133 BRILLIANT BLUE FCF**

**Synonyms**
CI Food Blue 2

**Definition**
Brilliant Blue FCF consists essentially of disodium $\alpha$-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-$\alpha$-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate and its isomers and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Brilliant Blue FCF is described as the sodium salt. The calcium and the potassium salt are also permitted.

**Colour Index No**
42090

**Einecs**
223-339-8

**Chemical name**
Disodium $\alpha$-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-$\alpha$-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate

**Chemical formula**
$C_{37}H_{34}N_{2}Na_{2}O_{9}S_{3}$

**Molecular weight**
792.84

**Assay**
Content not less than 85 % total colouring matters, calculated as the sodium salt
$E_{1%}^{1%}1630$ at ca. 630 nm in aqueous solution

**Description**
Reddish-blue powder or granules

**Appearance of the aqueous solution**
Blue

**Identification**
Spectrometry
Maximum in water at ca. 630 nm

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0,2 %</td>
</tr>
<tr>
<td>Subsidiary colouring matters</td>
<td>Not more than 6,0 %</td>
</tr>
<tr>
<td>Organic compounds other than colouring matters:</td>
<td></td>
</tr>
<tr>
<td>Sum of 2-, 3- and 4-formyl benzene sulfonic acids</td>
<td>Not more than 1,5 %</td>
</tr>
<tr>
<td>3-((ethyl)(4-sulfophenyl) amino) methyl benzene sulfonic acid</td>
<td>Not more than 0,3 %</td>
</tr>
<tr>
<td>Leuco base</td>
<td>Not more than 5,0 %</td>
</tr>
</tbody>
</table>
### Chlorophylls

**Synonyms**
CI Natural Green 3; Magnesium Chlorophyll; Magnesium Phaeophytin

**Definition**
Chlorophylls are obtained by solvent extraction of strains of edible plant material, grass, lucerne and nettle. During the subsequent removal of solvent, the naturally present coordinated magnesium may be wholly or partly removed from the chlorophylls to give the corresponding phaeophytins. The principal colouring matters are the phaeophytins and magnesium chlorophylls. The extracted product, from which the solvent has been removed, contains other pigments such as carotenoids as well as oils, fats and waxes derived from the source material. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

**Colour Index No**
75810

**Einecs**
Chlorophylls: 215-800-7, chlorophyll a: 207-536-6, Chlorophyll b: 208-272-4

**Chemical name**
The major colouring principles are:

- Phytol \((13^R, 17S, 18S) - 3-(8-ethyl-13^2-methoxycarbonyl-2,7,12,18-tetramethyl-13^3-oxo-3-vinyl-13^1,13^2,17,18-tetrahydrocyclopenta [at] porphyrin-17-yl)propanoate, \(\text{Phaeophytin a}\), or as the magnesium complex \(\text{Chlorophyll a}\)

- Phytol \((13^R, 17S, 18S) - 3-(8-ethyl-7-formyl-13^2-methoxycarbonyl-2,12,18-trimethyl-13^3-oxo-3-vinyl-13^1,13^2,17,18-tetrahydrocyclopenta [at] porphyrin-17-yl)propanoate, \(\text{Phaeophytin b}\), or as the magnesium complex \(\text{Chlorophyll b}\)

**Chemical formula**
- Chlorophyll a (magnesium complex): \(C_{55}H_{72}MgN_4O_5\)
- Chlorophyll a: \(C_{55}H_{74}N_4O_5\)
- Chlorophyll b (magnesium complex): \(C_{55}H_{70}MgN_4O_6\)
- Chlorophyll b: \(C_{35}H_{72}N_4O_6\)

**Molecular weight**
- Chlorophyll a (magnesium complex): 893.51
- Chlorophyll a: 871.22
- Chlorophyll b (magnesium complex): 907.49
- Chlorophyll b: 885.20
### Assay

Content of total combined Chlorophylls and their magnesium complexes is not less than 10% 

$E_{1%}^{1cm}$ 700 at ca. 409 nm in chloroform

### Description

Waxy solid ranging in colour from olive green to dark green depending on the content of coordinated magnesium

### Identification

**Spectrometry**

Maximum in chloroform at ca. 409 nm

### Purity

**Solvent residues**

- Acetone
- Methyl Ethyl ketone
- Methanol (Not more than 50 mg/kg, singly or in combination)
- Ethanol
- Propan-2-ol
- Hexane

Dichloromethane: Not more than 10 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

### E 140 (ii) CHLOROPHYLLINS

#### Synonyms

CI Natural Green 5; Sodium Chlorophyllin; Potassium Chlorophyllin

#### Definition

The alkali salts of chlorophyllins are obtained by the saponification of a solvent extract of strains of edible plant material, grass, lucerne and nettle. The saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. The acid groups are neutralised to form the salts of potassium and/or sodium.

Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

#### Colour Index No

75815
Chemical name
The major colouring principles in their acid forms are:
- 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinyl-phorbin-7-yl)propionate (chlorophyllin a) and
- 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinyl-phorbin-7-yl)propionate (chlorophyllin b)

Depending on the degree of hydrolysis the cyclopentenyl ring may be cleaved with the resultant production of a third carboxyl function. Magnesium complexes may also be present.

Chemical formula
Chlorophyllin a (acid form): C_{34}H_{34}N_4O_5
Chlorophyllin b (acid form): C_{34}H_{32}N_4O_6

Molecular weight
Chlorophyllin a: 578.68
Chlorophyllin b: 592.66

Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved.

Assay
Content of total chlorophyllins is not less than 95 % of the sample dried at ca. 100 °C for 1 hour.

E_{1%}^{1cm} 700 at ca. 405 nm in aqueous solution at pH 9
E_{1%}^{1cm} 140 at ca. 653 nm in aqueous solution at pH 9

Description
Dark green to blue/black powder

Identification
Spectrometry Maximum in aqueous phosphate buffer at pH 9 at ca. 405 nm and at ca. 653 nm

Purity
Solvent residues
- Acetone
- Methyl ethyl ketone
- Methanol
- Ethanol
- Propan-2-ol
- Hexane
- Dichloromethane: not more than 10 mg/kg

Arsenic
Not more than 3 mg/kg

Lead
Not more than 10 mg/kg
Mercury  
Not more than 1 mg/kg

Cadmium  
Not more than 1 mg/kg

**E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS**

**Synonyms**  
CI Natural Green 3; Copper Chlorophyll; Copper Phaeophytin

**Definition**  
Copper chlorophylls are obtained by addition of a salt of copper to the substance obtained by solvent extraction of strains of edible plant material, grass, lucerne, and nettle. The product, from which the solvent has been removed, contains other pigments such as carotenoids as well as fats and waxes derived from the source material. The principal colouring matters are the copper phaeophytins. Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide, methanol, ethanol, propan-2-ol and hexane.

**Colour Index No**  
75810

**Einecs**  
Copper chlorophyll a: 239-830-5; copper chlorophyll b: 246-020-5

**Chemical name**  
[Phytyl (13-R,17S,18S)-3-(8-ethyl-13′-methoxycarbonyl-2,12,18-tetramethyl-13′-oxo-3-vinyl-13\(^{2}\)-13′-18-tetrahydrocyclopenta[\(a\)]-porphyrin-17-yl)propionate] copper (II) (Copper Chlorophyll a)

[Phytyl (13-R,17S,18S)-3-(8-ethyl-7-formyl-13′-methoxycarbonyl-2,12,18-trimethyl-13′-oxo-3-vinyl-13\(^{2}\)-13′-18-tetrahydrocyclopenta[\(a\)]-porphyrin-17-yl)propionate] copper (II) (Copper Chlorophyll b)

**Chemical formula**  
Copper chlorophyll a: C\(_{55}\)H\(_{72}\)CuN\(_{4}\)O\(_{5}\)

Copper chlorophyll b: C\(_{55}\)H\(_{70}\)CuN\(_{4}\)O\(_{6}\)

**Molecular weight**  
Copper chlorophyll a: 932,75

Copper chlorophyll b: 946,73

**Assay**  
Content of total copper chlorophylls is not less than 10 %.

\[E^{1%}_{1cm} 540 \text{ at ca. 422 nm in chloroform}\]

\[E^{1%}_{1cm} 300 \text{ at ca. 652 nm in chloroform}\]

**Description**  
Waxy solid ranging in colour from blue green to dark green depending on the source material

**Identification**  
Spectrometry  
Maximum in chloroform at ca. 422 nm and at ca. 652 nm
Purity

Solvent residues

Acetone
Methyl ethyl ketone
Methanol
Ethanol
Propan-2-ol
Hexane
Dichloromethane: not more than 10 mg/kg

Not more than 50 mg/kg, singly or in combination

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Copper ions
Not more than 200 mg/kg

Total copper
Not more than 8.0% of the total copper phaeophytins

Aluminium lakes of this colour may be used.

E 141 (ii) COPPER COMPLEXES OF CHLOROPHYLLINS

Synonyms
Sodium Copper Chlorophyllin; Potassium Copper Chlorophyllin; CI Natural Green 5

Definition
The alkali salts of copper chlorophyllins are obtained by the addition of copper to the product obtained by the saponification of a solvent extraction of strains of edible plant material, grass, lucerne, and nettle; the saponification removes the methyl and phytol ester groups and may partially cleave the cyclopentenyl ring. After addition of copper to the purified chlorophyllins, the acid groups are neutralised to form the salts of potassium and/or sodium.

Only the following solvents may be used for the extraction: acetone, methyl ethyl ketone, dichloromethane, carbon dioxide methanol, ethanol, propan-2-ol and hexane.

Colour Index No 75815

Einecs

Chemical name
The major colouring principles in their acid forms are 3-(10-Carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-y1)propionate, copper complex (Copper chlorophyllin a) and 3-(10-Carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-y1) propionate, copper complex (Copper chlorophyllin b)
| Chemical formula | Copper chlorophyllin a (acid form): C$_{34}$H$_{32}$Cu N$_{4}$O$_{5}$  
|                  | Copper chlorophyllin b (acid form): C$_{34}$H$_{30}$Cu N$_{4}$O$_{6}$ |
| Molecular weight | Copper chlorophyllin a: 640.20  
|                  | Copper chlorophyllin b: 654.18  
|                  | Each may be increased by 18 daltons if the cyclopentenyl ring is cleaved. |
| Assay | Content of total copper chlorophyllins is not less than 95 % of the sample dried at 100 °C for 1 h.  
|       | $E_{\text{lim}}^1$ 565 at ca. 405 nm in aqueous phosphate buffer at pH 7.5  
|       | $E_{\text{lim}}^1$ 145 at ca. 630 nm in aqueous phosphate buffer at pH 7.5 |
| Description | Dark green to blue/black powder |
| Identification | Spectrometry Maximum in aqueous phosphate buffer at pH 7.5 at ca. 405 nm and at 630 nm |
| Purity | Solvent residues  
|        | Acetone  
|        | Methyl ethyl ketone  
|        | Methanol  
|        | Ethanol  
|        | Propan-2-ol  
|        | Hexane  
|        | Dichloromethane: not more than 10 mg/kg  
|        | Not more than 50 mg/kg, singly or in combination  
|        | 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  
|        | Copper ions Not more than 200 mg/kg  
|        | Total copper Not more than 8.0 % of the total copper chlorophyllins |

*Aluminium lakes of this colour may be used.*
### E 142 GREEN S

#### Synonyms
CI Food Green 4, Brilliant Green BS

#### Definition
Green S consists essentially of sodium N-[4-[[4-(dimethylamino)phenyl]2-hydroxy-3,6-disulfo-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured compounds.

Green S is described as the sodium salt. The calcium and the potassium salt are also permitted.

#### Colour Index No
44090

#### Einces
221-409-2

#### Chemical name
Sodium N-[4-[[4-(dimethylamino)phenyl]-2-hydroxy-3,6-disulfo-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methylmethanaminium; Sodium 5-[4-dimethylamino-α-(4-dimethyliminocyclohexa-2,5-dienylidene)-benzyl]-6-hydroxy-7-sulfonato-naphthalene-2-sulfonate (alternative chemical name).

#### Chemical formula
C_{27}H_{25}N_{2}NaO_{7}S_{2}

#### Molecular weight
576.63

#### Assay
Content not less than 80 % total colouring matters calculated as the sodium salt

\[ E_{1%}^{1cm} 1720 \text{ at ca. } 632 \text{ nm in aqueous solution} \]

#### Description
Dark blue or dark green powder or granules

#### Identification

- **Spectrometry**: Maximum in water at ca. 632 nm

#### Purity

- **Water insoluble matter**: Not more than 0.2 %
- **Subsidiary colouring matters**: Not more than 1.0 %
- **Organic compounds other than colouring matters:**
  - 4,4'-bis(dimethylamino)-benzhydryl alcohol: Not more than 0.1 %
  - 4,4'-bis(dimethylamino)-benzophenone: Not more than 0.1 %
  - 3-hydroxynaphthalene-2,7-disulfonic acid: Not more than 0.2 %
  - Leuco base: Not more than 5.0 %
Unsulfonated primary aromatic amines | Not more than 0.01 % (calculated as aniline)
Ether extractable matter | Not more than 0.2 % under neutral conditions
Arsenic | Not more than 3 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

*Aluminium lakes of this colour may be used.*

**E 150a PLAIN CARAMEL**

**Synonyms**
Caustic caramel

**Definition**
Plain caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose). To promote caramelisation, acids, alkalis and salts may be employed, with the exception of ammonium compounds and sulphites.

**Colour Index No**
Einecs 232-435-9

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**

**Description**
Dark brown to black liquids or solids

**Identification**

**Purity**

<table>
<thead>
<tr>
<th>Quality Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour bound by DEAE cellulose</td>
<td>Not more than 50 %</td>
</tr>
<tr>
<td>Colour bound by phosphoryl cellulose</td>
<td>Not more than 50 %</td>
</tr>
<tr>
<td>Colour intensity (1)</td>
<td>0.01-0.12</td>
</tr>
<tr>
<td>Total nitrogen</td>
<td>Not more than 0.1 %</td>
</tr>
</tbody>
</table>

(1) Colour intensity is defined as the absorbance of a 0.1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
Total sulphur | Not more than 0.2 %
Arsenic | Not more than 1 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

E 150b CAUSTIC SULPHITE CARAMEL

Synonyms

Definition
Caustic sulphite caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of sulphite compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite and sodium bisulphite); no ammonium compounds are used.

Colour Index No

Einecs 232-435-9

Chemical name

Chemical formula

Molecular weight

Assay

Description
Dark brown to black liquids or solids

Identification

Purity
Colour bound by DEAE cellulose | More than 50 %
Colour intensity (1) | 0.05-0.13
Total nitrogen | Not more than 0.3 % (2)
Sulphur dioxide | Not more than 0.2 % (2)
Total sulphur | 0.3-3.5 % (2)

(1) Colour intensity is defined as the absorbance of a 0.1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.
(2) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0.1 absorbance units.
<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphur bound by DEAE cellulose</td>
<td>More than 40%</td>
</tr>
<tr>
<td>Absorbance ratio of colour bound by DEAE cellulose</td>
<td>19-34</td>
</tr>
<tr>
<td>Absorbance ratio (\text{A}_{280/560})</td>
<td>Greater than 50</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 150c AMMONIA CARAMEL

**Synonyms**

**Definition**

Ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof, e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis, in the presence of ammonium compounds (ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate and ammonium phosphate); no sulphite compounds are used.

**Description**

Dark brown to black liquids or solids

**Identification**

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour bound by DEAE cellulose</td>
<td>Not more than 50%</td>
</tr>
<tr>
<td>Colour bound by phosphoryl cellulose</td>
<td>More than 50%</td>
</tr>
<tr>
<td>Colour intensity (^1)</td>
<td>0.08-0.36</td>
</tr>
<tr>
<td>Ammoniacal nitrogen (^2)</td>
<td>Not more than 0.3%</td>
</tr>
</tbody>
</table>

\(^1\) Colour intensity is defined as the absorbance of a 0.1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

\(^2\) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0.1 absorbance units.
### E 150d SULPHITE AMMONIA CARAMEL

**Synonyms**

**Definition**

Sulphite ammonia caramel is prepared by the controlled heat treatment of carbohydrates (commercially available food grade nutritive sweeteners which are the monomers glucose and fructose and/or polymers thereof (e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose) with or without acids or alkalis in the presence of both sulphite and ammonium compounds (sulphurous acid, potassium sulphite, potassium bisulphite, sodium sulphite, sodium bisulphite, ammonium hydroxide, ammonium carbonate, ammonium hydrogen carbonate, ammonium sulphate, ammonium sulphite and ammonium hydrogen sulphite).

**Assay**

- Colour bound by DEAE cellulose: More than 50 %
- Colour intensity ( ): 0,10-0,60
- Ammoniacal nitrogen: Not more than 0,6 %

( ) Colour intensity is defined as the absorbance of a 0,1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

( ) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0,1 absorbance units.
<table>
<thead>
<tr>
<th><strong>Sulphur dioxide</strong></th>
<th>Not more than 0.2 % ((^1))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4-methylimidazole</strong></td>
<td>Not more than 250 mg/kg ((^2))</td>
</tr>
<tr>
<td><strong>Total nitrogen</strong></td>
<td>0.3-1.7 % ((^2))</td>
</tr>
<tr>
<td><strong>Total sulphur</strong></td>
<td>0.8-2.5 % ((^2))</td>
</tr>
<tr>
<td><strong>Nitrogen/sulphur ratio of alcohol precipitate</strong></td>
<td>0.7-2.7</td>
</tr>
<tr>
<td><strong>Absorbance ratio of alcohol precipitate ((^1))</strong></td>
<td>8-14</td>
</tr>
<tr>
<td><strong>Absorbance ratio ((A_{280/560}))</strong></td>
<td>Not more than 50</td>
</tr>
<tr>
<td><strong>Arsenic</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td><strong>Mercury</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Cadmium</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 151 BRILLIANT BLACK BN, BLACK PN**

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>CI Food Black 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Brilliant Black BN consists essentially of tetraysodium-4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Brilliant Black BN is described as the sodium salt. The calcium and the potassium salt are also permitted.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Colour Index No</strong></th>
<th>28440</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Einecs</strong></td>
<td>219-746-5</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>Tetrasodium 4-acetamido-5-hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>(C_{28}H_{17}N_5Na_4O_{14}S_4)</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>867.69</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 80 % total colouring matters calculated as the sodium salt</td>
</tr>
<tr>
<td>(E_{1%}^{1\text{cm}})</td>
<td>530 at ca. 570 nm in solution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Description</strong></th>
<th>Black powder or granules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance of the aqueous solution</strong></td>
<td>Black-bluish</td>
</tr>
</tbody>
</table>

\(^1\) Absorbance ratio of alcohol precipitate is defined as the absorbance of the precipitate at 280 nm divided by the absorbance at 560 nm (1 cm cell).

\(^2\) Expressed on equivalent colour basis i.e. is expressed in terms of a product having a colour intensity of 0.1 absorbance units.
Identification

Spectrometry
Maximum in water at ca. 570 nm

Purity

Water insoluble matter
Not more than 0.2 %

Subsidiary colouring matters
Not more than 4 % (expressed on the dye content)

Organic compounds other than colouring matters:

- 4-acetamido-5-hydroxynaphthalene-1,7-disulfonic acid
- 4-amino-5-hydroxynaphthalene-1,7-disulfonic acid
- 8-aminonaphthalene-2-sulfonic acid
- 4,4'-diazooaminodi-(benzene-sulfonic acid)

| Total not more than 0.8 % |

Unsulfonated primary aromatic amines
Not more than 0.01 % (calculated as aniline)

Ether extractable matter
Not more than 0.2 % under neutral conditions

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 153 VEGETABLE CARBON

Synonyms
Vegetable black

Definition
Vegetable activated carbon is produced by the carbonisation of vegetable material such as wood, cellulose residues, peat and coconut and other shells. The activated carbon thus produced is milled by a roller mill and the resulting highly activated powdered carbon is treated by a cyclone. The fine fraction from the cyclone is purified by hydrochloric acid washing, neutralised and then dried. The resulting product is what is known traditionally as vegetable black. Products with a higher colouring power are produced from the fine fraction by a further cyclone treatment or by extra milling, followed by acid washing, neutralising and drying. It consists essentially of finely divided carbon. It may contain minor amounts of nitrogen, hydrogen and oxygen. Some moisture may be absorbed on the product after manufacture.

Colour Index No
77266

EINECS
231-153-3
Chemical name: Carbon

Chemical formula: C

Atomic weight: 12.01

Assay: Content not less than 95 % of carbon calculated on an anhydrous and ash-free basis

Loss on drying: Not more than 12 % (120 °C 4 h)

Description: Black, odourless powder

Identification:

Solubility: Insoluble in water and organic solvents

Burning: When heated to redness it burns slowly without a flame

Purity:

Ash (Total): Not more than 4.0 % (ignition temperature: 625 °C)

Arsenic: Not more than 3 mg/kg

Lead: Not more than 2 mg/kg

Mercury: Not more than 1 mg/kg

Cadmium: Not more than 1 mg/kg

Polycyclic aromatic hydrocarbons: Benzo(a)pyrene less than 50 μg/kg in the extract obtained by extraction of 1 g of the product with 10 g pure cyclohexane in a continuous extraction.

Alkali soluble matter: The filtrate obtained by boiling 2 g of the sample with 20 ml N sodium hydroxide and filtering shall be colourless

E 155 BROWN HT

Synonyms: CI Food Brown 3

Definition:

Brown HT consists essentially of disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo) di (naphthalene-1-sulfonate) and subsidiary colouring matters together with sodium chloride and/or sulphate as the principal uncoloured components.

Brown HT is described as the sodium salt. The calcium and potassium salt are also permitted.

Colour Index No: 20285

Einecs: 224-924-0

Chemical name: Disodium 4,4′-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylene bisazo) di (naphthalene-1-sulfonate)
Chemical formula  \( C_{27}H_{18}N_4Na_2O_9S_2 \)

Molecular weight  652.57

Assay  Content not less than 70 % total colouring matters calculated as the sodium salt.

\( \text{E}_{1%}^{1%} \text{ at ca. 460 nm in aqueous solution at pH 7} \)

**Description**

Reddish-brown powder or granules

Appearance of the aqueous solution  Brown

**Identification**

Spectrometry  Maximum in water of pH 7 at ca. 460 nm

**Purity**

Water insoluble matter  Not more than 0.2 %

Subsidiary colouring matters  Not more than 10 % (TLC method)

Organic compounds other than colouring matters:

4-aminonaphthalene-1-sulfonic acid  Not more than 0.7 %

Unsulfonated primary aromatic amines  Not more than 0.01 % (calculated as aniline)

Ether extractable matter  Not more than 0.2 % in a solution of pH 7

Arsenic  Not more than 3 mg/kg

Lead  Not more than 2 mg/kg

Mercury  Not more than 1 mg/kg

Cadmium  Not more than 1 mg/kg

**Aluminium lakes of this colour may be used.**

**E 160 a (i) BETA-CAROTENE**

**Synonyms**  CI Food Orange 5

**Definition**  These specifications apply predominantly to all trans isomer of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.

Colour Index No  40800

Einacs  230-636-6

Chemical name  Beta-carotene; beta, beta-carotene
<table>
<thead>
<tr>
<th>Chemical formula</th>
<th>( C_{40}H_{56} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>536.88</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 96 % total colouring matters (expressed as beta-carotene) ( E_{1%}^{1%} 2 500 ) at approximately by 440 nm to 457 nm in cyclohexane</td>
</tr>
</tbody>
</table>

**Description**

Red to brownish-red crystals or crystalline powder

**Identification**

Spectrometry

Maximum in cyclohexane at 453 nm to 456 nm

**Purity**

Sulphated ash

Not more than 0.1 %

Subsidiary colouring matters

Carotenoids other than beta-carotene: not more than 3.0 % of total colouring matters

Lead

Not more than 2 mg/kg

**E 160 a (ii) PLANT CAROTENES**

**Synonyms**

CI Food Orange 5

**Definition**

Plant carotenes are obtained by solvent extraction of strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane \(^{(1)}\), dichloromethane and carbon dioxide.

<table>
<thead>
<tr>
<th>Colour Index No</th>
<th>75130</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>230-636-6</td>
</tr>
<tr>
<td>Chemical name</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>( \text{Beta-carotene: } C_{40}H_{56} )</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>( \text{Beta-carotene: } 536.88 )</td>
</tr>
<tr>
<td>Assay</td>
<td>Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetable oils: not less than 0.2 % in edible fats ( E_{1%}^{1%} 2 500 ) at approximately 440 nm to 457 nm in cyclohexane</td>
</tr>
</tbody>
</table>

\(^{(1)}\) Benzene not more than 0.05 % v/v.
### Description

**Identification**

| Spectrometry | Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm |

### Purity

<table>
<thead>
<tr>
<th>Solvent residues</th>
<th>Acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl ethyl ketone</td>
<td></td>
</tr>
<tr>
<td>Methanol</td>
<td></td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td></td>
</tr>
<tr>
<td>Hexane</td>
<td></td>
</tr>
<tr>
<td>Ethanol</td>
<td></td>
</tr>
<tr>
<td>Dichloromethane</td>
<td></td>
</tr>
</tbody>
</table>

#### Solvent residues
- Acetone
- Methyl ethyl ketone
- Methanol
- Propan-2-ol
- Hexane
- Ethanol
- Dichloromethane

- Not more than 50 mg/kg, singly or in combination
- Not more than 10 mg/kg
- Not more than 2 mg/kg

---

**E 160 a (iii) BETA-CAROTENE FROM Blakeslea trispora**

### Synonyms

| CI Food Orange 5 |

### Definition

Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (−) of strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate or isobutyl acetate followed by propan-2-ol and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process approximately 3% of the product consists of mixed carotenoids, which is specific for the product.

**Colour Index No** 40800

**Einecs** 230-636-6

**Chemical name** Beta-carotene; beta, beta-carotene

**Chemical formula** C_{40}H_{56}

**Molecular weight** 536.88

**Assay** Not less than 96% total colouring matters (expressed as beta-carotene)

**E1% 2 500 at approximately 440 nm to 457 nm in cyclohexane**

### Description

Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)

### Identification

| Spectrometry | Maximum in cyclohexane at 453 nm to 456 nm |
### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent residues</td>
<td>Ethyl acetate: Not more than 0.8 %, singly or in combination</td>
</tr>
<tr>
<td></td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Isobutyl acetate: Not more than 1.0 %</td>
</tr>
<tr>
<td></td>
<td>Propan-2-ol: Not more than 0.1 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Subsidiary colouring matters</td>
<td>Carotenoids other than beta-carotene: not more than 3.0 % of total colouring matters</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

### Microbiological criteria

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moulds</td>
<td>Not more than 100 colonies per gram</td>
</tr>
<tr>
<td>Yeasts</td>
<td>Not more than 100 colonies per gram</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 25 g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 5 g</td>
</tr>
</tbody>
</table>

### E 160 a (iv) ALGAL CAROTENES

#### Synonyms

CI Food Orange 5

#### Definition

Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29.

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

#### Colour Index No

75130

#### Assay

Content of carotenes (calculated as beta-carotene) is not less than 20 % $E^{25}^\text{nm}$ 2 500 approximately by 440 nm to 457 nm in cyclohexane.
**Description**

**Identification**

- Spectrometry: Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm

**Purity**

- Natural tocopherols in edible oil: Not more than 0.3 %
- Lead: Not more than 2 mg/kg

---

**E 160 b ANNATTO, BIXIN, NORBIXIN**

(i) SOLVENT-EXTRACTED BIXIN AND NORBIXIN

**Synonyms**

- CI Natural Orange 4

**Definition**

Bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (*Bixa orellana* L.) with one or more of the following solvents: acetone, methanol, hexane or dichloromethane, carbon dioxide followed by the removal of the solvent.

Norbixin is prepared by hydrolysis by aqueous alkali of the extracted bixin.

Bixin and norbixin may contain other materials extracted from the annatto seed.

The bixin powder contains several coloured components, the major single one being bixin, which may be present in both cis- and trans-forms. Thermal degradation products of bixin may also be present.

The norbixin powder contains the hydrolysis product of bixin, in the form of the sodium or potassium salts as the major colouring principle. Both cis- and trans-forms may be present.

**Colour Index No**

- 75120

**Einecs**


**Chemical name**

- Bixin: \(\text{6}^\prime\text{-Methylhydrogen-9}^\prime\text{-cis-6,6}^\prime\text{-diapocarotene-6,6}^\prime\text{-dioate}}\)
  \[
  \text{6}^\prime\text{-Methylhydrogen-9}^\prime\text{-trans-6,6}^\prime\text{-diapocarotene-6,6}^\prime\text{-dioate}}
  \]
- Norbixin: \(9^\prime\text{cis-6,6}^\prime\text{-Diapocarotene-6,6}^\prime\text{-dioic acid}}\)
  \[
  9^\prime\text{trans-6,6}^\prime\text{-Diapocarotene-6,6}^\prime\text{-dioic acid}}
  \]

**Chemical formula**

- Bixin: \(\text{C}_{25}\text{H}_{30}\text{O}_{4}\)
- Norbixin: \(\text{C}_{26}\text{H}_{28}\text{O}_{4}\)
Molecular weight

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bixin:</td>
<td>394.51</td>
</tr>
<tr>
<td>Norbixin:</td>
<td>380.48</td>
</tr>
</tbody>
</table>

Assay

Content of bixin powders not less than 75% total carotenoids calculated as bixin.

Content of norbixin powders not less than 25% total carotenoids calculated as norbixin.

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bixin:</td>
<td>E_{1%} 2 870 at ca. 502 nm in chloroform</td>
</tr>
<tr>
<td>Norbixin:</td>
<td>E_{1%} 2 870 at ca. 482 nm in KOH solution</td>
</tr>
</tbody>
</table>

Description

Reddish-brown powder, suspension or solution

Identification

Spectrometry

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bixin:</td>
<td>maximum in chloroform at ca. 502 nm</td>
</tr>
<tr>
<td>Norbixin:</td>
<td>maximum in dilute KOH solution at ca. 482 nm</td>
</tr>
</tbody>
</table>

Purity

Solvent residues

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>not more than 50 mg/kg, singly or in combination</td>
</tr>
<tr>
<td>Methanol</td>
<td></td>
</tr>
<tr>
<td>Hexane</td>
<td></td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

(ii) ALKALI EXTRACTED ANNATTO

Synonyms

CI Natural Orange 4

Definition

Water soluble annatto is prepared by extraction with aqueous alkali (sodium or potassium hydroxide) of the outer coating of the seeds of the annatto tree (Bixa orellana L.).

Water soluble annatto contains norbixin, the hydrolysis product of bixin, in the form of the sodium or potassium salts, as the major colouring principle. Both cis- and trans- forms may be present.
Colour Index No 75120


Chemical name

Bixin: \(6'H\)-Methylhydrogen-9'-trans-6,6'-diapocarotene-6,6'-dioate

Norbixin: \(9'\)cis-6,6'-Diapocarotene-6,6'-dioic acid

Chemical formula

Bixin: \(C_{25}H_{30}O_4\)

Norbixin: \(C_{24}H_{28}O_4\)

Molecular weight

Bixin: 394.51

Norbixin: 380.48

Assay

Contains not less than 0.1% of total carotenoids expressed as norbixin

Norbixin: \(E_{1\%}^{1\text{cm}} 2\ 870\) at ca. 482 nm in KOH solution

Description

Reddish-brown powder, suspension or solution

Identification

Spectrometry

Bixin: maximum in chloroform at ca. 502 nm

Norbixin: maximum in dilute KOH solution at ca. 482 nm

Purity

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

(iii) OIL EXTRACTED ANNATTO

Synonyms

CI Natural Orange 4

Definition

Anatto extracts in oil, as solution or suspension, are prepared by extraction of the outer coating of the seeds of the annatto tree (Bixa orellana L) with edible vegetable oil. Anatto extract in oil contains several coloured components, the major single one being bixin, which may be present in both cis- and trans-forms. Thermal degradation products of bixin may also be present.
<table>
<thead>
<tr>
<th><strong>Colour Index No</strong></th>
<th>75120</th>
</tr>
</thead>
</table>
| **Chemical name**   | Bixin: $6'\text{-Methylhydrogen-9’-cis-6,6’-diapocarotene-6,6’-dioate}$  
|                     | Norbixin: $9’\text{-trans-6,6’-Diapocarotene-6,6’-dioic acid}$  
| **Chemical formula**| Bixin: $C_{25}H_{30}O_4$  
|                     | Norbixin: $C_{24}H_{28}O_4$  
| **Molecular weight**| Bixin: 394.51  
|                     | Norbixin: 380.48  
| **Assay**           | Contains not less than 0.1 % of total carotenoids expressed as bixin  
|                     | Bixin: $E_{1\%}^{1cm}$ 2 870 at ca. 502 nm in chloroform  
| **Description**     | Reddish-brown powder, suspension or solution  
| **Identification**  | Spectrometry Bixin: maximum in chloroform at ca. 502 nm  
|                     | Norbixin: maximum in dilute KOH solution at ca. 482 nm  
| **Purity**          | Arsenic Not more than 3 mg/kg  
|                     | Lead Not more than 2 mg/kg  
|                     | Mercury Not more than 1 mg/kg  
|                     | Cadmium Not more than 1 mg/kg  

**E 160 c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN**

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Paprika Oleoresin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Paprika extract is obtained by solvent extraction of the strains of paprika, which consists of the ground fruits pods, with or without seeds, of <em>Capsicum annuum</em> L., and contains the major colouring principles of this spice. The major colouring principles are capsanthin and capsurubin. A wide variety of other coloured compounds is known to be present.</td>
</tr>
</tbody>
</table>
Only the following solvents may be used in the extraction: methanol, ethanol, acetone, hexane, dichloromethane, ethyl acetate, propan-2-ol and carbon dioxide.

**Colour Index No**


**Chemical name**

Capsanthin: (3R, 3’S, 5’R)-3,3’-dihydroxy-β,κ-carotene-6-one
Capsorubin: (3S, 3’S, 5R, 5R’)-3,3’-dihydroxy-κ,κ-carotene-6,6’-dione

**Chemical formula**

Capsanthin: \( C_{40}H_{56}O_3 \)
Capsorubin: \( C_{40}H_{56}O_4 \)

**Molecular weight**

Capsanthin: 584.85
Capsorubin: 600.85

**Assay**

Paprika extract: content not less than 7.0 % carotenoids
Capsanthin/capsorubin: not less than 30 % of total carotenoids

\( E_{1%}^{1cm} \) 2 100 at ca. 462 nm in acetone

**Description**

Dark-red viscous liquid

**Identification**

**Spectrometry**

Maximum in acetone at ca. 462 nm

**Colour reaction**

A deep blue colour is produced by adding one drop of sulphuric acid to one drop of sample in 2-3 drops of chloroform

**Purity**

**Solvent residues**

Ethyl acetate
Methanol
Ethanol
Acetone
Hexane
Propan-2-ol
Dichloromethane: not more than 10 mg/kg

Capsaicin: Not more than 250 mg/kg
Arsenic | Not more than 3 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

**E 160 d LYCOPENE**

(i) SYNTHETIC LYCOPENE

**Synonyms**
Lycopene from chemical synthesis

**Definition**
Synthetic lycopene is a mixture of geometric isomers of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-trans-lycopene together with 5-cis-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.

**Colour Index No**
75125

**Einecs**
207-949-1

**Chemical name**
\( \psi, \psi\)-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene

**Chemical formula**
C\(_{40}\)H\(_{56}\)

**Molecular weight**
536.85

**Assay**
Not less than 96 % total lycopenes (not less than 70 % all-trans-lycopene)

**\( E_{100}^{1 \%} \) at 465-475 nm in hexane (for 100 % pure all-trans-lycopene) is 3 450**

**Description**
Red crystalline powder

**Identification**

Spectrophotometry
A solution in hexane shows an absorption maximum at approximately 470 nm

Test for carotenoids
The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid

**Solubility**
Insoluble in water, freely soluble in chloroform

**Properties of 1 % solution in chloroform**
Is clear and has intensive red-orange colour
Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5 % (40 °C, 4 h at 20 mm Hg)</td>
</tr>
<tr>
<td>Apo-12'-lycopenal</td>
<td>Not more than 0.15 %</td>
</tr>
<tr>
<td>Triphenyl phosphine oxide</td>
<td>Not more than 0.01 %</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Methanol not more than 200 mg/kg,</td>
</tr>
<tr>
<td></td>
<td>Hexane, Propan-2-ol: Not more than 10 mg/kg each.</td>
</tr>
<tr>
<td></td>
<td>Dichloromethane: Not more than 10 mg/kg (in commercial preparations only)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

(ii) LYCOPENE FROM RED TOMATOES

Synonyms

Natural Yellow 27

Definition

Lycopene is obtained by solvent extraction of red tomatoes (Lycopersicon esculentum L.) with subsequent removal of the solvent. Only the following solvent may be used: carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol and hexane. The major colouring principle of tomatoes is lycopene; minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes.

Colour Index No 75125

Einecs 207-949-1

Chemical name

Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene

Chemical formula C₄₀H₅₆

Molecular weight 536.85

Assay

\( E_1% \text{cm}^{-1} \text{ at } 465-475 \text{ nm in hexane (for 100 % pure all-trans-lycopene)} \) is \( 3450 \).

Content not less than 5 % total colouring matters

Description

Dark red viscous liquid

Identification

Spectrophotometry

Maximum in hexane at ca. 472 nm
### Purity

<table>
<thead>
<tr>
<th>Solvent residues</th>
<th>Propan-2-ol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hexane</td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
</tr>
<tr>
<td></td>
<td>Not more than 50 mg/kg, singly or in combination</td>
</tr>
<tr>
<td></td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Methanol</td>
</tr>
<tr>
<td></td>
<td>Ethylacetate</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

(iii) **LYCOPENE FROM BLAKESLEA TRISPORA**

### Synonyms

| Natural Yellow 27 |

### Definition

Lycopene from *Blakeslea trispora* is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-trans-lycopene. It also contains minor quantities of other carotenoids. Propan-2-ol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder.

### Colour Index No

75125

### Einecs

207-949-1

### Chemical name

Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, ((all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene

### Chemical formula

$C_{40}H_{56}$

### Molecular weight

536.85

### Assay

Not less than 95 % total lycopenes and not less than 90 % all-trans-lycopene of all colouring matters

$E_{1%}^{1%}$ at 465-475 nm in hexane (for 100 % pure all-trans-lycopene) is 3450

### Description

Red crystalline powder
### Identification

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectrophotometry</td>
<td>A solution in hexane shows an absorption maximum at approximately 470 nm</td>
</tr>
<tr>
<td>Test of carotenoids</td>
<td>The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water, freely soluble in chloroform</td>
</tr>
<tr>
<td>Properties of 1 % solution in chloroform</td>
<td>Is clear and has intensive red-orange colour</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5 % (40 °C, 4 h at 20 mm Hg)</td>
</tr>
<tr>
<td>Other carotenoids</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Propan-2-ol: not more than 0.1 % Isobutyl acetate: not more than 1.0 % Dichloromethane: not more than 10 mg/kg (in commercial preparations only)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 160 e BETA-APO-8'-CAROTENAL (C30)

<table>
<thead>
<tr>
<th>Synonym</th>
<th>CI Food Orange 6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>These specifications apply predominantly to the all-trans isomer of β-apo-8'-carotenal together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from β-apo-8'-carotenal meeting these specifications and include solutions or suspensions of β-apo-8'-carotenal in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios.</td>
</tr>
<tr>
<td>Colour Index No</td>
<td>40820</td>
</tr>
<tr>
<td>EINECS</td>
<td>214-171-6</td>
</tr>
<tr>
<td>Chemical name</td>
<td>β-Apo-8'-carotenal; trans-β-Apo-8’carotene-aldehyde</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{30}H_{40}O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>416.65</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 96 % of total colouring matters</td>
</tr>
<tr>
<td></td>
<td>$\text{E}_{1%}^{\text{1cm}}$ 2 640 at 460-462 nm in cyclohexane</td>
</tr>
<tr>
<td>Description</td>
<td>Dark violet crystals with metallic lustre or crystalline powder</td>
</tr>
</tbody>
</table>
**Identification**

Spectrometry  
Maximum in cyclohexane at 460-462 nm

**Purity**

Sulphated ash  
Not more than 0.1 %

Subsidiary colouring matters  
Carotenoids other than β-apo-8′-carotenal:  
not more than 3.0 % of total colouring matters

Arsenic  
Not more than 3 mg/kg

Lead  
Not more than 2 mg/kg

Mercury  
Not more than 1 mg/kg

Cadmium  
Not more than 1 mg/kg

---

**E 161 b LUTEIN**

**Synonyms**

Mixed Carotenoids; Xanthophylls

**Definition**

Lutein is obtained by solvent extraction of the strains of edible fruits and plants, grass, lucerne (alfalfa) and Tagetes erecta. The main colouring principle consists of carotenoids of which lutein and its fatty acid esters account for the major part. Variable amounts of carotenes will also be present. Lutein may contain fats, oils and waxes naturally occurring in the plant material.

Only the following solvents may be used for the extraction: methanol, ethanol, propan-2-ol, hexane, acetone, methyl ethyl ketone and carbon dioxide

**Colour Index No**

Einecs  
204-840-0

**Chemical name**

3,3′-dihydroxy-d-carotene

**Chemical formula**

C₄₀H₅₆O₂

**Molecular weight**

568,88

**Assay**

Content of total colouring matter not less than 4 % calculated as lutein

\[ E_{1%}^{1\text{cm}} = 2,550 \text{ at ca. } 445\text{ nm in chloroform/ethanol (10 + 90) or in hexane/ethanol/acetone (80 + 10 + 10)} \]

**Description**

Dark, yellowish brown liquid

**Identification**

Spectrometry  
Maximum in chloroform/ethanol (1:9) at ca. 445 nm
### Purity

<table>
<thead>
<tr>
<th>Solvent residues</th>
<th>Acetone</th>
<th>Methyl ethyl ketone</th>
<th>Methanol</th>
<th>Ethanol</th>
<th>Propan-2-ol</th>
<th>Hexane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Not more than 50 mg/kg, singly or in combination</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arsenic</th>
<th>Not more than 3 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 161g CANTHAXANTHIN

**Synonyms**

CI Food Orange 8

**Definition**

These specifications apply to predominantly all-trans isomers of canthaxanthin together with minor amounts of other carotenoids. Diluted and stabilised forms are prepared from canthaxanthin meeting these specifications and include solutions or suspensions of canthaxanthin in edible fats or oils, emulsions and water dispersible powders. These preparations may have different cis/trans isomer ratios.

**Colour Index No**

40850

**Einecs**

208-187-2

**Chemical name**

β-Carotene-4,4′-dione; canthaxanthin; 4,4′-dioxo-β-carotene

**Chemical formula**

C₄₀H₅₂O₂

**Molecular weight**

564,86

**Assay**

Not less than 96 % of total colouring matters (expressed as canthaxanthin)

\[
\text{E}_{1\%}^{1\text{cm}} = 2 \text{ 200}
\]

- at ca. 485 nm in chloroform
- at 468-472 nm in cyclohexane
- at 464-467 nm in petroleum ether

**Description**

Deep violet crystals or crystalline powder
Identification

Spectrometry
Maximum in chloroform at ca. 485 nm
Maximum in cyclohexane at 468-472 nm
Maximum in petroleum ether at 464-467 nm

Purity

Sulphated ash
Not more than 0.1 %

Subsidiary colouring matters
Carotenoids other than canthaxanthin: not more than 5.0 % of total colouring matters

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

E 162 BEETROOT RED, BETANIN

Synonyms
Beet Red

Definition
Beet red is obtained from the roots of strains of red beets (Beta vulgaris L. var. rubra) by pressing crushed beet as press juice or by aqueous extraction of shredded beet roots and subsequent enrichment in the active principle. The colour is composed of different pigments all belonging to the class betalaine. The main colouring principle consists of betacyanins (red) of which betanin accounts for 75-95 %. Minor amounts of betaxanthin (yellow) and degradation products of betalaines (light brown) may be present.

Besides the colour pigments the juice or extract consists of sugars, salts, and/or proteins naturally occurring in red beets. The solution may be concentrated and some products may be refined in order to remove most of the sugars, salts and proteins.

Colour Index No
231-628-5

Chemical name
(S,R')-4-(2-Carboxy-5-(β-D-glucopyranosyloxy)-2,3-dihydro-6-hydroxy-1H-indol-1-yl)ethenyl)-2,3-dihydro-2,6-pyridine-dicarboxylic acid: 1-(2-(2,6-dicarboxy-1,2,3,4-tetrahydropyridylidene)ethylidene)-5-(β-D-glucopyranosyloxy)-6-hydroxyindolium-2-carboxylate

Chemical formula
Betanin: C_{24}H_{26}N_{2}O_{13}

Molecular weight
550.48

Assay
Content of red colour (expressed as betanine) is not less than 0.4 %

Description
Red or dark red liquid, paste, powder or solid
**Identification**

| Spectrometry | Maximum in water of pH 5 at ca. 535 nm |

**Purity**

<table>
<thead>
<tr>
<th>Nitrate</th>
<th>Not more than 2 g nitrate anion/g of red colour (as calculated from assay).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 163 ANTHOCYANINS**

**Synonyms**

**Definition**

Anthocyanins are obtained by maceration or extraction with sulphonated water, acidified water, carbon dioxide, methanol or ethanol from the strains of vegetables and edible fruits, with subsequent concentration and/or purification if necessary. The resulting product can be transformed into powder by an industrial drying process. Anthocyanins contain common components of the source material, namely anthocyanine, organic acids, tannins, sugars, minerals etc., but not necessarily in the same proportions as found in the source material. Ethanol may naturally be present as a result of the maceration process. The colouring principle is anthocyanin. Products are marketed according to their colour strength as determined by the assay. Colour content is not expressed using quantitative units.

**Colour Index No**

- Cyanidin: 208-438-6
- Peonidin: 205-125-6
- Delphinidin: 208-437-0
- Malvidin: 211-403-8
- Pelargonidin: 205-127-7
- Petunidin: 215-849-4

**Chemical name**

- 3,3',4',5,7-Pentahydroxy-flavylium chloride (cyanidin)
- 3,4',5,7-Tetrahydroxy-3'-methoxyflavylium chloride (peonidin)
- 3,3',5,7-Tetrahydroxy-3',5'-dimethoxyflavylium chloride (malvidin)
- 3,5,7-Trihydroxy-2-(3,4,5,tri-hydroxyphenyl)-1-benzopyrylium chloride (delphinidin)
- 3,3',4',5,7-Pentahydroxy-5'-methoxyflavylium chloride (petunidin)
- 3,5,7-Trihydroxy-2-(4-hydroxyphenyl)-1-benzopyrylium chloride (pelargonidin)

**Chemical formula**

- Cyanidin: C_{15}H_{11}O_{6}Cl
- Peonidin: C_{16}H_{13}O_{6}Cl
- Malvidin: C_{17}H_{15}O_{7}Cl
- Delphinidin: C_{15}H_{17}O_{6}Cl
Petunidin: $C_{16}H_{13}O_7Cl$
Pelargonidin: $C_{13}H_{11}O_5Cl$

Molecular weight
- Cyanidin: 322.6
- Peonidin: 336.7
- Malvidin: 366.7
- Delphinidin: 340.6
- Petunidin: 352.7
- Pelargonidin: 306.7

Assay
$E_{1%}^{1%}$ 300 for the pure pigment at 515-535 nm at pH 3.0

Description
Purplish-red liquid, powder or paste, having a slight characteristic odour

Identification
Spectrometry Maximum in methanol with 0.01 % conc. HCl
- Cyanidin: 535 nm
- Peonidin: 532 nm
- Malvidin: 542 nm
- Delphinidin: 546 nm
- Petunidin: 543 nm
- Pelargonidin: 530 nm

Purity
Solvent residues
- Methanol Not more than 50 mg/kg
- Ethanol Not more than 200 mg/kg

Sulfur dioxide Not more than 1 000 mg/kg per percent pigment
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg

Aluminium lakes of this colour may be used.

E 170 CALCIUM CARBONATE

Synonyms
CI Pigment White 18; Chalk

Definition
Calcium carbonate is the product obtained from ground limestone or by the precipitation of calcium ions with carbonate ions.
<table>
<thead>
<tr>
<th>Description</th>
<th>White crystalline or amorphous, odourless and tasteless powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay</td>
<td>Content not less than 98 % on the anhydrous basis</td>
</tr>
<tr>
<td>Solubility</td>
<td>Practically insoluble in water and in alcohol. Dissolves with effervescence in diluted acetic acid, in diluted hydrochloric acid and in diluted nitric acid, and the resulting solutions, after boiling, give positive tests for calcium.</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 2.0 % (200 °C, 4 hours)</td>
</tr>
<tr>
<td>Acid-insoluble substances</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Magnesium and alkali salts</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Antimony (as Sb)</td>
<td></td>
</tr>
<tr>
<td>Copper (as Cu)</td>
<td>Not more than 100 mg/kg, singly or in combination</td>
</tr>
<tr>
<td>Chromium (as Cr)</td>
<td></td>
</tr>
<tr>
<td>Zinc (as Zn)</td>
<td></td>
</tr>
<tr>
<td>Barium (as Ba)</td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 171 TITANIUM DIOXIDE

Synonyms
CI Pigment White 6

Definition
Titanium dioxide consists essentially of pure anatase and/or rutile titanium dioxide which may be coated with small amounts of alumina and/or silica to improve the technological properties of the product.

The anatase grades of pigmented titanium dioxide can only be made by the sulphate process which creates a large amount of sulphuric acid as a by-product. The rutile grades of titanium dioxide are typically made by the chloride process.

Certain rutile grades of titanium dioxide are produced using mica (also known as potassium aluminum silicate) as a template to form the basic platelet structure. The surface of the mica is coated with titanium dioxide using a specialised patented process.

Rutile titanium dioxide, platelet form is manufactured by subjecting titanium dioxide (rutile) coated mica nacreous pigment to an extractive dissolution in acid followed by an extractive dissolution in alkali. All of the mica is removed during this process and the resulting product is a platelet form of rutile titanium dioxide.

Colour Index No 77891
Einecs 236-675-5
Chemical name Titanium dioxide
Chemical formula TiO₂
Molecular weight 79.88
Assay Content not less than 99 % on an alumina and silica-free basis

Description
White to slightly coloured powder

Identification
Solubility Insoluble in water and organic solvents. Dissolves slowly in hydrofluoric acid and in hot concentrated sulphuric acid.

Purity
Loss on drying Not more than 0.5 % (105 °C, 3 hours)
Loss on ignition Not more than 1.0 % on a volatile matter free basis (800 °C)
Aluminium oxide and/or silicon dioxide Total not more than 2.0 %
Matter soluble in 0.5 N HCl Not more than 0.5 % on an alumina and silica-free basis and, in addition, for products containing alumina and/or silica, not more than 1.5 % on the basis of the product as sold.
Water soluble matter Not more than 0.5 %

Cadmium Not more than 1 mg/kg after an extraction with 0.5 N HCl.
Antimony Not more than 2 mg/kg after an extraction with 0,5 N HCl.
Arsenic Not more than 1 mg/kg after an extraction with 0,5 N HCl.
Lead Not more than 10 mg/kg after an extraction with 0,5 N HCl.
Mercury Not more than 1 mg/kg after an extraction with 0,5 N HCl.

E 172 IRON OXIDES AND IRON HYDROXIDES

Synonyms
Iron Oxide Yellow: CI Pigment Yellow 42 and 43
Iron Oxide Red: CI Pigment Red 101 and 102
Iron Oxide Black: CI Pigment Black 11

Definition
Iron oxides and iron hydroxides are produced synthetically and consist essentially of anhydrous and/or hydrated iron oxides. The range of hues includes yellows, reds, browns and blacks. Food quality iron oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals. This is achieved by the selection and control of the source of the iron and/or by the extent of chemical purification during the manufacturing process.

Colour Index No
Iron Oxide Yellow: 77492
Iron Oxide Red: 77491
Iron Oxide Black: 77499

Einecs
Iron Oxide Yellow: 257-098-5
Iron Oxide Black: 235-442-5

Chemical name
Iron Oxide Yellow: hydrated ferric oxide, hydrated iron (III) oxide
Iron Oxide Red: anhydrous ferric oxide, anhydrous iron (III) oxide
Iron Oxide Black: ferroso ferric oxide, iron (II, III) oxide

Chemical formula
Iron Oxide Yellow: FeO(OH) · H₂O
Iron Oxide Red: Fe₂O₃
Iron Oxide Black: FeO.Fe₂O₃

Molecular weight
88,85: FeO(OH)
159,70: Fe₂O₃
231,55: FeO.Fe₂O₃

Assay
Yellow not less than 60 %, red and black not less than 68 % total iron, expressed as iron

Description
Powder; yellow, red, brown or black in hue
Identification

Solubility
- Insoluble in water and in organic solvents
- Soluble in concentrated mineral acids

Purity

- Water soluble matter: Not more than 1.0 %
- Arsenic: Not more than 3 mg/kg
- Cadmium: Not more than 1 mg/kg
- Chromium: Not more than 100 mg/kg
- Copper: Not more than 50 mg/kg (By total dissolution)
- Lead: Not more than 10 mg/kg
- Mercury: Not more than 1 mg/kg
- Nickel: Not more than 200 mg/kg
- Zinc: Not more than 100 mg/kg

E 173 ALUMINIUM

Synonyms
- CI Pigment Metal

Definition
Aluminium powder is composed of finely divided particles of aluminium. The grinding may or may not be carried out in the presence of edible vegetable oils and/or food additive quality fatty acids. It is free from admixture with substances other than edible vegetable oils and/or food additive quality fatty acids.

Colour Index No
- 77000

Einecs
- 231-072-3

Chemical name
- Aluminium

Chemical formula
- Al

Atomic weight
- 26.98

Assay
- Not less than 99 % calculated as Al on an oil-free basis

Description
- A silvery-grey powder or tiny sheets

Identification

Solubility
- Insoluble in water and in organic solvents. Soluble in dilute hydrochloric acid.

Test for aluminium
- A sample dissolved in dilute hydrochloric acid passes test
Purity

Loss on drying  Not more than 0,5 % (105 °C, to constant weight)
Arsenic  Not more than 3 mg/kg
Lead  Not more than 10 mg/kg
Mercury  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg

E 174 SILVER

Synonyms  Argentum
Definition

Colour Index No  77820
Einecs  231-131-3
Chemical name  Silver
Chemical formula  Ag
Atomic weight  107,87
Assay  Content not less than 99,5 % Ag

Description  Silver-coloured powder or tiny sheets

Identification

Purity

E 175 GOLD

Synonyms  Pigment Metal 3; Aurum
Definition

Colour Index No  77480
Einecs  231-165-9
Chemical name  Gold
Chemical formula  Au
Atomic weight  197,0
Assay  Content not less than 90 % Au
<table>
<thead>
<tr>
<th>Description</th>
<th>Gold-coloured powder or tiny sheets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Silver</td>
<td>Not more than 7 %</td>
</tr>
<tr>
<td>Copper</td>
<td>Not more than 4 %</td>
</tr>
<tr>
<td></td>
<td>After complete dissolution</td>
</tr>
</tbody>
</table>

**E 180 LITHOLRUBINE BK**

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>CI Pigment Red 57; Rubinpigment; Carmine 6B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Lithol Rubine BK consists essentially of calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalene-carboxylate and subsidiary colouring matters together with water, calcium chloride and/or calcium sulphate as the principal uncoloured components.</td>
</tr>
<tr>
<td>Colour Index No</td>
<td>15850:1</td>
</tr>
<tr>
<td>Einecs</td>
<td>226-109-5</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium 3-hydroxy-4-(4-methyl-2-sulfonatophenylazo)-2-naphthalene-carboxylate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{18}H_{12}CaN_{2}O_{6}S</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>424.45</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 90 % total colouring matters</td>
</tr>
<tr>
<td></td>
<td>$\text{E}^{1%}_{1\mathrm{cm}}$ 200 at ca. 442 nm in dimethylformamide</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Red powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>Spectrometry</td>
<td>Maximum in dimethylformamide at ca. 442 nm</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Subsidiary colouring matters</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Organic compounds other than colouring matters:</td>
<td></td>
</tr>
<tr>
<td>2-Amino-5-methylbenzene-sulfonic acid, calcium salt</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>3-hydroxy-2-naphthalene-carboxylic acid, calcium salt</td>
<td>Not more than 0.4 %</td>
</tr>
<tr>
<td>Unsulfonated primary aromatic amines</td>
<td>Not more than 0.01 % (expressed as aniline)</td>
</tr>
<tr>
<td>Ether extractable matter</td>
<td>From a solution of pH 7, not more than 0.2 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
</tbody>
</table>
Lead
Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg
Cadmium
Not more than 1 mg/kg

*Aluminium lakes of this colour may be used.*

**E 200 SORBIC ACID**

**Synonyms**

**Definition**

Einecs 203-768-7

Chemical name Sorbic acid; trans, trans-2,4-Hexadienoic acid

Chemical formula C₆H₈O₂

Molecular weight 112,12

Assay Content not less than 99 % on the anhydrous basis

**Description**

Colourless needles or white free flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C

**Identification**

Melting range Between 133 °C and 135 °C, after vacuum drying for four hours in a sulphuric acid desiccator

Spectrometry A propan-2-ol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm

Test for double bonds Passes test

Solubility Slightly soluble in water, soluble in ethanol.

**Purity**

Water content Not more than 0,5 % (Karl Fischer method)

Sulphated ash Not more than 0,2 %

Aldehydes Not more than 0,1 % (as formaldehyde)

Arsenic Not more than 3 mg/kg

Lead Not more than 2 mg/kg

Mercury Not more than 1 mg/kg
E 202 POTASSIUM SORBATE

Synonyms

Definition

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs 246-376-1</td>
<td>Potassium sorbate; Potassium (E,E)-2,4-hexadienoate; Potassium salt of trans, trans-2,4-hexadienoic acid</td>
</tr>
</tbody>
</table>

Chemical formula: \( \text{C}_6\text{H}_7\text{O}_2\text{K} \)

Molecular weight: 150.22

Assay: Content not less than 99% on the dried basis

Description

White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C

Identification

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range for sorbic acid</td>
<td>Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator</td>
</tr>
<tr>
<td>Test for potassium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for double bonds</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 1.0% (105 °C, 3 hours)</td>
</tr>
<tr>
<td>Acidity or alkalinity</td>
<td>Not more than about 1.0% (as sorbic acid or ( \text{K}_2\text{CO}_3 ))</td>
</tr>
<tr>
<td>Aldehydes</td>
<td>Not more than 0.1%, calculated as formaldehyde</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 203 CALCIUM SORBATE

Synonyms

Definition

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs 231-321-6</td>
<td>Calcium sorbate; Calcium salts of trans, trans-2,4-hexadienoic acid</td>
</tr>
</tbody>
</table>

Chemical formula: \( \text{C}_{12}\text{H}_{14}\text{O}_4\text{Ca} \)

Molecular weight: 262.32

Assay: Content not less than 98% on the dried basis
<table>
<thead>
<tr>
<th>Description</th>
<th>Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td>Melting range of sorbic acid isolated by acidification and not recrystallised 133 °C to 135 °C after vacuum drying in a sulphuric acid desiccator</td>
</tr>
<tr>
<td>Test for calcium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for double bonds</td>
<td>Passes test</td>
</tr>
<tr>
<td>Purity</td>
<td>Loss on drying  Not more than 2.0 %, determined by vacuum drying for four hours in a sulphuric acid desiccator</td>
</tr>
<tr>
<td>Aldehydes</td>
<td>Not more than 0.1 % (as formaldehyde)</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 210 BENZOIC ACID**

<table>
<thead>
<tr>
<th>Synonyms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Einecs 200-618-2</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Benzoic acid; Benzenecarboxylic acid; Phenylcarboxylic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₇H₆O₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>122.12</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.5 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>White crystalline powder</td>
</tr>
<tr>
<td>Identification</td>
<td>Melting range 121.5 °C -123.5 °C</td>
</tr>
<tr>
<td>Sublimation test</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for benzoate</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>About 4 (solution in water)</td>
</tr>
</tbody>
</table>
Purity

Loss on drying
Not more than 0.5 % (3 hours, over sulphuric acid)

Sulphated ash
Not more than 0.05 %

Chlorinated organic compounds
Not more than 0.07 % expressed as chloride corresponding to 0.3 % expressed as monochlorobenzoic acid

Readily oxidisable substances
Add 1.5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0.1 N KMnO₄ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N KMnO₄ to a pink colour that persists for 15 seconds. Not more than 0.5 ml should be required.

Readily carbonisable substances
A cold solution of 0.5 g of benzoic acid in 5 ml of 94.5 to 95.5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 ml of cobalt chloride TSC (1), 0.3 ml of ferric chloride TSC (2), 0.1 ml of copper sulphate TSC (3) and 4.4 ml of water.

Polycyclic acids
On fractional acidification of a neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid.

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

E 211 SODIUM BENZOATE

Synonyms

Definition

Einecs 208-534-8

Chemical name
Sodium benzoate; Sodium salt of benzenecarboxylic acid; Sodium salt of phenylcarboxylic acid

---

(1) Cobalt chloride TSC: dissolve approximately 65 g of cobalt chloride CoCl₂·6H₂O in a sufficient quantity of a mixture of 25 ml hydrochloric acid and 973 ml of water to give a total volume of 1 litre. Place exactly 5 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 5 ml of 3 % hydrogen peroxide, then 15 ml of a 20 % solution of sodium hydroxide. Boil for 10 minutes, allow to cool, add 2 g of potassium iodide and 20 ml of 25 % sulphuric acid. After the precipitate is completely dissolved, titrate the liberated iodine with sodium thiosulphate (0.1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0.1 N) corresponds to 23.80 mg of CoCl₂·6H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 59.5 mg of CoCl₂·6H₂O per ml.

(2) Ferric chloride TSC: dissolve approximately 55 g of ferric chloride in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 975 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 15 ml of water and 3 g of potassium iodide; leave the mixture to stand for 15 minutes. Dilute with 100 ml of water then titrate the liberated iodine with sodium thiosulphate (0.1 N) in the presence of starch TS. 1 ml of sodium thiosulphate (0.1 N) corresponds to 27.03 mg of FeCl₃·6H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water to give a solution containing 45.0 mg of FeCl₃·6H₂O per ml.

(3) Copper sulphate TSC: dissolve approximately by 63 g of copper sulphate CuSO₄·5H₂O in a sufficient quantity of a mixture of 25 ml of hydrochloric acid and 97.5 ml of water to give a total volume of 1 litre. Place 10 ml of this solution in a round-bottomed flask containing 250 ml of iodine solution, add 40 ml of water, 4 ml of acetic acid and 3 g of potassium iodide. Titrate the liberated iodine with sodium thiosulphate (0.1 N) in the presence of starch TS (4). 1 ml of sodium thiosulphate (0.1 N) corresponds to 24.97 mg of CuSO₄·5H₂O. Adjust final volume of solution by the addition of a sufficient quantity of the hydrochloric acid/water mixture to give a solution containing 62.4 mg of CuSO₄·5H₂O per ml.

(4) Starch TS: triturate 0.5 g starch (potato starch, maize starch or soluble starch) with 5 ml of water; to the resulting paste add a sufficient quantity of water to give a total volume of 100 ml, stirring all the time. Boil for a few minutes, allow to cool, filter. The starch must be freshly prepared.
Chemical formula | $\text{C}_7\text{H}_5\text{O}_2\text{Na}$
---|---
Molecular weight | 144.11
Assay | Not less than 99 % of $\text{C}_7\text{H}_5\text{O}_2\text{Na}$, after drying at 105 °C for four hours

**Description**
A white, almost odourless, crystalline powder or granules

**Identification**

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Freely soluble in water, sparingly soluble in ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range for benzoic acid</td>
<td>Melting range of benzoic acid isolated by acidification and not recrystallised 121.5 °C to 123.5 °C, after drying in a sulphuric acid desiccator</td>
</tr>
<tr>
<td>Test for benzoate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 1.5 % (105 °C, 4 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readily oxidisable substances</td>
<td>Add 1.5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0.1 N KMnO$_4$ in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N KMnO$_4$ to a pink colour that persists for 15 seconds. Not more than 0.5 ml should be required</td>
</tr>
<tr>
<td>Polycyclic acids</td>
<td>On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid</td>
</tr>
<tr>
<td>Chlorinated organic compounds</td>
<td>Not more than 0.06 % expressed as chloride, corresponding to 0.25 % expressed as monochlorobenzoic acid</td>
</tr>
<tr>
<td>Acidity or alkalinity</td>
<td>Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0.25 ml of 0.1 N NaOH or 0.1 N HCl</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 212 POTASSIUM BENZOATE**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>209-481-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Potassium benzoate; Potassium salt of benzenecarboxylic acid; Potassium salt of phenylcarboxylic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>( C_7H_5KO_2 \cdot 3H_2O )</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>214.27</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99 % ( C_7H_5KO_2 ) after drying at 105 °C to constant weight</td>
</tr>
</tbody>
</table>

**Description**

White crystalline powder

**Identification**

- **Melting range for benzoic acid**
  Melting range of benzoic acid isolated by acidification and not recrystallised 121.5 °C to 123.5 °C, after vacuum drying in a sulphuric acid desiccator

- **Test for benzoate**
  Passes test

- **Test for potassium**
  Passes test

**Purity**

- **Loss on drying**
  Not more than 26.5 % (105 °C, 4 hours)

- **Chlorinated organic compounds**
  Not more than 0.06 % expressed as chloride, corresponding to 0.25 % expressed as monochlorobenzoic acid

- **Readily oxidisable substances**
  Add 1.5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0.1 N \( KMnO_4 \) in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N \( KMnO_4 \) to a pink colour that persists for 15 seconds. Not more than 0.5 ml should be required

- **Readily carbonisable substances**
  A cold solution of 0.5 g of benzoic acid in 5 ml 94.5 to 95.5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 ml of cobalt chloride TSC, 0.3 ml of ferric chloride TSC, 0.1 ml of copper sulphate TSC and 4.4 ml of water

- **Polycyclic acids**
  On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid

- **Acidity or alkalinity**
  Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0.25 ml of 0.1 N \( NaOH \) or 0.1 N \( HCl \)
Arsenic | Not more than 3 mg/kg

Lead | Not more than 2 mg/kg

Mercury | Not more than 1 mg/kg

E 213 CALCIUM BENZOATE

**Synonyms**

| Monocalcium benzoate

**Definition**

| Einecs | 218-235-4

| Chemical name | Calcium benzoate; Calcium dibenzoate

| Chemical formula | Anhydrous: \( C_{14}H_{10}O_4Ca \)  
| | Monohydrate: \( C_{14}H_{10}O_4Ca\cdot H_2O \)  
| | Trihydrate: \( C_{14}H_{10}O_4Ca\cdot 3H_2O \)  

| Molecular weight | Anhydrous: 282,31  
| | Monohydrate: 300,32  
| | Trihydrate: 336,36

**Assay**

| Content not less than 99 % after drying at 105 °C

**Description**

| White or colourless crystals, or white powder

**Identification**

| Melting range for benzoic acid | Melting range of benzoic acid isolated by acidification and not recrystallised 121,5 °C to 123,5 °C, after vacuum drying in a sulphuric acid desiccator

| Test for benzoate | Passes test

| Test for calcium | Passes test

**Purity**

| Loss on drying | Not more than 17,5 % (105 °C, to constant weight)

| Water insoluble matter | Not more than 0,3 %

| Chlorinated organic compounds | Not more than 0,06 % expressed as chloride, corresponding to 0,25 % expressed as monochlorobenzoic acid

| Readily oxidisable substances | Add 1,5 ml of sulphuric acid to 100 ml of water, heat to boiling point and add 0,1 N \( \text{KMnO}_4 \) in drops, until the pink colour persists for 30 seconds. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0,1 N \( \text{KMnO}_4 \) to a pink colour that persists for 15 seconds. Not more than 0,5 ml should be required
<table>
<thead>
<tr>
<th>Substance</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readily carbonisable substances</td>
<td>Cold solution of 0.5 g of benzoic acid in 5 ml of 94.5 to 95.5 % sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 ml of cobalt chloride TSC, 0.3 ml of ferric chloride TSC, 0.1 ml of copper sulphate TSC and 4.4 ml of water</td>
</tr>
<tr>
<td>Polycyclic acids</td>
<td>On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not be a different melting range from that of benzoic acid</td>
</tr>
<tr>
<td>Acidity or alkalinity</td>
<td>Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0.25 ml of 0.1 N NaOH or 0.1 N HCl</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 214 ETHYL p-HYDROXYBENZOATE**

**Synonyms**

Ethylparaben; Ethyl p-oxybenzoate

**Definition**

- **Einecs**: 204-399-4
- **Chemical name**: Ethyl-p-hydroxybenzoate; Ethyl ester of p-hydroxybenzoic acid
- **Chemical formula**: C<sub>9</sub>H<sub>10</sub>O<sub>3</sub>
- **Molecular weight**: 166.8
- **Assay**: Content not less than 99.5 % after drying for two hours at 80 °C

**Description**

Almost odourless, small, colourless crystals or a white, crystalline powder

**Identification**

- **Melting range**: 115-118 °C
- **Test for p-hydroxybenzoate**: Melting range of p-hydroxybenzoic acid isolated by acidification and not recrystallised: 213 °C to 217 °C, after vacuum drying in a sulphuric acid desiccator
- **Test for alcohol**: Passes test

**Purity**

- **Loss on drying**: Not more than 0.5 % (80 °C, 2 hours)
- **Sulphated ash**: Not more than 0.05 %
p-Hydroxybenzoic acid and salicylic acid  Not more than 0.35 % expressed as p-hydroxybenzoic acid

Arsenic  Not more than 3 mg/kg

Lead  Not more than 2 mg/kg

Mercury  Not more than 1 mg/kg

E 215 SODIUM ETHYL p-HYDROXYBENZOATE

**Synonyms**

**Definition**

Einecs 252-487-6

Chemical name  Sodium ethyl p-hydroxybenzoate; Sodium compound of the ethyl ester of p-hydroxybenzoic acid

Chemical formula  \( \text{C}_9\text{H}_9\text{O}_3\text{Na} \)

Molecular weight  188.8

Assay  Content of ethylester of p-hydroxybenzoic acid not less than 83 % on the anhydrous basis

**Description**  White, crystalline hygroscopic powder

**Identification**

Melting range  115 °C to 118 °C, after vacuum drying in a sulphuric acid desiccator

Test for p-hydroxybenzoate  Melting range of p-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C

Test for sodium  Passes test

\( \text{pH} \)  9.9-10.3 (0.1 % aqueous solution)

**Purity**

Loss on drying  Not more than 5 %, (by vacuum drying in a sulphuric acid desiccator)

Sulphated ash  37 to 39 %

p-Hydroxybenzoic acid and salicylic acid  Not more than 0.35 % expressed as p-hydroxybenzoic acid

Arsenic  Not more than 3 mg/kg

Lead  Not more than 2 mg/kg

Mercury  Not more than 1 mg/kg
**E 218 METHYL p-HYDROXYBENZOATE**

**Synonyms**
- Methylparaben; Methyl-p-oxybenzoate

**Definition**
- **Einecs**: 243-171-5
- **Chemical name**: Methyl p-hydroxybenzoate; Methyl ester of p-hydroxybenzoic acid
- **Chemical formula**: C₈H₈O₃
- **Molecular weight**: 152.15
- **Assay**: Content not less than 99% after drying for two hours at 80 °C

**Description**
- Almost odourless, small colourless crystals or white crystalline powder

**Identification**
- **Melting range**: 125 °C - 128 °C
- **Test for p-hydroxybenzoate**: Melting range of p-hydroxybenzoic acid derived from the sample is 213 °C to 217 °C after drying for two hours at 80 °C

**Purity**
- **Loss on drying**: Not more than 0.5% (80 °C, 2 hours)
- **Sulphated ash**: Not more than 0.05%
- **p-Hydroxybenzoic acid and salicylic acid**: Not more than 0.35% expressed as p-hydroxybenzoic acid
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg

**E 219 SODIUM METHYL p-HYDROXYBENZOATE**

**Synonyms**

**Definition**
- **Einecs**: Sodium methyl p-hydroxybenzoate; Sodium compound of the methylester of p-hydroxybenzoic acid
- **Chemical formula**: C₈H₇O₃Na
- **Molecular weight**: 174.15
- **Assay**: Content not less than 99.5% on the anhydrous basis
Description

White, hygroscopic powder

Identification

Melting range

The white precipitate formed by acidifying with hydrochloric acid a 10 % (w/v) aqueous solution of the sodium derivative of methyl p-hydroxybenzoate (using litmus paper as indicator) shall, when washed with water and dried at 80 °C for two hours, have a melting range of 125 °C to 128 °C.

Test for sodium

Passes test

pH

9.7-10.3 (0.1 % solution in carbon dioxide free water)

Purity

Water content

Not more than 5 % (Karl Fischer method)

Sulphated ash

40 % to 44.5 % on the anhydrous basis

p-Hydroxybenzoic acid and salicylic acid

Not more than 0.35 % expressed as p-hydroxybenzoic acid

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

E 220 SULPHUR DIOXIDE

Synonyms

Definition

Einecs 231-195-2

Chemical name

Sulphur dioxide; Sulphurous acid anhydride

Chemical formula

SO₂

Molecular weight

64.07

Assay

Content not less than 99 %

Description

Colourless, non-flammable gas with strong pungent suffocating odour

Identification

Test for sulphurous substances

Passes test

Purity

Water content

Not more than 0.05 % (Karl Fischer method)

Non-volatile residue

Not more than 0.01 %
E 221 SODIUM SULPHITE

Synonyms
Definition
Einecs 231-821-4
Chemical name Sodium sulphite (anhydrous or heptahydrate)
Chemical formula Anhydrous: \( \text{Na}_2\text{SO}_3 \)
Heptahydrate: \( \text{Na}_2\text{SO}_3\cdot7\text{H}_2\text{O} \)
Molecular weight Anhydrous: 126.04
Heptahydrate: 252.16
Assay Anhydrous: Not less than 95 % of \( \text{Na}_2\text{SO}_3 \) and not less than 48 % of \( \text{SO}_2 \)
Heptahydrate: Not less than 48 % of \( \text{Na}_2\text{SO}_3 \) and not less than 24 % of \( \text{SO}_2 \)

Description
White crystalline powder or colourless crystals

Identification
Test for sulphite Passes test
Test for sodium Passes test
\( \text{pH} \) 8.5-11.5 (anhydrous: 10 % solution; heptahydrate: 20 % solution)

Purity
Thiosulphate Not more than 0.1 % based on the \( \text{SO}_2 \) content
Iron Not more than 10 mg/kg based on the \( \text{SO}_2 \) content
Selenium Not more than 5 mg/kg based on the \( \text{SO}_2 \) content

Sulphur trioxide Not more than 0.1 %
Selenium Not more than 10 mg/kg
Other gases not normally present in the air No trace
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg
Arsenic  Not more than 3 mg/kg
Lead  Not more than 2 mg/kg
Mercury  Not more than 1 mg/kg

E 222 SODIUM BISULPHITE

Synonyms

Definition

Einecs  231-921-4
Chemical name  Sodium bisulphite; Sodium hydrogen sulphite
Chemical formula  NaHSO₃ in aqueous solution
Molecular weight  104.06
Assay  Content not less than 32 % w/w NaHSO₃

Description  A clear, colourless to yellow solution

Identification

Test for sulphite  Passes test
Test for sodium  Passes test
pH  2.5-5.5 (10 % aqueous solution)

Purity

Iron  Not more than 10 mg/kg of Na₂SO₃ based on the SO₂ content
Selenium  Not more than 5 mg/kg based on the SO₂ content
Arsenic  Not more than 3 mg/kg
Lead  Not more than 2 mg/kg
Mercury  Not more than 1 mg/kg

E 223 SODIUM METABISULPHITE

Synonyms  Pyrosulphite; Sodium pyrosulphite

Definition

Einecs  231-673-0
Chemical name  Sodium disulphite; Disodium pentaoxodisulphate
<table>
<thead>
<tr>
<th>Chemical formula</th>
<th>Na₂S₂O₅</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>190.11</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95% Na₂S₂O₅ and not less than 64% of SO₂</td>
</tr>
</tbody>
</table>

**Description**
White crystals or crystalline powder

**Identification**
- Test for sulphite: Passes test
- Test for sodium: Passes test
- pH: 4.0-5.5 (10% aqueous solution)

**Purity**
- Thiosulphate: Not more than 0.1% based on the SO₂ content
- Iron: Not more than 10 mg/kg based on the SO₂ content
- Selenium: Not more than 5 mg/kg based on the SO₂ content
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

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**E 224 POTASSIUM METABISULPHITE**

**Synonyms**
Potassium pyrosulphite

**Definition**
- Einecs: 240-795-3
- Chemical name: Potassium disulphite; Potassium pentaoxo disulphate
- Chemical formula: K₂S₂O₅
- Molecular weight: 222.33
- Assay: Content not less than 90% K₂S₂O₅ and not less than 51.8% of SO₂, the remainder being composed almost entirely of potassium sulphate

**Description**
Colourless crystals or white crystalline powder

**Identification**
- Test for sulphite: Passes test
- Test for potassium: Passes test
Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Sample Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiosulphate</td>
<td>Not more than 0.1 % based on the SO₂ content</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 10 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 5 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 226 CALCIUM SULPHITE

Synonyms

Definition

Einecs 218-235-4
Chemical name: Calcium sulphite
Chemical formula: CaSO₃·2H₂O
Molecular weight: 156.17
Assay: Content not less than 95 % of CaSO₃·2H₂O and not less than 39 % of SO₂

Description

White crystals or white crystalline powder

Identification

Test for sulphite: Passes test
Test for calcium: Passes test

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Sample Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>Not more than 10 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 5 mg/kg based on the SO₂ content</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 227 CALCIUM BISULPHITE

Synonyms

Definition

Einecs 237-423-7
Chemical name  Calcium bisulphite; Calcium hydrogen sulphite  
Chemical formula  \( \text{Ca(HSO}_3\text{)}_2 \)  
Molecular weight  202.22  
Assay  6 to 8 % (w/v) of sulphur dioxide and 2.5 to 3.5 % (w/v) of calcium dioxide corresponding to 10 to 14 % (w/v) of calcium bisulphite \([\text{Ca(HSO}_3\text{)}_2]\)  

Description  
Clear greenish-yellow aqueous solution having a distinct odour of sulphur dioxide  

Identification  
Test for sulphite  Passes test  
Test for calcium  Passes test  

Purity  
Iron  Not more than 10 mg/kg based on the SO\(_2\) content  
Selenium  Not more than 5 mg/kg based on the SO\(_2\) content  
Arsenic  Not more than 3 mg/kg  
Lead  Not more than 2 mg/kg  
Mercury  Not more than 1 mg/kg  

E 228 POTASSIUM BISULPHITE  

Synonyms  

Definition  
Einecs  231-870-1  
Chemical name  Potassium bisulphite; Potassium hydrogen sulphite  
Chemical formula  \( \text{KHSO}_3 \) in aqueous solution  
Molecular weight  120.17  
Assay  Content not less than 280 g \( \text{KHSO}_3 \) per litre (or 150 g SO\(_2\) per litre)  

Description  
Clear colourless aqueous solution  

Identification  
Test for sulphite  Passes test  
Test for potassium  Passes test  

Purity  
Iron  Not more than 10 mg/kg based on the SO\(_2\) content  
Selenium  Not more than 5 mg/kg based on the SO\(_2\) content
**E 234 NISIN**

**Synonyms**

**Definition**
Nisin consists of several closely related polypeptides produced by strains of *Lactococcus lactis* subsp. *lactis*

**Einecs**
215-807-5

**Chemical name**

**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 solids and a minimum sodium chloride content of 50 %

**Description**
White powder

**Identification**

**Purity**

**Loss on drying**
Not more than 3 % (102 °C to 103 °C, to constant weight)

**Arsenic**
Not more than 1 mg/kg

**Lead**
Not more than 1 mg/kg

**Mercury**
Not more than 1 mg/kg

---

**E 235 NATAMYCIN**

**Synonyms**
Pimaricin

**Definition**
Natamycin is a fungicide of the polyene macrolide group, and is produced by strains of *Streptomyces natalensis* and other relevant species

**Einecs**
231-683-5

**Chemical name**
A stereoisomer of 22-(3-Amino-3,6-dideoxy-β-D-mannopyranosyloxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0^{5,7}]octacosa-8,14,16,18,20-pentaene-25-carboxylic acid.

**Chemical formula**
C_{33}H_{47}O_{13}N

**Molecular weight**
665,74

**Assay**
Content not less than 95 % on the dried basis
### Description
White to creamy-white crystalline powder

### Identification

**Colour reactions**  
On adding a few crystals of natamycin on a spot plate, to a drop of:  
- concentrated hydrochloric acid, a blue colour develops,  
- concentrated phosphoric acid, a green colour develops, which changes into pale red after a few minutes

**Spectrometry**  
A 0.0005% w/v solution in 1% methanolic acetic acid solution has absorption maxima at about 290 nm, 303 nm and 318 nm, a shoulder at about 280 nm and exhibits minima at about 250 nm, 295.5 nm and 311 nm

**pH**  
5.5-7.5 (1% w/v solution in previously neutralised mixture of 20 parts dimethylformamide and 80 parts of water)

**Specific rotation**  
\[ \alpha \] D^20 +250° to +295° (a 1% w/v solution in glacial acetic acid, at 20 °C and calculated with reference to the dried material)

### Purity

**Loss on drying**  
Not more than 8% (over P_2O_5, in vacuum at 60 °C to constant weight)

**Sulphated ash**  
Not more than 0.5%

**Arsenic**  
Not more than 3 mg/kg

**Lead**  
Not more than 2 mg/kg

**Mercury**  
Not more than 1 mg/kg

### Microbiological criteria

**Total plate count**  
Not more than 100 colonies per gram

### E 239 HEXAMETHYLENE TETRAMINE

**Synonyms**  
Hexamine; Methenamine

**Definition**

- **Einecs**  
  202-905-8

- **Chemical name**  
  1,3,5,7-Tetraazatricyclo [3.3.1.1^3,7]-decane, hexamethylenetetramine

- **Chemical formula**  
  C_6H_{12}N_4

- **Molecular weight**  
  140.19

- **Assay**  
  Content not less than 99% on the anhydrous basis

**Description**  
Colourless or white crystalline powder

**Identification**

**Test for formaldehyde**  
Passes test
Test for ammonia

Passes test

Sublimation point:

Approximately 260 °C

Purity

Loss on drying

Not more than 0,5 % (at 105 °C in vacuum over P₂O₅ for 2 hours)

Sulphated ash

Not more than 0,05 %

Sulphates

Not more than 0,005 % expressed as SO₄

Chlorides

Not more than 0,005 % expressed as Cl

Ammonium salts

Not detectable

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

E 242 DIMETHYL DICARBONATE

Synonyms

DMDC; Dimethyl pyrocarbonate

Definition

Einecs 224-859-8

Chemical name

Dimethyl dicarbonate; Pyrocarbonic acid dimethyl ester

Chemical formula

C₄H₆O₅

Molecular weight

134,09

Assay

Content not less than 99,8 %

Description

Colourless liquid, decomposes in aqueous solution. It is corrosive to skin and eyes and toxic by inhalation and ingestion

Identification

Decomposition

After dilution positive tests for CO₂ and methanol

Melting point

17 °C

Boiling point

172 °C with decomposition

Density 20 °C

Approximately 1,25 g/cm³

Infrared absorption spectrum

Maxima at 1 156 and 1 832 cm⁻¹
Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethyl carbonate</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Chlorine, total</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 249 POTASSIUM NITRITE**

**Synonyms**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-832-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Potassium nitrite</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>KNO₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>85.11</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95 % on the anhydrous basis (*)</td>
</tr>
</tbody>
</table>

**Definition**

White or slightly yellow, deliquescent granules

**Identification**

Test for nitrite: Passes test
Test for potassium: Passes test
pH: 6.0-9.0 (5 % solution)

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 3 % (4 hours, over silica gel)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 250 SODIUM NITRITE**

**Synonyms**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-555-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sodium nitrite</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>NaNO₂</td>
</tr>
</tbody>
</table>

**Definition**

(*) May only be sold in a mixture with salt or a salt substitute.
<table>
<thead>
<tr>
<th>Description</th>
<th>White crystalline powder or yellowish lumps</th>
</tr>
</thead>
</table>
| Identification | Test for nitrite: Passes test  
Test for sodium: Passes test |
| Purity | Loss on drying: Not more than 0.25 % (4 hours, over silica gel)  
Arsenic: Not more than 3 mg/kg  
Lead: Not more than 2 mg/kg  
Mercury: Not more than 1 mg/kg |

**E 251 SODIUM NITRATE**

- (*) SOLID SODIUM NITRATE

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Chile saltpetre; Cubic or soda nitre</th>
</tr>
</thead>
</table>
| Definition | Einecs: 231-554-3  
Sodium nitrate: NaNO₃  
Molecular weight: 85.00  
Assay: Content not less than 99 % on the anhydrous basis |
| Description | White crystalline, slightly hygroscopic powder |
| Identification | Test for nitrate: Passes test  
Test for sodium: Passes test  
pH: 5.5-8.3 (5 % solution) |
| Purity | Loss on drying: Not more than 2 % (105 °C, 4 hours)  
Nitrites: Not more than 30 mg/kg expressed as NaNO₂  
Arsenic: Not more than 3 mg/kg  
Lead: Not more than 2 mg/kg  
Mercury: Not more than 1 mg/kg |

(*) May only be sold in a mixture with salt or a salt substitute.
(ii) LIQUID SODIUM NITRATE

Synonyms

Definition
Liquid sodium nitrate is an aqueous solution of sodium nitrate as the direct result of the chemical reaction between sodium hydroxide and nitric acid in stoichiometric amounts, without subsequent crystallisation. Standardised forms prepared from liquid sodium nitrate meeting these specifications may contain nitric acid in excessive amounts, if clearly stated or labelled.

Einecs: 231-554-3
Chemical name: Sodium nitrate
Chemical formula: NaNO₃
Molecular weight: 85.00
Assay: Content between 33.5% and 40.0% of NaNO₃

Description
Clear colourless liquid

Identification
Test for nitrate: Passes test
Test for sodium: Passes test
pH: 1.5-3.5

Purity
Free nitric acid: Not more than 0.01%
Nitrites: Not more than 10 mg/kg expressed as NaNO₂
Arsenic: Not more than 1 mg/kg
Lead: Not more than 1 mg/kg
Mercury: Not more than 0.3 mg/kg

This specification refers to a 35% aqueous solution.

E 252 POTASSIUM NITRATE

Synonyms
Chile saltpetre; Cubic or soda nitre

Definition

Einecs: 231-818-8
Chemical name: Potassium nitrate
Chemical formula: KNO₃
Molecular weight: 101.11
Assay: Content not less than 99% on the anhydrous basis

Description
White crystalline powder or transparent prisms having a cooling, saline, pungent taste

Identification
Test for nitrate: Passes test
Test for potassium: Passes test
pH: 4.5-8.5 (5% solution)
Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 1 % (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Nitrites</td>
<td>Not more than 20 mg/kg expressed as KNO₂</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 260 ACETIC ACID

Synonyms

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>200-580-7</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Acetic acid; Ethanoic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₂H₄O₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>60.05</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.8 %</td>
</tr>
</tbody>
</table>

Description

Clear, colourless liquid having a pungent, characteristic odour

Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling point</td>
<td>118 °C at 760 mm pressure (of mercury)</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>About 1.049</td>
</tr>
<tr>
<td>Test for acetate</td>
<td>A one in three solution gives positive tests for acetate</td>
</tr>
<tr>
<td>Solidification point</td>
<td>Not lower than 14.5 °C</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-volatile residue</td>
<td>Not more than 100 mg/kg</td>
</tr>
<tr>
<td>Formic acid, formates and other oxidisable substances</td>
<td>Not more than 1 000 mg/kg expressed as formic acid</td>
</tr>
<tr>
<td>Readily oxidisable substances</td>
<td>Dilute 2 ml of the sample in a glass-stoppered container with 10 ml of water and add 0.1 ml of 0.1 N potassium permanganate. The pink colour does not change to brown within 30 minutes</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 0.5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 261 POTASSIUM ACETATE

Synonyms

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>204-822-2</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Potassium acetate</td>
</tr>
</tbody>
</table>
### Chemical formula
\[ C_2H_3O_2K \]

### Molecular weight
98.14

### Assay
Content not less than 99 % on the anhydrous basis

### Description
Colourless, deliquescent crystals or a white crystalline powder, odourless or with a faint acetic odour

### Identification
- **pH**: 7.5-9.0 (5 % aqueous solution)
- **Test for acetate**: Passes test
- **Test for potassium**: Passes test

### Purity
- **Loss on drying**: Not more than 8 % (150 °C, 2 hours)
- **Formic acid, formates and other oxidisable substances**: Not more than 1 000 mg/kg expressed as formic acid
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg

---

### E 262 (i) SODIUM ACETATE

#### Synonyms

#### Definition

- **Einecs**: 204-823-8
- **Chemical name**: Sodium acetate
- **Chemical formula**: \( C_2H_3NaO_2 \cdot nH_2O \) \( n = 0 \) or 3
- **Molecular weight**: 
  - Anhydrous: 82.03
  - Trihydrate: 136.08
- **Assay**: Content (for both of anhydrous and trihydrate form) not less than 98.5 % on the anhydrous basis

#### Description

- **Anhydrous**: White, odourless, granular, hygroscopic powder
- **Trihydrate**: Colourless, transparent crystals or a granular crystalline powder, odourless or with a faint, acetic odour. Effloresces in warm, dry air

#### Identification

- **pH**: 8.0-9.5 (1 % aqueous solution)
- **Test for acetate**: Passes test
E 262 (ii) SODIUM DIACETATE

Synonyms

Definition
Sodium diacetate is a molecular compound of sodium acetate and acetic acid

Einecs 204-814-9
Chemical name Sodium hydrogen diacetate
Chemical formula C₄H₇NaO₄nH₂O (n = 0 or 3)
Molecular weight 142,09 (anhydrous)
Assay Content 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate

Description
White, hygroscopic crystalline solid with an acetic odour

Identification
pH 4.5-5.0 (10 % aqueous solution)
Test for acetate Passes test
Test for sodium Passes test

Purity
Water content Not more than 2 % (Karl Fischer method)
Formic acid, formates and other oxidisable substances Not more than 1 000 mg/kg expressed as formic acid
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg

E 263 CALCIUM ACETATE

Synonyms

Definition

Einecs 200-540-9
Chemical name Calcium acetate
### Chemical formula

<table>
<thead>
<tr>
<th></th>
<th>Anhydrous:</th>
<th>C₄H₆O₄Ca</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Monohydrate:</td>
<td>C₄H₆O₄Ca·H₂O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Anhydrous:</td>
<td>158.17</td>
</tr>
<tr>
<td></td>
<td>Monohydrate:</td>
<td>176.18</td>
</tr>
</tbody>
</table>

### Assay

Content not less than 98 % on the anhydrous basis

### Description

Anhydrous calcium acetate is a white, hygroscopic, bulky, crystalline solid with a slightly bitter taste. A slight odour of acetic acid may be present. The monohydrate may be needles, granules or powder.

### Identification

<table>
<thead>
<tr>
<th>pH</th>
<th>6.0-9.0 (10 % aqueous solution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for acetate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for calcium</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

### Purify

- **Loss on drying**
  - Not more than 11 % (155 °C to constant weight, for the monohydrate)
- **Water insoluble matter**
  - Not more than 0.3 %
- **Formic acid, formates and other oxidisable substances**
  - Not more than 1 000 mg/kg expressed as formic acid
- **Arsenic**
  - Not more than 3 mg/kg
- **Lead**
  - Not more than 2 mg/kg
- **Mercury**
  - Not more than 1 mg/kg

### E 270 LACTIC ACID

#### Synonyms

Consists of a mixture of lactic acid (C₃H₆O₃) and lactic acid lactate (C₆H₁₀O₅). It is obtained by the lactic fermentation of sugars or is prepared synthetically.

Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid lactate, which on dilution and heating hydrolyses to lactic acid.

#### Chemical name

Lactic acid; 2-Hydroxypropionic acid; 1-Hydroxyethane-1-carboxylic acid

#### Chemical formula

C₃H₆O₃

#### Molecular weight

90.08

#### Assay

Content not less than 76 %

#### Description

Colourless or yellowish, nearly odourless, syrupy liquid to solid

#### Identification

| Test for lactate | Passes test |

#### Purity

- **Sulphated ash**
  - Not more than 0.1 %
- **Chloride**
  - Not more than 0.2 %
### E 280 PROPIONIC ACID

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>201-176-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Propionic acid; Propanoic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₃H₆O₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>74.08</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.5 %</td>
</tr>
</tbody>
</table>

**Description**

Colourless or slightly yellowish, oily liquid with a slightly pungent odour

**Identification**

- Melting point: – 22 °C
- Distillation range: 138.5 °C to 142.5 °C

**Purity**

- Non-volatile residue: Not more than 0.01 % when dried at 140 °C to constant weight
- Aldehydes: Not more than 0.1 % expressed as formaldehyde
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

### E 281 SODIUM PROPIONATE

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>205-290-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sodium propionate; Sodium propanoate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₃H₆O₂Na</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>96.06</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99 % after drying for two hours at 105 °C</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White crystalline hygroscopic powder, or a fine white powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>Test for propionate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>7,5-10,5 (10 % aqueous solution)</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 4 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0,1 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 282 CALCIUM PROPIONATE**

**Synonyms**

**Definition**

| Einecs | 223-795-8 |
| Chemical name | Calcium propionate |
| Chemical formula | C₆H₁₀O₄Ca |
| Molecular weight | 186,22 |
| Assay | Content not less than 99 %, after drying for two hours at 105 °C |

**Description**

White crystalline powder

**Identification**

| Test for propionate | Passes test |
| Test for calcium | Passes test |
| pH | 6,0-9,0 (10 % aqueous solution) |

**Purity**

| Loss on drying | Not more than 4 % (105 °C, 2 hours) |
| Water insoluble matter | Not more than 0,3 % |
| Iron | Not more than 50 mg/kg |
| Fluoride | Not more than 10 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |
**E 283 POTASSIUM PROPIONATE**

**Synonyms**

**Definition**

- Einecs: 206-323-5
- Chemical name: Potassium propionate; Potassium propanoate
- Chemical formula: $\text{C}_3\text{H}_5\text{KO}_2$
- Molecular weight: 112.17
- Assay: Content not less than 99 % after drying for two hours at 105 °C

**Description**

- White crystalline powder

**Identification**

- Test for propionate: Passes test
- Test for potassium: Passes test

**Purity**

- Loss on drying: Not more than 4 % (105 °C, 2 hours)
- Water insoluble matter: Not more than 0.1 %
- Iron: Not more than 30 mg/kg
- Fluoride: Not more than 10 mg/kg
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 5 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 284 BORIC ACID**

**Synonyms**

- Boracic acid; Orthoboric acid; Borofax

**Definition**

- Einecs: 233-139-2
- Chemical name
- Chemical formula: $\text{H}_3\text{BO}_3$
- Molecular weight: 61.84
- Assay: Content not less than 99.5 %

**Description**

- Colourless, odourless, transparent crystals or white granules or powder; slightly unctuous to the touch; occurs in nature as the mineral sassolite

**Identification**

- Melting point: At approximately 171 °C
- Burning test: Burns with a nice green flame
- pH: 3.8-4.8 (3.3 % aqueous solution)

**Purity**

- Peroxides: No colour develops with added KI-solution
- Arsenic: Not more than 1 mg/kg
### E 285 SODIUM TETRABORATE (BORAX)

#### Synonyms
- Sodium borate

#### Definition
- **Einecs**: 215-540-4
- **Chemical name**: Sodium tetraborate; Sodium biborate; Sodium pyroborate; Anhydrous tetraborate
- **Chemical formula**: \( \text{Na}_2\text{B}_4\text{O}_7 \)
- **Molecular weight**: 201.27

#### Assay

#### Description
- Powder or glass-like plates becoming opaque on exposure to air; slowly soluble in water

#### Identification
- **Melting range**: Between 171 °C and 175 °C with decomposition

#### Purity
- **Peroxides**: No colour develops with added KI-solution
- **Arsenic**: Not more than 1 mg/kg
- **Lead**: Not more than 5 mg/kg
- **Mercury**: Not more than 1 mg/kg

### E 290 CARBON DIOXIDE

#### Synonyms
- Carbonic acid gas; Dry ice (solid form); Carbonic anhydride

#### Definition
- **Einecs**: 204-696-9
- **Chemical name**: Carbon dioxide
- **Chemical formula**: \( \text{CO}_2 \)
- **Molecular weight**: 44.01

#### Assay
- Content not less than 99 % v/v on the gaseous basis

#### Description
- A colourless gas under normal environmental conditions with a slight pungent odour. Commercial carbon dioxide is shipped and handled as a liquid in pressurised cylinders or bulk storage systems, or in compressed solid blocks of ‘dry ice’. Solid (dry ice) forms usually contain added substances, such as propylene glycol or mineral oil, as binders
Identification

Precipitate formation
When a stream of the sample is passed through a solution of barium hydroxide, a white precipitate is produced which dissolves with effervescence in dilute acetic acid.

Purity

Acidity
915 ml of gas bubbled through 50 ml of freshly boiled water must not render the latter more acid to methylorange than is 50 ml freshly boiled water to which has been added 1 ml of hydrochloric acid (0.01 N).

Reducing substances, hydrogen phosphide and sulphide
915 ml of gas bubbled through 25 ml of ammoniacal silver nitrate reagent to which has been added 3 ml of ammonia must not cause clouding or blackening of this solution.

Carbon monoxide
Not more than 10 μl/l.

Oil content
Not more than 5 mg/kg.

E 296 MALIC ACID

Synonyms
Pomalous acid

Definition

Einecs 230-022-8, 210-514-9, 202-601-5

Chemical name
Hydroxybutanedioic acid; hydroxysuccinic acid

Chemical formula
C₄H₆O₅

Molecular weight
134.09

Assay
Content not less than 99.0 %

Description
White or nearly white crystalline powder or granules

Identification

Melting range
127-132 °C

Test for malate
Passes test

Purity

Sulphated ash
Not more than 0.1 %

Fumaric acid
Not more than 1.0 %

Maleic acid
Not more than 0.05 %

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

E 297 FUMARIC ACID

Synonyms

Definition

Einecs 203-743-0

Chemical name
Trans-Butenedioic acid; trans-1,2-Ethylene-dicarboxylic acid
### E 300 ASCORBIC ACID, L-ASCORBIC ACID

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>L-xylo-Ascorbic acid; L(+)- Ascorbic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Einecs 200-066-2</td>
</tr>
<tr>
<td></td>
<td>Chemical name: Ascorbic acid; 2,3-Didehydro-L-threo-hexono-1,4-lactone; 3-Keto-L-gulofuranolactone</td>
</tr>
<tr>
<td></td>
<td>Chemical formula: $\text{C}_6\text{H}_8\text{O}_6$</td>
</tr>
<tr>
<td></td>
<td>Molecular weight: 176.13</td>
</tr>
<tr>
<td></td>
<td>Assay: contains not less than 99% of $\text{C}_6\text{H}_8\text{O}_6$ after drying in a vacuum desiccator over sulphuric acid for 24 hours,</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>White to pale yellow, odourless crystalline powder</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>Melting range: Between 189 °C and 193 °C with decomposition</td>
</tr>
<tr>
<td>Test for ascorbic acid</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>Between 2.4 and 2.8 (2 % aqueous solution)</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_{D}^{20}$ between $+20.5^\circ$ and $+21.5^\circ$ (10 % w/v aqueous solution)</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td>Loss on drying: Not more than 0.4 % (in vacuum over sulphuric acid, 24 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td></td>
<td>Arsenic</td>
</tr>
<tr>
<td>----------</td>
<td>------------------</td>
</tr>
<tr>
<td></td>
<td>Lead</td>
</tr>
<tr>
<td></td>
<td>Mercury</td>
</tr>
</tbody>
</table>

### E 301 SODIUM ASCORBATE

**Synonyms**

Sodium L-ascorbate; L-Ascorbic acid monosodium salt

**Definition**

Einecs 205-126-1

Chemical name: Sodium ascorbate; Sodium L-ascorbate; 2,3-Didehydro-L-threo-hexono-1,4-lactone sodium enolate; 3-Keto-L-gulofurano-lactone sodium enolate

Chemical formula: \( \text{C}_6\text{H}_7\text{O}_6\text{Na} \)

Molecular weight: 198.11

Assay: Sodium ascorbate, after drying in a vacuum desiccator over sulphuric acid for 24 hours, contains not less than 99 % of \( \text{C}_6\text{H}_7\text{O}_6\text{Na} \)

**Description**

White or almost white, odourless crystalline powder which darkens on exposure to light

**Identification**

- Test for ascorbate: Passes test
- Test for sodium: Passes test
- pH: Between 6.5 and 8.0 (10 % aqueous solution)
- Specific rotation: \( [\alpha]_D^{20} \) between + 103° and + 106° (10 % v/v aqueous solution)

**Purity**

- Loss on drying: Not more than 0.25 % (in vacuum over sulphuric acid, 24 hours)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

### E 302 CALCIUM ASCORBATE

**Synonyms**

Calcium ascorbate dihydrate

**Definition**

Einecs 227-261-5

Chemical name: Calcium ascorbate dihydrate; Calcium salt of 2,3-didehydro-L-threo-hexono-1,4-lactone dihydrate

Chemical formula: \( \text{C}_{12}\text{H}_{14}\text{O}_{12}\text{Ca2H}_2\text{O} \)

Molecular weight: 426.35

Assay: Content not less than 98 % on a volatile matter-free basis
### Description
White to slightly pale greyish-yellow odourless crystalline powder

### Identification
- **Test for ascorbate**: Passes test
- **Test for calcium**: Passes test
- **pH**: Between 6.0 and 7.5 (10 % aqueous solution)
- **Specific rotation**: $\left[\alpha\right]_{D}^{20}$ between + 95° and + 97° (5 % w/v aqueous solution)

### Purity
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Volatile matter**: Not more than 0.3 % determined by drying at room temperature for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg

---

### E 304 (i) ASCORBYL PALMITATE

### Synonyms
- L-ascorbyl palmitate

### Definition
- **Einecs**: 205-305-4
- **Chemical name**: Ascorbyl palmitate; L-ascorbyl palmitate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate; 6-palmitoyl-3-keto-L-gulofuranolactone
- **Chemical formula**: $C_{22}H_{38}O_{7}$
- **Molecular weight**: 414.55
- **Assay**: Content not less than 98 % on the dried basis

### Description
White or yellowish-white powder with a citrus-like odour

### Identification
- **Melting range**: Between 107 °C and 117 °C
- **Specific rotation**: $\left[\alpha\right]_{D}^{20}$ between + 21° and + 24° (5 % w/v in methanol solution)

### Purity
- **Loss on drying**: Not more than 2.0 % (vacuum oven, 56-60 °C, 1 hour)
- **Sulphated ash**: Not more than 0.1 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg
**E 304 (ii) ASCORBYL STEARATE**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>246-944-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Ascorbyl stearate; L-ascorbyle stearate; 2,3-didehydro-L-threohexono-1,4-lactone-6-stearate; 6-stearoyl-3-ketol-L-gulofuranolactone</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C(<em>{24}H</em>{42}O_7)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>442.6</td>
</tr>
</tbody>
</table>

**Assay**

Content not less than 98 %

**Description**

White or yellowish, white powder with a citrus-like odour

**Identification**

| Melting point | About 116 °C |

**Purity**

| Loss on drying | Not more than 2.0 % (vacuum oven, 56-60 °C, 1 hour) |
| Sulphated ash  | Not more than 0.1 % |
| Arsenic        | Not more than 3 mg/kg |
| Lead           | Not more than 2 mg/kg |
| Mercury        | Not more than 1 mg/kg |

---

**E 306 TOCOPHEROL-RICH EXTRACT**

**Synonyms**

**Definition**

Product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols

Contains tocopherols such as d-α-, d-β-, d-γ- and d-δ-tocopherols

<table>
<thead>
<tr>
<th>Einecs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>430.71 (d-α-tocopherol)</td>
</tr>
</tbody>
</table>

**Assay**

Content not less than 34 % of total tocopherols

**Description**

Brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. May show a slight separation of wax-like constituents in microcrystalline form

**Identification**

By suitable gas liquid chromatographic method

| Specific rotation | [\(\alpha\)]\(_D\)\(_{20}^0\) not less than + 20° |

**Solubility**

Insoluble in water. Soluble in ethanol. Miscible in ether

**Purity**

| Sulphated ash | Not more than 0.1 % |
Arsenic                                      Not more than 3 mg/kg
Lead                                          Not more than 2 mg/kg
Mercury                                      Not more than 1 mg/kg

**E 307 ALPHA-TOCOPHEROL**

**Synonyms**
l-α-Tocopherol; (all rac)-α-Tocopherol

**Definition**
Einecs 233-466-0
Chemical name DL-5,7,8-Trimethyltocol; DL-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula C_{29}H_{50}O_{2}
Molecular weight 430.71
Assay Content not less than 96 %

**Description**
Slightly yellow to amber, nearly odourless, clear, viscous oil which oxidises and darkens on exposure to air or light

**Identification**
Solubility Insoluble in water, freely soluble in ethanol, miscible in ether
Spectrophotometry In absolute ethanol the maximum absorption is about 292 nm
Specific rotation \([\alpha]_D^{25} 0° ± 0.05° (1 in 10 solution in chloroform)\)

**Purity**
Refractive index \([n]_D^{20} 1.503-1.507\)
Specific absorption in ethanol \(E_{1\%}^{1cm} (292 nm) 71-76\)
(0.01 g in 200 ml of absolute ethanol)
Sulphated ash Not more than 0.1 %
Lead Not more than 2 mg/kg

**E 308 GAMMA-TOCOPHEROL**

**Synonyms**
l-γ-Tocopherol

**Definition**
Einecs 231-523-4
Chemical name 2,7,8-trimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
Chemical formula C_{28}H_{44}O_{2}
Molecular weight 416.69
Assay Content not less than 97 %

**Description**
Clear, viscous, pale yellow oil which oxidises and darkens on exposure to air or light

**Identification**
Spectrometry Maximum absorptions in absolute ethanol at about 298 nm and 257 nm
### E 309 DELTA-TOCOPHEROL

**Synonyms**
- Einecs 204-299-0

**Definition**
- Chemical name: 2,8-dimethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol
- Chemical formula: \( \text{C}_{27}\text{H}_{46}\text{O}_{2} \)
- Molecular weight: 402.7
- Assay: Content not less than 97%

**Description**
- Clear, viscous, pale yellowish or orange oil which oxidises and darkens on exposure to air or light

**Identification**
- Spectrometry: Maximum absorptions in absolute ethanol at about 298 nm and 257 nm

**Purity**
- Specific absorption \( E_{1\,\text{cm}}^{1\%} \) in ethanol: \( E_{1\,\text{cm}}^{1\%} \) (298 nm) between 91 and 97
- \( E_{1\,\text{cm}}^{1\%} \) (257 nm) between 5.0 and 8.0
- Refractive index: \( [n]_{20}^{\text{D}} \) 1.503-1.507
- Sulphated ash: Not more than 0.1 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

### E 310 PROPYL GALLATE

**Synonyms**
- Einecs 204-498-2

**Definition**
- Chemical name: Propyl gallate; Propyl ester of gallic acid; n-propyl ester of 3,4,5-trihydroxybenzoic acid
**E 311 OCTYL GALLATE**

### Synonyms

Einecs 213-853-0

### Definition

Octyl gallate; Octyl ester of gallic acid; n-octyl ester of 3,4,5-trihydroxybenzoic acid

### Description

White to creamy-white odourless solid

### Identification

Insoluble in water, freely soluble in ethanol, ether and propane-1,2-diol

### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5% (90 °C, 6 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.05%</td>
</tr>
<tr>
<td>Free acid</td>
<td>Not more than 0.5% (as gallic acid)</td>
</tr>
<tr>
<td>Chlorinated organic compound</td>
<td>Not more than 100 mg/kg (as C1)</td>
</tr>
<tr>
<td>Specific absorption in ethanol</td>
<td>$E_{1%}^{\text{1cm}}$ (275 nm) not less than 375 and not more than 390</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

---

**Chemical formula**

C<sub>10</sub>H<sub>12</sub>O<sub>5</sub>

**Molecular weight**

212.20

**Assay**

Content not less than 98% on the anhydrous basis

**Description**

White to creamy-white, crystalline, odourless solid

**Identification**

- Solubility: Slightly soluble in water, freely soluble in ethanol, ether and propane-1,2-diol
- Melting range: Between 146 °C and 150 °C after drying at 110 °C for four hours

**Purity**

- Loss on drying: Not more than 0.5% (110 °C, 4 hours)
- Sulphated ash: Not more than 0.1%
- Free acid: Not more than 0.5% (as gallic acid)
- Chlorinated organic compound: Not more than 100 mg/kg (as C1)
- Specific absorption in ethanol: $E_{1%}^{\text{1cm}}$ (275 nm) not less than 485 and not more than 520
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
### E 312 DODECYL GALLATE

**Synonyms**
- Lauryl gallate

**Definition**
- **Einecs**: 214-620-6
- **Chemical name**: Dodecyl gallate; n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid; Dodecyl ester of gallic acid
- **Chemical formula**: C_{19}H_{30}O_{5}
- **Molecular weight**: 338.45
- **Assay**: Content not less than 98 % after drying at 90 °C for six hours

**Description**
- White or creamy-white odourless solid

**Identification**
- **Solubility**: Insoluble in water, freely soluble in ethanol and ether
- **Melting range**: Between 95 °C and 98 °C after drying at 90 °C for six hours

**Purity**
- **Loss on drying**: Not more than 0.5 % (90 °C, 6 hours)
- **Sulphated ash**: Not more than 0.05 %
- **Free acid**: Not more than 0.5 % (as gallic acid)
- **Chlorinated organic compound**: Not more than 100 mg/kg (as Cl)
- **Specific absorption in ethanol**: E$_{1%}$ (275 nm) not less than 300 and not more than 325

#### Contaminants

<table>
<thead>
<tr>
<th>Element</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 315 ERYTHORBIC ACID

**Synonyms**
- Isoascorbic acid; D-Araboascorbic acid

**Definition**
- **Einecs**: 201-928-0
- **Chemical name**: D-Erythro-hex-2-enoic acid γ-lactone; Isoascorbic acid; D-Isoascorbic acid
- **Chemical formula**: C$_6$H$_8$O$_6$
- **Molecular weight**: 176.13
- **Assay**: Content not less than 98 % on the anhydrous basis

**Description**
- White to slightly yellow crystalline solid which darkens gradually on exposure to light
### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>About 164 °C to 172 °C with decomposition</td>
</tr>
<tr>
<td>Test for ascorbic acid/colour reaction</td>
<td>Passes test</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between – 16,5° to – 18,0°</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.4 % after drying under (reduced pressure on silica gel, 3 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>Oxalate</td>
<td>To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear.</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**E 316 SODIUM ERYTHORBATE**

**Synonyms**

<table>
<thead>
<tr>
<th>Synonym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium isoascorbate</td>
<td></td>
</tr>
</tbody>
</table>

**Definition**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>228-973-9</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium isoascorbate; Sodium D-isoscorbic acid; Sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone; 3-keto-D-gulofurano-lactone sodium enolate monohydrate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$C_6H_7O_6Na\cdotH_2O$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>216,13</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98 % after drying in a vacuum desiccator over sulphuric acid for 24 hours expressed on the monohydrate basis</td>
</tr>
</tbody>
</table>

**Description**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>White crystalline solid</td>
</tr>
</tbody>
</table>

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Freely soluble in water, very slightly soluble in ethanol</td>
</tr>
<tr>
<td>Test for ascorbic acid/colour reaction</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>5,5 to 8,0 (10 % aqueous solution)</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_D^{25}$ 10 % (w/v) aqueous solution between + 95° and + 98°</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0,25 % after drying (in vacuum over sulphuric acid, 24 hours)</td>
</tr>
<tr>
<td>Oxalate</td>
<td>To a solution of 1 g in 10 ml of water add 2 drops of glacial acetic acid and 5 ml of 10 % calcium acetate solution. The solution should remain clear.</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### E 319 TERTIARY-BUTYLHYDROQUINONE (TBHQ)

**Synonyms**  
TBHQ

**Definition**

<table>
<thead>
<tr>
<th>Element</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eines</td>
<td>217-752-2</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Tert-butyl-1,4-benzenediol; 2-(1,1-Dimethylethyl)-1,4-benzenediol</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C\textsubscript{10}H\textsubscript{14}O\textsubscript{2}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>166.22</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99% of C\textsubscript{10}H\textsubscript{14}O\textsubscript{2}</td>
</tr>
</tbody>
</table>

**Description**  
White crystalline solid having a characteristic odour

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Practically insoluble in water; soluble in ethanol</td>
</tr>
<tr>
<td>Melting point</td>
<td>Not less than 126.5 °C</td>
</tr>
<tr>
<td>Phenolics</td>
<td>Dissolve about 5 mg of the sample in 10 ml of methanol and add 10.5 ml of dimethylamine solution (1 in 4). A red to pink colour is produced</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tertiary-Butyl-p-benzoquinone</td>
<td>Not more than 0.2%</td>
</tr>
<tr>
<td>2,5-Di-tertiary-butyl hydroquinone</td>
<td>Not more than 0.2%</td>
</tr>
<tr>
<td>Hydroxyquinone</td>
<td>Not more than 0.1%</td>
</tr>
<tr>
<td>Toluene</td>
<td>Not more than 25 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

### E 320 BUTYLATED HYDROXYANISOLE (BHA)

**Synonyms**  
BHA

**Definition**

<table>
<thead>
<tr>
<th>Element</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eines</td>
<td>246-563-8</td>
</tr>
<tr>
<td>Chemical name</td>
<td>3-Tertiary-butyl-4-hydroxyanisole; A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C\textsubscript{11}H\textsubscript{16}O\textsubscript{2}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>180.25</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.5% of C\textsubscript{11}H\textsubscript{16}O\textsubscript{2} and not less than 85% of 3-tertiary-butyl-4-hydroxyanisole isomer</td>
</tr>
</tbody>
</table>

**Description**  
White or slightly yellow flakes or waxy solid with a slight aromatic smell

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Insoluble in water, freely soluble in ethanol</td>
</tr>
<tr>
<td>Melting range</td>
<td>Between 48 °C and 63 °C</td>
</tr>
<tr>
<td>Colour reaction</td>
<td>Passes test for phenol groups</td>
</tr>
</tbody>
</table>
### Purity

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.05 % after calcination at 800 ± 25 °C</td>
</tr>
<tr>
<td>Phenolic impurities</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Specific absorption</td>
<td>( E_{1%}^{1\text{cm}} ) (290 nm) not less than 190 and not more than 210 ( E_{1%}^{1\text{cm}} ) (228 nm) not less than 326 and not more than 345</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 321 BUTYLATED HYDROXYTOLUENE (BHT)

**Synonyms**

- BHT

**Definition**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>204-881-4</td>
</tr>
<tr>
<td>Chemical name</td>
<td>2,6-Ditertiary-butyl-p-cresol; 4-Methyl-2,6-ditertiarybutylphenol</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>( \text{C}<em>{15}\text{H}</em>{24}\text{O} )</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>220.36</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99 %</td>
</tr>
</tbody>
</table>

**Description**

White, crystalline or flaked solid, odourless or having a characteristic faint aromatic odour

**Identification**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Insoluble in water and propane- 1,2-diol</td>
</tr>
<tr>
<td></td>
<td>Freely soluble in ethanol</td>
</tr>
<tr>
<td>Melting point</td>
<td>At 70 °C</td>
</tr>
<tr>
<td>Spectrometry</td>
<td>The absorption in the range 230 to 320 nm of a 2 cm layer of a 1 in 100 000 solution in dehydrated ethanol exhibits a maximum only at 278 nm</td>
</tr>
</tbody>
</table>

### Purity

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.005 %</td>
</tr>
<tr>
<td>Phenolic impurities</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Specific absorption in ethanol</td>
<td>( E_{1%}^{1\text{cm}} ) (278 nm) not less than 81 and not more than 88</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 322 LECITHINS

Synonyms

Phosphatides; Phospholipids

Definition

Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity.

The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides.

Einecs 232-307-2

Chemical name

Chemical formula

Molecular weight

Assay

Lecithins: not less than 60.0 % of substances insoluble in acetone

Hydrolysed lecithins: not less than 56.0 % of substances insoluble in acetone

Description

Lecithins: brown liquid or viscous semi-liquid or powder

Hydrolysed lecithins: light brown to brown viscous liquid or paste

Identification

Test for choline: Passes test

Test for phosphorus: Passes test

Test for fatty acids: Passes test

Test for hydrolysed lecithin:

To a 800 ml beaker add 500 ml of water (30-35 °C). Then slowly add 50 ml of the sample with constant stirring. Hydrolysed lecithin will form a homogeneous emulsion. Non-hydrolysed lecithin will form a distinct mass of about 50 g

Purity

Loss on drying: Not more than 2.0 % (105 °C, 1 hour)

Toluene-insoluble matter: Not more than 0.3 %

Acid value:

Lecithins: not more than 35 mg of potassium hydroxide per gram

Hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram

Peroxide value: Equal to or less than 10

Arsenic: Not more than 3 mg/kg

Lead: Not more than 2 mg/kg

Mercury: Not more than 1 mg/kg

E 325 SODIUM LACTATE

Synonyms

Definition

Einecs 200-772-0

Chemical name

Sodium lactate; Sodium 2-hydroxypropanoate
Chemical formula: C₃H₅NaO₃
Molecular weight: 112.06 (anhydrous)
Assay: Content not less than 57 % and not more than 66 %

**Description**
Colourless, transparent, liquid. Odourless, or with a slight, characteristic odour

**Identification**
Test for lactate: Passes test
Test for potassium: Passes test
pH: 6.5 to 7.5 (20 % aqueous solution)

**Purity**
- Acidity: Not more than 0.5 % after drying expressed as lactic acid
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Reducing substances: No reduction of Fehling’s solution

Note: This specification refers to a 60 % aqueous solution

---

E 326 POTASSIUM LACTATE

**Synonyms**

**Definition**
- Eines 213-631-3
- Chemical name: Potassium lactate; Potassium 2-hydroxypropanoate
- Chemical formula: C₃H₅O₃K
- Molecular weight: 128.17 (anhydrous)
- Assay: Content not less than 57 % and not more than 66 %

**Description**
Slightly viscous, almost odourless clear liquid. Odourless, or with a slight, characteristic odour

**Identification**
- Ignition: Ignite potassium lactate solution to an ash. The ash is alkaline, and an effervescence occurs when acid is added
- Colour reaction: Overlay 2 ml of potassium lactate solution on 5 ml of a 1 in 100 solution of catechol in sulphuric acid. A deep red colour is produced at the zone of contact
- Test for potassium: Passes test
- Test for lactate: Passes test

**Purity**
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg

Acidity
Dissolve 1 g of potassium lactate solution in 20 ml of water, add 3 drops of phenolphthalein TS and titrate with 0.1 N sodium hydroxide. Not more than 0.2 ml should be required

Reducing substances
No reduction of Fehling's solution

Note: This specification refers to a 60 % aqueous solution

E 327 CALCIUM LACTATE

Synonyms

Definition
Einecs 212-406-7
Chemical name Calcium dilactate; Calcium dilactate hydrate; 2-Hydroxypropanoic acid calcium salt
Chemical formula \((\text{C}_3\text{H}_5\text{O}_2)_2\text{Ca} \cdot n\text{H}_2\text{O} \ (n = 0 - 5)\)
Molecular weight 218.22 (anhydrous)
Assay Content not less than 98 % on the anhydrous basis

Description
Almost odourless, white crystalline powder or granules

Identification
Test for lactate Passes test
Test for calcium Passes test
Solubility Soluble in water and practically insoluble in ethanol
pH Between 6.0 and 8.0 (5 % solution)

Purity
Loss on drying anhydrous: not more than 3.0 % (120 °C, 4 hours)
with 1 molecule of water: not more than 8.0 % (120 °C, 4 hours)
with 3 molecules of water: not more than 20.0 % (120 °C, 4 hours)
with 4.5 molecules of water: not more than 27.0 % (120 °C, 4 hours)

Acidity Not more than 0.5 % of the dry matter expressed as lactic acid
Fluoride Not more than 30 mg/kg (expressed as fluorine)
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg
Reducing substances No reduction of Fehling's solution

E 330 CITRIC ACID

Synonyms

Definition
Citric acid is produced from lemon or pineapple juice, by fermentation of carbohydrate solutions or other suitable media using Candida spp. or non-toxicogenic strains of Aspergillus niger
<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical name</strong></td>
<td>Citric acid; 2-Hydroxy-1,2,3-propanetricarboxylic acid; β-Hydroxytricarballylic acid</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>(a) C₆H₈O₇ (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>(b) C₆H₈O₇·H₂O (monohydrate)</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>(a) 192.13 (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>(b) 210.15 (monohydrate)</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Citric acid may be anhydrous or it may contain 1 molecule of water.</td>
</tr>
<tr>
<td></td>
<td>Citric acid contains not less than 99.5 % of C₆H₈O₇, calculated on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste. The monohydrate effloresces in dry air</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Very soluble in water; freely soluble in ethanol; soluble in ether</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Water content</strong></td>
<td>Anhydrous citric acid contains not more than 0.5 % water; citric acid monohydrate contains not more than 8.8 % water (Karl Fischer method)</td>
</tr>
<tr>
<td><strong>Sulphated ash</strong></td>
<td>Not more than 0.05 % after calcination at 800 ± 25 °C</td>
</tr>
<tr>
<td><strong>Arsenic</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 0.5 mg/kg</td>
</tr>
<tr>
<td><strong>Mercury</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Oxalates</strong></td>
<td>Not more than 100 mg/kg, expressed as oxalic acid, after drying</td>
</tr>
<tr>
<td><strong>Readily carbonisable substances</strong></td>
<td>Heat 1 g of powdered sample with 10 ml of 98 % minimum sulphuric acid in a water bath at 90 °C in the dark for one hour. Not more than a pale brown colour should be produced (Matching Fluid K)</td>
</tr>
</tbody>
</table>

**E 331 (i) MONOSODIUM CITRATE**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
<td>Monobasic sodium citrate</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>Monosodium citrate; Monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid</td>
</tr>
<tr>
<td><strong>Chemical formula</strong></td>
<td>(a) C₆H₇O₇Na (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>(b) C₆H₇O₇Na·H₂O (monohydrate)</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>(a) 214.11 (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>(b) 232.23 (monohydrate)</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99 % on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Crystalline white powder or colourless crystals</td>
</tr>
</tbody>
</table>
Identification

Test for citrate  Passes test
Test for sodium  Passes test
pH  Between 3.5 and 3.8 (1 % aqueous solution)

Purity

Loss on drying  
anhydrous: not more than 1.0 % (140 °C, 0.5 hour)
monohydrate: not more than 8.8 % (180 °C, 4 hours)
Oxalates  Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg

E 331 (ii) DISODIUM CITRATE

Synonyms  Dibasic sodium citrate

Definition

Einecs  205-623-3
Chemical name  Disodium citrate; Disodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Disodium salt of citric acid with 1,5 molecules of water
Chemical formula  C_6H_6O_7Na_2·1,5H_2O
Molecular weight  263,11
Assay  Content not less than 99 % on the anhydrous basis

Description  Crystalline white powder or colourless crystals

Identification

Test for citrate  Passes test
Test for sodium  Passes test
pH  Between 4.9 and 5.2 (1 % aqueous solution)

Purity

Loss on drying  Not more than 13.0 % (180 °C, 4 hours)
Oxalates  Not more than 100 mg/kg expressed as oxalic acid, after drying
Arsenic  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg

E 331 (iii) TRISODIUM CITRATE

Synonyms  Tribasic sodium citrate

Definition

Einecs  200-675-3
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Trisodium citrate; Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form</th>
</tr>
</thead>
</table>
| Chemical formula | Anhydrous: C_{6}H_{5}O_{7}Na_{3}  
Hydrated: C_{6}H_{5}O_{7}Na_{3}·nH_{2}O (n = 2 or 5) |
| Molecular weight | 258,07 (anhydrous)  
294,10 (hydrated n = 2)  
348,16 (hydrated n = 5) |
| Assay | Not less than 99 % on the anhydrous basis |

**Description**
Crystalline white powder or colourless crystals

**Identification**
- Test for citrate: Passes test
- Test for sodium: Passes test
- pH: Between 7.5 and 9.0 (5 % aqueous solution)

**Purity**
- Loss of drying:  
  - Anhydrous: not more than 1.0 % (180 °C, 18 hours)  
  - Dihydrate: 10.0 to 13.0 % (180 °C, 18 hours)  
  - Pentahydrate: not more than 30.3 % (180 °C, 4 hours)
- Oxalates: Not more than 100 mg/kg expressed as oxalic acid, after drying
- Arsenic: Not more than 1 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 332 (i) MONOPOTASSIUM CITRATE**

**Synonyms**
Monobasic potassium citrate

**Definition**

<table>
<thead>
<tr>
<th>Einacs</th>
<th>212-753-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Monopotassium citrate; Monopotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Anhydrous monopotassium salt of citric acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{6}H_{7}O_{7}K</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>230.21</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**
White, hygroscopic, granular powder or transparent crystals

**Identification**
- Test for citrate: Passes test
- Test for potassium: Passes test
- pH: Between 3.5 and 3.8 (1 % aqueous solution)
### E 332 (ii) TRIPOTASSIUM CITRATE

#### Synonyms
Tribasic potassium citrate

#### Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>212-755-5</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Tripotassium citrate; Tripotassium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Monohydrated tripotassium salt of citric acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{6}H_{5}O_{7}K_{3}·H_{2}O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>324.42</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

#### Description
White, hygroscopic, granular powder or transparent crystals

#### Identification
- Test for citrate: Passes test
- Test for potassium: Passes test
- pH: Between 7.5 and 9.0 (5 % aqueous solution)

#### Purity
- Loss on drying: Not more than 6.0 % (180 °C, 4 hours)
- Oxalates: Not more than 100 mg/kg (expressed as oxalic acid, after drying)
- Arsenic: Not more than 1 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg

---

### E 333 (i) MONOCALCIUM CITRATE

#### Synonyms
Monobasic calcium citrate

#### Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Monocalcium citrate; Monocalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Monohydrate monocalcium salt of citric acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>(C_{6}H_{7}O_{7})<em>{2}CaH</em>{2}O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>440.32</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97.5 % on the anhydrous basis</td>
</tr>
</tbody>
</table>
Description
Fine white powder

Identification
Test for citrate  Passes test
Test for calcium  Passes test
pH  Between 3,2 and 3,5 (1 % aqueous solution)

Purity
Loss on drying  Not more than 7,0 % (180 °C, 4 hours)
Oxalates  Not more than 100 mg/kg (expressed as oxalic acid, after drying)
Fluoride  Not more than 30 mg/kg (expressed as fluorine)
Arsenic  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg
Aluminium  Not more than 30 mg/kg (only if added to food for infants and young children)
  Not more than 200 mg/kg (for all uses except food for infants and young children)
Carbonates  Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 333 (ii) DICALCIUM CITRATE

Synonyms
Dibasic calcium citrate

Definition
Einecs
Chemical name  Dicalcium citrate; Dicalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Trihydrated dicalcium salt of citric acid
Chemical formula  \((\text{C}_6\text{H}_7\text{O}_7)\text{Ca}_2\cdot3\text{H}_2\text{O}\)
Molecular weight  530,42
Assay  Not less than 97,5 % on the anhydrous basis

Description
Fine white powder

Identification
Test for citrate  Passes test
Test for calcium  Passes test

Purity
Loss on drying  Not more than 20,0 % (180 °C, 4 hours)
Oxalates  Not more than 100 mg/kg (expressed as oxalic acid, after drying)
Fluoride  Not more than 30 mg/kg (expressed as fluorine)
Arsenic  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg
Aluminium

Not more than 30 mg/kg (only if added to food for infants and young children)
Not more than 200 mg/kg (for all uses except food for infants and young children)

Carbonates

Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 333 (iii) TRICALCIUM CITRATE

Synonyms

Tribasic calcium citrate

Definition

Einecs 212-391-7
Chemical name Tricalcium citrate; Tricalcium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid; Tetrahydrated tricalcium salt of citric acid
Chemical formula \((C_6H_6O_7)_{2}Ca_{3} \cdot 4H_2O\)
Molecular weight 570.51
Assay Not less than 97.5 % on the anhydrous basis

Description

Fine white powder

Identification

Test for citrate Passes test
Test for calcium Passes test

Purity

Loss on drying Not more than 14.0 % (180 °C, 4 hours)
Oxalates Not more than 100 mg/kg (expressed as oxalic acid, after drying)
Fluoride Not more than 30 mg/kg (expressed as fluorine)
Arsenic Not more than 1 mg/kg
Lead Not more than 1 mg/kg
Mercury Not more than 1 mg/kg
Aluminium Not more than 30 mg/kg (only if added to food for infants and young children)
Not more than 200 mg/kg (for all uses except food for infants and young children)
Carbonates Dissolving 1 g of calcium citrate in 10 ml 2 N hydrochloric acid must not liberate more than a few isolated bubbles

E 334 L(+)-TARTARIC ACID, TARTARIC ACID

Synonyms

Definition

Einecs 201-766-0
Chemical name  L-tartaric acid; L-2,3-dihydroxybutanedioic acid; d-α,β-dihydroxy-
succinic acid

Chemical formula  C₄H₆O₆

Molecular weight  150,09

Assay  Content not less than 99,5 % on the anhydrous basis

Description  Colourless or translucent crystalline solid or white crystalline powder

Identification

Melting range  Between 168 °C and 170 °C

Test for tartrate  Passes test

Specific rotation  [α]D20 between + 11,5° and + 13,5° (20 % w/v aqueous solution)

Purity

Loss on drying  Not more than 0,5 % (over P₂O₅, 3 hours)

Sulphated ash  Not more than 1 000 mg/kg (after calcination at 800 ± 25 °C)

Lead  Not more than 2 mg/kg

Mercury  Not more than 1 mg/kg

Oxalates  Not more than 100 mg/kg expressed as oxalic acid, after drying

E 335 (i) MONOSODIUM TARTRATE

Synonyms  Monosodium salt of L-(+)-tartaric acid

Definition  Einecs

Monosodium salt of L-2,3-dihydroxybutanedioic acid; Monohydrated monosodium salt of L-(+)-tartaric acid

Chemical formula  C₄H₅O₆NaH₂O

Molecular weight  194,05

Assay  Content not less than 99 % on the anhydrous basis

Description  Transparent colourless crystals

Identification

Test for tartrate  Passes test

Test for sodium  Passes test

Purity

Loss on drying  Not more than 10,0 % (105 °C, 4 hours)

Oxalates  Not more than 100 mg/kg (expressed as oxalic acid, after drying)

Arsenic  Not more than 3 mg/kg

Lead  Not more than 2 mg/kg

Mercury  Not more than 1 mg/kg
### E 335 (ii) DISODIUM TARTRATE

**Synonyms**
- Einecs: 212-773-3

**Definition**
- Chemical name: Disodium L-tartrate; Disodium (+)-tartrate; Disodium salt of (+)-2,3-dihydroxybutanedioic acid; Dihydrated disodium salt of L-(+)-tartaric acid
- Chemical formula: C$_4$H$_4$O$_6$Na$_2$·2H$_2$O
- Molecular weight: 230.8
- Assay: Content not less than 99 % on the anhydrous basis

**Description**
- Transparent, colourless crystals

**Identification**
- Test for tartrate: Passes test
- Test for sodium: Passes test
- Solubility: 1 gram is insoluble in 3 ml of water. Insoluble in ethanol
- pH: Between 7.0 and 7.5 (1 % aqueous solution)

**Purity**
- Loss on drying: Not more than 17.0 % (150 °C, 4 hours)
- Oxalates: Not more than 100 mg/kg (expressed as oxalic acid, after drying)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

### E 336 (i) MONOPOTASSIUM TARTRATE

**Synonyms**
- Monobasic potassium tartrate

**Definition**
- Chemical name: Anhydrous monopotassium salt of L-(+)-tartaric acid; Monopotassium salt of L-2,3-dihydroxybutanedioic acid
- Chemical formula: C$_4$H$_5$O$_6$K
- Molecular weight: 188.16
- Assay: Content not less than 98 % on the anhydrous basis

**Description**
- White crystalline or granulated powder

**Identification**
- Test for tartrate: Passes test
- Test for potassium: Passes test
- Melting point: 230 °C
- pH: 3.4 (1 % aqueous solution)
E 336 (ii) DIPOTASSIUM TARTRATE

Synonyms
- Dibasic potassium tartrate

Definition
- Einecs 213-067-8
- Chemical name: Dipotassium salt of L-2,3-dihydroxybutanedioic acid; Dipotassium salt with half a molecule of water of L-(+)-tartaric acid
- Chemical formula: $C_4H_4O_6K_2$·$\frac{1}{2}H_2O$
- Molecular weight: 235.2
- Assay: Content not less than 99 % on the anhydrous basis

Description
- White crystalline or granulated powder

Identification
- Test for tartrate: Passes test
- Test for potassium: Passes test
- pH: Between 7.0 and 9.0 (1 % aqueous solution)

Purity
- Loss on drying: Not more than 4.0 % (150 °C, 4 hours)
- Oxalates: Not more than 100 mg/kg (expressed as oxalic acid, after drying)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

E 337 POTASSIUM SODIUM TARTRATE

Synonyms
- Potassium sodium L-(+)-tartrate; Rochelle salt; Seignette salt

Definition
- Einecs 206-156-8
- Chemical name: Potassium sodium salt of L-2,3-dihydroxybutanedioic acid; Potassium sodium L-(+)-tartaric acid
- Chemical formula: $C_4H_4O_6KNa$·$4H_2O$
- Molecular weight: 282.23
- Assay: Content not less than 99 % on the anhydrous basis
**Description**

Colourless crystals or white crystalline powder

**Identification**

- Test for tartrate: Passes test
- Test for potassium: Passes test
- Test for sodium: Passes test
- Solubility: 1 gram is soluble in 1 ml of water, insoluble in ethanol
- Melting range: 70-80 °C
- pH: Between 6,5 and 8,5 (1 % aqueous solution)

**Purity**

- Loss on drying: Not more than 26,0 % and not less than 21,0 % (150 °C, 3 hours)
- Oxalates: Not more than 100 mg/kg (expressed as oxalic acid, after drying)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 338 PHOSPHORIC ACID**

**Synonyms**

Orthophosphoric acid; Monophosphoric acid

**Definition**

- Einecs: 231-633-2
- Chemical name: Phosphoric acid
- Chemical formula: H₃PO₄
- Molecular weight: 98,00
- Assay: Content not less than 67,0 % and not more than 85,7 %. Phosphoric acid is commercially available as an aqueous solution at variable concentrations.

**Description**

Clear, colourless, viscous liquid

**Identification**

- Test for acid: Passes test
- Test for phosphate: Passes test

**Purity**

- Volatile acids: Not more than 10 mg/kg (as acetic acid)
- Chlorides: Not more than 200 mg/kg (expressed as chlorine)
- Nitrates: Not more than 5 mg/kg (as NaNO₃)
- Sulphates: Not more than 1 500 mg/kg (as CaSO₄)
- Fluoride: Not more than 10 mg/kg (expressed as fluorine)
- Arsenic: Not more than 1 mg/kg
<table>
<thead>
<tr>
<th></th>
<th>Not more than 1 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

Note: This specification refers to a 75 % aqueous solution

---

**E 339 (i) MONOSODIUM PHOSPHATE**

**Synonyms**

Monosodium monophosphate; Acid monosodium monophosphate; Monosodium orthophosphate; Monobasic sodium phosphate; Sodium dihydrogen monophosphate

**Definition**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>231-449-2</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium dihydrogen monophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Anhydrous: NaH$_2$PO$_4$</td>
</tr>
<tr>
<td></td>
<td>Monohydrate: NaH$_2$PO$_4$·H$_2$O</td>
</tr>
<tr>
<td></td>
<td>Dihydrate: NaH$_2$PO$_4$·2H$_2$O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Anhydrous: 119,98</td>
</tr>
<tr>
<td></td>
<td>Monohydrate: 138,00</td>
</tr>
<tr>
<td></td>
<td>Dihydrate: 156,01</td>
</tr>
</tbody>
</table>

**Assay**

After drying at 60 °C for one hour and then at 105 °C for four hours, contains not less than 97 % of NaH$_2$PO$_4$; P$_2$O$_5$ content between 58,0 % and 60,0 % on the anhydrous basis

**Description**

A white odourless, slightly deliquescent powder, crystals or granules

**Identification**

<table>
<thead>
<tr>
<th>Test for sodium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol or ether</td>
</tr>
<tr>
<td>pH</td>
<td>Between 4.1 and 5.0 (1 % solution)</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>The anhydrous salt loses not more than 2.0 %, the monohydrate not more than 15.0 %, the dihydrate not more than 25 % (60 °C, 1 hour then 105 °C, 4 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 % on the anhydrous basis</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### E 339 (ii) DISODIUM PHOSPHATE

**Synonyms**
- Disodium monophosphate; Secondary sodium phosphate; Disodium orthophosphate;

**Definition**
- **Einecs**: 231-448-7
- **Chemical name**: Disodium hydrogen monophosphate; Disodium hydrogen orthophosphate
- **Chemical formula**: Anhydrous: $\text{Na}_2\text{HPO}_4$  
  Hydrate: $\text{Na}_2\text{HPO}_4 \cdot n\text{H}_2\text{O}$ ($n = 2, 7$ or $12$)
- **Molecular weight**: 141.98 (anhydrous)
- **Assay**: After drying at 40 °C for three hours and subsequently at 105 °C for five hours, contains not less than 98 % of $\text{Na}_2\text{HPO}_4$  
  $\text{P}_2\text{O}_5$ content between 49 % and 51 % on the anhydrous basis

**Description**
- Anhydrous disodium hydrogen phosphate is a white, hygroscopic, odourless powder. Hydrated forms available include the dihydrate: a white crystalline, odourless solid; the heptahydrate: white, odourless, efflorescent crystals or granular powder; and the dodecahydrate: white, efflorescent, odourless powder or crystals

**Identification**
- **Test for sodium**: Passes test
- **Test for phosphate**: Passes test
- **Solubility**: Freely soluble in water. Insoluble in ethanol
- **pH**: Between 8.4 and 9.6 (1 % solution)

**Purity**
- **Loss on drying**: The anhydrous salt loses not more than 5.0 %, the dihydrate not more than 22.0 %, the heptahydrate not more than 50.0 %, the dodecahydrate not more than 61.0 % (40 °C, 3 hours then 105 °C, 5 hours)
- **Water insoluble matter**: Not more than 0.2 % on the anhydrous basis
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 1 mg/kg
- **Mercury**: Not more than 1 mg/kg

### E 339 (iii) TRISODIUM PHOSPHATE

**Synonyms**
- Sodium phosphate; Tribasic sodium phosphate; Trisodium orthophosphate

**Definition**
- Trisodium phosphate is obtained from aqueous solutions and crystallises in the anhydrous form and with $1/2, 1, 6, 8$ or $12$ $\text{H}_2\text{O}$. The dodecahydrate always crystallises from aqueous solutions with an excess of sodium hydroxide. It contains $\frac{1}{4}$ molecule of $\text{NaOH}$
### Trisodium Monophosphate

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>231-509-8</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Trisodium monophosphate; Trisodium phosphate; Trisodium orthophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Anhydrous: Na₃PO₄</td>
</tr>
<tr>
<td></td>
<td>Hydrated: Na₃PO₄ₙH₂O (ₙ = 1/₂, 1, 6, 8, or 12)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>163.94 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Sodium phosphate anhydrous and the hydrated forms, with the exception of the dodecahydrate, contain not less than 97.0 % of Na₃PO₄ calculated on the dried basis. Sodium phosphate dodecahydrate contains not less than 92.0 % of Na₃PO₄ calculated on the ignited basis. P₂O₅ content between 40.5 % and 43.5 % on the anhydrous basis</td>
</tr>
<tr>
<td>Description</td>
<td>White odourless crystals, granules or crystalline powder</td>
</tr>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 11.5 and 12.5 (1 % solution)</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>When dried at 120 °C for two hours and then ignited at about 800 °C for 30 minutes, the losses in weight are as follows: Anhydrous not more than 2.0 %, monohydrate not more than 11.0 %, dodecahydrate: between 45.0 % and 58.0 %</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 % on the anhydrous basis</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### Monopotassium Phosphate

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>231-913-4</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Monobasic potassium phosphate; Monopotassium monophosphate; Mono potassium orthophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>KH₂PO₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>136.09</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.0 % after drying at 105 °C for four hours. P₂O₅ content between 51.0 % and 53.0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>
### Description
Odourless, colourless crystals or white granular or crystalline powder

### Identification

<table>
<thead>
<tr>
<th>Test for potassium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 4.2 and 4.8 (1 % solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 2.0 % (105 °C, 4 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 % on the anhydrous basis</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 340 (ii) DIPOTASSIUM PHOSPHATE

### Synonyms
Dipotassium monophosphate; Secondary potassium phosphate; Dipotassium orthophosphate; Dibasic potassium phosphate

### Definition

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-834-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Dipotassium hydrogen monophosphate; Dipotassium hydrogen phosphate; Dipotassium hydrogen orthophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>K₂HPO₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>174.18</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98 % after drying at 105 °C for four hours</td>
</tr>
<tr>
<td></td>
<td>P₂O₅ content between 40.3 % and 41.5 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

### Description
Colourless or white granular powder, crystals or masses; deliquescent substance, hygroscopic

### Identification

<table>
<thead>
<tr>
<th>Test for potassium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 8.7 and 9.4 (1 % solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 2.0 % (105 °C, 4 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 % on the anhydrous basis</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
</tbody>
</table>
## E 340 (iii) TRIPOTASSIUM PHOSPHATE

### Synonyms

- Tribasic potassium phosphate; Tripotassium orthophosphate

### Definition

- **EINECS**: 231-907-1
- **Chemical name**: Tripotassium monophosphate; Tripotassium phosphate; Tripotassium orthophosphate
- **Chemical formula**: Anhydrous: $\text{K}_3\text{PO}_4$
  
  Hydrated: $\text{K}_3\text{PO}_4 \cdot n\text{H}_2\text{O}$ ($n = 1$ or $3$)
- **Molecular weight**: 212.27 (anhydrous)
- **Assay**: Content not less than 97 % calculated on the ignited basis
  
  $\text{P}_2\text{O}_5$ content between 30.5 % and 34.0 % on the ignited basis

### Description

- Colourless or white, odourless hygroscopic crystals or granules.
  
  Hydrated forms available include the monohydrate and trihydrate

### Identification

- **Test for potassium**: Passes test
- **Test for phosphate**: Passes test
- **Solubility**: Freely soluble in water. Insoluble in ethanol
- **pH**: Between 11.5 and 12.3 (1 % solution)

### Purity

- **Loss on ignition**: Anhydrous: not more than 3.0 %; hydrated: not more than 23.0 %
  
  (determined by drying at 105 °C for one hour and then ignite at about 800 °C ± 25 °C for 30 minutes)
- **Water insoluble matter**: Not more than 0.2 % (on the anhydrous basis)
- **Fluoride**: Not more than 10 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 1 mg/kg
- **Mercury**: Not more than 1 mg/kg

## E 341 (i) MONOCALCIUM PHOSPHATE

### Synonyms

- Monobasic calcium phosphate; Monocalcium orthophosphate

### Definition

- **EINECS**: 231-837-1
Chemical name  Calcium dihydrogen phosphate
Chemical formula  Anhydrous: Ca(H$_2$PO$_4$)$_2$
                  Monohydrate: Ca(H$_2$PO$_4$)$_2$ · H$_2$O
Molecular weight  234.05 (anhydrous)
                  252.08 (monohydrate)
Assay  Content not less than 95 % on the dried basis
       P$_2$O$_5$ content between 55.5 % and 61.1 % on the anhydrous basis
Description  Granular powder or white, deliquescent crystals or granules
Identification  Test for calcium  Passes test
                 Test for phosphate  Passes test
                 CaO content  Between 23.0 % and 27.5 % (anhydrous)
                              Between 19.0 % and 24.8 % (monohydrate)
Purity
Loss on drying  Anhydrous: not more than 14 % (105 °C, 4 hours)
                 Monohydrate: not more than 17.5 % (105 °C, 4 hours)
Loss on ignition  Anhydrous: not more than 17.5 % (after ignition at 800 °C ± 25 °C for 30 minutes)
                 Monohydrate: not more than 25.0 % (determined by drying at 105 °C for one hour, then ignite at 800 °C ± 25 °C for 30 minutes)
Fluoride  Not more than 30 mg/kg (expressed as fluorine)
Arsenic  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg
Aluminium  Not more than 70 mg/kg (only if added to food for infants and young children)
          Not more than 200 mg/kg (for all uses except food for infants and young children)

E 341 (ii) DICALCIUM PHOSPHATE

Synonyms  Dibasic calcium phosphate; Dicalcium orthophosphate
Definition
Einacs  231-826-1
Chemical name  Calcium monohydrogen phosphate; Calcium hydrogen orthophosphate; Secondary calcium phosphate
Chemical formula  Anhydrous: CaHPO$_4$
                   Dihydrate: CaHPO$_4$ · 2H$_2$O
Molecular weight

136.06 (anhydrous)
172.09 (dihydate)

Assay

Dicalcium phosphate, after drying at 200 °C for three hours, contains not less than 98 % and not more than the equivalent of 102 % of CaHPO₄

P₂O₅ content between 50.0 % and 52.5 % on the anhydrous basis

Description

White crystals or granules, granular powder or powder

Identification

Test for calcium Passes test
Test for phosphate Passes test

Solubility

Sparingly soluble in water. Insoluble in ethanol

Purity

Loss on ignition
Not more than 8.5 % (anhydrous), or 26.5 % (dihydrate) after ignition at 800 °C ± 25 °C for 30 minutes

Fluoride
Not more than 50 mg/kg (expressed as fluorine)

Arsenic
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Lead
Not more than 1 mg/kg

Mercury
Not more than 1 mg/kg

Aluminium
Not more than 100 mg/kg for the anhydrous form and not more than 80 mg/kg for the dihydrated form (only if added to food for infants and young children)

Not more than 600 mg/kg for the anhydrous form and not more than 500 mg/kg for the dihydrated form (for all uses except food for infants and young children). This applies until 31 March 2015.

Not more than 200 mg/kg for the anhydrous form and the dihydrated form (for all uses except food for infants and young children). This applies from 1 April 2015.

E 341 (iii) TRICALCIUM PHOSPHATE

Synonyms

Calcium phosphate, tribasic; Calcium orthophosphate; Pentacalcium hydroxy monophosphate; Calcium hydroxyapatite

Definition

Tricalcium phosphate consists of a variable mixture of calcium phosphates obtained from neutralisation of phosphoric acid with calcium hydroxide and having the approximate composition of 10CaO·3P₂O₅·H₂O

Einecs

235-330-6 (Pentacalcium hydroxy monophosphate)
231-840-8 (Calcium orthophosphate)

Chemical name

Pentacalcium hydroxy monophosphate; Tricalcium monophosphate

Chemical formula

Ca₅(PO₄)₃·OH or Ca₃(PO₄)₂

Molecular weight

502 or 310
### Assay
- Content not less than 90% calculated on the ignited basis
- $P_2O_5$ content between 38.5% and 48.0% on the anhydrous basis

### Description
- A white, odourless powder which is stable in air

### Identification
- Test for calcium: Passes test
- Test for phosphate: Passes test
- Solubility: Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid

### Purity
- **Loss on ignition:** Not more than 8% after ignition at 800 °C ± 25 °C for 0.5 hour
- **Fluoride:** Not more than 50 mg/kg (expressed as fluorine)
- **Arsenic:** Not more than 1 mg/kg
- **Cadmium:** Not more than 1 mg/kg
- **Lead:** Not more than 1 mg/kg
- **Mercury:** Not more than 1 mg/kg
- **Aluminium:**
  - Not more than 150 mg/kg (only if added to food for infants and young children)
  - Not more than 500 mg/kg (for all uses except food for infants and young children). This applies until 31 March 2015
  - Not more than 200 mg/kg (for all uses except food for infants and young children). This applies from 1 April 2015.

---

### E 343 (i) MONOMAGNESIUM PHOSPHATE

#### Synonyms
- Magnesiumdihydrogenphosphate; Magnesiumphosphate, monobasic; Monomagnesium orthophosphate

#### Definition
- **Einacs:** 236-004-6
- **Chemical name:** Monomagnesiumdihydrogenmonophosphate
- **Chemical formula:** $\text{Mg(H}_2\text{PO}_4)_2 \cdot n\text{H}_2\text{O}$ (where $n = 0$ to 4)
- **Molecular weight:** 218.30 (anhydrous)
- **Assay:** Not less than 51.0% after ignition calculated as $P_2O_5$ at the ignited basis (800 °C ± 25 °C for 30 minutes)

#### Description
- White, odourless, crystalline powder, slightly soluble in water

#### Identification
- Test for magnesium: Passes test
- Test for phosphate: Passes test
- **MgO content:** Not less than 21.5% after ignition or at an anhydrous basis (105 °C, 4 hours)
### E 343 (ii) DIMAGNESIUM PHOSPHATE

#### Synonyms

Magnesiumhydrogenphosphate; Magnesiumphosphate, dibasic; Dimagnesium orthophosphate; Secondary magnesiumphosphate

#### Definition

- **Einecs**: 231-823-5
- **Chemical name**: Dimagnesiummonohydrogenmonophosphate
- **Chemical formula**: $\text{MgHPO}_4 \cdot n\text{H}_2\text{O}$ (where $n = 0-3$)
- **Molecular weight**: 120,30 (anhydrous)
- **Assay**: Not less than 96 % after ignition (800 °C ± 25 °C for 30 minutes)

#### Description

White, odourless, crystalline powder, slightly soluble in water

#### Identification

- **Test for magnesium**: Passes test
- **Test for phosphate**: Passes test
- **MgO content**: Not less than 33,0 % calculated on the anhydrous basis (105 °C, 4 hours)

#### Purity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 350 (i) SODIUM MALATE

#### Synonyms

Sodium salt of malic acid

#### Definition

- **Einecs**: 231-823-5
- **Chemical name**: Disodium DL-malate; disodium salt of hydroxybutanedioic acid
- **Chemical formula**: 
  - Hemihydrate: $\text{C}_4\text{H}_4\text{Na}_2\text{O}_5 \cdot \frac{1}{2}\text{H}_2\text{O}$
  - Trihydrate: $\text{C}_4\text{H}_4\text{Na}_2\text{O}_5 \cdot 3\text{H}_2\text{O}$
<table>
<thead>
<tr>
<th>Molecular weight</th>
<th>Hemihydrate: 187,05</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trihydrate: 232,10</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98,0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

White crystalline powder or lumps

**Identification**

- Test for 1,2-dicarboxylic acid: Passes test
- Test for sodium: Passes test
- Azo dye formation: Positive
- Solubility: Freely soluble in water

**Purity**

- Loss on drying:
  - Hemihydrate: Not more than 7,0 % (130 °C, 4 hours)
  - Trihydrate: 20,5-23,5 % (130 °C, 4 hours)
- Alkalinity: Not more than 0,2 % as Na₂CO₃
- Fumaric acid: Not more than 1,0 %
- Maleic acid: Not more than 0,05 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 350 (ii) SODIUM HYDROGEN MALATE**

**Synonyms**

Monosodium salt of DL-malic acid

**Definition**

Einecs

- Chemical name: Monosodium DL-malate; monosodium 2-DL-hydroxy succinate
- Chemical formula: C₄H₅NaO₅
- Molecular weight: 156,07
- Assay: Content not less than 99,0 % on the anhydrous basis

**Description**

White powder

**Identification**

- Test for 1,2-dicarboxylic acid: Passes test
- Test for sodium: Passes test
- Azo dye formation: Positive

**Purity**

- Loss on drying: Not more than 2,0 % (110 °C, 3 hours)
- Maleic acid: Not more than 0,05 %
- Fumaric acid: Not more than 1,0 %
<table>
<thead>
<tr>
<th>Arsenic</th>
<th>Not more than 3 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 351 POTASSIUM MALATE**

**Synonyms**
Potassium salt of malic acid

**Definition**

- **Einecs**
- **Chemical name**: Dipotassium DL-malate; dipotassium salt of hydroxybutanedioic acid
- **Chemical formula**: C₄H₄K₂O₅
- **Molecular weight**: 210.27
- **Assay**: Content not less than 59.5 %

**Description**
Colourless or almost colourless aqueous solution

**Identification**

- Test for 1,2-dicarboxylic acid: Passes test
- Test for potassium: Passes test
- Azo dye formation: Positive

**Purity**

- **Alkalinity**: Not more than 0.2 % as K₂CO₃
- **Fumaric acid**: Not more than 1.0 %
- **Maleic acid**: Not more than 0.05 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg

**E 352 (i) CALCIUM MALATE**

**Synonyms**
Calcium salt of malic acid

**Definition**

- **Einecs**
- **Chemical name**: Calcium DL-malate; calcium-α-hydroxysuccinate; calcium salt of hydroxybutanedioic acid
- **Chemical formula**: C₄H₅CaO₅
- **Molecular weight**: 172.14
- **Assay**: Content not less than 97.5 % on the anhydrous basis

**Description**
White powder

**Identification**

- Test for malate: Passes test
- Test 1,2-dicarboxylic acid: Passes test
Test for calcium | Passes test  
Azo dye formation | Positive  
Solubility | Slightly soluble in water  

**Purity**  
Loss on drying | Not more than 2 % (100 °C, 3 hours)  
Alkalinity | Not more than 0,2 % as CaCO₃  
Maleic acid | Not more than 0,05 %  
Fumaric acid | Not more than 1,0 %  
Fluoride | Not more than 30 mg/kg  
Arsenic | Not more than 3 mg/kg  
Lead | Not more than 2 mg/kg  
Mercury | Not more than 1 mg/kg  

**E 352 (ii) CALCIUM HYDROGEN MALATE**  

**Synonyms** | Monocalcium salt of DL-malic acid  
**Definition**  
Einecs |  
Chemical name | Monocalcium DL-malate; monocalcium 2-DL-hydroxysuccinate  
Chemical formula | \((\text{C}_4\text{H}_5\text{O}_5)_2\text{Ca}\)  
Molecular weight |  
Assay | Content not less than 97,5 % on the anhydrous basis  
**Description** | White powder  
**Identification**  
Test for 1,2-dicarboxylic acid | Passes test  
Test for calcium | Passes test  
Azo dye formation | Positive  

**Purity**  
Loss on drying | Not more than 2,0 % (110 °C, 3 hours)  
Maleic acid | Not more than 0,05 %  
Fumaric acid | Not more than 1,0 %  
Fluoride | Not more than 30 mg/kg  
Arsenic | Not more than 3 mg/kg  
Lead | Not more than 2 mg/kg  
Mercury | Not more than 1 mg/kg
E 353 METATARTARIC ACID

Synonyms
Ditartaric acid

Definition
Einecs
Chemical name Metatartaric acid
Chemical formula C₄H₆O₆
Molecular weight
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
Solubility Very soluble in water and ethanol
Identification test Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulphuric 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 2 mg/kg
Mercury Not more than 1 mg/kg

E 354 CALCIUM TARTRATE

Synonyms
L-Calcium tartrate

Definition
Einecs
Chemical name Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate
Chemical formula C₄H₄CaO₆·2H₂O
Molecular weight 224,18
Assay Not less than 98,0 %

Description
Fine crystalline powder with a white or off-white colour

Identification
Solubility 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
Specific rotation [α]D₂₀ + 7,0° to + 7,4° (0,1 % in a 1N HCl solution)
pH Between 6,0 and 9,0 (5 % slurry)

Purity
Sulphates Not more than 1 g/kg (as H₂SO₄)
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg
### E 355 ADIPIC ACID

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einacs</th>
<th>204-673-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Hexanedioic acid; 1,4-butanedicarboxylic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₆H₁₀O₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>146.14</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,6 %</td>
</tr>
</tbody>
</table>

**Description**

White odourless crystals or crystalline powder

**Identification**

<table>
<thead>
<tr>
<th>Melting range</th>
<th>151,5-154,0 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Slightly soluble in water. Freely soluble in ethanol</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Water</th>
<th>Not more than 0,2 % (Karl Fischer method)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 356 SODIUM ADIPATE

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einacs</th>
<th>231-293-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sodium adipate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₆H₁₀Na₂O₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>190.11</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,0 % (on anhydrous basis)</td>
</tr>
</tbody>
</table>

**Description**

White odourless crystals or crystalline powder

**Identification**

<table>
<thead>
<tr>
<th>Melting range</th>
<th>151-152 °C (for adipic acid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Approximately 50 g/100 ml water (20 °C)</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Water content</th>
<th>Not more than 3 % (Karl Fischer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 357 POTASSIUM ADIPATE

Synonyms

Definition

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>Potassium adipate</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Potassium adipate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₆H₈K₂O₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>222,32</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,0 % (on anhydrous basis)</td>
</tr>
</tbody>
</table>

Description

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>White odourless crystals or crystalline powder</td>
<td></td>
</tr>
</tbody>
</table>

Identification

<table>
<thead>
<tr>
<th>Identification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>151-152 °C (for adipic acid)</td>
</tr>
<tr>
<td>Solubility</td>
<td>Approximately 60 g/100 ml water (20 °C)</td>
</tr>
<tr>
<td>Test for potassium</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Purity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not more than 3 % (Karl Fischer)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 363 SUCCINIC ACID

Synonyms

Definition

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>Butanedioic acid</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Butanedioic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₄H₆O₄</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>118,09</td>
</tr>
<tr>
<td>Assay</td>
<td>Content no less than 99,0 %</td>
</tr>
</tbody>
</table>

Description

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Colourless or white, odourless crystals</td>
<td></td>
</tr>
</tbody>
</table>

Identification

<table>
<thead>
<tr>
<th>Identification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>185,0-190,0 °C</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Purity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Residue on ignition</td>
<td>Not more than 0,025 % (800 °C, 15 min)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 380 TRIAMMONIUM CITRATE

Synonyms
Tribasic ammonium citrate

Definition
Einecs 222-394-5
Chemical name Triammonium salt of 2-hydroxypropan-1,2,3-tricarboxylic acid
Chemical formula C₆H₁₇N₃O₇
Molecular weight 243.22
Assay Content not less than 97.0 %

Description
White to off-white crystals or powder

Identification
Test for ammonium Passes test
Test for citrate Passes test
Solubility Freely soluble in water

Purity
Oxalate Not more than 0.04 % (as oxalic acid)
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg

E 385 CALCIUM DISODIUM ETHYLENEDIAMINETRiacetaTe

Synonyms
Calcium disodium EDTA; Calcium disodium edetate

Definition
Einecs 200-529-9
Chemical name N,N′-1,2-Ethanediylbis [N-(carboxymethyl)-glycinate] [(4-)-O,O′,O,N,O,N]
calcilate(2)-disodium; Calcium disodium ethylenediaminetetraacetate; Calcium disodium (ethylenedinitrilo)tetra acetate
Chemical formula C₁₀H₁₂O₈CaN₂Na₂·2H₂O
Molecular weight 410.31
Assay Content not less than 97 % on the anhydrous basis

Description
White, odourless crystalline granules or white to nearly white powder, slightly hygroscopic

Identification
Test for sodium Passes test
Test for calcium Passes test
Chelating activity to metal ions Positive
pH Between 6.5 and 7.5 (1 % solution)

Purity
Water content 5 to 13 % (Karl Fischer method)
Arsenic | Not more than 3 mg/kg
---|---
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg

### E 392 EXTRACTS OF ROSEMARY

**Synonyms**
Extract of rosemary leaf (antioxidant)

**Definition**
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 (Rosmarinus officinalis)

**Description**
Rosemary leaf extract antioxidant is prepared by extraction of the leaves of *Rosmarinus officinalis* using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised.

**Identification**
- Reference antioxidative compounds: Carnosic acid (C_{20}H_{28}O_{4}) and Carnosol (C_{20}H_{26}O_{4}) (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

**Purity**
- Loss of drying: < 5%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg

1 — Extracts of rosemary produced from dried rosemary leaves by acetone extraction.

**Description**
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.

**Identification**
- Content of reference antioxidative compounds: ≥ 10% w/w, expressed as the total of carnosic acid and carnosol
- Antioxidant/Volatiles — Ratio: (Total % w/w of carnosic acid and 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’)

**Purity**
- Residual solvents: Acetone: Not more than 500 mg/kg
2 — **Extracts of rosemary prepared by extraction of dried rosemary leaves by means of supercritical carbon dioxide.**

**Description**

Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer.

**Identification**

- **Content of reference antioxidative compounds**
  - \( \geq 13 \% \text{ w/w} \), expressed as the total of carnosic acid and carnosol

- **Antioxidant/Volatiles – Ratio**
  - (Total % w/w of carnosic acid and carnosol) \( \geq 15 \)
  - (% w/w of reference key volatiles)*

  (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, ‘GC-MSD’)

**Purity**

- **Residual solvents**
  - Ethanol: not more than 2 %

3 — **Extracts of rosemary prepared from a deodorised ethanolic extract of rosemary.**

**Description**

Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary. The extracts may be further purified, for example by treatment with active carbon and/or molecular distillation. The extracts may be suspended in suitable and approved carriers or spray dried.

**Identification**

- **Content of reference antioxidative compounds**
  - \( \geq 5 \% \text{ w/w} \), expressed as the total of carnosic acid and carnosol

- **Antioxidant/Volatiles – Ratio**
  - (Total % w/w of carnosic acid and carnosol) \( \geq 15 \)
  - (% w/w of reference key volatiles)*

  (* as a percentage of total volatiles in the extract, measured by Gas Chromatography – Mass Spectrometry Detection, ‘GC-MSD’)

**Purity**

- **Residual solvents**
  - Ethanol: not more than 500 mg/kg

4 — **Extracts of rosemary decolourised and deodorised, obtained by a two-step extraction using hexane and ethanol.**

**Description**

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.

**Identification**

- **Content of reference antioxidative compounds**
  - \( \geq 5 \% \text{ w/w} \), expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles – Ratio

(Total % w/w of carnosic acid and 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’)

Purity

Residual solvents

Hexane: not more than 25 mg/kg

Ethanol: not more than 500 mg/kg

E 400 ALGINIC ACID

Synonyms

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 strains of various species of brown seaweeds (Phaeophyceae)

Einesc 232-680-1

Chemical name

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

Solubility

Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate

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.

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.

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.

pH

Between 2,0 and 3,5 (3 % suspension)
Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 8% on the anhydrous basis</td>
</tr>
<tr>
<td>Sodium hydroxide insoluble matter (1 M solution)</td>
<td>Not more than 2% on the anhydrous basis</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

Microbiological criteria

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 500 colonies per gram</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>

E 401 SODIUM ALGINATE

Synonyms

Definition

Einecs

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

Test for sodium: Passes test

Test for alginic acid: Passes test

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 2% on the anhydrous basis</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Substance</td>
<td>Limit</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Microbiological criteria**

<table>
<thead>
<tr>
<th></th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 500 colonies per gram</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>

**E 402 POTASSIUM ALGINATE**

**Synonyms**

**Definition**

Einecs  
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**

Test for potassium: Passes test  
Test for alginic acid: Passes test

**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

**Microbiological criteria**

<table>
<thead>
<tr>
<th></th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
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<tr>
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</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>
### E 403 AMMONIUM ALGINATE

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>Ammonium salt of alginic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>(C₆H₁₁NO₆)ₙ</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>10 000-600 000 (typical average)</td>
</tr>
<tr>
<td>Assay</td>
<td>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)</td>
</tr>
</tbody>
</table>

**Description**

White to yellowish fibrous or granular powder

**Identification**

| Test for ammonium | Passes test |
| Test for alginic acid | Passes test |

**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 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

**Microbiological criteria**

| Total plate count | Not more than 5 000 colonies per gram |
| Yeast and moulds | Not more than 500 colonies per gram |
| *Escherichia coli* | Absent in 5 g |
| *Salmonella* spp. | Absent in 10 g |

### E 404 CALCIUM ALGINATE

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>Calcium salt of alginate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Calcium salt of alginic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>(C₆H₇Ca₁/₂O₆)ₙ</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>10 000-600 000 (typical average)</td>
</tr>
<tr>
<td>Assay</td>
<td>Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of 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)</td>
</tr>
</tbody>
</table>
**Description**

Nearly odourless, white to yellowish brown fibrous or granular powder

**Identification**

<table>
<thead>
<tr>
<th>Test for calcium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for alginic acid</td>
<td>Passes test</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15.0 % (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Microbiological criteria**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 500 colonies per gram</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>

**E 405 PROPANE-1,2-DIOL ALGINATE**

**Synonyms**

Hydroxypropyl alginate; 1,2-Propanediol ester of alginic acid; Propylene glycol alginate

**Definition**

<table>
<thead>
<tr>
<th>Entry</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>1,2-Propanediol 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</td>
</tr>
<tr>
<td>Chemical name</td>
<td>(C₉H₁₄O₇)ₓ (esterified)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>10 000-600 000 (typical average)</td>
</tr>
</tbody>
</table>

**Description**

Nearly odourless, white to yellowish brown fibrous or granular powder

**Identification**

<table>
<thead>
<tr>
<th>Test for 1,2-propanediol</th>
<th>Passes test (after hydrolysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for alginic acid</td>
<td>Passes test (after hydrolysis)</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 20 % (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Total propane-1,2-diol content</td>
<td>Not less than 15 % and not more than 45 %</td>
</tr>
<tr>
<td>Free propane-1,2-diol content</td>
<td>Not more than 15 %</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 2 % on the anhydrous basis</td>
</tr>
</tbody>
</table>
### 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

### Microbiological criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5,000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 500 colonies per gram</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td><em>Salmonella</em> <em>spp.</em></td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>

### E 406 AGAR

#### Synonyms
Gelose; Kanten, Bengal, Ceylon, Chinese or Japanese isinglass; Layor Carang

#### Definition
Agar is a hydrophilic colloidal polysaccharide consisting mainly of galactose units with a regular alternation of L and D isomeric forms. These hexoses are alternately linked with alpha-1,3 and beta-1,4 bonds in the copolymer. On about every tenth D-galactopyranose unit one of the hydroxyl groups is esterified with sulphuric acid which is neutralised by calcium, magnesium, potassium or sodium. It is extracted from certain strains of marine algae of the families *Gelidiaceae* and *Gracilariaceae* and relevant red algae of the class *Rhodophyceae*.

#### Einecs
232-658-1

#### Chemical name

#### Chemical formula

#### Molecular weight

#### Assay
The threshold gel concentration should not be higher than 0.25 %

#### Description
Agar is odourless or has a slight characteristic odour. Unground agar usually occurs in bundles consisting of thin, membranous, agglutinated strips, or in cut, flaked or granulated forms. It may be light yellowish-orange, yellowish-grey to pale yellow, or colourless. It is tough when damp, brittle when dry. Powdered agar is white to yellowish-white or pale yellow. When examined in water under a microscope, agar powder appears more transparent. In chloral hydrate solution, the powdered agar appears more transparent than in water, more or less granular, striated, angular and occasionally contains frustules of diatoms. Gel strength may be standardised by the addition of dextrose and maltodextrines or sucrose.

#### Identification

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Insoluble in cold water; soluble in boiling water</th>
</tr>
</thead>
</table>

#### Purity

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 22 % (105 °C, 5 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ash</td>
<td>Not more than 6.5 % on the anhydrous basis determined at 550 °C</td>
</tr>
<tr>
<td>Acid-insoluble ash (insoluble in approximately 3N Hydrochloric acid)</td>
<td>Not more than 0.5 % determined at 550 °C on the anhydrous basis</td>
</tr>
</tbody>
</table>
Insoluble matter (after stirring for 10 minutes in hot water) | Not more than 1.0 %
---|---
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
Gelatin and other proteins | Dissolve about 1 g of agar in 100 ml of boiling water and allow to cool of about 50 °C. To 5 ml of the solution add 5 ml of trinitrophenol solution (1 g of anhydrous trinitrophenol/100 ml of hot water). No turbidity appears within 10 minutes
Water absorption | Place 5 g to agar in a 100 ml graduated cylinder, fill to the mark with water, mix and allow to stand at about 25 °C for 24 hours. Pour the contents of the cylinder through moistened glass wool, allowing the water to drain into a second 100 ml graduated cylinder. Not more than 75 ml of water is obtained
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

Microbiological criteria

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| Total plate count | Not more than 5 000 colonies per gram
| Yeast and moulds | Not more than 300 colonies per gram
| Escherichia coli | Absent in 5 g
| Salmonella spp. | Absent in 5 g

**E 407 CARRAGEENAN**

**Synonyms**

Products of commerce are sold under different names such as:

- Irish moss gelose; Eucheuma (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 extraction with water or dilute aqueous alkali of strains of seaweeds of *Gigartinaceae*, *Soloriaceae*, *Hypneaceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds).

Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysacharide. These hexoses are alternately linked α-1,3 and β-1,4 in the copolymer.

The prevalent polysaccharides in carrageenan are designated as kappa, iota, lambda depending on the number of sulphate by repeating unit (i.e. 1,2,3 sulphate). Between kappa and iota there is a continuum of intermediate compositions differing in number of sulphates per repeat units between 1 and 2.

During the process, no organic precipitant shall be used other than methanol, ethanol and propan-2-ol.

The wording carrageenan is reserved for the non hydrolysed or otherwise chemically degraded polymer.

Formaldehyde may be present as an adventitious impurity up to a maximum of 5 mg/kg.
Einecs | 232-524-2
---|---
Chemical name | Sulphate esters of polygalactose
Chemical formula | 
Molecular weight | 
Assay | 

**Description**

Yellowish to colourless, coarse to fine powder which is practically odourless

**Identification**

Test for galactose | Passes test
Test for anhydrogalactose | Passes test
Test for sulphate | Passes test

**Solubility**

Soluble in hot water; insoluble in alcohol for a 1.5% dilution

**Purity**

Solvent residues | Not more than 0.1% of methanol, ethanol, propan-2-ol, singly or in combination
Viscosity | Not less than 5 mPa.s (1.5% solution at 75°C)
Loss on drying | Not more than 12% (105°C, 4 hours)
Sulphates | Not less than 15% and not more than 40% on the dried basis (as SO₄)
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

**Microbiological criteria**

Total plate count | Not more than 5 000 colonies per gram
Yeast and moulds | Not more than 300 colonies per gram
*Escherichia coli* | Absent in 5 g
*Salmonella* spp. | Absent in 10 g

**E 407a PROCESSED EUCHEUMA SEAWEED**

**Synonyms**

PES (acronym for processed eucheuma seaweed). The PES obtained from *Euchema cottonii* is generally called kappa PES and the PES from *Euchema spinosum* iota PES.
Definition

Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment at high temperature of the strains of seaweeds Eucheuma cottonii and Eucheuma spinosum, of the class Rhodophyceae (red seaweeds) followed by fresh water washing to remove impurities and drying to obtain the product. Further purification may be achieved by washing with an alcohol. The alcohols authorised are restricted to methanol, ethanol or propan-2-ol. The product consists chiefly of the potassium, sodium, magnesium and calcium sulphate esters of galactose and 3,6-anhydrogalactose polysaccharide. Up to 15 % algal cellulose is also present in the product. The wording processed eucheuma seaweed is reserved to the non hydrolysed or otherwise chemically degraded polymer. Formaldehyde may be present up to a maximum of 5 mg/kg.

Description

Tan to yellowish, coarse to fine powder which is practically odourless

Identification

Test for galactose  Passes test
Test for anhydrogalactose  Passes test
Test for sulphate  Passes test
Solubility  Forms cloudy viscous suspensions in water. Insoluble in ethanol for a 1,5 % solution.

Purity

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent residues</td>
<td>Not more than 0,1 % of methanol, ethanol, propan-2-ol, singly or in combination</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not less than 5 mPa.s (1,5 % solution at 75 °C)</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not less than 15 % and not more than 40 % on the dried basis (as SO₄)</td>
</tr>
<tr>
<td>Ash</td>
<td>Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C</td>
</tr>
<tr>
<td>Acid-insoluble ash</td>
<td>Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)</td>
</tr>
<tr>
<td>Acid-insoluble matter</td>
<td>Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)</td>
</tr>
<tr>
<td>Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

Microbiological criteria

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5 000 colonies per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 300 colonies per gram</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 5 g</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 10 g</td>
</tr>
</tbody>
</table>
### E 410 LOCUST BEAN GUM

**Synonyms**
Carob gum; Algaroba gum

**Definition**
Locust bean gum is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (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 galactomannan.

**Einacs**
232-541-5

**Chemical name**

**Chemical formula**

**Molecular weight**
50 000-3 000 000

**Assay**
Galactomannan content not less than 75 %

**Description**
White to yellowish-white, nearly odourless powder

**Identification**

**Test for galactose**
Passes test

**Test for mannose**
Passes test

**Microscopic examination**
Place some ground sample in an aqueous solution containing 0.5 % iodine and 1 % potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown.

**Solubility**
Soluble in hot water, insoluble in ethanol

**Purity**

**Loss on drying**
Not more than 15 % (105 °C, 5 hours)

**Ash**
Not more than 1.2 % determined at 800 °C

**Protein (N × 6.25)**
Not more than 7 %

**Acid-insoluble matter**
Not more than 4 %

**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

**Arsenic**
Not more than 3 mg/kg

**Lead**
Not more than 2 mg/kg

**Mercury**
Not more than 1 mg/kg

**Cadmium**
Not more than 1 mg/kg

**Ethanol and propan-2-ol**
Not more than 1 %, single or in combination
E 412 GUAR GUM

Synonyms
Gum cyamopsis; Guar flour

Definition
Guar gum is the ground endosperm of the seeds of strains of the guar plant, Cyamopsis tetragonolobus (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 galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alkaline oxidative treatment for viscosity adjustment.

Einecs 232-536-0

Chemical name

Chemical formula

Molecular weight 50 000-8 000 000

Assay
Galactomannan content not less than 75 %

Description
A white to yellowish-white, nearly odourless powder

Identification
Test for galactose Passes test
Test for mannose Passes test
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 Not more than 10 % (factor N x 6,25)
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
Pentachlorophenol Not more than 0,01 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg
Cadmium Not more than 1 mg/kg

E 413 TRAGACANTH

Synonyms
Tragacanth gum; Tragant

Definition
Tragacanth is a dried exudation obtained from the stems and branches of strains of Astragalus gummifer Labillardiere and other Asiatic species of Astragalus (family Leguminosae). It consists mainly of high molecular weight polysaccharides (galactoarabans and acidic polysaccharides) which, on hydrolysis, yield galacturonic acid, galactose, arabinose, xylose and fucose. Small amounts of rhamnose and of glucose (derived from traces of starch and/or cellulose) may also be present.
### Einecs 232-252-5

**Chemical name**

**Chemical formula**

**Molecular weight** Approximately 800 000

**Assay**

#### Description

Unground Tragacanth gum occurs as flattened, lamellated, straight or curved fragments or as spirally twisted pieces 0.5-2.5 mm thick and up to 3 cm in length. It is white to pale yellow in colour but some pieces may have a red tinge. The pieces are horny in texture, with a short fracture. It is odourless and solutions have an insipid mucilaginous taste. Powdered tragacanth is white to pale yellow or pinkish brown (pale tan) in colour.

#### Identification

**Solubility**

1 g of the sample in 50 ml of water swells to form a smooth, stiff, opalescent mucilage; insoluble in ethanol and does not swell in 60 % (w/v) aqueous ethanol.

#### Purity

- **Test for Karaya gum**
  
  Negative. Boil 1 g with 20 ml of water until a mucilage is formed. Add 5 ml of hydrochloric acid and again boil the mixture for five minutes. No permanent pink or red colour develops.

- **Loss on drying**
  
  Not more than 16 % (105 °C, 5 hours)

- **Total ash**
  
  Not more than 4 %

- **Acid insoluble ash**
  
  Not more than 0.5 %

- **Acid insoluble matter**
  
  Not more than 2 %

- **Arsenic**
  
  Not more than 3 mg/kg

- **Lead**
  
  Not more than 2 mg/kg

- **Mercury**
  
  Not more than 1 mg/kg

- **Cadmium**
  
  Not more than 1 mg/kg

#### Microbiological criteria

- **Salmonella spp.**
  
  Absent in 10 g

- **Escherichia coli**
  
  Absent in 5 g

### E 414 ACACIA GUM

**Synonyms**

Gum arabic

**Definition**

Acacia gum is a dried exudation obtained from the stems and branches of strains of *Acacia senegal* (L) Willdenow or closely related species of Acacia (family Leguminosae). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid.

### Einecs 232-519-5

**Chemical name**

**Chemical formula**

**EN 22.3.2012 Official Journal of the European Union L 83/145**
Molecular weight

Approximately 350 000

Assay

Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material.

Identification

Solubility

1 g dissolves in 2 ml of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol

Purity

Loss on drying

Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material

Total ash

Not more than 4 %

Acid insoluble ash

Not more than 0,5 %

Acid insoluble matter

Not more than 1 %

Starch or dextrin

Boil a 1 in 50 solution of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced

Tannin

To 10 ml of a 1 in 50 solution add about 0,1 ml of ferric chloride solution (9 g FeCl₃·6H₂O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

Hydrolysis products

Mannose, xylose and galacturonic acid are absent (determined by chromatography)

Microbiological criteria

Salmonella spp.

Absent in 10 g

Escherichia coli

Absent in 5 g

E 415 XANTHAN GUM

Synonyms

Definition

Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with strains of Xanthomonas campestris, purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions are neutral

Einecs

234-394-2

Chemical name

Chemical formula
Molecular weight
Approximately 1 000 000

Assay
Yields, on dried basis, not less than 4.2 % and not more than 5 % of CO₂ corresponding to between 91 % and 108 % of xanthan gum

Description
Cream-coloured powder

Identification
Solubility
Soluble in water. Insoluble in ethanol

Purity
Loss on drying
Not more than 15 % (105 °C, 2,5 hours)

Total ash
Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours

Pyruvic acid
Not less than 1,5 %

Nitrogen
Not more than 1,5 %

Ethanol and propan-2-ol
Not more than 500 mg/kg singly or in combination

Lead
Not more than 2 mg/kg

Microbiological criteria
Total plate count
Not more than 5 000 colonies per gram

Yeast and moulds
Not more than 300 colonies per gram

Escherichia coli
Absent in 5 g

Salmonella spp.
Absent in 10 g

Xanthomonas campestris
Viable cells absent in 1 g

E 416 KARAYA-GUM

Synonyms
Katilo; Kadaya; Gum sterculia; Sterculia; Karaya, gum karaya; Kullo; Kuterra

Definition
Karaya gum is a dried exudation from the stems and branches of strains of Sterculia urens Roxburgh and other species of Sterculia (family Sterculiaceae) or from Cochlospermum gossypiun A.P. De Candolle or other species of Cochlospermum (family Bixaceae). It consists mainly of high molecular weight acetylated polysaccharides, which on hydrolysis yield galactose, rhamnose, and galacturonic acid, together with minor amounts of glucuronic acid

Einecs
232-539-4

Chemical name

Chemical formula

Molecular weight

Assay

Description
Karaya gum occurs in tears of variable size and in broken irregular pieces having a characteristic semi-crystalline appearance. It is pale yellow to pinkish brown in colour, translucent and horny. Powdered karaya gum is a pale grey to pinkish brown. The gum has a distinctive odour of acetic acid
### Identification

**Solubility**
Insoluble in ethanol

**Swelling in ethanol solution**
Karaya gum swells in 60 % ethanol distinguishing it from other gums

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 20 % (105 °C, 5 hours)</td>
</tr>
<tr>
<td>Total ash</td>
<td>Not more than 8 %</td>
</tr>
<tr>
<td>Acid insoluble ash</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Volatile acid</td>
<td>Not less than 10 % (as acetic acid)</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### Microbiological criteria

<table>
<thead>
<tr>
<th>Organ</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonellla spp.</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 5 g</td>
</tr>
</tbody>
</table>

### Definition

Tara gum is obtained by grinding the endosperm of the seeds of strains of *Caesalpinia spinosa* (family Leguminosae). It consists chiefly of polysaccharides of high molecular weight composed mainly of galactomannans. The principal component consists of a linear chain of (1-4)-\(\beta\)-D-mannopyranose units with α-D-galactopyranose units attached by (1-6) linkages. The ratio of mannose to galactose in tara gum is 3:1. (In locust bean gum this ratio is 4:1 and in guar gum 2:1)

Einecs 254-409-6

### Assay

A white to white-yellow odourless powder

### Description

To an aqueous solution of the sample add small amounts of sodium borate. A gel is formed

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 %</td>
</tr>
<tr>
<td>Ash</td>
<td>Not more than 1,5 %</td>
</tr>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Protein</td>
<td>Not more than 3,5 % (factor N x 5,7)</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Starch</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 418 GELLAN GUM**

**Synonyms**

**Definition**

Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by strains of *Pseudomonas elodea*, purified by recovery with propan-2-ol or ethanol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucose, and substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters. The glucuronic acid is neutralised to a mixed potassium, sodium, calcium, and magnesium salt.

**Einecs**

275-117-5

**Chemical name**

**Chemical formula**

**Molecular weight**

Approximately 500 000

**Assay**

Yields, on the dried basis, not less than 3,3 % and not more than 6,8 % of CO₂

**Description**

An off-white powder

**Identification**

Solubility

Soluble in water, forming a viscous solution.

Insoluble in ethanol

**Purity**

Loss on drying

Not more than 15 % after drying (105 °C, 2,5 hours)

Nitrogen

Not more than 3 %

Propan-2-ol

Not more than 750 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 2 mg/kg

Mercury

Not more than 1 mg/kg

Cadmium

Not more than 1 mg/kg

**Microbiological criteria**

Total plate count

Not more than 10 000 colonies per gram

Yeast and moulds

Not more than 400 colonies per gram

*Escherichia coli*

Negative in 5 g

Salmonella spp.

Negative in 10 g
**E 420 (i) SORBITOL**

**Synonyms**
D-glucitol; D-sorbitol

**Definition**
Sorbitol is obtained by hydrogenation of D-glucose. It is mainly composed of D-sorbitol. According to the level of D-glucose, the part of the products which is not D-sorbitol is composed of related substances such as mannitol, iditol, maltitol.

**Einecs**
200-061-5

**Chemical name**
D-glucitol

**Chemical formula**
C$_6$H$_{14}$O$_6$

**Molecular weight**
182.2

**Assay**
Content not less than 97 % of total glycitols and not less than 91 % of D-sorbitol on dry weight basis (glycitols are compounds with the structural formula CH$_2$OH-(CHOH)$_n$-CH$_2$OH, where 'n' is an integer).

**Description**
White hygroscopic powder, crystalline powder, flakes or granules.

Appearance of the aqueous solution: The solution is clear.

**Identification**

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Very soluble in water, slightly soluble in ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>88 to 102 °C</td>
</tr>
<tr>
<td>Sorbitol monobenzylidene derivative</td>
<td>To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate; filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Water content</th>
<th>Not more than 1.5 % (Karl Fischer method)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 % (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3 % (expressed as glucose on dry weight basis)</td>
</tr>
<tr>
<td>Total sugars</td>
<td>Not more than 1 % (expressed as glucose on dry weight basis)</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 50 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 100 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>
E 420 (ii) SORBITOL SYRUP

**Synonyms**
D-glucitol syrup

**Definition**
Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides.

The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where \( n \leq 4 \) may be present (glycitols are compounds with the structural formula \( \text{CH}_2\text{OH-(CHOH)}_n\text{-CH}_2\text{OH} \), where \( 'n' \) is an integer).

**Einecs**
270-337-8

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**
Content not less than 69% total solids and not less than 50% of D-sorbitol on the anhydrous basis

**Description**
Clear and colourless aqueous solution

**Identification**
Miscible with water, with glycerol, and with propane-1,2-diol

**Solubility**
To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 31% (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1% (on dry weight basis)</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3% (expressed as glucose on dry weight basis)</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 50 mg/kg (on dry weight basis)</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 100 mg/kg (on dry weight basis)</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg (on dry weight basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (on dry weight basis)</td>
</tr>
</tbody>
</table>

E 421 MANNITOL

(i) MANNITOL

**Synonyms**
D-mannitol

**Definition**
The product contains min. 96% mannitol. The part of the product which is not mannitol is mainly composed of sorbitol (2% max), maltitol (2% max) and isomalt (1,1 GPM (1-O-alpha-D-Glucopyranosyl-D-mannitol dehydrate); 2% max and 1,6 GPS (6-O-alpha-D-Glucopyranosyl-D-Sorbitol); 2% max). Unspecified impurities shall not represent more than 0.1% of each.

Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose
**Einecs** 200-711-8

**Chemical name** D-mannitol

**Chemical formula** $C_6H_{14}O_6$

**Molecular weight** 182.2

**Assay** Content not less than 96.0 % D-mannitol and not more than 102 % on the dried basis

**Description** White, odourless, crystalline powder

**Identification**

- **Solubility** Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
- **Melting range** Between 164 and 169 °C
- **Infrared absorption spectrometry** Comparison with a reference standard e.g. EP or USP
- **Specific rotation** $[\alpha]_D^{20} + 23^\circ$ to $+ 25^\circ$ (borate solution)
- **pH** Between 5 and 8. Add 0.5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

**Purity**

- **Water content** Not more than 0.5 % (Karl Fischer method)
- **Reducing sugars** Not more than 0.3 % (as glucose)
- **Total sugars** Not more than 1 % (expressed as glucose)
- **Sulphated ash** Not more than 0.1 %
- **Chlorides** Not more than 70 mg/kg
- **Sulphate** Not more than 100 mg/kg
- **Nickel** Not more than 2 mg/kg
- **Lead** Not more than 1 mg/kg

**(ii) MANNITOL MANUFACTURED BY FERMENTATION**

**Synonyms** D-mannitol

**Definition** Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii*. The part of the product which is not mannitol is mainly composed of sorbitol, maltitol and isomalt.

**Einecs** 200-711-8

**Chemical name** D-mannitol

**Chemical formula** $C_6H_{14}O_6$

**Molecular weight** 182.2

**Assay** Not less than 99 % on the dried basis

**Description** White, odourless crystalline powder
### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Soluble in water, very slightly soluble in ethanol, practically insoluble in ether</td>
</tr>
<tr>
<td>Melting range</td>
<td>Between 164 and 169 °C</td>
</tr>
<tr>
<td>Infrared absorption spectrometry</td>
<td>Comparison with a reference standard e.g. EP or USP</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_D^{20} + 23^\circ$ to $+ 25^\circ$ (borate solution)</td>
</tr>
<tr>
<td>pH</td>
<td>Between 5 and 8</td>
</tr>
<tr>
<td></td>
<td>Add 0.5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arabitol</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>Water content</td>
<td>Not more than 0.5 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3 % (expressed as glucose)</td>
</tr>
<tr>
<td>Total sugars</td>
<td>Not more than 1 % (as glucose)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 70 mg/kg</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not more than 100 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### Microbiological criteria

<table>
<thead>
<tr>
<th>Organism</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic mesophilic bacteria</td>
<td>Not more than 1 000 colonies per gram</td>
</tr>
<tr>
<td>Coliforms</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 25 g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Absent in 10 g</td>
</tr>
<tr>
<td>Moulds</td>
<td>Not more than 100 colonies per gram</td>
</tr>
<tr>
<td>Yeasts</td>
<td>Not more than 100 colonies per gram</td>
</tr>
</tbody>
</table>

### E 422 GLYCEROL

### Synonyms

Glycerin; Glycerine

### Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einces</td>
<td>200-289-5</td>
</tr>
<tr>
<td>Chemical name</td>
<td>1,2,3-propanetriol; Glycerol; Trihydroxypropane</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C$_3$H$_8$O$_3$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>92,10</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98 % of glycerol on the anhydrous basis</td>
</tr>
</tbody>
</table>

### Description

Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable.
### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrolein formation on heating</td>
<td>Heat a few drops of the sample in a test tube with about 0.5 g of potassium bisulphate. The characteristic pungent vapours of acrolein are evolved</td>
</tr>
<tr>
<td>Specific gravity (25 °C/25 °C)</td>
<td>Not less than 1.257</td>
</tr>
<tr>
<td>Refractive index</td>
<td>[n]_D^20 between 1.471 and 1.474</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 5 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.01 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Butanetriols</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Acrolein, glucose and ammonium compounds</td>
<td>Heat a mixture of 5 ml of glycerol and 5 ml of potassium hydroxide solution (1 in 10) at 60 °C for five minutes. It neither becomes yellow nor emits an odour of ammonia</td>
</tr>
<tr>
<td>Fatty acids and esters</td>
<td>Not more than 0.1 % calculated as butyric acid</td>
</tr>
<tr>
<td>Chlorinated compounds</td>
<td>Not more than 30 mg/kg (as chlorine)</td>
</tr>
<tr>
<td>3-Monochloropropane-1,2-diol (3-MCPD)</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 425 (i) KONJAC GUM

#### Synonyms

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 *Amorphophallus konjac*. 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 β(1-4)-glycosidic bonds. Shorter side chains are attached through β(1-3)-glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units.

#### Chemical name

Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction.

#### Chemical formula

Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction.

#### 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

Dispersible in hot or cold water forming a highly viscous solution with a pH between 4.0 and 7.0
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.

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.

Purity

- Loss on drying: Not more than 12 % (105 °C, 5 hours)
- Starch: Not more than 3 %
- Protein: Not more than 3 % (factor N × 5,7)
- Viscosity (1 % solution): Not less than 3 kgm⁻¹s⁻¹ at 25 °C
- Ether-soluble material: Not more than 0,1 %
- Total ash: Not more than 5,0 % (800 °C, 3 to 4 hours)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg

Microbiological criteria

- Salmonella spp.: Absent in 12,5 g
- Escherichia coli: Absent in 5 g

E 425 (ii) KONJAC GLUCOMANNAN

Synonyms

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.

Einecs

Chemical name

Chemical formula

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

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.
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.

**Purity**

- **Loss on drying**
  - Not more than 8% (105°C, 3 hours)

- **Starch**
  - Not more than 1%

- **Viscosity (1% solution)**
  - Not less than 20 kgm⁻¹s⁻¹ at 25°C

- **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 SO₂)**
  - Not more than 4 mg/kg

- **Chloride**
  - Not more than 0.02%

- **50% Alcohol-soluble material**
  - Not more than 2.0%

- **Total ash**
  - Not more than 2.0% (800°C, 3 to 4 hours)

- **Lead**
  - Not more than 1 mg/kg

**Microbiological criteria**

- **Salmonella spp.**
  - Absent in 12.5 g

- **Escherichia coli**
  - Absent in 5 g

**E 426 SOYBEAN HEMICELLULOSE**

**Synonyms**

**Definition**

Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol.

**Einecs**

- Chemical name: Water soluble soybean polysaccharides; Water soluble soybean fibre

- Molecular weight: Not less than 74% carbohydrate

**Description**

Free flowing white or yellowish white powder

**Identification**

- **Solubility**
  - Soluble in hot and cold water without gel formation

- **pH**
  - 5.5 ± 1.5 (1% solution)

**Purity**

- **Loss on drying**
  - Not more than 7% (105°C, 4 hours)
<table>
<thead>
<tr>
<th><strong>Protein</strong></th>
<th>Not more than 14 %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not more than 200 mPa.s (10 % solution)</td>
</tr>
<tr>
<td><strong>Total ash</strong></td>
<td>Not more than 9.5 % (600 °C, 4 hours)</td>
</tr>
<tr>
<td><strong>Arsenic</strong></td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td><strong>Ethanol</strong></td>
<td>Not more than 2%</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td><strong>Mercury</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td><strong>Cadmium</strong></td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Microbiological criteria**

| **Total plate count** | Not more than 3 000 colonies per gram |
| **Yeast and moulds** | Not more than 100 colonies per gram |
| **Escherichia coli** | Absent in 10 g |

**E 427 CASSIA GUM**

**Synonyms**

**Definition**

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-β-D-mannopyranose units linked with 1,6-α-D-galactopyranose units. The ratio of mannose to galactose is about 5:1.

In the manufacture the seeds are dehusked and degemred by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with propan-2-ol.

**Assay**

Not less than 75 % of Galactomannan

**Description**

Pale yellow to off-white, odourless powder

**Identification**

| **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 test solution (TS) to raise the pH to above 9; a gel is formed. |
| **Gel formation with xanthan gum** | 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 °C 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 °C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h. A firm, viscoelastic gel forms after the temperature drops below 40 °C, but no such gel forms in a 1 % control solution of cassia gum or xanthan gum alone prepared in a similar manner. |
| **Viscosity** | Less than 500 mPa.s (25 °C, 2h, 1 % solution) corresponding to an average molecular weight of 200 000-300 000 Da |
Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid insoluble matter</td>
<td>Not more than 2.0 %</td>
</tr>
<tr>
<td>pH</td>
<td>5.5-8 (1 % aqueous solution)</td>
</tr>
<tr>
<td>Crude fat</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Protein</td>
<td>Not more than 7 %</td>
</tr>
<tr>
<td>Total ash</td>
<td>Not more than 1.2 %</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (5h, 105 °C)</td>
</tr>
<tr>
<td>Total anthraquinones</td>
<td>Not more than 0.5 mg/kg (detection limit)</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Not more than 750 mg/kg Propan-2-ol</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

Microbiological criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count</td>
<td>Not more than 5,000 colony forming units per gram</td>
</tr>
<tr>
<td>Yeast and moulds</td>
<td>Not more than 100 colony forming units per gram</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 25 g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 1 g</td>
</tr>
</tbody>
</table>

E 431 POLYOXYETHYLENE (40) STEARATE

Synonyms

<table>
<thead>
<tr>
<th>Synonym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyoxyl (40) stearate</td>
<td>A mixture of the mono- and diesters of edible commercial stearic acid and mixed polyoxyethylene diols (having an average polymer length of about 40 oxyethylene units) together with free polyol</td>
</tr>
<tr>
<td>Polyoxyethylene (40) monostearate</td>
<td></td>
</tr>
</tbody>
</table>

Definition

- **Enercs**
- **Chemical name**
- **Chemical formula**
- **Molecular weight**
- **Assay** Content not less than 97.5 % on the anhydrous basis

Description

Cream-coloured flakes or waxy solid at 25 °C with a faint odour

Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Soluble in water, ethanol, methanol and ethyl acetate. Insoluble in mineral oil</td>
</tr>
<tr>
<td>Congealing range</td>
<td>39-44 °C</td>
</tr>
<tr>
<td>Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyoxyethylated polyol</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 3 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 1</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 25 and not more than 35</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 27 and not more than 40</td>
</tr>
</tbody>
</table>
1,4-Dioxane  Not more than 5 mg/kg
Ethylene oxide  Not more than 0.2 mg/kg
Ethylene glycols (mono- and di-)  Not more than 0.25 %
Arsenic  Not more than 3 mg/kg
Lead  Not more than 2 mg/kg
Mercury  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg

E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)

Synonyms  Polysorbate 20; Polyoxyethylene (20) sorbitan monolaurate

Definition  A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial lauric acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Einacs  
Chemical name  
Chemical formula  
Molecular weight  
Assay  Content not less than 70 % of oxyethylene groups, equivalent to not less than 97.3 % of polyoxyethylene (20) sorbitan monolaurate on the anhydrous basis

Description  A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

Identification  Solubility  Soluble in water, ethanol, methanol, ethyl acetate and dioxane. Insoluble in mineral oil and petroleum ether
Infrared absorption spectrum  Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

Purity  
Water content  Not more than 3 % (Karl Fischer method)
Acid value  Not more than 2
Saponification value  Not less than 40 and not more than 50
Hydroxyl value  Not less than 96 and not more than 108
1,4-dioxane  Not more than 5 mg/kg
Ethylene oxide  Not more than 0.2 mg/kg
Ethylene glycols (mono- and di-)  Not more than 0.25 %
Arsenic  Not more than 3 mg/kg
Lead  Not more than 2 mg/kg
Mercury  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg
### E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)

**Synonyms**
- Polysorbate 80; Polyoxyethylene (20) sorbitan monooleate

**Definition**
A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial oleic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

| **Einecs** |  |
| **Chemical name** |  |
| **Chemical formula** |  |
| **Molecular weight** |  |
| **Assay** | Content not less than 65 % of oxyethylene groups, equivalent to not less than 96,5 % of polyoxyethylene (20) sorbitan monooleate on the anhydrous basis |

**Description**
A lemon to amber-coloured oily liquid at 25 °C with a faint characteristic odour

**Identification**
- Solubility: Soluble in water, ethanol, methanol, ethyl acetate and toluene. Insoluble in mineral oil and petroleum ether
- Infrared absorption spectrum: Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

**Purity**
- Water content: Not more than 3 % (Karl Fischer method)
- Acid value: Not more than 2
- Saponification value: Not less than 45 and not more than 55
- Hydroxyl value: Not less than 65 and not more than 80
- 1,4-dioxane: Not more than 5 mg/kg
- Ethylene oxide: Not more than 0.2 mg/kg
- Ethylene glycols (mono- and di-): Not more than 0.25 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg

### E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)

**Synonyms**
- Polysorbate 40; Polyoxyethylene (20) sorbitan monopalmitate

**Definition**
A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial palmitic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides
Einecs
Chemical name
Chemical formula
Molecular weight
Assay

**Description**

A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour

**Identification**

Solubility
Soluble in water, ethanol, methanol, ethyl acetate and acetone. Insoluble in mineral oil

Infrared absorption spectrum
Characteristic of a partial fatty acid ester of a polyoxyethylated polyol

**Purity**

Water content
Not more than 3 % (Karl Fischer method)

Acid value
Not more than 2

Saponification value
Not less than 41 and not more than 52

Hydroxyl value
Not less than 90 and not more than 107

1,4-dioxane
Not more than 5 mg/kg

Ethylene oxide
Not more than 0,2 mg/kg

Ethylene glycols (mono- and di-)
Not more than 0,25 %

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

---

**E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)**

**Synonyms**

Polysorbate 60; Polyoxyethylene (20) sorbitan monostearate

**Definition**

A mixture of the partial esters of sorbitol and its mono- and di-anhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

Einecs
Chemical name
Chemical formula
Molecular weight
Assay

Content not less than 65 % of oxyethylene groups, equivalent to not less than 97 % of polyoxyethylene (20) sorbitan monostearate on the anhydrous basis
**Description**

A lemon to orange-coloured oily liquid or semi-gel at 25 °C with a faint characteristic odour

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Soluble in water, ethyl acetate and toluene. Insoluble in mineral oil and vegetable oils</td>
</tr>
<tr>
<td>Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyoxyethylated polyol</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 3 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 45 and not more than 55</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 81 and not more than 96</td>
</tr>
<tr>
<td>1,4-dioxane</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td>Not more than 0.2 mg/kg</td>
</tr>
<tr>
<td>Ethylene glycols (mono- and di-)</td>
<td>Not more than 0.25 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)**

**Synonyms**

Polysorbate 65; Polyoxyethylene (20) sorbitan tristearate

**Definition**

A mixture of the partial esters of sorbitol and its mono- and dianhydrides with edible commercial stearic acid and condensed with approximately 20 moles of ethylene oxide per mole of sorbitol and its anhydrides

**Description**

A tan-coloured, waxy solid at 25 °C with a faint characteristic odour

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Dispersible in water. Soluble in mineral oil, vegetal oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol</td>
</tr>
<tr>
<td>Congealing range</td>
<td>29-33 °C</td>
</tr>
<tr>
<td>Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of a polyoxyethylated polyol</td>
</tr>
<tr>
<td>Property</td>
<td>Requirement</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Water content</td>
<td>Not more than 3 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 2</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 88 and not more than 98</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 40 and not more than 60</td>
</tr>
<tr>
<td>1,4-dioxane</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td>Not more than 0.2 mg/kg</td>
</tr>
<tr>
<td>Ethylene glycols (mono-and di-)</td>
<td>Not more than 0.25 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 440 (i) PECTIN

#### Synonyms

#### Definition

Pectin consists mainly of the partial methyl esters of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of strains of appropriate edible plant material, usually citrus fruits or apples. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol.

#### Einecs

232-553-0

#### Chemical name

#### Chemical formula

#### Molecular weight

#### Assay

Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol

#### Description

White, light yellow, light grey or light brown powder

#### Identification

Solubility

Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Acid insoluble ash</td>
<td>Not more than 1 % (insoluble in approximately 3N hydrochloric acid)</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>Not more than 50 mg/kg on the anhydrous basis</td>
</tr>
<tr>
<td>Nitrogen content</td>
<td>Not more than 1.0 % after washing with acid and ethanol</td>
</tr>
<tr>
<td>Total insolubles</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Not more than 1 % of free methanol, ethanol and propan-2-ol, singly or in combination, on the volatile matter-free basis</td>
</tr>
<tr>
<td>Substance</td>
<td>Limit</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 440 (ii) AMIDATED PECTIN

#### Synonyms

#### Definition

Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of appropriate strains of edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol.

#### Description

White, light yellow, light greyish or light brownish powder.

#### Identification

Soluble in water forming a colloidal, opalescent solution. Insoluble in ethanol.

#### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Acid-insoluble ash</td>
<td>Not more than 1 % (insoluble in approximately 3N hydrochloric acid)</td>
</tr>
<tr>
<td>Degree of amidation</td>
<td>Not more than 25 % of total carboxyl groups</td>
</tr>
<tr>
<td>Sulphur dioxide residue</td>
<td>Not more than 50 mg/kg on the anhydrous basis</td>
</tr>
<tr>
<td>Nitrogen content</td>
<td>Not more than 2.5 % after washing with acid and ethanol</td>
</tr>
<tr>
<td>Total insolubles:</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Not more than 1 % of methanol, ethanol and propan-2-ol, singly or in combination, on a volatile matter-free basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### E 442 AMMONIUM PHOSPHATIDES

**Synonyms**
Ammonium salts of phosphatidic acid; Mixed ammonium salts of phosphorylated glycerides

**Definition**
A mixture of the ammonium compounds of phosphatidic acids derived from edible fat and oil. One or two or three glyceride moieties may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides

<table>
<thead>
<tr>
<th>Einacs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td></td>
</tr>
</tbody>
</table>

**Assay**
The phosphorus content is not less than 3 % and not more than 3,4 % by weight; the ammonium content is not less than 1,2 % and not more than 1,5 % (calculated as N)

**Description**
Unctuous semi-solid to oily solid

**Identification**

| Solubility | Soluble in fats. Insoluble in water. Partially soluble in ethanol and in acetone |
| Test for glycerol | Passes test |
| Test fatty acids | Passes test |
| Test for phosphate | Passes test |

**Purity**

| Petroleum ether insoluble matter | Not more than 2,5 % |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |

### E 444 SUCROSE ACETATE ISOBYTURATE

**Synonyms**
SAIB

**Definition**
Sucrose acetate isobutyrate is a mixture of the reaction products formed by the esterification of food grade sucrose with acetic acid anhydride and isobutyric anhydride, followed by distillation. The mixture contains all possible combinations of esters in which the molar ratio of acetate to butyrate is about 2:6

<table>
<thead>
<tr>
<th>Einacs</th>
<th>204-771-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sucrose diacetate hexaisobutyrate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{40}H_{62}O_{19}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>832-856 (approximate), C_{40}H_{62}O_{19}: 846,9</td>
</tr>
</tbody>
</table>

**Assay**
Content not less than 98,8 % and not more than 101,9 % of C_{40}H_{62}O_{19}

**Description**
A pale straw-coloured liquid, clear and free of sediment and having a bland odour
**E 445 GLYCEROL ESTERS OF WOOD ROSIN**

**Synonyms**

Ester gum

**Definition**

A complex mixture of tri- and diglycerol esters of resin acids from wood rosin. The rosin is obtained by the solvent extraction of aged pine stumps followed by a liquid-liquid solvent refining process. Excluded from these specifications are substances derived from gum rosin, and exudate of living pine trees, and substances derived from tall oil rosin, a by-product of kraft (paper) pulp processing. The final product is composed of approximately 90 % resin acids and 10 % neutrals (non-acidic compounds). The resin acid fraction is a complex mixture of isomeric diterpenoid monocarboxylic acids having the empirical molecular formula of C_{20}H_{30}O_{2}, chiefly abietic acid. The substance is purified by steam stripping or by countercurrent steam distillation.

**Identification**

- **Solubility**: Insoluble in water, soluble in acetone
- **Infrared absorption spectrum**: Characteristic of the compound

**Purity**

- **Triacetin**: Not more than 0,1 %
- **Acid value**: Not more than 0,2
- **Saponification value**: Not less than 524 and not more than 540
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Specific gravity of solution**: [d]^{20,2}_{25} not less than 0,935 when determined in a 50 % solution in d-limonene (97 %, boiling point 175,5-176 °C, d^{20}: 0,84)
- **Ring and ball softening range**: Between 82 °C and 90 °C
- **Acid value**: Not less than 3 and not more than 9
- **Hydroxyl value**: Not less than 15 and not more than 45
- **Arsenic**: Not more than 3 mg/kg
Mercury: Not more than 1 mg/kg
Cadmium: Not more than 1 mg/kg

Test for absence of tall oil rosin (sulphur test)

When sulphur-containing organic compounds are heated in the presence of sodium formate, the sulphur is converted to hydrogen sulphide which can readily be detected by the use of lead acetate paper. A positive test indicates the use of tall oil rosin instead of wood rosin.

E 450 (i) DISODIUM DIPHOSPHATE

**Synonyms**
Disodium dihydrogen diphosphate; Disodium dihydrogen pyrophosphate; Sodium acid pyrophosphate; Disodium pyrophosphate

**Definition**

<table>
<thead>
<tr>
<th>EINECS</th>
<th>231-835-0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Disodium dihydrogen diphosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Na₂H₂P₂O₇</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>221.94</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95% of disodium diphosphate</td>
</tr>
</tbody>
</table>

**Description**
White powder or grains

**Identification**

- Test for sodium: Passes test
- Test for phosphate: Passes test
- Solubility: Soluble in water
- pH: Between 3.7 and 5.0 (1% solution)

**Purity**

- Loss on drying: Not more than 0.5% (105 °C, 4 hours)
- Water insoluble matter: Not more than 1%
- Fluoride: Not more than 10 mg/kg (expressed as fluorine)
- Arsenic: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg
- Aluminium: Not more than 200 mg/kg

E 450 (ii) TRISODIUM DIPHOSPHATE

**Synonyms**
Trisodium pyrophosphate; Trisodium monohydrogen diphosphate; Trisodium monohydrogen pyrophosphate; Trisodium diphosphate

**Definition**

<p>| EINECS | 238-735-6 |</p>
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Monohydrate: Na₃HP₂O₇ · H₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anhydrous: Na₃HP₂O₇</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Monohydrate: 261.95</td>
</tr>
<tr>
<td></td>
<td>Anhydrous: 243.93</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95 % on the dried basis</td>
</tr>
<tr>
<td></td>
<td>P₂O₅ content not less than 57 % and not more than 59 %</td>
</tr>
<tr>
<td>Description</td>
<td>White powder or grains, occurs anhydrous or as a monohydrate</td>
</tr>
<tr>
<td>Identification</td>
<td>Test for sodium: Passes test</td>
</tr>
<tr>
<td></td>
<td>Test for phosphate: Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>pH</td>
<td>Between 6.7 and 7.5 (1 % solution)</td>
</tr>
<tr>
<td>Purity</td>
<td>Loss on ignition: Not more than 4.5 % on the anhydrous compound (450-550 °C).</td>
</tr>
<tr>
<td></td>
<td>Loss on drying: Not more than 0.5 % (105 °C, 4 hours) for anhydrous</td>
</tr>
<tr>
<td></td>
<td>Water insoluble matter: Not more than 0.2 %</td>
</tr>
<tr>
<td></td>
<td>Fluoride: Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td></td>
<td>Arsenic: Not more than 1 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Cadmium: Not more than 1 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Lead: Not more than 1 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mercury: Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 450 (iii) TETRASODIUM DIPHOSPHATE**

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Tetrasodium pyrophosphate; Tetrasodium disphosphate; Tetrasodium phosphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td><strong>Einecs</strong> 231-767-1 <strong>Chemical name</strong> Tetrasodium diphosphate <strong>Chemical formula</strong> Anhydrous: Na₄P₂O₇ <strong>Decahydrate</strong>: Na₄P₂O₇ · 10H₂O <strong>Molecular weight</strong> Anhydrous: 265.94 <strong>Decahydrate</strong>: 446.09 <strong>Assay</strong> Content not less than 95 % of Na₄P₂O₇ on the ignited basis <strong>P₂O₅</strong> content not less than 52.5 % and not more than 54.0 % <strong>Description</strong> Colourless or white crystals, or a white crystalline or granular powder. The decahydrate effloresces slightly in dry air</td>
</tr>
</tbody>
</table>
### Identification

<table>
<thead>
<tr>
<th>Test for sodium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 9.8 and 10.8 (1 % solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Loss on ignition</th>
<th>Not more than 0.5 % for the anhydrous salt, not less than 38 % and not more than 42 % for the decahydrate (105 °C, 4 hours then 550 °C, 30 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### Synonyms

- Tetrapotassium pyrophosphate

### Definition

<table>
<thead>
<tr>
<th>Einecs</th>
<th>230-785-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Tetrapotassium diphosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$K_4P_2O_7$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>330.34 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95 % (800 °C for 0.5 hours) $P_2O_5$ content not less than 42.0 % and not more than 43.7 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

### Description

Colourless crystals or white, very hygroscopic powder

### Identification

<table>
<thead>
<tr>
<th>Test for potassium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water, insoluble in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 10.0 and 10.8 (1 % solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Loss on ignition</th>
<th>Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 450 (vi) DICALCIUM DIPHOSPHATE

**Synonyms**
Calcium pyrophosphate

**Definition**

<table>
<thead>
<tr>
<th>Einces</th>
<th>232-221-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Dicalcium diphosphate</td>
</tr>
<tr>
<td>Dicalcium pyrophosphate</td>
<td></td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Ca₂P₂O₇</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>254.12</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 96 %</td>
</tr>
<tr>
<td>P₂O₅ content not less than 55 % and not more than 56 %</td>
<td></td>
</tr>
</tbody>
</table>

**Description**
A fine, white, odourless powder

**Identification**

| Test for calcium | Passes test |
| Test for phosphate | Passes test |
| Solubility | Insoluble in water. Soluble in dilute hydrochloric and nitric acids |
| pH | Between 5.5 and 7.0 (10 % suspension in water) |

**Purity**

| Loss on ignition | Not more than 1.5 % (800 °C ± 25 °C, 30 minutes |
| Fluoride | Not more than 50 mg/kg (expressed as fluorine) |
| Arsenic | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Lead | Not more than 1 mg/kg |
| Mercury | Not more than 1 mg/kg |

---

E 450 (vii) CALCIUM DIHYDROGEN DIPHOSPHATE

**Synonyms**
Acid calcium pyrophosphate; Monocalcium dihydrogen pyrophosphate

**Definition**

<table>
<thead>
<tr>
<th>Einces</th>
<th>238-933-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Calcium dihydrogen diphosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>CaH₂P₂O₇</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>215.97</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 90 % on the anhydrous basis</td>
</tr>
<tr>
<td>P₂O₅ content not less than 61 % and not more than 66 %</td>
<td></td>
</tr>
</tbody>
</table>

**Description**
White crystals or powder

**Identification**

| Test for calcium | Passes test |
| Test for phosphate | Passes test |
**Purity**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid-insoluble matter</td>
<td>Not more than 0.4 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 30 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Aluminium</td>
<td>Not more than 800 mg/kg. This applies until 31 March 2015. Not more than 200 mg/kg. This applies from 1 April 2015.</td>
</tr>
</tbody>
</table>

**E 451 (i) PENTASODIUM TRIPHOSPHATE**

**Synonyms**

Pentasodium tripolyphosphate; Sodium tripolyphosphate

**Definition**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>231-838-7</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Pentasodium tripolyphosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Na₅O₁₀P₃·nH₂O (n = 0 or 6)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>367.86</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 85.0 % (anhydrous) or 65.0 % (hexahydrate)</td>
</tr>
<tr>
<td></td>
<td>P₂O₅ content not less than 56 % and not more than 59 % (anhydrous) or not less than 43 % and not more than 45 % (hexahydrate)</td>
</tr>
</tbody>
</table>

**Description**

White, slightly hygroscopic granules or powder

**Identification**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>Between 9.1 and 10.2 (1 % solution)</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Anhydrous: Not more than 0.7 % (105 °C, 1 hour)</td>
</tr>
<tr>
<td></td>
<td>Hexahydrate: Not more than 23.5 % (60 °C, 1 hour, then 105 °C, 4 hours)</td>
</tr>
<tr>
<td>Water insoluble matter</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Higher polyphosphates</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg (expressed as fluorine)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 451 (ii) PENTAPOTASSIUM TRIPHOSPHATE

**Synonyms**
- Pentapotassium tripolyphosphate; Potassium triphosphate; Potassium tripolyphosphate

**Definition**
- Einecs: 237-574-9
- Chemical name: Pentapotassium triphosphate; Pentapotassium tripolyphosphate
- Chemical formula: $K_5O_{10}P_3$
- Molecular weight: 448.42
- Assay: Content not less than 85% on the anhydrous basis
  - $P_2O_5$ content not less than 46.5% and not more than 48%

**Description**
- White, very hygroscopic powder or granules

**Identification**
- Solubility: Very soluble in water
- Test for potassium: Passes test
- Test for phosphate: Passes test
- pH: Between 9.2 and 10.5 (1% solution)

**Purity**
- Loss on ignition: Not more than 0.4% (105°C, 4 hours, then 550°C, 30 minutes)
- Water insoluble matter: Not more than 2%
- Fluoride: Not more than 10 mg/kg (expressed as fluorine)
- Arsenic: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg

---

E 452 (i) SODIUM POLYPHOSPHATE

I. SOLUBLE POLYPHOSPHATE

**Synonyms**
- Sodium hexametaphosphate; Sodium tetrapolyphosphate; Graham’s salt; Sodium polyphosphates, glassy; Sodium polymetaphosphate; Sodium metaphosphate

**Definition**
- Soluble sodium polyphosphates are obtained by fusion and subsequent chilling of sodium orthophosphates. These compounds are a class consisting of several amorphous, water-soluble polyphosphates composed of linear chains of metaphosphate units, $(NaPO_3)_x$ where $x \geq 2$, terminated by $Na_2PO_4$ groups. These substances are usually identified by their $Na_2O/P_2O_5$ ratio or their $P_2O_5$ content. The $Na_2O/P_2O_5$ ratios vary from about 1.3 for sodium tetrapolyphosphate, where $x = $ approximately 4; to about 1.1 for Graham’s salt, commonly called sodium hexametaphosphate, where $x = 13$ to 18; and to about 1.0 for the higher molecular weight sodium polyphosphates, where $x = 20$ to 100 or more. The pH of their solutions varies from 3.0 to 9.0

**Einecs**
- 272-808-3

**Chemical name**
- Sodium polyphosphate
<table>
<thead>
<tr>
<th><strong>Chemical formula</strong></th>
<th>Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where ‘$n$’ is not less than 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Molecular weight</strong></td>
<td>$(102)_n$</td>
</tr>
<tr>
<td><strong>Assay</strong></td>
<td>$P_2O_5$ content not less than 60% and not more than 71% on the ignited basis</td>
</tr>
</tbody>
</table>

**Description**

- Colourless or white, transparent platelets, granules, or powders
- Very soluble in water
- Passes test for sodium
- Passes test for phosphate
- Between 3.0 and 9.0 (1 % solution)

**Purity**

- Loss on ignition: Not more than 1%
- Water insoluble matter: Not more than 0.1%
- Fluoride: Not more than 10 mg/kg (expressed as fluorine)
- Arsenic: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg

---

**II. INSOLUBLE POLYPHOSPHATE**

**Synonyms**

- Insoluble sodium metaphosphate; Maddrell’s salt; Insoluble sodium polyphosphate; IMP

**Definition**

Insoluble sodium metaphosphate is a high molecular weight sodium polyphosphate composed of two long metaphosphate chains $(NaPO_3)_x$ that spiral in opposite directions about a common axis. The $Na_2O/P_2O_5$ ratio is about 1.0. The pH of 1 in 3 suspension in water is about 6.5

**Einecs**

272-808-3

**Chemical name**

Sodium polyphosphate

**Chemical formula**

Heterogenous mixtures of sodium salts of linear condensed polyphosphoric acids of general formula $H_{(n+2)}P_nO_{(3n+1)}$ where ‘$n$’ is not less than 2

**Molecular weight**

$(102)_n$

**Assay**

$P_2O_5$ content not less than 68.7% and not more than 70.0%

**Description**

- White crystalline powder
- Insoluble in water, soluble in mineral acids and in solutions of potassium and ammonium (but not sodium) chlorides
- Passes test for sodium
- Passes test for phosphate
- About 6.5 (1 in 3 suspension in water)
Purity

Fluoride  Not more than 10 mg/kg (expressed as fluorine)
Arsenic  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg

E 452(ii) POTASSIUM POLYPHOSPHATE

Synonyms  Potassium metaphosphate; Potassium polymetaphosphate; Kurrol salt

Definition  
Einecs  232-212-6
Chemical name  Potassium polyphosphate
Chemical formula  \((KPO_3)_n\)
Heterogenous mixtures of potassium salts of linear condensed polyphosphoric acids of general formula \(H_{(n+2)}P_nO_{(3n+1)}\) where ‘n’ is not less than 2
Molecular weight  \((118)_n\)
Assay  \(P_2O_5\) content not less than 53.5 % and not more than 61.5 % on the ignited basis

Description  Fine white powder or crystals or colourless glassy platelets

Identification  
Solubility  1 g dissolves in 100 ml of a 1 in 25 solution of sodium acetate
Test for potassium  Passes test
Test for phosphate  Passes test
pH  Not more than 7.8 (1 % suspension)

Purity  
Loss on ignition  Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)
Cyclic phosphate  Not more than 8 % on \(P_2O_5\) content
Fluoride  Not more than 10 mg/kg (expressed as fluorine)
Arsenic  Not more than 1 mg/kg
Cadmium  Not more than 1 mg/kg
Lead  Not more than 1 mg/kg
Mercury  Not more than 1 mg/kg

E 452(iii) SODIUM CALCIUM POLYPHOSPHATE

Synonyms  Sodium calcium polyphosphate, glassy

Definition  
Einecs  233-782-9
Chemical name  Sodium calcium polyphosphate
### E 452 (iv) CALCIUM POLYPHOSPHATE

| **Synonyms** | Calcium metaphosphate; Calcium polymetaphosphate |
| **Definition** | Calcium polyphosphate |

#### Chemical formula
\[(\text{NaPO}_3)_n \text{CaO} \text{ where n is typically 5}\]

#### Molecular weight

#### Assay
\[\text{P}_2\text{O}_5 \text{ content not less than 61 % and not more than 69 % on the ignited basis}\]

#### Description
White glassy crystals, spheres

#### Identification
- **pH**: Approximately 5 to 7 (1 % m/m slurry)
- **CaO content**: 7 % - 15 % m/m

#### Purity
- **Fluoride**: Not more than 10 mg/kg
- **Arsenic**: Not more than 1 mg/kg
- **Lead**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Mercury**: Not more than 1 mg/kg

---

| **Synonyms** | Calcium metaphosphate; Calcium polymetaphosphate |
| **Definition** | Calcium polyphosphate |

#### Chemical name
\[(\text{CaP}_2\text{O}_6)_n\]

#### Molecular weight
\[(198)_n\]

#### Assay
\[\text{P}_2\text{O}_5 \text{ content not less than 71 % and not more than 73 % on the ignited basis}\]

#### Description
Odourless, colourless crystals or white powder

#### Identification
- **Solubility**: Usually sparingly soluble in water. Soluble in acid medium
- **Test for calcium**: Passes test
- **Test for phosphate**: Passes test
- **CaO content**: 27 to 29,5 %

#### Purity
- **Loss on ignition**: Not more than 2 % (105 °C, 4 hours then 550 °C, 30 minutes)
- **Cyclic phosphate**: Not more than 8 % (on \(\text{P}_2\text{O}_5\) content)
- **Fluoride**: Not more than 30 mg/kg (expressed as fluorine)
- **Arsenic**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg
- **Lead**: Not more than 1 mg/kg
- **Mercury**: Not more than 1 mg/kg
**E 459 BETA-CYCLODEXTRIN**

**Synonyms**

**Definition**

Beta-cyclodextrin is a non-reducing cyclic saccharide consisting of seven α-1,4-linked D-glucopyranosyl units. The product is manufactured by the action of the enzyme cycloglycosyltransferase (CGTase) obtained from *Bacillus circulans*, *Paenibacillus macerans* or recombinant *Bacillus licheniformis* strain SJ1608 on partially hydrolysed starch.

- EINECS: 231-493-2
- Chemical name: Cycloheptaamylose
- Chemical formula: \((C_6H_{10}O_5)_7\)
- Molecular weight: 1135
- Assay: Content not less than 98.0 % of \((C_6H_{10}O_5)_7\) on an anhydrous basis

**Description**

- Appearance of the aqueous solution: Clear and colourless

**Identification**

- Solubility: Sparingly soluble in water; freely soluble in hot water; slightly soluble in ethanol
- Specific rotation: \([\alpha]_D^{25} + 160^\circ\) to \(+164^\circ\) (1 % solution)
- pH value: 5.0-8.0 (1 % solution)

**Purity**

- Water content: Not more than 14 % (Karl Fischer method)
- Other cyclodextrins: Not more than 2 % on an anhydrous basis
- Solvent residues: Not more than 1 mg/kg of each of toluene and trichloroethylene
- Sulphated ash: Not more than 0.1 %
- Arsenic: Not more than 1 mg/kg
- Lead: Not more than 1 mg/kg

---

**E 460 (i) MICROCRYSTALLINE CELLULOSE**

**Synonyms**

**Definition**

Microcrystalline cellulose is purified, partially depolymerised cellulose prepared by treating alpha-cellulose, obtained as a pulp from strains of fibrous plant material, with mineral acids. The degree of polymerisation is typically less than 400.

- EINECS: 232-674-9
- Chemical name: Cellulose
- Chemical formula: \((C_6H_{10}O_5)_{n}\)
- Molecular weight: About 36 000
- Assay: Not less than 97 % calculated as cellulose on the anhydrous basis
- Particle size: Not less than 5 μm (not more than 10 % of particles of less than 5 μm)

**Description**

A fine white or almost white odourless powder
**Identification**

Solubility

Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution.

Colour reaction

To 1 mg of the sample, add 1 ml of phosphoric acid and heat on a water bath for 30 minutes. Add 4 ml of a 1 in 4 solution of pyrocatechol in phosphoric acid and heat for 30 minutes. A red colour is produced.

Infrared absorption spectroscopy

To be identified.

Suspension test

Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-following suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settles and a supernatant liquid appears.

pH

The pH of the supernatant liquid is between 5.0 and 7.5 (10% suspension in water).

**Purity**

Loss on drying

Not more than 7% (105°C, 3 hours).

Water soluble matter

Not more than 0.24%.

Sulphated ash

Not more than 0.5% (800 ± 25°C).

Starch

Not detectable.

Carboxyl groups

Not more than 1%.

Arsenic

Not more than 3 mg/kg.

Lead

Not more than 2 mg/kg.

Mercury

Not more than 1 mg/kg.

Cadmium

Not more than 1 mg/kg.

**E 460 (ii) POWDERED CELLULOSE**

**Definition**

Purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from strains of fibrous plant materials.

**Einecs**

232-674-9

**Chemical name**

Cellulose; Linear polymer of 1:4 linked glucose residues.

**Chemical formula**

\((C_{6}H_{10}O_{5})_n\)

**Molecular weight**

\((162)_n\) (n is predominantly 1 000 and greater).

**Assay**

Content not less than 92%.

**Particle size**

Not less than 5 μm (not more than 10% of particles of less than 5 μm).

**Description**

A white, odourless powder.

**Identification**

Solubility

Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution.
Suspension test
Mix 30 g of the sample with 270 ml of water in a high-speed (12 000 rpm) power blender for 5 minutes. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free-flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 hour. The solids settle and a supernatant liquid appears.

pH
The pH of the supernatant liquid is between 5.0 and 7.5 (10 % suspension in water)

Purity
Loss on drying
Not more than 7 % (105 °C, 3 hours)
Water soluble matter
Not more than 1.0 %
Sulphated ash
Not more than 0.3 % (800 ± 25 °C)
Starch
Not detectable
To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced.
Arsenic
Not more than 3 mg/kg
Lead
Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg
Cadmium
Not more than 1 mg/kg

E 461 METHYL CELLULOSE

Synonyms
Cellulose methyl ether

Definition
Methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups

Einecs

Chemical name
Methyl ether of cellulose

Chemical formula
The polymers contain substituted anhydroglucose units with the following general formula:

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]

where \( R_1, R_2, R_3 \) each may be one of the following:

- H
- \( CH_3 \) or
- \( CH_2CH_3 \)

Molecular weight
From about 20 000 to 380 000

Assay
Content not less than 25 % and not more than 33 % of methoxyl groups \((-OCH_3)\) and not more than 5 % of hydroxyethoxyl groups \((-OCH_2CH_2OH)\)

Description
Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid.</td>
</tr>
<tr>
<td>pH</td>
<td>Not less than 5.0 and not more than 8.0 (1 % colloidal solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10 % (105 °C, 3 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 1.5 % (800 ± 25 °C)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 462 ETHYL CELLULOSE

#### Synonyms

Cellulose ethyl ether

#### Definition

Ethyl cellulose is cellulose obtained directly from fibrous plant material and partially etherified with ethyl groups.

#### Einecs

Chemical name: Ethyl ether of cellulose

#### Chemical formula

The polymers contain substituted anhydroglucose units with the following general formula:

\[ C_6H_7O_2(OR_1)(OR_2) \]

where \( R_1 \) and \( R_2 \) may be any of the following:

- \( H \)
- \( CH_2CH_3 \)

#### Molecular weight

Assay

Content not less than 44 % and not more than 50 % of ethoxyl groups (-OC\(_2\)H\(_5\)) on the dried basis (equivalent to not more than 2.6 ethoxyl groups per anhydroglucose unit).

#### Description

Slightly hygroscopic white to off-white, odourless and tasteless powder.

#### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Practically insoluble in water, in glycerol and in propane-1,2-diol but soluble in varying proportions in certain organic solvents depending upon the ethoxyl content. Ethyl cellulose containing less than 46 to 48 % of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform and in aromatic hydrocarbon ethanol mixtures. Ethyl cellulose containing 46 to 48 % or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform and in ethyl acetate.</td>
</tr>
</tbody>
</table>
Film forming test
Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene ethanol. A clear, stable, slightly yellow solution is formed. Pour a few ml of the solution onto a glass plate and allow the solvent to evaporate. A thick, tough, continuous, clear film remains. The film is flammable.

pH
Neutral to litmus (1 % colloidal solution)

Purity
Loss on drying
Not more than 3 % (105 °C, 2 hours)
Sulphated ash
Not more than 0,4 %
Arsenic
Not more than 3 mg/kg
Lead
Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg
Cadmium
Not more than 1 mg/kg

E 463 HYDROXYPROPYL CELLULOSE

Synonyms
Cellulose hydroxypropyl ether

Definition
Hydroxypropylcellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with hydroxypropyl groups

Einecs
Chemical name
Hydroxypropyl ether of cellulose

Chemical formula
The polymers contain substituted anhydroglucose units with the following general formula:
\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]
where \( R_1, R_2, R_3 \) each may be one of the following:
- \( \text{H} \)
- \( \text{CH}_2\text{CHOHCH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3 \)
- \( \text{CH}_2\text{CHO}(\text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_1)\text{CH}_3 \)

Molecular weight
From about 30 000 to 1 000 000

Assay
Content not more than 80,5 % of hydroxypropoyl groups (-OCH₂CHOHCH₃) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis

Description
Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

Identification
Solubility
Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether

Gas chromatography
Determine the substituents by gas chromatography

pH
Not less than 5,0 and not more than 8,0 (1 % colloidal solution)
E 464 HYDROXYPROPYL METHYL CELLULOSE

Synonyms

Definition

Hydroxypropyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution.

Einecs

Chemical name 2-Hydroxypropyl ether of methylcellulose

Chemical formula The polymers contain substituted anhydroglucose units with the following general formula:

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3), \]

where \( R_1, R_2, R_3 \) each may be one of the following:

- \( H \)
- \( CH_3 \)
- \( CH_2CHOCH_3 \)
- \( CH_2CHO(CH_2CHOCH_3)CH_3 \)
- \( CH_2CHO(CH_2CHO(CH_2CHOHCH_3))CH_3CH_3 \)

Molecular weight From about 13 000 to 200 000

Assay Content not less than 19% and not more than 30% methoxyl groups (\(-OCH_3\)) and not less than 3% and not more than 12% hydroxypropoxy groups (\(-OCH_2CHOHCH_3\)), on the anhydrous basis

Description Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

Identification

Solubility Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol

Gas chromatography Determine the substituents by gas chromatography

pH Not less than 5.0 and not more than 8.0 (1% colloidal solution)

Purity

Loss on drying Not more than 10% (105°C, 3 hours)
<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit(s)</th>
</tr>
</thead>
</table>
| Sulphated ash                 | Not more than 1.5% for products with viscosities of 50 mPa.s or above  
|                               | Not more than 3% for products with viscosities below 50 mPa.s             |
| Propylene chlorohydrins       | Not more than 0.1 mg/kg                      |
| Arsenic                       | Not more than 3 mg/kg                       |
| Lead                          | Not more than 2 mg/kg                       |
| Mercury                       | Not more than 1 mg/kg                       |
| Cadmium                       | Not more than 1 mg/kg                       |

### E 465 ETHYL METHYL CELLULOSE

**Synonyms**

Methylethylcellulose

**Definition**

Ethyl methyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl and ethyl groups.

**Einecs**

Chemical name: Ethyl methyl ether of cellulose

Chemical formula: The polymers contain substituted anhydroglucose units with the following general formula:

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]

where \( R_1, R_2, R_3 \) each may be one of the following:

- \( H \)
- \( CH_3 \)
- \( CH_2CH_3 \)

Molecular weight: From about 30 000 to 40 000

**Assay**

Content on the anhydrous basis not less than 3.5% and not more than 6.5% of methoxyl groups (-OCH₃) and not less than 14.5% and not more than 19% of ethoxyl groups (-OCH₂CH₃), and not less than 13.2% and not more than 19.6% of total alkoxyl groups, calculated as methoxyl.

**Description**

Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

**Identification**

Solubility: Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Soluble in ethanol. Insoluble in ether

pH: Not less than 5.0 and not more than 8.0 (1% colloidal solution)

**Purity**

Loss on drying: Not more than 15% for the fibrous form, and not more than 10% for the powdered form (105°C to constant weight)
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,6 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 466 SODIUM CARBOXY METHYL CELLULOSE, CARBOXY METHYL CELLULOSE, CELLULOSE GUM**

**Synonyms**  
CMC; NaCMC; Sodium CMC;

**Definition**  
Carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from strains of fibrous plant material

**Einecs**

**Chemical name**  
Sodium salt of the carboxymethyl ether of cellulose

**Chemical formula**  
The polymers contain substituted anhydroglucose units with the following general formula:  
\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \], where \( R_1, R_2, R_3 \) each may be one of the following:  
- \( H \)  
- \( CH_2COONa \)  
- \( CH_2COOH \)

**Molecular weight**  
Higher than approximately 17 000 (degree of polymerisation approximately 100)

**Assay**  
Content on the anhydrous basis not less than 99,5 %

**Description**  
Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder

**Identification**

**Solubility**  
Yields a viscous colloidal solution with water. Insoluble in ethanol

**Foam test**  
A 0,1 % solution of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)

**Precipitate formation**  
To 5 ml of a 0,5 % solution of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)

**Colour reaction**  
Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce an uniform dispersion. Continue the stirring until a clear solution is produced, and use the solution for the following test.
To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface.

**pH**

Not less than 5.0 and not more than 8.5 (1 % colloidal solution)

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of substitution</td>
<td>Not less than 0.2 and not more than 1.5 carboxymethyl groups (-CH₂COOH) per anhydroglucose unit</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 12 % (105 °C to constant weight)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Total glycolate</td>
<td>Not more than 0.4 %, calculated as sodium glycolate on the anhydrous basis</td>
</tr>
<tr>
<td>Sodium</td>
<td>Not more than 12.4 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**E 468 CROSS-LINKED SODIUM CARBOXYMETHYLCELLULOSE, CROSS-LINKED CELLULOSE GUM**

**Synonyms**

Cross-linked carboxymethyl cellulose; Cross-linked CMC; Cross-linked sodium CMC;

**Definition**

Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose.

**Einecs**

Chemical name: Sodium salt of the cross-linked carboxymethyl ether cellulose

Chemical formula: The polymers containing substituted anhydroglucose units with the general formula:

\[ C_6H_7O_2(OR_1)(OR_2)(OR_3) \]

where \( R_1, R_2, \) and \( R_3 \) may be any of the following:

- \( \text{H} \)
- \( \text{CH}_2\text{COONa} \)
- \( \text{CH}_2\text{COOH} \)

**Molecular weight**

**Assay**

**Description**

Slightly hygroscopic, white to off white, odourless powder

**Identification**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precipitate formation</td>
<td>Shake 1 g with 100 ml of a solution containing 4 mg/kg methylene blue and allow to settle. The substance to be examined absorbs the methylene blue and settles as a blue, fibrous mass</td>
</tr>
<tr>
<td>Colour reaction</td>
<td>Shake 1 g with 50 ml of water. Transfer 1 ml of the mixture to a test tube, add 1 ml water and 0.05 ml of freshly prepared 40 g/l solution of alpha-naphthol in methanol. Incline the test tube and add carefully 2 ml of sulphuric acid down the side so that it forms a lower layer. A reddish-violet colour develops at the interface</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>Not less than 5.0 and not more than 7.0 (1 % solution)</td>
</tr>
</tbody>
</table>
### E 469 ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE, ENZYMATICALLY HYDROLISED CELLULOSE GUM

#### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 6 % (105 °C, 3 hours)</td>
</tr>
<tr>
<td>Water soluble matter</td>
<td>Not more than 10 %</td>
</tr>
<tr>
<td>Degree of substitution</td>
<td>Not less than 0.2 and not more than 1.5 carboxymethyl groups per anhydroglucose unit</td>
</tr>
<tr>
<td>Sodium content</td>
<td>Not more than 12.4 % on anhydrous basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

#### Synonyms

- Sodium carboxymethyl cellulose, enzymatically hydrolysed

#### Definition

Enzymatically hydrolysed carboxymethylcellulose is obtained from carboxymethylcellulose by enzymatic digestion with a cellulase produced by *Trichoderma longibrachiatum* (formerly *T. reesei*).

#### Einecs

- Chemical name: Carboxymethyl cellulose, sodium, partially enzymatically hydrolysed
- Chemical formula: Sodium salts of polymers containing substituted anhydroglucose units with the general formula: 
  \[
  \left[\text{C}_6\text{H}_7\text{O}_2(\text{OH})_x(\text{OCH}_2\text{COONa})_y\right]_n
  \]
  where \( n \) is the degree of polymerisation, \( x = 1.50 \) to 2.80, \( y = 0.2 \) to 1.50, \( x + y = 3.0 \) (\( y \) = degree of substitution)

#### Molecular weight

- 178.14 where \( y = 0.20 \)
- 282.18 where \( y = 1.50 \)
  - Macromolecules: Not less than 800 (\( n \) about 4)

#### Assay

- Not less than 99.5 %, including mono- and disaccharides, on the dried basis
### Description
White or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder

### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Soluble in water, insoluble in ethanol</td>
</tr>
<tr>
<td>Foam test</td>
<td>Vigorously shake a 0.1% solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums</td>
</tr>
<tr>
<td>Precipitate formation</td>
<td>To 5 ml of a 0.5% solution of the sample add 5 ml of a 0.5% solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum</td>
</tr>
<tr>
<td>Colour reaction</td>
<td>Add 0.5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. Dilute 1 ml of the solution with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface</td>
</tr>
<tr>
<td>Viscosity (60% solids)</td>
<td>Not less than 2 500 kgm⁻¹ s⁻¹ at 25 °C corresponding to an average molecule weight of 5 000 Da</td>
</tr>
<tr>
<td>pH</td>
<td>Not less than 6.0 and not more than 8.5 (1% colloidal solution)</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 12% (105 °C to constant weight)</td>
</tr>
<tr>
<td>Degree of substitution</td>
<td>Not less than 0.2 and not more than 1.5 carboxymethyl groups per anhydroglucose unit on the dried basis</td>
</tr>
<tr>
<td>Sodium chloride and sodium glycolate</td>
<td>Not more than 0.5% singly or in combination</td>
</tr>
<tr>
<td>Residual enzyme activity</td>
<td>Passes test. No change in viscosity of test solution occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg</td>
</tr>
</tbody>
</table>

### E 470a SODIUM, POTASSIUM AND CALCIUM SALTS OF FATTY ACIDS

### Synonyms

### Definition
Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids.

### Einecs

### Chemical name

### Chemical formula

### Molecular weight

### Assay
Content on the anhydrous basis not less than 95% (105 °C till a constant weight)
### Description
White or creamy white light powders, flakes or semi-solids

### Identification

| Solubility | Sodium and potassium salts: soluble in water and ethanol. Calcium salts: insoluble in water, ethanol and ether |
| Test for cations | Passes test |
| Test for fatty acids | Passes test |

### Purity

| Sodium | Not less than 9% and not more than 14% expressed as Na₂O |
| Potassium | Not less than 13% and not more than 21.5% expressed as K₂O |
| Calcium | Not less than 8.5% and not more than 13% expressed as CaO |
| Unsaponifiable matter | Not more than 2% |
| Free fatty acids | Not more than 3% estimated as oleic acid |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Free alkali | Not more than 0.1% expressed as NaOH |
| Matter insoluble in alcohol | Not more than 0.2% (sodium and potassium salts only) |

### E 470b MAGNESIUM SALTS OF FATTY ACIDS

| Synonyms |
| Definition | Magnesium salts of fatty acids occurring in foods oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids |

| Einecs |
| Chemical formula |
| Molecular weight |
| Assay | Content on the anhydrous basis not less than 95% (105 °C till a constant weight) |

### Description
White or creamy-white light powders, flakes or semi-solids

### Identification

| Solubility | Insoluble in water, partially soluble in ethanol and ether |
| Test for magnesium | Passes test |
| Test for fatty acids | Passes test |

### Purity

| Magnesium | Not less than 6.5% and not more than 11% expressed as MgO |
| Free alkali | Not more than 0.1% expressed as MgO |
| Unsaponifiable matter | Not more than 2% |
| Free fatty acids | Not more than 3% estimated as oleic acid |
| Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate) |

| E 471 MONO- AND DIGLYCERIDES OF FATTY ACIDS |
| Synonyms | Glyceryl monostearate; Glyceryl monopalmitate; Glyceryl monooleate, etc.; Monostearin; Monopalmitin; Monoolein, etc.; GMS (for glyceryl monostearate) |
| Definition | Mono- and diglycerides of fatty acids consist of mixtures of glycerol mono-, di- and triesters of fatty acids occurring in food oils and fats. They may contain small amounts of free fatty acids and glycerol |

| Description | The product varies from a pale yellow to pale brown oily liquid to a white or slightly off-white hard waxy solid. The solids may be in the form of flakes, powders or small beads |

| Assay | Content of mono- and diesters: not less than 70 % |

| Purity | Water content: Not more than 2 % (Karl Fischer method) |
| Acid value | Not more than 6 |
| Free glycerol | Not more than 7 % |
| Polyglycerols | Not more than 4 % diglycerol and not more than 1 % higher polyglycerols both based on total glycerol content |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Total glycerol | Not less than 16 % and not more than 33 % |
| Sulphated ash | Not more than 0,5 % determined at 800 ± 25 °C |
E 472 a ACETIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms
Acetic acid esters of mono- and diglycerides; Acetoglycerides; Acetylated mono- and diglycerides; Acetic and fatty acid esters of glycerol

Definition
Esters of glycerol with acetic and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free acetic acid and free glycerides

Einacs

Chemical name

Chemical formula

Molecular weight

Assay

Description
Clear, mobile liquids to solids, from white to pale yellow in colour

Identification
Test for glycerol
Passes test

Test for fatty acids
Passes test

Test for acetic acid
Passes test

Solubility
Insoluble in water. Soluble in ethanol

Purity
Acids other than acetic and fatty acids
Less than 1 %

Free glycerol
Not more than 2 %

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Total acetic acid
Not less than 9 % and not more than 32 %

Free fatty acids (and acetic acid)
Not more than 3 % estimated as oleic acid

Total glycerol
Not less than 14 % and not more than 31 %

Sulphated ash
Not more than 0,5 % determined at 800 ± 25 °C

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)

E 472 b LACTIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms
Lactic acid esters of mono- and diglycerides; Lactoglycerides; Mono- and diglycerides of fatty acids esterified with lactic acid

Definition
Esters of glycerol with lactic acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free lactic acid and free glycerides

Description
Clear, mobile liquids to waxy solids of variable consistency, from white to pale yellow in colour
Identification

Test for glycerol,  Passes test
Test for fatty acids  Passes test
Test for lactic acid  Passes test
Solubility  Insoluble in cold water but dispersible in hot water

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than lactic and fatty acids</td>
<td>Less than 1 %</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Total lactic acid</td>
<td>Not less than 13 % and not more than 45 %</td>
</tr>
<tr>
<td>Free fatty acids (and lactic acid)</td>
<td>Not more than 3 % estimated as oleic acid</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 13 % and not more than 30 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 % (800 ± 25 °C)</td>
</tr>
</tbody>
</table>

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)

E 472 c CITRIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms

Citrem; Citric acid esters of mono- and diglycerides; Citroglycerides; Mono- and diglycerides of fatty acids esterified with citric acid

Definition

Esters of glycerol with citric acid and fatty acids occurring in food oils and fats. They may contain small amounts of free glycerol, free fatty acids, free citric acid and free glycerides. They may be partially or wholly neutralised with sodium, potassium or calcium salts suitable for the purpose and authorised as food additives according to this Regulation.

Description

Yellowish or light brown liquids to waxy solids or semi-solids

Identification

Test for glycerol  Passes test
Test for fatty acids  Passes test
Test for citric acid  Passes test
Solubility  Insoluble in cold water, dispersible in hot water, soluble in oils and fats, insoluble in cold ethanol
### Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than citric and fatty acids</td>
<td>Less than 1 %</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 8 % and not more than 33 %</td>
</tr>
<tr>
<td>Total citric acid</td>
<td>Not less than 13 % and not more than 50 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Non-neutralised products: not more than 0.5 % (800 ± 25 °C)</td>
</tr>
<tr>
<td></td>
<td>Partially or wholly neutralised products: not more than 10 % (800 ± 25 °C)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 130</td>
</tr>
</tbody>
</table>

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however, these substances may be present up to a maximum level of 6 % (expressed as sodium oleate).

---

**E 472 d TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS**

**Synonyms**

- Tartaric acid esters of mono- and diglycerides; Mono- and diglycerides of fatty acids esterified with tartaric acid

**Definition**

Esters of glycerol with tartaric acid and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric acid and free glycerides

**Einacs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**

**Description**

Sticky viscous yellowish liquids to hard yellow waxes

**Identification**

- Test for glycerol: Passes test
- Test for fatty acids: Passes test
- Test for tartaric acid: Passes test

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than tartaric and fatty acids</td>
<td>Less than 1.0 %</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 12 % and not more than 29 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Total tartaric acid</td>
<td>Not less than 15 % and not more than 50 %</td>
</tr>
</tbody>
</table>
Free fatty acids | Not more than 3 % estimated as oleic acid
Sulphated ash | Not more than 0,5 % (800 ± 25 °C)

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)

### E 472 e MONO- AND DIACETYLTARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

#### Synonyms
Diacetyltartaric acid esters of mono- and diglycerides; Mono-and diglycerides of fatty acids esterified with mono- and diacetyltartaric acid; Diacetyltartaric and fatty acid esters of glycerol

#### Definition
Mixed esters of glycerol with mono- and diacetyltartaric acids (obtained from tartaric acid) and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids and their combinations, and free glycerides. Contains also tartaric and acetic esters of fatty acids

#### Description
Sticky viscous liquids through a fat-like consistency to yellow waxes which hydrolyse in moist air to liberate acetic acid

#### Identification
- Test for glycerol: Passes test
- Test for fatty acids: Passes test
- Test for tartaric acid: Passes test
- Test for acetic acid: Passes test

#### Purity

<table>
<thead>
<tr>
<th>Purity criteria</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acids other than acetic, tartaric and fatty acids</td>
<td>Less than 1 %</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>Not less than 11 % and not more than 28 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 % determined at 800 ± 25 °C</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Total tartaric acid</td>
<td>Not less than 10 % and not more than 40 %</td>
</tr>
<tr>
<td>Total acetic acid</td>
<td>Not less than 8 % and not more than 32 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 40 and not more than 130</td>
</tr>
</tbody>
</table>

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)
E 472 f MIXED ACETIC AND TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES OF FATTY ACIDS

Synonyms
Mono- and diglycerides of fatty acids esterified with acetic acid and tartaric acid

Definition
Esters of glycerol with acetic and tartaric acids and fatty acids occurring in food fats and oils. They may contain small amounts of free glycerol, free fatty acids, free tartaric and acetic acids, and free glycerides. May contain mono- and diacetyltartaric esters of mono- and diglycerides of fatty acids

Description
Sticky liquids to solids, from white to pale-yellow in colour

Identification
- Test for glycerol: Passes test
- Test for fatty acids: Passes test
- Test for tartaric acid: Passes test
- Test for acetic acid: Passes test

Purity
- Acids other than acetic, tartaric and fatty acids: Less than 1.0 %
- Free glycerol: Not more than 2 %
- Total glycerol: Not less than 12 % and not more than 27 %
- Sulphated ash: Not more than 0.5 % (800 ± 25 °C)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
- Total acetic acid: Not less than 10 % and not more than 20 %
- Total tartaric acid: Not less than 20 % and not more than 40 %
- Free fatty acids: Not more than 3 % estimated as oleic acid

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)
E 473 SUCROSE ESTERS OF FATTY ACIDS

Synonyms
Sucroesters; Sugar esters

Definition
Essentially the mono-, di- and triesters of sucrose with fatty acids occurring in food fats and oils. They may be prepared from sucrose and the methyl, ethyl and vinyl esters of food fatty acids (including lauric acid) or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, dimethylformamide, ethyl acetate, propan-2-ol, 2-methyl-1-propanol, propylene glycol, methyl ethyl ketone and supercritical carbondioxide may be used for their preparation. p-methoxy phenol can be used as a stabiliser during the manufacturing procedure.

Einesc
Chemical name
Chemical formula
Molecular weight
Assay
Content not less than 80 %

Description
Stiff gels, soft solids or white to slightly greyish-white powders

Identification
Test for sugar
Passes test
Test for fatty acids
Passes test
Solubility
Sparingly soluble in water, soluble in ethanol

Purity
Sulphated ash
Not more than 2 % (800 ± 25 °C)
Free sugar
Not more than 5 %
Free fatty acids
Not more than 3 % estimated as oleic acid
p-methoxy-phenol
Not more than 100 μg/kg
Acetaldehyde
Not more than 50 mg/kg
Arsenic
Not more than 3 mg/kg
Lead
Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg
Cadmium
Not more than 1 mg/kg
Methanol
Not more than 10 mg/kg
Dimethylsulphoxide
Not more than 2 mg/kg
Dimethylformamide
Not more than 1 mg/kg
2-methyl-1-propanol
Not more than 10 mg/kg
Ethyl acetate

Propan-2-ol

Propylene glycol

Methyl ethyl ketone
Not more than 10 mg/kg

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)
**E 474 SUCROGLYCERIDES**

**Synonyms**
Sugar glycerides

**Definition**
Sucroglycerides are produced by reacting sucrose with an edible fat or oil to produce a mixture of essentially mono-, di- and triesters of sucrose and fatty acids (including lauric acid) together with residual mono-, di- and triglycerides from fat or oil. No organic solvents shall be used in their preparation other than cyclohexane, dimethylformamide, ethyl acetate, 2-methyl-1-propanol and propan-2-ol.

**Einacs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**
Content not less than 40% and not more than 60% of sucrose fatty acid esters.

**Description**
Soft solid masses, stiff gels or white to off-white powders.

**Identification**

Test for sugar
Passes test

Test for fatty acids
Passes test

Solubility
Insoluble in cold water, soluble in ethanol.

**Purity**

Sulphated ash
Not more than 2% (800 ± 25 °C)

Free sugar
Not more than 5%

Free fatty acids
Not more than 3% (estimated as oleic acid)

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

Methanol
Not more than 10 mg/kg

Dimethylformamide
Not more than 1 mg/kg

2-Methyl-1-propanol
Not more than 10 mg/kg, single or in combination

Cyclohexane
Not more than 1 mg/kg

Ethyl acetate
Not more than 350 mg/kg, single or in combination

Propan-2-ol

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6% (expressed as sodium oleate).
### E 475 POLYGLYCEROL ESTERS OF FATTY ACIDS

**Synonyms**
Polyglycerol fatty acid esters; Polyglycerin esters of fatty acid esters

**Definition**
Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetracylglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol.

**Einecs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**
Content of total fatty acid ester not less than 90 %

**Description**
Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids.

**Identification**
- Test for glycerol: Passes test
- Test for polyglycerols: Passes test
- Test for fatty acids: Passes test

**Solubility**
The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils.

**Purity**
- **Sulphated ash**: Not more than 0.5 % (800 ± 25 °C)
- **Acids other than fatty acids**: Less than 1 %
- **Free fatty acids**: Not more than 6 % estimated as oleic acid
- **Total glycerol and polyglycerol**: Not less than 18 % and not more than 60 %
- **Free glycerol and polyglycerol**: Not more than 7 %
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg

**Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate)**

### E 476 POLYGLYCEROL POLYRICINOLEATE

**Synonyms**
Glycerol esters of condensed castor oil fatty acids; Polyglycerol esters of polycondensed fatty acids from castor oil; Polyglycerol esters of interesterified ricinoleic acid; PGPR

**Definition**
Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids.
## Description
Clear, highly viscous liquid

### Identification
- **Solubility**: Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons
- **Test for glycerol**: Passes test
- **Test for polyglycerol**: Passes test
- **Test for ricinoleic acid**: Passes test
- **Refractive index**: \([n]_D^{65}\) between 1.4630 and 1.4665

### Purity
- **Polyglycerols**: The polyglycerol moiety shall be composed of not less than 75% of di-, tri- and tetruglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol
- **Hydroxyl value**: Not less than 80 and not more than 100
- **Acid value**: Not more than 6
- **Arsenic**: Not more than 3 mg/kg
- **Lead**: Not more than 2 mg/kg
- **Mercury**: Not more than 1 mg/kg
- **Cadmium**: Not more than 1 mg/kg

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**E 477 PROPANE-1,2-DIOL ESTERS OF FATTY ACIDS**

### Synonyms
Propylene glycol esters of fatty acids

### Definition
Consists of mixtures of propane-1,2-diol mono- and diesters of fatty acids occurring in food fats and oils. The alcohol moiety is exclusively propane-1,2-diol together with dimer and traces of trimer. Organic acids other than food fatty acids are absent

### Assay
Content of total fatty acid ester not less than 85%

### Description
Clear liquids or waxy white flakes, beads or solids having a bland odour

### Identification
- **Test for propylene glycol**: Passes test
- **Test for fatty acids**: Passes test
### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.5 % (800 ± 25 °C)</td>
</tr>
<tr>
<td>Acids other than fatty acids</td>
<td>Less than 1 %</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 6 % estimated as oleic acid</td>
</tr>
<tr>
<td>Total propane-1,2-diol</td>
<td>Not less than 11 % and not more than 31 %</td>
</tr>
<tr>
<td>Free propane-1,2-diol</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Dimer and trimer of propylene glycol</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate).

### E 479 b THERMALLY OXIDISED SOYA BEAN OIL INTERACTED WITH MONO- AND DIGLYCERIDES OF FATTY ACIDS

#### Synonyms
- TOSOM

#### Definition
Thermally oxidised soya bean oil interacted with mono- and diglycerides of fatty acids is a complex mixture of esters of glycerol and fatty acids found in edible fat and fatty acids from thermally oxidised soya bean oil. It is produced by interaction and deodorisation under vacuum at 130 °C of 10 % of thermally oxidised soya bean oil and 90 % mono- and diglycerides of food fatty acids. Soya bean oil is exclusively made from strains of soya beans.

#### Description
Pale yellow to light brown a waxy or solid consistency

#### Identification
- Insoluble in water. Soluble in hot oil or fat

#### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>55-65 °C</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>Not more than 1.5 % estimated as oleic acid</td>
</tr>
<tr>
<td>Free glycerol</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Total fatty acids</td>
<td>83-90 %</td>
</tr>
<tr>
<td>Total glycerol</td>
<td>16-22 %</td>
</tr>
<tr>
<td>Parameter</td>
<td>Requirement</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Fatty acid methyl esters, not forming adduct with urea</td>
<td>Not more than 9% of total fatty acid methyl esters</td>
</tr>
<tr>
<td>Fatty acids, insoluble in petroleum ether</td>
<td>Not more than 2% of total fatty acids</td>
</tr>
<tr>
<td>Peroxide value</td>
<td>Not more than 3</td>
</tr>
<tr>
<td>Epoxides</td>
<td>Not more than 0.03% oxirane oxygen</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 481 SODIUM STEAROYL-2-LACTYLATE**

**Synonyms**

Sodium stearoyl lactylate; Sodium stearoyl lactate

**Definition**

A mixture of the sodium salts of stearoyl lactylic acids and its polymers and minor amounts of sodium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used.

**Einecs**

246-929-7

**Chemical name**

Sodium di-2-stearoyl lactate

**Chemical formula**

C\(_{21}\)H\(_{39}\)O\(_4\)Na; C\(_{19}\)H\(_{35}\)O\(_4\)Na (major components)

**Molecular weight**

**Assay**

**Description**

White or slightly yellowish powder or brittle solid with a characteristic odour

**Identification**

- Test for sodium: Passes test
- Test for fatty acids: Passes test
- Test for lactic acid: Passes test
- Solubility: Insoluble in water. Soluble in ethanol

**Purity**

- Sodium: Not less than 2.5% and not more than 5%
- Ester value: Not less than 90 and not more than 190
- Acid value: Not less than 60 and not more than 130
- Total lactic acid: Not less than 15% and not more than 40%
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Cadmium: Not more than 1 mg/kg
E 482 CALCIUM STEAROYL-2-LACTYLATE

Synonyms
Calcium stearoyl lactate

Definition
A mixture of the calcium salts of stearoyl lactylic acids and its polymers and minor amounts of calcium salts of other related acids, manufactured by the reaction of stearic acid and lactic acid. Other food fatty acids may also be present, free or esterified, due to their presence in the stearic acid used

Eines
227-335-7

Chemical name
Calcium di-2-stearoyl lactate
Calcium di(2-stearoyloxy)propionate

Chemical formula
C_{42}H_{78}O_{8}Ca; C_{38}H_{70}O_{8}Ca, C_{40}H_{74}O_{8}Ca (major components)

Molecular weight

Assay

Description
White or slightly yellowish powder or brittle solid with a characteristic odour

Identification
Test for calcium
Passes test

Test for fatty acids
Passes test

Test for lactic acid
Passes test

Solubility
Slightly soluble in hot water

Purity
Calcium
Not less than 1 % and not more than 5,2 %

Ester value
Not less than 125 and not more than 190

Total lactic acid
Not less than 15 % and not more than 40 %

Acid value
Not less than 50 and not more than 130

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg

Cadmium
Not more than 1 mg/kg

E 483 STEARYL TARTRATE

Synonyms
Stearyl palmityl tartrate

Definition
Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials

Eines

Chemical name
Distearyl tartrate
Dipalmityl tartrate
Stearylpalmityl tartrate
Chemical formula  \( C_{40}H_{78}O_6 \) (Distearyl tartrate)  
\( C_{36}H_{70}O_6 \) (Dipalmityl tartrate)  
\( C_{38}H_{74}O_6 \) (Stearylpalmityl tartrate)  
Molecular weight  655 (Distearyl tartrate)  
599 (Dipalmityl tartrate)  
627 (Stearylpalmityl tartrate)  
Assay  Content of total ester not less than 90 % corresponding to an ester value of not less than 163 and not more than 180  
Description  Cream-coloured unctuous solid (at 25 °C)  
Identification  Test for tartrate  Passes test  
Melting range  Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49 °C to 55 °C  
Purity  Hydroxyl value  Not less than 200 and not more than 220  
Acid value  Not more than 5,6  
Total tartaric acid  Not less than 18 % and not more than 35 %  
Sulphated ash  Not more than 0,5 % (800 ± 25 °C)  
Arsenic  Not more than 3 mg/kg  
Lead  Not more than 2 mg/kg  
Mercury  Not more than 1 mg/kg  
Cadmium  Not more than 1 mg/kg  
Unsaponifiable matter  Not less than 77 % and not more than 83 %  
Iodine value  Not more than 4 (Wijs method)  

E 491 SORBITAN MONOSTEARATE  
Synonyms  
Definition  A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid  
Einecs  215-664-9  
Chemical name  
Chemical formula  
Molecular weight  
Assay  Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters  
Description  Light, cream- to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour
Identification
Solubility
Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol and aniline; insoluble in petroleum ether and acetone; insoluble in cold water but dispersible in warm water; soluble with haze at temperatures above 50 °C in mineral oil and ethyl acetate
Congealing range
50-52 °C
Infrared absorption spectrum
Characteristic of a partial fatty acid ester of a polyol

Purity
Water content
Not more than 2 % (Karl Fischer method)
Sulphated ash
Not more than 0.5 %
Acid value
Not more than 10
Saponification value
Not less than 147 and not more than 157
Hydroxyl value
Not less than 235 and not more than 260
Arsenic
Not more than 3 mg/kg
Lead
Not more than 2 mg/kg
Mercury
Not more than 1 mg/kg
Cadmium
Not more than 1 mg/kg

E 492 SORBITAN TRISTEARATE

Synonyms
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid

Definition
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial stearic acid

Eines
247-891-4
Chemical name
Chemical formula
Molecular weight
Assay
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters

Description
Light, cream- to tan-coloured beads or flakes or hard, waxy solid with a slight odour

Identification
Solubility
Slightly soluble in toluene, ether, carbon tetrachloride and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone and dioxane; insoluble in water, methanol and ethanol
Congealing range
47-50 °C
Infrared absorption spectrum
Characteristic of a partial fatty acid ester of a polyol

Purity
Water content
Not more than 2 % (Karl Fischer method)
Sulphated ash
Not more than 0.5 %
Acid value | Not more than 15
Saponification value | Not less than 176 and not more than 188
Hydroxyl value | Not less than 66 and not more than 80
Arsenic | Not more than 3 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

E 493 SORBITAN MONOLAURATE

Synonyms
Definition
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial lauric acid
Einecs 215-663-3
Chemical name
Chemical formula
Molecular weight
Assay
Content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters
Description
Amber-coloured oily viscous liquid, light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight odour
Identification
Solubility
Dispersible in hot and cold water
Infrared absorption spectrum
Characteristic of a partial fatty acid ester of a polyol
Purity
Water content | Not more than 2 % (Karl Fischer method)
Sulphated ash | Not more than 0,5 %
Acid value | Not more than 7
Saponification value | Not less than 155 and not more than 170
Hydroxyl value | Not less than 330 and not more than 358
Arsenic | Not more than 3 mg/kg
Lead | Not more than 2 mg/kg
Mercury | Not more than 1 mg/kg
Cadmium | Not more than 1 mg/kg

E 494 SORBITAN MONOOLEATE

Synonyms
Definition
A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial oleic acid. Major constituent is 1,4-sorbitan monooleate. Other constituents include isosorbide monooleate, sorbitan dioleate and sorbitan trioleate
### E 495 SORBITAN MONOPALMITATE

**Synonyms**
- Sorbitan palmitate

**Definition**
- A mixture of the partial esters of sorbitol and its anhydrides with edible, commercial palmitic acid

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Chemical formula</th>
<th>Molecular weight</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td></td>
<td>247-568-8</td>
<td></td>
</tr>
</tbody>
</table>

**Description**
- Light cream to tan-coloured beads or flakes or a hard, waxy solid with a slight characteristic odour

**Identification**

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Iodine value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether and carbon tetrachloride. Insoluble in cold water but dispersible in warm water</td>
<td>The residue of oleic acid, obtained from the saponification of the sorbitan monooleate in assay, has a iodine value between 80 and 100</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 2 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,5 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 8</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 145 and not more than 160</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 193 and not more than 210</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Property</td>
<td>Specification</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-------------------------------------------------------------------</td>
</tr>
<tr>
<td>Congealing range</td>
<td>45-47 °C</td>
</tr>
<tr>
<td>Infrared absorption spectrum</td>
<td>Characteristic of a partial fatty acid ester of polyol</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Water content</td>
<td>Not more than 2 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Sulphate ash</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not more than 7.5</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 140 and not more than 150</td>
</tr>
<tr>
<td>Hydroxyl value</td>
<td>Not less than 270 and not more than 305</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 500 (i) SODIUM CARBONATE**

**Synonyms**

<table>
<thead>
<tr>
<th>Synonym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soda ash</td>
<td>Colourless crystals or white, granular or crystalline powder</td>
</tr>
</tbody>
</table>

**Definition**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS</td>
<td>207-838-8</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium carbonate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>( \text{Na}_2\text{CO}_3 \cdot \text{nH}_2\text{O} \ (n = 0, 1 or 10) )</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>106.00 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99% of ( \text{Na}_2\text{CO}_3 ) on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

The anhydrous form is hygroscopic, the decahydrate efflorescent.

**Identification**

<table>
<thead>
<tr>
<th>Property</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for carbonate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 2% (anhydrous), 15% (monohydrate) or 55%-65% (decahydrate) (70 °C raising gradually to 300 °C, to constant weight)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### E 500 (ii) SODIUM HYDROGEN CARBONATE

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Sodium bicarbonate; sodium acid carbonate; Bicarbonate of soda; Baking soda</th>
</tr>
</thead>
</table>
| **Definition** | **Einecs** 205-633-8  
  Chemical name: Sodium hydrogen carbonate  
  Chemical formula: NaHCO₃  
  Molecular weight: 84.01  
  Assay: Content not less than 99 % on the anhydrous basis |
| **Description** | Colourless or white crystalline masses or crystalline powder |
| **Identification** | Test for sodium: Passes test  
  Test for carbonate: Passes test  
  pH: Between 8.0 and 8.6 (1 % solution)  
  Solubility: Soluble in water. Insoluble in ethanol |
| **Purity** | Loss on drying: Not more than 0.25 % (over silica gel, 4 hours)  
  Ammonium salts: No odour of ammonia detectable after heating  
  Arsenic: Not more than 3 mg/kg  
  Lead: Not more than 2 mg/kg  
  Mercury: Not more than 1 mg/kg |

### E 500 (iii) SODIUM SESQUICARBONATE

| **Synonyms** |  |
|--------------|  |
| **Definition** | **Einecs** 208-580-9  
  Chemical name: Sodium monohydrogen dicarbonate  
  Chemical formula: Na₂CO₃ · NaHCO₃ · 2H₂O  
  Molecular weight: 226.03  
  Assay: Content between 35.0 % and 38.6 % of NaHCO₃ and between 46.4 % and 50.0 % of Na₂CO₃ |
| **Description** | White flakes, crystals or crystalline powder |
| **Identification** | Test for sodium: Passes test  
  Test for carbonate: Passes test  
  Solubility: Freely soluble in water |
Purity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 20 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 501 (i) POTASSIUM CARBONATE**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>EINECS</th>
<th>209-529-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Potassium carbonate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$K_2CO_3 \cdot nH_2O$ (n = 0 or 1.5)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>138.21 (anhdyrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

White, very deliquescent powder.
The hydrate occurs as small, white, translucent crystals or granules

**Identification**

- Test for potassium: Passes test
- Test for carbonate: Passes test
- Solubility: Very soluble in water. Insoluble in ethanol

**Purity**

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 5 % (anhdyrous) or 18 % (hydrate) (180 °C, 4 hours)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 501 (ii) POTASSIUM HYDROGEN CARBONATE**

**Synonyms**

Potassium bicarbonate; Acid potassium carbonate

**Definition**

<table>
<thead>
<tr>
<th>EINECS</th>
<th>206-059-0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Potassium hydrogen carbonate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$KHCO_3$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>100.11</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0 % and not more than 101.0 % $KHCO_3$ on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Colourless crystals or white powder or granules</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>Test for potassium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for carbonate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water. Insoluble in ethanol</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.25 % (over silica gel, 4 hours)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 503 (i) AMMONIUM CARBONATE**

**Synonyms**

**Definition**

Ammonium carbonate consists of ammonium carbamate, ammonium carbonate and ammonium hydrogen carbonate in varying proportions

**Einecs**
233-786-0

**Chemical name**
Ammonium carbonate

**Chemical formula**
CH₆N₂O₂, CH₈N₂O₃ and CH₅NO₃

**Molecular weight**
Ammonium carbamate 78.06; ammonium carbonate 98.73; ammonium hydrogen carbonate 79.06

**Assay**
Content not less than 30.0 % and not more than 34.0 % of NH₃

**Description**
White powder or hard, white or translucent masses or crystals. Becomes opaque on exposure to air and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide

**Identification**

Test for ammonium
Passes test

Test for carbonate
Passes test

**pH**
About 8.6 (5 % solution)

**Solubility**
Soluble in water

**Purity**

Non-volatile matter
Not more than 500 mg/kg

Chlorides
Not more than 30 mg/kg

Sulphate
Not more than 30 mg/kg

Arsenic
Not more than 3 mg/kg

Lead
Not more than 2 mg/kg

Mercury
Not more than 1 mg/kg
E 503 (ii) AMMONIUM HYDROGEN CARBONATE

Synonyms
Ammonium bicarbonate

Definition
Einecs 213-911-5
Chemical name Ammonium hydrogen carbonate
Chemical formula CH$_3$NO$_3$
Molecular weight 79.06
Assay Content not less than 99.0 %

Description
White crystals or crystalline powder

Identification
Test for ammonium Passes test
Test for carbonate Passes test
pH About 8.0 (5 % solution)
Solubility Freely soluble in water. Insoluble in ethanol

Purity
Non-volatile matter Not more than 500 mg/kg
Chlorides Not more than 30 mg/kg
Sulphate Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 2 mg/kg
Mercury Not more than 1 mg/kg

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.
Einecs 208-915-9
Chemical name Magnesium carbonate
Chemical formula MgCO$_3$ $\cdot$ nH$_2$O
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
Test for magnesium Passes test
Test for carbonate Passes test
Solubility Practically insoluble both in water or ethanol
### E 504 (ii) MAGNESIUM HYDROXIDE CARBONATE

**Synonyms**
Magnesium hydrogen carbonate; Magnesium subcarbonate (light or heavy); Hydrated basic magnesium carbonate; Magnesium carbonate hydroxide

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>235-192-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Magnesium carbonate hydroxide hydrated</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>4MgCO₃Mg(OH)₂·5H₂O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>485</td>
</tr>
<tr>
<td>Assay</td>
<td>Mg content not less than 40.0 % and not more than 45.0 % calculated as MgO</td>
</tr>
</tbody>
</table>

**Description**
Light, white friable mass or bulky white powder

**Identification**
- Test for magnesium: Passes test
- Test for carbonate: Passes test
- 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 0.4 %
- Arsenic: Not more than 4 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

### E 507 HYDROCHLORIC ACID

**Synonyms**
Hydrogen chloride; Muriatic acid

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-595-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Hydrochloric acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>HCl</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>36.46</td>
</tr>
</tbody>
</table>
**Assay**

Hydrochloric acid is commercially available in varying concentrations. Concentrated hydrochloric acid contains not less than 35.0 % HCl

### Description

Clear, colourless or slightly yellowish, corrosive liquid having a pungent odour

### Identification

| Test for acid | Passes test |
| Test for chloride | Passes test |
| Solubility | Soluble in water and in ethanol |

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total organic compounds</td>
<td>Total organic compounds (non-fluorine containing): not more than 5 mg/kg</td>
</tr>
<tr>
<td>Non-volatile matter</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 70 mg/kg (as SO₂)</td>
</tr>
<tr>
<td>Oxidising substances</td>
<td>Not more than 30 mg/kg (as Cl₂)</td>
</tr>
<tr>
<td>Sulphate</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

---

**E 508 POTASSIUM CHLORIDE**

### Synonyms

Sylvine; Sylvite

### Definition

| Einecs | 231-211-8 |
| Chemical name | Potassium chloride |
| Chemical formula | KCl |
| Molecular weight | 74.56 |
| Assay | Content not less than 99 % on the dried basis |

### Description

Colourless, elongated, prismatic or cubital crystals or white granular powder. Odourless

### Identification

| Solubility | Freely soluble in water. Insoluble in ethanol |
| Test for potassium | Passes test |
| Test for chloride | Passes test |
### E 509 CALCIUM CHLORIDE

**Synonyms**

Einecs 233-140-8

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Calcium chloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>CaCl&lt;sub&gt;2&lt;/sub&gt; · nH&lt;sub&gt;2&lt;/sub&gt;O (n = 0,2 or 6)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>110,99 (anhydrous), 147,02 (dihydrate), 219,08 (hexahydrate)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 93,0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

White, odourless, hygroscopic powder or deliquescent crystals

**Identification**

- Test for calcium: Passes test
- Test for chloride: Passes test
- Solubility: Soluble in water and in ethanol

**Purity**

- Magnesium and alkali salts: Not more than 5 % on the dried basis (calculated as sulphates)
- Fluoride: Not more than 40 mg/kg
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

### E 511 MAGNESIUM CHLORIDE

**Synonyms**

Einecs 232-094-6

**Definition**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Magnesium chloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>MgCl&lt;sub&gt;2&lt;/sub&gt; · 6H&lt;sub&gt;2&lt;/sub&gt;O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>203,30</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,0 %</td>
</tr>
</tbody>
</table>
**E 512 STANNOUS CHLORIDE**

**Synonyms**
- Tin chloride; Tin dichloride

**Definition**
- **Einecs**: 231-868-0
- **Chemical name**: Stannous chloride dihydrate
- **Chemical formula**: SnCl₂ · 2H₂O
- **Molecular weight**: 225.63
- **Assay**: Content not less than 98.0 %

**Description**
- Colourless or white crystals
- May have a slight odour of hydrochloric acid

**Identification**
- Test for tin (II): Passes test
- Test for chloride: Passes test
- Solubility: Water: soluble in less than its own weight of water, but it forms an insoluble basic salt with excess water
- Ethanol: soluble

**Purity**
- Sulphate: Not more than 30 mg/kg
- Arsenic: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg
- Lead: Not more than 2 mg/kg

---

**E 513 SULPHURIC ACID**

**Synonyms**
- Oil of vitriol; Dihydrogen sulphate

**Definition**
- **Einecs**: 231-639-5
- **Chemical name**: Sulphuric acid
Chemical formula | $\text{H}_2\text{SO}_4$
Molecular weight | 98.07
Assay | Sulphuric acid is commercially available in varying concentrations. The concentrated form contains not less than 96.0 %

**Description**
Clear, colourless or slightly brown, very corrosive oily liquid

**Identification**
- Test for acid: Passes test
- Test for sulphate: Passes test
- Solubility: Miscible with water, with generation of much heat, also with ethanol

**Purity**
- Ash: Not more than 0.02 %
- Reducing matter: Not more than 40 mg/kg (as SO$_3$)
- Nitrate: Not more than 10 mg/kg (on H$_2$SO$_4$ basis)
- Chloride: Not more than 50 mg/kg
- Iron: Not more than 20 mg/kg
- Selenium: Not more than 20 mg/kg
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 514 (i) SODIUM SULPHATE**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sodium sulphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Na$_2$SO$_4$ · nH$_2$O (n = 0 or 10)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>142.04 (anhydrous)</td>
</tr>
<tr>
<td></td>
<td>322.04 (decahydrate)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**
Colourless crystals or a fine, white, crystalline powder
The decahydrate is efflorescent

**Identification**
- Test for sodium: Passes test
- Test for sulphate: Passes test
- $pH$: Neutral or slightly alkaline to litmus paper (5 % solution)
Purity

| Loss on drying | Not more than 1.0 % (anhydrous) or not more than 57 % (decahydrate) at 130 °C |
| Selenium      | Not more than 30 mg/kg |
| Arsenic       | Not more than 3 mg/kg |
| Lead          | Not more than 2 mg/kg |
| Mercury       | Not more than 1 mg/kg |

E 514 (ii) SODIUM HYDROGEN SULPHATE

Synonyms  
Acid sodium sulphate; Sodium bisulphate; Nitre cake

Definition

- Chemical name: Sodium hydrogen sulphate
- Chemical formula: NaHSO₄
- Molecular weight: 120.06
- Assay: Content not less than 95.2 %

Description  
White, odourless crystals or granules

Identification

- Test for sodium: Passes test
- Test for sulphate: Passes test
- pH: Solutions are strongly acidic

Purity

| Loss on drying | Not more than 0.8 % |
| Water insoluble matter | Not more than 0.05 % |
| Selenium      | Not more than 30 mg/kg |
| Arsenic       | Not more than 3 mg/kg |
| Lead          | Not more than 2 mg/kg |
| Mercury       | Not more than 1 mg/kg |

E 515 (i) POTASSIUM SULPHATE

Synonyms

Definition

- Einces
- Chemical name: Potassium sulphate
- Chemical formula: K₂SO₄
- Molecular weight: 174.25
- Assay: Content not less than 99.0 %
### E 515 (ii) POTASSIUM HYDROGEN SULPHATE

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Potassium bisulphate; Potassium acid sulphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td><strong>Einecs</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Chemical name</strong> Potassium hydrogen sulphate</td>
</tr>
<tr>
<td></td>
<td><strong>Chemical formula</strong> KHSO₄</td>
</tr>
<tr>
<td></td>
<td><strong>Molecular weight</strong> 136.17</td>
</tr>
<tr>
<td></td>
<td><strong>Assay</strong> Content not less than 99 %</td>
</tr>
<tr>
<td>Description</td>
<td>White deliquescent crystals, pieces or granules</td>
</tr>
<tr>
<td>Identification</td>
<td><strong>Melting point</strong> 197 °C</td>
</tr>
<tr>
<td></td>
<td><strong>Test for potassium</strong> Passes test</td>
</tr>
<tr>
<td></td>
<td><strong>Solubility</strong> Freely soluble in water, insoluble in ethanol</td>
</tr>
<tr>
<td>Purity</td>
<td><strong>Selenium</strong> Not more than 30 mg/kg</td>
</tr>
<tr>
<td></td>
<td><strong>Arsenic</strong> Not more than 3 mg/kg</td>
</tr>
<tr>
<td></td>
<td><strong>Lead</strong> Not more than 2 mg/kg</td>
</tr>
<tr>
<td></td>
<td><strong>Mercury</strong> Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 516 CALCIUM SULPHATE

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Gypsum; Selenite; Anhydrite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td><strong>Einecs</strong> 231-900-3</td>
</tr>
<tr>
<td></td>
<td><strong>Chemical name</strong> Calcium sulphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>CaSO₄ · nH₂O (n = 0 or 2)</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>136,14 (anhydrous), 172,18 (dihydrate)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

Fine, white to slightly yellowish-white odourless powder

**Identification**

- Test for calcium: Passes test
- Test for sulphate: Passes test
- Solubility: Slightly soluble in water, insoluble in ethanol

**Purity**

- Loss on drying: Anhydrous: not more than 1,5 % (250 °C, constant weight)  
  Dihydrate: not more than 23 % (250 °C, constant weight)
- Fluoride: Not more than 30 mg/kg
- Selenium: Not more than 30 mg/kg
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg
- Mercury: Not more than 1 mg/kg

---

**E 517 AMMONIUM SULPHATE**

**Synonyms**

**Definition**

- Einecs: 231-984-1
- Chemical name: Ammonium sulphate
- Chemical formula: (NH₄)₂SO₄
- Molecular weight: 132,14
- Assay: Content not less than 99,0 % and not more than 100,5 %

**Description**

White powder, shining plates or crystalline fragments

**Identification**

- Test for ammonium: Passes test
- Test for sulphate: Passes test
- Solubility: Freely soluble in water, insoluble in ethanol

**Purity**

- Loss on ignition: Not more than 0,25 %
- Selenium: Not more than 30 mg/kg
- Lead: Not more than 3 mg/kg

---
**E 520 ALUMINIUM SULPHATE**

**Synonyms**
- Alum

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>Aluminium sulphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Al₂(SO₄)₃</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>342,13</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99,5 % on the ignited basis</td>
</tr>
</tbody>
</table>

**Description**
- White powder, shining plates or crystalline fragments

**Identification**

<table>
<thead>
<tr>
<th>Test for aluminium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for sulphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>2,9 or above (5 % solution)</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water, insoluble in ethanol</td>
</tr>
</tbody>
</table>

**Purity**

| Loss on ignition | Not more than 5 % (500 °C, 3 hours) |
| Alkalies and alkaline earths | Not more than 0.4 % |
| Selenium | Not more than 30 mg/kg |
| Fluoride | Not more than 30 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 5 mg/kg |
| Mercury | Not more than 1 mg/kg |

**E 521 ALUMINIUM SODIUM SULPHATE**

**Synonyms**
- Soda alum; Sodium alum

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>233-277-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Aluminium sodium sulphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>AlNa(SO₄)₂ · nH₂O (n = 0 or 12)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>242,09 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content on the anhydrous basis not less than 96,5 % (anhydrous) and 99,5 % (dodecahydrate)</td>
</tr>
</tbody>
</table>

**Description**
- Transparent crystals or white crystalline powder

**Identification**

<table>
<thead>
<tr>
<th>Test for aluminium</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
</tbody>
</table>
Test for sulphate
Passes test

Solubility
Dodecahydrate is freely soluble in water. The anhydrous form is slowly soluble in water. Both forms are insoluble in ethanol

Purity

Loss on drying
Anhydrous form: not more than 10.0% (220 °C, 16 hours)
Dodecahydrate: not more than 47.2% (50-55 °C, 1 hour then 200 °C, 16 hours)

Ammonium salts
No odour of ammonia detectable after heating

Selenium
Not more than 30 mg/kg

Fluoride
Not more than 30 mg/kg

Arsenic
Not more than 3 mg/kg

Lead
Not more than 5 mg/kg

Mercury
Not more than 1 mg/kg

E 522 ALUMINIUM POTASSIUM SULPHATE

Synonyms
Potassium alum; Potash alum

Definition
Einecs 233-141-3
Chemical name Aluminium potassium sulphate dodecahydrate
Chemical formula AlK(SO₄)₂ · 12 H₂O
Molecular weight 474.38
Assay Content not less than 99.5%

Description
Large, transparent crystals or white crystalline powder

Identification
Test for aluminium Passes test
Test for potassium Passes test
Test for sulphate Passes test
pH Between 3.0 and 4.0 (10% solution)
Solubility Freely soluble in water, insoluble in ethanol

Purity
Ammonium salts No odour of ammonia detectable after heating
Selenium Not more than 30 mg/kg
Fluoride Not more than 30 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg
### E 523 ALUMINIUM AMMONIUM SULPHATE

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Ammonium alum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Einecs | 232-055-3  
| Chemical name | Aluminium ammonium sulphate  
| Chemical formula | $\text{AlNH}_4(\text{SO}_4)_2 \cdot 12 \text{H}_2\text{O}$  
| Molecular weight | 453,32  
| **Assay** | Content not less than 99,5% |
| **Description** | Large, colourless crystals or white powder |
| **Identification** |  
| Test for aluminium | Passes test  
| Test for ammonium | Passes test  
| Test for sulphate | Passes test  
| **Solubility** | Freely soluble in water, soluble in ethanol |
| **Purity** |  
| Alkali metals and alkaline earths | Not more than 0,5%  
| Selenium | Not more than 30 mg/kg  
| Fluoride | Not more than 30 mg/kg  
| Arsenic | Not more than 3 mg/kg  
| Lead | Not more than 3 mg/kg  
| Mercury | Not more than 1 mg/kg |

### E 524 SODIUM HYDROXIDE

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Caustic soda; Lye</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Einecs | 215-185-5  
| Chemical name | Sodium hydroxide  
| Chemical formula | NaOH  
| Molecular weight | 40,0  
| **Assay** | Content of solid forms not less than 98,0 % of total alkali (as NaOH). Content of solutions accordingly, based on the stated or labelled percentage of NaOH |
| **Description** | White or nearly white pellets, flakes, sticks, fused masses or other forms. Solutions are clear or slightly turbid, colourless or slightly coloured, strongly caustic and hygroscopic and when exposed to the air they absorb carbon dioxide, forming sodium carbonate |
| **Identification** |  
| Test for sodium | Passes test  
| **pH** | Strongly alkaline (1 % solution)  
| **Solubility** | Very soluble in water. Freely soluble in ethanol |
### E 525 POTASSIUM HYDROXIDE

<table>
<thead>
<tr>
<th>Purity</th>
<th>A 5 % solution is completely clear and colourless to slightly coloured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble and organic matter</td>
<td></td>
</tr>
<tr>
<td>Carbonate</td>
<td>Not more than 0,5 % (as Na(_2)CO(_3))</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 0,5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Synonyms**
- Caustic potash

**Definition**
- **Einecs**: 215-181-3
- **Chemical name**: Potassium hydroxide
- **Chemical formula**: KOH
- **Molecular weight**: 56,11
- **Assay**: Content not less than 85,0 % of alkali calculated as KOH

**Description**
- White or nearly white pellets, flakes, sticks, fused masses or other forms

**Identification**
- Test for potassium: Passes test
- **pH**: Strongly alkaline (1 % solution)
- **Solubility**: Very soluble in water. Freely soluble in ethanol

<table>
<thead>
<tr>
<th>Purity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>A 5 % solution is completely clear and colourless</td>
</tr>
<tr>
<td>Carbonate</td>
<td>Not more than 3,5 % (as K(_2)CO(_3))</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 526 CALCIUM HYDROXIDE

<table>
<thead>
<tr>
<th>Purity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water insoluble matter</td>
<td>A 5 % solution is completely clear and colourless</td>
</tr>
<tr>
<td>Carbonate</td>
<td>Not more than 3,5 % (as K(_2)CO(_3))</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**Synonyms**
- Slaked lime; Hydrated lime

**Definition**
- **Einecs**: 215-137-3
- **Chemical name**: Calcium hydroxide
- **Chemical formula**: Ca(OH)\(_2\)
- **Molecular weight**: 74,09
- **Assay**: Content not less than 92,0 %
**Description**
White powder

**Identification**
- Test for alkali: Passes test
- Test for calcium: Passes test
- 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 2 mg/kg

**E 527 AMMONIUM HYDROXIDE**

**Synonyms**
- Aqua ammonia; Strong ammonia solution

**Definition**
- Einecs
- Chemical name: Ammonium hydroxide
- Chemical formula: NH₄OH
- Molecular weight: 35.05
- Assay: Content not less than 27 % of NH₃

**Description**
Clear, colourless solution, having an exceedingly pungent, characteristic odour

**Identification**
- Test for ammonia: Passes test

**Purity**
- Non-volatile matter: Not more than 0.02 %
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg

**E 528 MAGNESIUM HYDROXIDE**

**Synonyms**

**Definition**
- Einecs
- Chemical name: Magnesium hydroxide
- Chemical formula: Mg(OH)₂
- Molecular weight: 58.32
- Assay: Content not less than 95.0 % on the anhydrous basis
<table>
<thead>
<tr>
<th>Description</th>
<th>Odourless, white bulky powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Test for magnesium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for alkali</td>
<td>Passes test</td>
</tr>
<tr>
<td>Solubility</td>
<td>Practically insoluble in water and in ethanol</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 2.0 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not more than 33 % (800 °C to constant weight)</td>
</tr>
<tr>
<td>Calcium oxide</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**E 529 CALCIUM OXIDE**

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Burnt lime</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>EINECS</td>
<td>215-138-9</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium oxide</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>CaO</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>56.08</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 95.0 % on the ignited basis</td>
</tr>
<tr>
<td>Description</td>
<td>Odourless, hard, white or greyish white masses of granules, or white to greyish powder</td>
</tr>
</tbody>
</table>

| Identification       |                              |
| Test for alkali      | Passes test                  |
| Test for calcium     | Passes test                  |
| Reaction with water  | Heat is generated on moistening the sample with water |
| Solubility           | Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol |

| Purity               |                              |
| Loss on ignition     | Not more than 10.0 % (ca. 800 °C to constant weight) |
| Acid insoluble matter| Not more than 1.0 %           |
| 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 2 mg/kg        |
E 530 MAGNESIUM OXIDE

Synonyms

Definition

Einecs
Chemical name
Chemical formula
Molecular weight
Assay

Content not less than 98,0 % on the ignited basis

Description

A very bulky, white powder known as light magnesium oxide or a relative dense, white powder known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of at least 33 ml, while 5 g of heavy magnesium oxide occupy a volume of not more than 20 ml

Identification

Test for alkali
Test for magnesium
Solubility

Practically insoluble in water. Insoluble in ethanol

Purity

Loss on ignition
Calcium oxide
Arsenic
Lead

Not more than 5,0 % (ca. 800 °C to constant weight)
Not more than 1,5 %
Not more than 3 mg/kg
Not more than 2 mg/kg

E 535 SODIUM FERROCYANIDE

Synonyms

Yellow prussiate of soda; Sodium hexacyanoferate

Definition

Einecs
Chemical name
Chemical formula
Molecular weight
Assay

Content not less than 99,0 %

Description

Yellow crystals or crystalline powder

Identification

Test for sodium
Test for ferrocyanide

Passes test
Passes test

Purity

Free moisture
Water insoluble matter
Chloride

Not more than 1,0 %
Not more than 0,03 %
Not more than 0,2 %
Sulphate | Not more than 0.1 %
Free cyanide | Not detectable
Ferricyanide | Not detectable
Lead | Not more than 5 mg/kg

**E 536 POTASSIUM FERROCYANIDE**

**Synonyms**
Yellow prussiate of potash; Potassium hexacyanoferrate

**Definition**

| Einecs | 237-722-2 |
| Chemical name | Potassium ferrocyanide |
| Chemical formula | K₄Fe(CN)₆ · 3 H₂O |
| Molecular weight | 422.4 |

**Assay**
Content not less than 99.0 %

**Description**
Lemon yellow crystals

**Identification**

| Test for potassium | Passes test |
| Test for ferrocyanide | Passes test |

**Purity**

| Free moisture | Not more than 1.0 % |
| Water insoluble matter | Not more than 0.03 % |
| Chloride | Not more than 0.2 % |
| Sulphate | Not more than 0.1 % |
| Free cyanide | Not detectable |
| Ferricyanide | Not detectable |
| Lead | Not more than 5 mg/kg |

**E 538 CALCIUM FERROCYANIDE**

**Synonyms**
Yellow prussiate of lime; Calcium hexacyanoferrate

**Definition**

| Einecs | 215-476-7 |
| Chemical name | Calcium ferrocyanide |
| Chemical formula | Ca₂Fe(CN)₆ · 12H₂O |
| Molecular weight | 508,3 |

**Assay**
Content not less than 99.0 %

**Description**
Yellow crystals or crystalline powder

**Identification**

<p>| Test for calcium | Passes test |
| Test for ferrocyanide | Passes test |</p>
<table>
<thead>
<tr>
<th>Purity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free moisture</td>
</tr>
<tr>
<td>Water insoluble matter</td>
</tr>
<tr>
<td>Chloride</td>
</tr>
<tr>
<td>Sulphate</td>
</tr>
<tr>
<td>Free cyanide</td>
</tr>
<tr>
<td>Ferricyanide</td>
</tr>
<tr>
<td>Lead</td>
</tr>
</tbody>
</table>

**E 541 SODIUM ALUMINIUM PHOSPHATE, ACIDIC**

**Synonyms**

SALP

**Definition**

Einecs 232-090-4

Chemical name

Sodium trialuminium tetradecahydrogen octaphosphate tetrahydrate (A); Trisodium dialuminium pentadecahydrogen octaphosphate (B)

Chemical formula

\( \text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O} \) (A)  
\( \text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8 \) (B)

Molecular weight

949.88 (A)  
897.82 (B)

**Assay**

Content not less than 95.0 % (both forms)

**Description**

White odourless powder

**Identification**

Test for sodium

Passes test

Test for aluminium

Passes test

Test for phosphate

Passes test

\( \text{pH} \)

Acid to litmus

Solubility

Insoluble in water. Soluble in hydrochloric acid

**Purity**

Loss on ignition

19.5-21.0 % (A) (750-800 °C, 2 hours)  
15-16 % (B) (750-800 °C, 2 hours)

Fluoride

Not more than 25 mg/kg

Arsenic

Not more than 3 mg/kg

Lead

Not more than 4 mg/kg

Cadmium

Not more than 1 mg/kg

Mercury

Not more than 1 mg/kg
### E 551 SILICON DIOXIDE

**Synonyms**
- Silica; Silicium dioxide

**Definition**
Silicon dioxide is an amorphous substance, which is produced synthetically by either a vapour-phase hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gel, or hydrous silica. Fumed silica is produced in essentially an anhydrous state, whereas the wet-process products are obtained as hydrates or contain surface absorbed water.

<table>
<thead>
<tr>
<th>EINECS</th>
<th>231-545-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Silicon dioxide</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>(SiO$_2$)$_n$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>60.08 (SiO$_2$)</td>
</tr>
</tbody>
</table>

**Assay**
Content after ignition not less than 99.0% (fumed silica) or 94.0% (hydrated forms)

**Description**
White, fluffy powder or granules. Hygroscopic

**Identification**
- Test for silica: Positive

**Purity**
- **Loss on drying**
  - Not more than 2.5% (fumed silica, 105°C, 2 hours)
  - Not more than 8.0% (precipitated silica and silica gel, 105°C, 2 hours)
  - Not more than 70% (hydrous silica, 105°C, 2 hours)
- **Loss on ignition**
  - Not more than 2.5% after drying (1 000°C, fumed silica)
  - Not more than 8.5% after drying (1 000°C, hydrated forms)
- **Soluble ionisable salts**
  - Not more than 5.0% (as Na$_2$SO$_4$)
- **Arsenic**
  - Not more than 3 mg/kg
- **Lead**
  - Not more than 5 mg/kg
- **Mercury**
  - Not more than 1 mg/kg

### E 552 CALCIUM SILICATE

**Synonyms**

**Definition**
Calcium silicate is a hydrous or anhydrous silicate with varying proportions of CaO and SiO$_2$. The product should be free of asbestos.

<table>
<thead>
<tr>
<th>EINECS</th>
<th>215-710-8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Calcium silicate</td>
</tr>
</tbody>
</table>

**Assay**
Content on the anhydrous basis:
- as SiO$_2$ not less than 50% and not more than 95%
- as CaO not less than 3% and not more than 35%

**Description**
White to off-white free-flowing powder that remains so after absorbing relatively large amounts of water or other liquids.
**Identification**

Test for silicate  | Passes test
Test for calcium | Passes test
Gel formation | Forms a gel with mineral acids

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10% (105°C, 2 hours)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not less than 5% and not more than 14% (1,000°C, constant weight)</td>
</tr>
<tr>
<td>Sodium</td>
<td>Not more than 3%</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 553a (i) MAGNESIUM SILICATE**

**Synonyms**

**Definition**

Magnesium silicate is a synthetic compound of which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5

**Assay**

Content not less than 15% of MgO and not less than 67% of SiO₂ on the ignited basis

**Description**

Very fine, white, odourless powder, free from grittiness

**Identification**

Test for magnesium | Passes test
Test for silicate | Passes test
pH | Between 7.0 and 10.8 (10% slurry)

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15% (105°C, 2 hours)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not more than 15% after drying (1,000°C, 20 min)</td>
</tr>
<tr>
<td>Water soluble salts</td>
<td>Not more than 3%</td>
</tr>
<tr>
<td>Free alkali</td>
<td>Not more than 1% (as NaOH)</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
E 553a (ii) MAGNESIUM TRISILICATE

Synonyms

Definition

Einecs 239-076-7
Chemical name Magnesium trisilicate
Chemical formula Mg₂Si₃O₈ · nH₂O (approximate composition)
Molecular weight
Assay Content not less than 29.0 % of MgO and not less than 65.0 % of SiO₂ both on the ignited basis

Description

Fine, white powder, free from grittiness

Identification

Test for magnesium Passes test
Test for silicate Passes test
pH Between 6.3 and 9.5 (5 % slurry)

Purity

Loss on ignition Not less than 17 % and not more than 34 % (1 000 °C)
Water soluble salts Not more than 2 %
Free alkali Not more than 1 % (as NaOH)
Fluoride Not more than 10 mg/kg
Arsenic Not more than 3 mg/kg
Lead Not more than 5 mg/kg
Mercury Not more than 1 mg/kg

E 553b TALC

Synonyms

Definition

Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite. The product should be free of asbestos.

Einecs 238-877-9
Chemical name Magnesium hydrogen metasilicate
Chemical formula Mg₃(Si₄O₁₀)(OH)₂
Molecular weight 379.22
Assay

Description

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

Identification

Infrared absorption spectrum Characteristic peaks at 3 677, 1 018 and 669 cm⁻¹
X-ray diffraction Peaks at 9.34/4.66/3.12 Å
Solubility Insoluble in water and ethanol
Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.5 % (105 °C, 1 hour)</td>
</tr>
<tr>
<td>Acid soluble matter</td>
<td>Not more than 6 %</td>
</tr>
<tr>
<td>Water soluble matter</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Acid-soluble iron</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

E 554 SODIUM ALUMINIUM SILICATE

Synonyms

Sodium silicoaluminate; Sodium aluminosilicate; Aluminium sodium silicate

Definition

Einecs

Chemical name
Sodium aluminium silicate

Chemical formula

Molecular weight

Assay

Content on the anhydrous basis:
— as SiO₂ not less than 66.0 % and not more than 88.0 %
— as Al₂O₃ not less than 5.0 % and not more than 15.0 %

Description

Fine white amorphous powder or beads

Identification

Test for sodium: Passes test
Test for aluminium: Passes test
Test for silicate: Passes test
pH: Between 6.5 and 11.5 (5 % slurry)

Purity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 8.0 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not less than 5.0 % and not more than 11.0 % on the anhydrous basis (1 000 °C to constant weight)</td>
</tr>
<tr>
<td>Sodium</td>
<td>Not less than 5 % and not more than 8.5 % (as Na₂O) on the anhydrous basis</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 555 POTASSIUM ALUMINIUM SILICATE

Synonyms

Mica

Definition

Natural mica consists of mainly potassium aluminium silicate (moscovite)
Einecs 310-127-6
Chemical name Potassium aluminium silicate
Chemical formula $\text{KAl}_2[\text{AlSi}_3\text{O}_{10}](\text{OH})_2$
Molecular weight 398
Assay Content not less than 98 %

**Description**
Light grey to white crystalline platelets or powder

**Identification**
Solubility Insoluble in water, diluted acids and alkali and organic solvents

**Purity**
Loss on drying Not more than 0.5 % (105 °C, 2 hours)
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 5 mg/kg

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**E 556 CALCIUM ALUMINIUM SILICATE**

**Synonyms**
Calcium aluminosilicate; Calcium silicoaluminate; Aluminium calcium silicate

**Definition**
Calcium aluminium silicate

**Description**
Fine white, free-flowing powder

**Identification**
Test for calcium Passes test
Test for aluminium Passes test
Test for silicate Passes test
### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10.0 % (105 °C, 2 hours)</td>
</tr>
<tr>
<td>Loss on ignition</td>
<td>Not less than 14.0 % and not more than 18.0 on the anhydrous basis (1 000 °C, constant weight)</td>
</tr>
<tr>
<td>Fluoride</td>
<td>Not more than 50 mg/kg</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### 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. The raw kaolinitic clay used in the production of aluminium silicate shall have a level of dioxin which does not make it injurious to health or unfit for human consumption. The product should be free of asbestos.

### Chemical name

**Aluminium Silicate (Kaolin)**

**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

- **Test for alumina**: Passes test
- **Test for silicate**: Passes test
- **X-ray diffraction**: Characteristic peaks at 7.18/3.58/2.38/1.78 Å
- **Infrared absorption spectrum**: Peaks at 3 700 and 3 620 cm\(^{-1}\)

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on ignition</td>
<td>Between 10 and 14 % (1 000 °C, constant weight)</td>
</tr>
<tr>
<td>Water soluble matter</td>
<td>Not more than 0.3 %</td>
</tr>
<tr>
<td>Acid soluble matter</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Iron</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Potassium oxide (( \text{K}_2\text{O} ))</td>
<td>Not more than 5 %</td>
</tr>
<tr>
<td>Carbon</td>
<td>Not more than 0.5 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
</tbody>
</table>
### E 570 FATTY ACIDS

**Synonyms**

Linear fatty acids, caprylic acid (C8), capric acid (C10), lauric acid (C12), myristic acid (C14), palmitic acid (C16), stearic acid (C18), oleic acid (C18:1)

**Einescs**

Octanoic acid (C8); decanoic acid (C10); dodecanoic acid (C12); tetradecanoic acid (C14); hexadecanoic acid (C16); octadecanoic acid (C18); 9-octadecenoic acid (C18:1)

**Chemical formula**

Molecular weight

**Assay**

Not less than 98 % by chromatography

**Description**

A colourless liquid or white solid obtained from oils and fats

**Identification**

Individual fatty acids can be identified by acid value, iodine value, gas chromatography

**Purity**

- Residue on ignition: Not more than 0,1 %
- Unsaponifiable matter: Not more than 1,5 %
- Water content: Not more than 0,2 % (Karl Fischer method)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg

### E 574 GLUCONIC ACID

**Synonyms**

D-gluconic acid; Dextronic acid

**Definition**

Gluconic acid is an aqueous solution of gluconic acid and gluconolactone

**Einescs**

Gluconic acid

**Chemical formula**

$C_6H_{12}O_7$ (gluconic acid)

**Molecular weight**

196.2

**Assay**

Content not less than 49.0 % (as gluconic acid)

**Description**

Colourless to light yellow, clear syrupy liquid

**Identification**

Formation of phenylhydrazine derivative

Positive. Compound formed melts between 196 °C and 202 °C with decomposition
### E 575 GLUCONO-DELTA-LACTONE

**Synonyms**
- Gluconolactone; GDL; D-Gluconic acid delta-lactone; Delta-gluconolactone

**Definition**
Glucono-delta-lactone is the cyclic 1,5-intramolecular ester of D-gluconic acid. In aqueous media it is hydrolysed to an equilibrium mixture of D-gluconic acid (55 % - 66 %) and the delta- and gamma-lactones.

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>202-016-5</td>
</tr>
<tr>
<td>Chemical name</td>
<td>D-Glucono-1,5-lactone</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₆H₁₀O₆</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>178.14</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**
Fine, white, nearly odourless, crystalline powder

**Identification**
- Formation of phenylhydrazine derivative of gluconic acid: Positive. Compound formed melts between 196 °C and 202 °C with decomposition
- Solubility: Freely soluble in water. Sparingly soluble in ethanol

**Purity**
- Water content: Not more than 0.2 % (Karl Fischer method)
- Reducing substances: Not more than 0.5 % (as D-glucose)
- Lead: Not more than 1 mg/kg

### E 576 SODIUM GLUCONATE

**Synonyms**
- Sodium salt of D-gluconic acid

**Definition**
Manufactured by fermentation or chemical catalytic oxidation

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>208-407-7</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium D-gluconate</td>
</tr>
</tbody>
</table>
**Chemical formula**  \( \text{C}_6\text{H}_{11}\text{NaO}_7 \) (anhydrous)

**Molecular weight**  218.14

**Assay**  Content not less than 99.0%

**Description**  White to tan, granular to fine, crystalline powder

**Identification**
- **Test for sodium**: Passes test
- **Test for gluconate**: Passes test
- **Solubility**: Very soluble in water. Sparingly soluble in ethanol
- **pH**: Between 6.5 and 7.5 (10 % solution)

**Purity**
- **Reducing matter**: Not more than 1.0 % (as D-glucose)
- **Lead**: Not more than 1 mg/kg

---

**E 577 POTASSIUM GLUCONATE**

**Synonyms**  Potassium salt of D-gluconic acid

**Definition**
- **Einecs**: 206-074-2
- **Chemical name**: Potassium D-gluconate
- **Chemical formula**  \( \text{C}_6\text{H}_{11}\text{KO}_7 \) (anhydrous) \( \text{C}_6\text{H}_{11}\text{KO}_7 \cdot \text{H}_2\text{O} \) (monohydrate)
- **Molecular weight**  234.25 (anhydrous) \( 252.26 \) (monohydrate)
- **Assay**  Content not less than 97.0 % and not more than 103.0 % on dried basis

**Description**  Odourless, free flowing white to yellowish white, crystalline powder or granules

**Identification**
- **Test for potassium**: Passes test
- **Test for gluconate**: Passes test
- **pH**: Between 7.0 and 8.3 (10 % solution)

**Purity**
- **Loss on drying**  Anhydrous: not more than 3.0 % (105 °C, 4 hours, vacuum) Monohydrate: not less than 6 % and not more than 7.5 % (105 °C, 4 hours, vacuum)
- **Reducing substances**: Not more than 1.0 % (as D-glucose)
- **Lead**: Not more than 2 mg/kg
E 578 CALCIUM GLUCONATE

Synonyms  Calcium salt of D-gluconic acid

Definition

- Einecs 206-075-8
- Chemical name  Calcium di-D-gluconate
- Chemical formula  $C_{12}H_{22}CaO_{14}$ (anhydrous)
  $C_{12}H_{22}CaO_{14} \cdot H_2O$ (monohydrate)
- Molecular weight  430.38 (anhydrous form)
  448.39 (monohydrate)
- Assay  anhydrous: Content not less than 98 % and not more than 102 % on the dried basis
  monohydrate: not less than 98 % and not more than 102 % on the ‘as is’ basis.

Description  Odourless, white crystalline granules or powder, stable in air

Identification

- Test for calcium  Passes test
- Test for gluconate  Passes test
- Solubility  Soluble in water, insoluble in ethanol
- pH  Between 6.0 and 8.0 (5 % solution)

Purity

- Loss on drying  Not more than 3.0 % (105 °C, 16 hours) (anhydrous)
  Not more than 2.0 % (105 °C, 16 hours) (monohydrate)
- Reducing substances  Not more than 1.0 % (as D-glucose)
- Lead  Not more than 2 mg/kg

E 579 FERROUS GLUCONATE

Synonyms

Definition

- Einecs 206-076-3
- Chemical name  Ferrous di-D-gluconate dihydrate; Iron(II) di-gluconate dihydrate
- Chemical formula  $C_{12}H_{22}FeO_{14} \cdot 2H_2O$
- Molecular weight  482.17
- Assay  Content not less than 95 % on the dried basis

Description  Pale greenish-yellow to yellowish-grey powder or granules, which may have a faint odour of burnt sugar

Identification

- Solubility  Soluble with slight heating in water. Practically insoluble in ethanol
- Test for ferrous ion  Passes test
- Formation of phenylhydrazine derivative of gluconic acid  Positive
- pH  Between 4 and 5.5 (10 % solution)
Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 10 % (105 °C, 16 hours)</td>
</tr>
<tr>
<td>Oxalic acid</td>
<td>Not detectable</td>
</tr>
<tr>
<td>Iron (Fe III)</td>
<td>Not more than 2 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 0.5 % expressed as glucose</td>
</tr>
</tbody>
</table>

E 585 FERROUS LACTATE

Synonyms
Iron(II) lactate; Iron(II) 2-hydroxy propanoate; Propanoic acid, 2-hydroxy-iron(2+) salt (2:1)

Definition
Einecs 227-608-0
Chemical name Ferrous 2-hydroxy propanoate
Chemical formula C₆H₁₀FeO₆·nH₂O (n = 2 or 3)
Molecular weight 270.02 (dihydrate)
288.03 (trihydrate)
Assay Content not less than 96 % on the dried basis

Description Greenish-white crystals or light green powder having a characteristic smell

Identification
Solubility Soluble in water. Practically insoluble in ethanol
Test for ferrous ion Passes test
Test for lactate Passes test
pH Between 4 and 6 (2 % solution)

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 18 % (100 °C, under vacuum, approximately 700 mm Hg)</td>
</tr>
<tr>
<td>Iron (Fe III)</td>
<td>Not more than 0.6 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
### E 586 4-HEXYLRESORCINOL

**Synonyms**

4-Hexyl-1,3-benzenediol; Hexylresorcinol

**Definition**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>205-257-4</td>
</tr>
<tr>
<td>Chemical name</td>
<td>4-Hexylresorcinol</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{12}H_{18}O_{2}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>197.24</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 98 % on the dried basis (4 hours at room temperature)</td>
</tr>
</tbody>
</table>

**Description**

White powder

**Identification**

<table>
<thead>
<tr>
<th>Test</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>Freely soluble in ether and acetone; very slightly soluble in water</td>
</tr>
<tr>
<td>Nitric acid test</td>
<td>To 1 ml of a saturated solution of the sample, add 1 ml of nitric acid. A light red colour appears</td>
</tr>
<tr>
<td>Bromine test</td>
<td>To 1 ml of saturated solution of the sample, add 1 ml of bromine TS. A yellow, flocculent precipitate dissolves producing a yellow solution</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>62 to 67 °C</td>
</tr>
<tr>
<td>Acidity</td>
<td>Not more than 0.05 %</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Resorcinol and other phenols</td>
<td>Shake about 1 g of the sample with 50 ml of water for a few minutes, filter, and to the filtrate add 3 drops of ferric chloride TS. No red or blue colour is produced</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 3 mg/kg</td>
</tr>
</tbody>
</table>

### E 620 GLUTAMIC ACID

**Synonyms**

L-Glutamic acid; L-α-Aminoglutaric acid

**Definition**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>200-293-7</td>
</tr>
<tr>
<td>Chemical name</td>
<td>L-Glutamic acid; L-2-amino-pentanedioic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{5}H_{9}NO_{4}</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>147.13</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0 % and not more than 101.0 % on the anhydrous basis</td>
</tr>
<tr>
<td>Solubility</td>
<td>Sparingly soluble in water; practically insoluble in ethanol or ether</td>
</tr>
</tbody>
</table>
**Description**  
White, practically odourless crystals or crystalline powder

**Identification**

- Test for glutamic acid (by thin-layer chromatography)  
  Passes test
- Specific rotation  
  \([\alpha]_D^{20}\) between + 31.5° and + 32.2°  
  (10% solution (anhydrous basis) in 2N HCl, 200 mm tube)
- pH  
  Between 3.0 and 3.5 (saturated solution)

**Purity**

- Loss on drying  
  Not more than 0.2% (80°C, 3 hours)
- Sulphated ash  
  Not more than 0.2%
- Chloride  
  Not more than 0.2%
- Pyrrolidone carboxylic acid  
  Not more than 0.2%
- Arsenic  
  Not more than 2.5 mg/kg
- Lead  
  Not more than 1 mg/kg

---

**E 621 MONOSODIUM GLUTAMATE**

**Synonyms**  
Sodium glutamate; MSG

**Definition**

- EINECS 205-538-1
- Chemical name  
  Monosodium L-glutamate monohydrate
- Chemical formula  
  \(\text{C}_5\text{H}_8\text{NaNO}_4 \cdot \text{H}_2\text{O}\)
- Molecular weight  
  187.13
- Assay  
  Content not less than 99.0% and not more than 101.0% on the anhydrous basis
- Solubility  
  Freely soluble in water; practically insoluble in ethanol or ether

**Description**  
White, practically odourless crystals or crystalline powder

**Identification**

- Test for sodium  
  Passes test
- Test for glutamic acid (by thin-layer chromatography)  
  Passes test
- Specific rotation  
  \([\alpha]_D^{20}\) between + 24.8° and + 25.3°  
  (10% solution (anhydrous basis) in 2N HCl, 200 mm tube)
- pH  
  Between 6.7 and 7.2 (5% solution)

**Purity**

- Loss on drying  
  Not more than 0.5% (98°C, 5 hours)
- Chloride  
  Not more than 0.2%
- Pyrrolidone carboxylic acid  
  Not more than 0.2%
- Lead  
  Not more than 1 mg/kg
E 622 MONOPOTASSIUM GLUTAMATE

Synonyms
Potassium glutamate; MPG

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>243-094-0</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Monopotassium L-glutamate monohydrate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$\text{C}_5\text{H}_8\text{KNO}_4 \cdot \text{H}_2\text{O}$</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>203.24</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 99.0% and not more than 101.0% on the anhydrous basis</td>
</tr>
</tbody>
</table>

Solubility
Freely soluble in water; practically insoluble in ethanol or ether

Description
White, practically odourless crystals or crystalline powder

Identification

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for potassium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for glutamic acid (by thin-layer chromatography)</td>
<td>Passes test</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>$[\alpha]_{D}^{20}$ between +22.5° and +24.0° (10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)</td>
</tr>
<tr>
<td>pH</td>
<td>Between 6.7 and 7.3 (2 % solution)</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.2 % (80 °C, 5 hours)</td>
</tr>
<tr>
<td>Chloride</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Pyrrolidone carboxylic acid</td>
<td>Not more than 0.2 %</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 623 CALCIUM DIGLUTAMATE

Synonyms
Calcium glutamate

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>242-905-5</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Monocalcium di-L-glutamate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>$\text{C}<em>{10}\text{H}</em>{16}\text{CaN}_2\text{O}_8 \cdot n\text{H}_2\text{O}$ ($n = 0, 1, 2$ or $4$)</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>332.32 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.0% and not more than 102.0% on the anhydrous basis</td>
</tr>
</tbody>
</table>

Solubility
Freely soluble in water; practically insoluble in ethanol or ether

Description
White, practically odourless crystals or crystalline powder

Identification

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for calcium</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for glutamic acid (by thin-layer chromatography)</td>
<td>Passes test</td>
</tr>
</tbody>
</table>
Specific rotation | $\alpha_D^{20}$ between +27.4° and +29.2° (for calcium diglutamate with $n = 4$) (10% solution (anhydrous basis) in 2N HCl, 200 mm tube)
---|---
Purity | 
Water content | Not more than 19.0% (for calcium diglutamate with $n = 4$) (Karl Fischer)
Chloride | Not more than 0.2%
Pyrrolidone carboxylic acid | Not more than 0.2%
Lead | Not more than 1 mg/kg

### E 624 MONOAMMONIUM GLUTamate

**Synonyms**
Ammonium glutamate

**Definition**

| Einecs | 231-447-1 |
| Chemical name | Monoammonium L-glutamate monohydrate |
| Chemical formula | C$_5$H$_{12}$N$_2$O$_4$ · H$_2$O |
| Molecular weight | 182.18 |
| 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**

| Test for ammonium | Passes test |
| Test for glutamic acid (by thin-layer chromatography) | Passes test |
| Specific rotation | $\alpha_D^{20}$ between + 25.4° and + 26.4° (10% solution (anhydrous basis) in 2N HCl, 200 mm tube) |
| pH | Between 6.0 and 7.0 (5% solution) |

**Purity**

| Loss on drying | Not more than 0.5% (50°C, 4 hours) |
| Sulphated ash | Not more than 0.1% |
| Pyrrolidone carboxylic acid | Not more than 0.2% |
| Lead | Not more than 1 mg/kg |

### E 625 MAGNESIUM DIGLUTAMATE

**Synonyms**
Magnesium glutamate

**Definition**

| Einecs | 242-413-0 |
| Chemical name | Monomagnesium di-L-glutamate tetrahydrate |
Chemical formula \( C_{16}H_{14}MgN_2O_8 \cdot 4H_2O \)
Molecular weight 388.62
Assay Content not less than 95.0 % and not more than 105.0 % on the anhydrous basis
Solubility Very soluble in water; practically insoluble in ethanol or ether

**Description**
Odourless, white or off-white crystals or powder

**Identification**
Test for magnesium Passes test
Test for glutamic acid (by thin-layer chromatography) Passes test
Specific rotation \([\alpha]_D^{20}\) between +23.8° and +24.4°
(10 % solution (anhydrous basis) in 2N HCl, 200 mm tube)
\(pH\) Between 6.4 and 7.5 (10 % solution)

**Purity**
Water content Not more than 24 % (Karl Fischer)
Chloride Not more than 0.2 %
Pyrrolidone carboxylic acid Not more than 0.2 %
Lead Not more than 1 mg/kg

---

**E 626 GUANYLIC ACID**

**Synonyms**
5'-Guanylic acid

**Definition**
Einecs 201-598-8
Chemical name Guanosine-5'-monophosphoric acid
Chemical formula \( C_{10}H_{14}N_5O_8P \)
Molecular weight 363.22
Assay Content not less than 97.0 % on the anhydrous basis
Solubility Slightly soluble in water, practically insoluble in ethanol

**Description**
Odourless, colourless or white crystals or white crystalline powder

**Identification**
Test for ribose Passes test
Test for organic phosphate Passes test
\(pH\) Between 1.5 and 2.5 (0.25 % solution)
Spectrometry Maximum absorption of a 20 mg/l solution in 0.01N HCl at 256 nm

**Purity**
Loss on drying Not more than 1.5 % (120 °C, 4 hours)
Other nucleotides Not detectable by thin-layer chromatography
Lead Not more than 1 mg/kg
E 627 DISODIUM GUANYLATE

**Synonyms**
Sodium guanylate; Sodium 5’-guanylate

**Definition**
- Einecs: 221-849-5
- Chemical name: Disodium guanosine-5’-monophosphate
- Chemical formula: $C_{10}H_{12}N_{5}Na_{2}O_{8}P \cdot nH_{2}O$ ($n = ca. 7$)
- Molecular weight: 407.19 (anhydrous)
- Assay: Content not less than 97.0 % on the anhydrous basis
- Solubility: Soluble in water, sparingly soluble in ethanol, practically insoluble in ether

**Description**
Odourless, colourless or white crystals or white crystalline powder

**Identification**
- Test for ribose: Passes test
- Test for organic phosphate: Passes test
- Test for sodium: Passes test
- pH: Between 7.0 and 8.5 (5 % solution)
- 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, 4 hours)
- Other nucleotides: Not detectable by thin-layer chromatography
- Lead: Not more than 1 mg/kg

---

E 628 DIPOTASSIUM GUANYLATE

**Synonyms**
Potassium guanylate; Potassium 5’-guanylate

**Definition**
- Einecs: 226-914-1
- Chemical name: Dipotassium guanosine-5’-monophosphate
- Chemical formula: $C_{10}H_{12}K_{2}N_{5}O_{8}P$
- Molecular weight: 439.40
- Assay: Content not less than 97.0 % on the anhydrous basis
- Solubility: Freely soluble in water, practically insoluble in ethanol

**Description**
Odourless, colourless or white crystals or white crystalline powder

**Identification**
- Test for ribose: Passes test
- Test for organic phosphate: Passes test
- Test for potassium: Passes test
- pH: Between 7.0 and 8.5 (5 % solution)
- Spectrometry: Maximum absorption of a 20 mg/l solution in 0.01N HCl at 256 nm
### E 629 CALCIUM GUANYLATE

**Synonyms**
- Calcium 5'-guanylate

**Definition**
- **Einecs**: 205-045-1
- **Chemical name**: Calcium guanosine-5'-monophosphate
- **Chemical formula**: \( \text{C}_{10}\text{H}_{12}\text{CaN}_{5}\text{O}_{8}\text{P} \cdot n\text{H}_{2}\text{O} \)
- **Molecular weight**: 401.20 (anhydrous)
- **Assay**: Content not less than 97.0 % on the anhydrous basis
- **Solubility**: Sparingly soluble in water

**Description**
- Odourless, white or off-white crystals or powder

**Identification**
- Test for ribose: Passes test
- Test for organic phosphate: Passes test
- Test for calcium: Passes test
- **pH**: Between 7.0 and 8.0 (0.05 % solution)
- **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, 4 hours)
- **Other nucleotides**: Not detectable by thin-layer chromatography
- **Lead**: Not more than 1 mg/kg

### E 630 INOSINIC ACID

**Synonyms**
- 5'-Inosinic acid

**Definition**
- **Einecs**: 205-045-1
- **Chemical name**: Inosine-5'-monophosphoric acid
- **Chemical formula**: \( \text{C}_{10}\text{H}_{13}\text{N}_{4}\text{O}_{8}\text{P} \)
- **Molecular weight**: 348.21
- **Assay**: Content not less than 97.0 % on the anhydrous basis
- **Solubility**: Freely soluble in water, slightly soluble in ethanol

**Description**
- Odourless, colourless or white crystals or powder
### Identification

<table>
<thead>
<tr>
<th>Test for ribose</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for organic phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>Between 1.0 and 2.0 (5 % solution)</td>
</tr>
<tr>
<td>Spectrometry</td>
<td>Maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 3.0 % (120 °C, 4 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 631 DISODIUM INOSINATE

#### Synonyms

| Sodium inosinate; Sodium 5'-inosinate |

#### Definition

<table>
<thead>
<tr>
<th>Einecs</th>
<th>225-146-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Disodium inosine-5'-monophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{10}H_{11}N_{4}Na_{2}O_{8}P · H_{2}O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>392.17 (anhydrous)</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97.0 % on the anhydrous basis</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water, sparingly soluble in ethanol, practically insoluble in ether</td>
</tr>
</tbody>
</table>

#### Description

| Odourless, colourless or white crystals or powder |

#### Identification

<table>
<thead>
<tr>
<th>Test for ribose</th>
<th>Passes test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for organic phosphate</td>
<td>Passes test</td>
</tr>
<tr>
<td>Test for sodium</td>
<td>Passes test</td>
</tr>
<tr>
<td>pH</td>
<td>Between 7.0 and 8.5</td>
</tr>
<tr>
<td>Spectrometry</td>
<td>Maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm</td>
</tr>
</tbody>
</table>

#### Purity

<table>
<thead>
<tr>
<th>Water content</th>
<th>Not more than 28.5 % (Karl Fischer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other nucleotides</td>
<td>Not detectable by thin-layer chromatography</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 632 DIPOTASSIUM INOSINATE

#### Synonyms

| Potassium inosinate; Potassium 5'-inosinate |

#### Definition

<table>
<thead>
<tr>
<th>Einecs</th>
<th>243-652-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Dipotassium inosine-5'-monophosphate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C_{10}H_{11}K_{2}N_{4}O_{8}P</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>424.39</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 97.0% on the anhydrous basis</td>
</tr>
<tr>
<td>Solubility</td>
<td>Freely soluble in water; practically insoluble in ethanol</td>
</tr>
</tbody>
</table>

**Description**

Odourless, colourless or white crystals or powder

**Identification**

- Test for ribose: Passes test
- Test for organic phosphate: Passes test
- Test for potassium: Passes test
- pH: Between 7.0 and 8.5 (5% solution)
- Spectrometry: Maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm

**Purity**

- Water content: Not more than 10.0% (Karl Fischer)
- Other nucleotides: Not detectable by thin-layer chromatography
- Lead: Not more than 1 mg/kg

---

**E 633 CALCIUM INOSINATE**

**Synonyms**

Calcium 5'-inosinate

**Definition**

Einecs

- Chemical name: Calcium inosine-5'-monophosphate
- Chemical formula: C_{10}H_{11}CaN_{4}O_{8}P \cdot nH_{2}O
- Molecular weight: 386.19 (anhydrous)
- Assay: Content not less than 97.0% on the anhydrous basis
- Solubility: Sparingly soluble in water

**Description**

Odourless, colourless or white crystals or powder

**Identification**

- Test for ribose: Passes test
- Test for organic phosphate: Passes test
- Test for calcium: Passes test
- pH: Between 7.0 and 8.0 (0.05% solution)
- Spectrometry: Maximum absorption of a 20 mg/l solution in 0.01N HCl at 250 nm

**Purity**

- Water content: Not more than 23.0% (Karl Fischer)
- Other nucleotides: Not detectable by thin-layer chromatography
- Lead: Not more than 1 mg/kg
### E 634 CALCIUM 5’-RIBONUCLEOTIDE

**Synonyms**

**Definition**

Einecs

Chemical name  Calcium 5’-ribonucleotide is essentially a mixture of calcium inosine-5’-monophosphate and calcium guanosine-5’-monophosphate

Chemical formula  $C_{10}H_{11}N_{4}CaO_{8}P \cdot nH_{2}O$

$C_{10}H_{12}N_{4}CaO_{8}P \cdot nH_{2}O$

Molecular weight

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

Solubility  Sparingly soluble in water

**Description**  Odourless, white or nearly white crystals or powder

**Identification**

Test for ribose  Passes test

Test for organic phosphate  Passes test

Test for calcium  Passes test

pH  Between 7.0 and 8.0 (0.05 % solution)

**Purity**

Water content  Not more than 23.0 % (Karl Fischer)

Other nucleotides  Not detectable by thin-layer chromatography

Lead  Not more than 1 mg/kg

### E 635 DISODIUM 5’-RIBONUCLEOTIDE

**Synonyms**  Sodium 5’-ribonucleotide

**Definition**

Einecs

Chemical name  Disodium 5’-ribonucleotide is essentially a mixture of disodium inosine-5’-monophosphate and disodium guanosine-5’-monophosphate

Chemical formula  $C_{10}H_{11}N_{4}O_{8}P \cdot nH_{2}O$

$C_{10}H_{12}N_{4}Na_{2}O_{8}P \cdot nH_{2}O$

Molecular weight

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

Solubility  Soluble in water, sparingly soluble in ethanol practically insoluble in ether

**Description**  Odourless, white or nearly white crystals or powder
<table>
<thead>
<tr>
<th>Identification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for ribose Passes test</td>
<td></td>
</tr>
<tr>
<td>Test for organic phosphate Passes test</td>
<td></td>
</tr>
<tr>
<td>Test for sodium Passes test</td>
<td></td>
</tr>
<tr>
<td>pH Between 7.0 and 8.5 (5 % solution)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content Not more than 26.0 % (Karl Fischer)</td>
<td></td>
</tr>
<tr>
<td>Other nucleotides Not detectable by thin-layer chromatography</td>
<td></td>
</tr>
<tr>
<td>Lead Not more than 1 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

**E 640 GLYCINE AND ITS SODIUM SALT**

(i) GLYCINE

**Synonyms**

| Aminoacetic acid; Glycocoll |

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>200-272-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Aminoacetic acid</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₂H₅NO₂</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>75.07</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.5 % on the anhydrous basis</td>
</tr>
</tbody>
</table>

**Description**

White crystals or crystalline powder

**Identification**

| Test for amino acid Passes test |

**Purity**

<table>
<thead>
<tr>
<th>Loss on drying</th>
<th>Not more than 0.2 % (105 °C, 3 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residue on ignition</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

(ii) SODIUM GLYCINATE

**Synonyms**

|  |

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>227-842-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Sodium glycinate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C₂H₃NO₂ Na</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>98</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98.5 % on the anhydrous basis</td>
</tr>
</tbody>
</table>
### Description
White crystals or crystalline powder

### Identification
| Test for amino acid | Passes test |
| Test for sodium    | Passes test |

### Purity
| Test for acetate | Passes test |
| Test for zinc    | Passes test |
| pH               | Between 6.0 and 8.0 (5 % solution) |

### E 650 ZINC ACETATE

#### Synonyms
Acetic acid, zinc salt, dihydrate

#### Definition
<table>
<thead>
<tr>
<th>Acins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc acetate dihydrate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Zinc acetate dihydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>C₄H₆O₄Zn · 2H₂O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>219.51</td>
</tr>
<tr>
<td>Assay</td>
<td>Content not less than 98 % and not more than 102 % of C₄H₆O₄Zn · 2H₂O</td>
</tr>
</tbody>
</table>

### Description
Colourless crystals or fine, off-white powder

### Identification
| Test for acetate | Passes test |
| Test for zinc    | Passes test |
| pH               | Between 6.0 and 8.0 (5 % solution) |

### Purity
| Water insoluble matter | Not more than 0.005 % |
| Chlorides             | Not more than 50 mg/kg |
| Sulphates             | Not more than 100 mg/kg |
| Alkalines and alkaline earths | Not more than 0.2 % |
| Organic volatile impurities | Passes test |
| Iron                  | Not more than 50 mg/kg |
| Arsenic               | Not more than 3 mg/kg |
| Lead                  | Not more than 20 mg/kg |
| Cadmium               | Not more than 5 mg/kg |
### E 900 DIMETHYL POLYSILOXANE

**Synonyms**
Polydimethyl siloxane; Silicone fluid; Silicone oil; Dimethyl silicone

**Definition**
Dimethylpolysiloxane is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula \((\text{CH}_3)_2\text{SiO}\) and stabilised with trimethylsiloxy end-blocking units of the formula \((\text{CH}_3)_3\text{SiO}\)

**Einecs**
Chemical name: Siloxanes and silicones, di-methyl
Chemical formula: \((\text{CH}_3)_3\text{-Si-}[\text{O-Si(\text{CH}_3)_2\text{]}_n\text{-O-Si(\text{CH}_3)_3}\)

**Molecular weight**

**Assay**
Content of total silicon not less than 37.3% and not more than 38.5%

**Description**
Clear, colourless, viscous liquid

**Identification**
- Specific gravity (25° C/25° C): Between 0.964 and 0.977
- Refractive index \([\text{n}]_D^{25}\): Between 1.400 and 1.405
- Infrared absorption spectrum: The infrared absorption spectrum of a liquid film of the sample between two sodium chloride plates exhibits relative maxima at the same wavelengths as those of a similar preparation of Dimethylpolysiloxane Reference Standard

**Purity**
- Loss on drying: Not more than 0.5% (150° C, 4h)
- Viscosity: Not less than \(1.00 \cdot 10^{-6} \text{ m}^2\text{s}^{-1}\) at 25° C
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 1 mg/kg
- Mercury: Not more than 1 mg/kg

### E 901 BEESWAX, WHITE AND YELLOW

**Synonyms**
White wax; Yellow wax

**Definition**
Yellow bees wax 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**
Chemical name: 232-383-7

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>Between 62 °C and 65 °C</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>About 0.96</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water, sparingly soluble in alcohol, very soluble in chloroform and ether</td>
</tr>
</tbody>
</table>

### Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid value</td>
<td>Not less than 17 and not more than 24</td>
</tr>
<tr>
<td>Saponification value</td>
<td>87-104</td>
</tr>
<tr>
<td>Peroxide value</td>
<td>Not more than 5</td>
</tr>
<tr>
<td>Glycerol and other polyols</td>
<td>Not more than 0.5 % (as glycerol)</td>
</tr>
<tr>
<td>Ceresin, paraffins and certain other waxes</td>
<td>Transfer 3.0 g of the sample to a 100 ml round-bottomed flask, add 30 ml of a 4% w/v solution of potassium hydroxide in aldehyde-free ethanol and boil gently under a reflux condenser for 2 h. Remove the condenser and immediately insert a thermometer. Place the flask in water at 80 °C and allow to cool, swirling the solution continuously. No precipitate is formed before the temperature reaches 65 °C, although the solution may be opalescent.</td>
</tr>
<tr>
<td>Fats, Japan wax, rosin and soaps</td>
<td>Boil 1 g of the sample for 30 min with 35 ml of a 1 in 7 solution of sodium hydroxide, maintaining the volume by the occasional addition of water, and cool the mixture. The wax separates and the liquid remains clear. Filter the cold mixture and acidify the filtrate with hydrochloric acid. No precipitate is formed.</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

### E 902 CANDELILLA WAX

#### Synonymns

- Candelilla wax is a purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisiphilitica*

#### Description

Hard, yellowish brown, opaque to translucent wax

#### Identification

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific gravity</td>
<td>About 0.98</td>
</tr>
<tr>
<td>Melting range</td>
<td>Between 68,5 °C and 72,5 °C</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water, soluble in chloroform and toluene</td>
</tr>
</tbody>
</table>
Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid value</td>
<td>Not less than 12 and not more than 22</td>
</tr>
<tr>
<td>Saponification value</td>
<td>Not less than 43 and not more than 65</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 903 CARNAUBA WAX

Synonyms

Definition: Carnauba wax is a purified wax obtained from the leaf buds and leaves of the Brazilian Mart wax palm, *Copernicia cerifera*.

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specefic gravity</td>
<td>About 0,997</td>
</tr>
<tr>
<td>Melting range</td>
<td>Between 82 °C and 86 °C</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water, partly soluble in boiling ethanol, soluble in chloroform and diethyl ether</td>
</tr>
</tbody>
</table>

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,25 %</td>
</tr>
<tr>
<td>Acid value</td>
<td>Not less than 2 and not more than 7</td>
</tr>
<tr>
<td>Ester value</td>
<td>Not less than 71 and not more than 88</td>
</tr>
<tr>
<td>Unsoaponifiable matter</td>
<td>Not less than 50 % and not more than 55 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

E 904 SHELLAC

Synonyms

Definition: Shellac is the purified and bleached lac, the resinous secretion of the insect *Laccifer (Tachardia) laca* Kerr (Fam. Coccidae).

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleached shellac</td>
<td>White shellac</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
</tr>
<tr>
<td></td>
<td>232-549-9</td>
</tr>
</tbody>
</table>
Chemical formula  
Molecular weight  
Assay  

**Description**  
*Bleached shellac* — off-white, amorphous, granular resin  
**Wax-free bleached shellac** — light yellow, amorphous, granular resin  

**Identification**  
**Solubility**  
Insoluble in water; freely (though very slowly) soluble in alcohol; slightly soluble in acetone  
**Acid value**  
Between 60 and 89  

**Purity**  
**Loss on drying**  
Not more than 6,0 % (40 °C, over silica gel, 15 hours)  
**Rosin**  
Absent  
**Wax**  
Bleached shellac: not more than 5,5 %  
Wax-free bleached shellac: not more than 0,2 %  
**Lead**  
Not more than 2 mg/kg  

**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**  
**Solubility**  
Insoluble in water, very slightly soluble in ethanol  
**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 \( 1,1 \times 10^{-5} \) m²s⁻¹ at 100 °C  
Alternative: Not less than \( 0,8 \times 10^{-5} \) m²s⁻¹ at 120 °C, if solid at 100 °C  
**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 wt %  
**Arsenic**  
Not more than 3 mg/kg  
**Lead**  
Not more than 3 mg/kg  
**Polycyclic aromatic compounds**  
Benzo(a)pyrene no more than 50 μg/kg
### E 907 HYDROGENATED POLY-1-DECENE

**Synonyms**
- Hydrogenated polydec-1-ene; Hydrogenated poly-alpha-olefin

**Definition**
- **Einecs**
- **Chemical name**
- **Chemical formula** $C_{10n}H_{20n+2}$ where $n = 3-6$
- **Molecular weight** 560 (average)
- **Assay** Not less than 98.5% of hydrogenated poly-1-decene, having the following oligomer distribution:
  - $C_{30}$: 13-37%
  - $C_{40}$: 35-70%
  - $C_{50}$: 9-25%
  - $C_{60}$: 1-7%

**Description**
- **Identification**
  - **Solubility** Insoluble in water; slightly soluble in ethanol; soluble in toluene
  - **Burning** Burns with a bright flame and a paraffin-like characteristic smell
  - **Viscosity** Between $5.7 \times 10^{-6}$ and $6.1 \times 10^{-6}$ m²s⁻¹ at 100 °C

**Purity**
- **Compounds with carbon number less than 30** Not more than 1.5%
- **Readily carbonisable substances**
  - After 10 minutes shaking in a boiling water bath, a tube of sulphuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
- **Nickel** Not more than 1 mg/kg
- **Lead** Not more than 1 mg/kg

### E 912 MONTAN ACID ESTERS

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

**Definition**
- **Einecs**
- **Chemical name** Montan acid esters
- **Chemical formula**
- **Molecular weight**
- **Assay**

**Description**
- **Identification**
  - **Density** Between 0.98 and 1.05 (20 °C)
  - **Drop point** Greater than 77 °C
Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid value</td>
<td>Not more than 40</td>
</tr>
<tr>
<td>Glycerol</td>
<td>Not more than 1 % (by gas chromatography)</td>
</tr>
<tr>
<td>Other polyols</td>
<td>Not more than 1 % (by gas chromatography)</td>
</tr>
<tr>
<td>Other wax types</td>
<td>Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Chromium</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

E 914 OXIDISED POLYETHYLENE WAX

Synonyms

Definition

Polar reaction products from mild oxidation of polyethylene

Einecs

Chemical name

Oxidised polyethylene

Chemical formula

Molecular weight

Assay

Description

Almost white flakes, powder, granules or pellets

Identification

Density

Between 0.92 and 1.05 (20 °C)

Drop point

Greater than 95 °C

Purity

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid value</td>
<td>Not more than 70</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not less than 8.1 · 10⁻³ m²s⁻¹ at 120 °C</td>
</tr>
<tr>
<td>Other wax types</td>
<td>Not detectable (by differential scanning calorimetry and/or infrared spectroscopy)</td>
</tr>
<tr>
<td>Oxygen</td>
<td>Not more than 9.5 %</td>
</tr>
<tr>
<td>Chromium</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

E 920 L-CYSTEINE

Synonyms

Definition

L-cysteine hydrochloride or hydrochloride monohydrate. Human hair may not be used as a source for this substance

Einecs

Chemical name

Chemical formula

\[ \text{C}_3\text{H}_7\text{NO}_2\text{S} \cdot \text{HCl} \cdot \text{nH}_2\text{O} \text{ (where n = 0 or 1)} \]
Molecular weight  157.62 (anhydrous)
Assay Content not less than 98.0 % and not more than 101.5 % on the anhydrous basis

**Description**
White powder or colourless crystals

**Identification**
- Solubility: Freely soluble in water and in ethanol
- Melting range: Anhydrous form melts at about 175 °C
- Specific rotation: \([\alpha]_D^{20}: \text{between } +5.0° \text{ and } +8.0° \text{ or} \ [\alpha]_D^{25}: \text{between } +4.9° \text{ and } 7.9°\)

**Purity**
- Loss on drying: Between 8.0 % and 12.0 %
- Residue on ignition: Not more than 0.1 %
- Ammonium-ion: Not more than 200 mg/kg
- Arsenic: Not more than 1.5 mg/kg
- Lead: Not more than 5 mg/kg

---

**E 927b CARBAMIDE**

**Synonyms**
Urea

**Definition**
- Einecs: 200-315-5
- Chemical name: \(\text{CH}_4\text{N}_2\text{O}\)
- Molecular weight: 60.06
- Assay: Content not less than 99.0 % on the anhydrous basis

**Description**
Colourless to white, prismatic, crystalline powder or small, white pellets

**Identification**
- Solubility: Very soluble in water
- Precipitation with nitric acid: To pass the test a white, crystalline precipitate is formed
- Colour reaction: To pass the test a reddish-violet colour is produced
- Melting range: 132 °C to 135 °C

**Purity**
- Loss on drying: Not more than 1.0 % (105 °C, 1 hour)
- Sulphated ash: Not more than 0.1 %
- Ethanol-insoluble matter: Not more than 0.04 %
- Alkalinity: Passes test
- Ammonium-ion: Not more than 500 mg/kg
| **Biuret** | Not more than 0.1 % |
| **Arsenic** | Not more than 3 mg/kg |
| **Lead** | Not more than 2 mg/kg |

**E 938 ARGON**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-147-0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Argon</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>Ar</td>
</tr>
<tr>
<td>Atomic weight</td>
<td>40</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
</tr>
</tbody>
</table>

**Description**

Colourless, odourless, non-flammable gas

**Identification**

**Purity**

<table>
<thead>
<tr>
<th>Water content</th>
<th>Not more than 0.05 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane and other hydrocarbons</td>
<td>Not more than 100 μl/l (calculated as methane)</td>
</tr>
</tbody>
</table>

**E 939 HELIUM**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-168-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Helium</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>He</td>
</tr>
<tr>
<td>Atomic weight</td>
<td>4</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 %</td>
</tr>
</tbody>
</table>

**Description**

Colourless, odourless, non-flammable gas

**Identification**

**Purity**

<table>
<thead>
<tr>
<th>Water content</th>
<th>Not more than 0.05 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane and other hydrocarbons</td>
<td>Not more than 100 μl/l (calculated as methane)</td>
</tr>
</tbody>
</table>

**E 941 NITROGEN**

**Synonyms**

**Definition**

<table>
<thead>
<tr>
<th>Einecs</th>
<th>231-783-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Nitrogen</td>
</tr>
</tbody>
</table>
Chemical formula: \( \text{N}_2 \)
Molecular weight: 28
Assay: Not less than 99%

**Description**
Colourless, odourless, non-flammable gas

**Identification**

**Purity**
- Water content: Not more than 0.05%
- Carbon monoxide: Not more than 10 μl/l
- Methane and other hydrocarbons: Not more than 100 μl/l (calculated as methane)
- Nitrogen dioxide and nitrogen oxide: Not more than 10 μl/l
- Oxygen: Not more than 1%

**E 942 NITROUS OXIDE**

**Synonyms**

**Definition**
- Einecs: 233-032-0
- Chemical name: Nitrous oxide
- Chemical formula: \( \text{N}_2\text{O} \)
- Molecular weight: 44
- Assay: Not less than 99%

**Description**
Colourless, non-flammable gas, sweetish odour

**Identification**

**Purity**
- Water content: Not more than 0.05%
- Carbon monoxide: Not more than 30 μl/l
- Nitrogen dioxide and nitrogen oxide: Not more than 10 μl/l

**E 943a BUTANE**

**Synonyms**
n-Butane

**Definition**
- Einecs
- Chemical name: Butane
- Chemical formula: \( \text{CH}_3\text{CH}_2\text{CH}_2\text{CH}_3 \)
- Molecular weight: 58.12
- Assay: Content not less than 96%

**Description**
Colourless gas or liquid with mild, characteristic odour
### Identification

Vapour pressure: 108,935 kPa at 20 °C

### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane</td>
<td>Not more than 0.15 % v/v</td>
</tr>
<tr>
<td>Ethane</td>
<td>Not more than 0.5 % v/v</td>
</tr>
<tr>
<td>Propane</td>
<td>Not more than 1.5 % v/v</td>
</tr>
<tr>
<td>Isobutane</td>
<td>Not more than 3.0 % v/v</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>Not more than 0.1 % v/v</td>
</tr>
<tr>
<td>Moisture</td>
<td>Not more than 0.005 %</td>
</tr>
</tbody>
</table>

### Definition

**E 943b ISOBUTANE**

**Synonyms**

2-Methyl propane

**Chemical name**

2-methyl propane

**Chemical formula**

(CH₂)₂CH CH₃

**Molecular weight**

58.12

**Assay**

Content not less than 94 %

**Description**

Colourless gas or liquid with mild, characteristic odour

### Identification

Vapour pressure: 205,465 kPa at 20 °C

### Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane</td>
<td>Not more than 0.15 % v/v</td>
</tr>
<tr>
<td>Ethane</td>
<td>Not more than 0.5 % v/v</td>
</tr>
<tr>
<td>Propane</td>
<td>Not more than 2.0 % v/v</td>
</tr>
<tr>
<td>n-Butane</td>
<td>Not more than 4.0 % v/v</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>Not more than 0.1 % v/v</td>
</tr>
<tr>
<td>Moisture</td>
<td>Not more than 0.005 %</td>
</tr>
</tbody>
</table>

### E 944 PROPANE

**Synonyms**

**Definition**

**Chemical name**

Propane

**Chemical formula**

CH₃CH₂CH₃

**Molecular weight**

44.09

**Assay**

Content not less than 95 %
<table>
<thead>
<tr>
<th>Description</th>
<th>Colourless gas or liquid with mild, characteristic odour</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>732,910 kPa at 20 °C</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Methane</td>
<td>Not more than 0.15 % v/v</td>
</tr>
<tr>
<td>Ethane</td>
<td>Not more than 1.5 % v/v</td>
</tr>
<tr>
<td>Isobutane</td>
<td>Not more than 2.0 % v/v</td>
</tr>
<tr>
<td>n-Butane</td>
<td>Not more than 1.0 % v/v</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>Not more than 0.1 % v/v</td>
</tr>
<tr>
<td>Moisture</td>
<td>Not more than 0.005 %</td>
</tr>
</tbody>
</table>

**E 948 OXYGEN**

**Synonyms**

**Definition**

Einecs: 231-956-9  
Chemical name: Oxygen  
Chemical formula: O₂  
Molecular weight: 32  
Assay: Not less than 99 %

**Description**  
Colourless, odourless, non-flammable gas

**Identification**

**Purity**

Water content: Not more than 0.05 %  
Methane and other hydrocarbons: Not more than 100 μl/l (calculated as methane)

**E 949 HYDROGEN**

**Synonyms**

**Definition**

Einecs: 215-605-7  
Chemical name: Hydrogen  
Chemical formula: H₂  
Molecular weight: 2  
Assay: Content not less than 99.9 %

**Description**  
Colourless, odourless, highly flammable gas
E 950 ACESULFAME K

Synonyms

Acetosulfame potassium; Potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2,2-dioxide

Definition

Einecs 259-715-3

Chemical name 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt

Chemical formula C₄H₄KNO₄S

Molecular weight 201.24

Assay Content not less than 99 % of C₄H₄KNO₄S on the anhydrous basis

Description Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose

Identification

Solubility Very soluble in water, very slightly soluble in ethanol

Ultraviolet absorption Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water

Test for potassium Passes test (test the residue obtained by igniting 2 g of the sample)

Precipitation test Add a few drops of a 10 % solution of sodium cobaltnitrite to a solution of 0.2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced

Purity

Loss on drying Not more than 1 % (105 °C, 2 hours)

Organic impurities Passes test for 20 mg/kg of UV active components

Fluoride Not more than 3 mg/kg

Lead Not more than 1 mg/kg

Mercury Not more than 1 mg/kg

E 951 ASPARTAME

Synonyms

Aspartyl phenylalanine methyl ester

Definition

Einecs 245-261-3

Chemical name N-L-α-Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbomethoxy-phenethyl)-succinamic acid-N-methyl ester

Chemical formula C₁₄H₁₈N₂O₅

Molecular weight 294.31

Assay Not less than 98 % and not more than 102 % of C₁₄H₁₈N₂O₅ on the anhydrous basis
**E 952 CYCLAMIC ACID AND ITS Na AND Ca SALTS**

(i) CYCLAMIC ACID

<table>
<thead>
<tr>
<th>Description</th>
<th>White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Solubility</td>
<td>Slightly soluble in water and in ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>Between 4.5 and 6.0 (1 in 125 solution)</td>
</tr>
<tr>
<td>Specific rotation</td>
<td>([\alpha]_D^{20}: +14.5^\circ \text{ to } +16.5^\circ) Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 4.5% (105 °C, 4 hours)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.2% (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Transmittance</td>
<td>The transmittance of a 1% solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0.95, equivalent to an absorbance of not more than approximately 0.022</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>5-Benzyl-3,6-dioxo-2-piperazineacetic acid</td>
<td>Not more than 1.5% (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>

**Synonyms**

Cyclohexylsulphamic acid; Cyclamate

**Definition**

Einecs 202-898-1

Chemical name  Cyclohexanesulphamic acid; cyclohexylaminosulphonic acid

Chemical formula  \(C_6H_{13}NO_3S\)

Molecular weight  179.24

Assay  Cyclohexylsulphamic acid contains not less than 98% and not more than the equivalent of 102% of \(C_6H_{13}NO_3S\), calculated on the anhydrous basis

**Description**

A practically colourless, white crystalline powder. Approximately 40 times as sweet as sucrose

**Identification**

Solubility   Soluble in water and in ethanol

Precipitation test  Acidify a 2% solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10% solution of sodium nitrite. A white precipitate forms.

**Purity**

| Loss on drying    | Not more than 1% (105 °C, 1 hour)                                                                |
| Selenium         | Not more than 30 mg/kg (expressed as selenium on dry weight basis)                               |
| Lead             | Not more than 1 mg/kg (expressed on dry weight basis)                                             |
(ii) SODIUM CYCLAMATE

**Synonyms**
Cyclamate; Sodium salt of cyclamic acid

**Definition**
Einecs 205-348-9
Chemical name Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate
Chemical formula $\text{C}_6\text{H}_{12}\text{NaO}_3\text{S}$ and the dihydrate form $\text{C}_6\text{H}_{12}\text{NaO}_3\text{S}.2\text{H}_2\text{O}$
Molecular weight 201.22 calculated on the anhydrous form
237.22 calculated on the hydrated form
Assay Not less than 98 % and not more than 102 % on the dried basis
Dihydrate form: not less than 84 % on the dried basis

**Description**
White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose

**Identification**
Solubility Soluble in water, practically insoluble in ethanol

**Purity**
Loss on drying Not more than 1 % (105 °C, 1 hour)
Not more than 15.2 % (105 °C, 2 hours) for the dihydrate form
Selenium Not more than 30 mg/kg (expressed as selenium on dry weight basis)
Arsenic Not more than 3 mg/kg (expressed on dry weight basis)
Lead Not more than 1 mg/kg (expressed on dry weight basis)
Cyclohexylamine Not more than 10 mg/kg (expressed on dry weight basis)
Dicyclohexylamine Not more than 1 mg/kg (expressed on dry weight basis)
Aniline Not more than 1 mg/kg (expressed on dry weight basis)

(iii) CALCIUM CYCLAMATE

**Synonyms**
Cyclamate; Calcium salt of cyclamic acid

**Definition**
Einecs 205-349-4
Chemical name Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate
Chemical formula $\text{C}_{12}\text{H}_{24}\text{CaN}_2\text{O}_6\text{S}_2$. $2\text{H}_2\text{O}$
Molecular weight 432.57
Assay Not less than 98 % and not more than 101 % on the dried basis
**E 953 ISOMALT**

**Synonyms**

Hydrogenated isomaltulose.

**Definition**

Manufactured by enzymatic conversion of sucrose with nonviable cells of *Protaminobacter rubrum* followed by catalytic hydrogenation

**EinCs**

Chemical name  
Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides:  
6-O-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and  
1-O-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)

Chemical formula  
6-O-α-D-Glucopyranosyl-D-sorbitol: C$_{12}$H$_{24}$O$_{11}$  
1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: C$_{12}$H$_{24}$O$_{11}$.2H$_2$O

Molecular weight  
6-O-α-D-Glucopyranosyl-D-sorbitol: 344,3  
1-O-α-D-Glucopyranosyl-D-mannitol dihydrate: 380,3

**Assay**

Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis.

**Description**

Odourless, white, slightly hygroscopic, crystalline mass.

**Identification**

Solubility  
Soluble in water, very slightly soluble in ethanol.

HPLC test  
Comparison with an appropriate reference standard of Isomalt shows that the 2 principal peaks in the chromatogram of the test solution are similar in retention time to the 2 principal peaks in the chromatogram obtained with the reference solution.

**Purity**

Water content  
Not more than 7 % (Karl Fischer Method)

Sulphated ash  
Not more than 0.05 % (expressed on dry weight basis)

---

**Description**

White, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose

**Identification**

Solubility  
Soluble in water, sparingly soluble in ethanol

**Purity**

Loss on drying  
Not more than 1 % (105 °C, 1 hour)
Not more than 8,5 % (140 °C, 4 hours) for the dihydrate form

Selenium  
Not more than 30 mg/kg (expressed as selenium on dry weight basis)

Arsenic  
Not more than 3 mg/kg (expressed on dry weight basis)

Lead  
Not more than 1 mg/kg (expressed on dry weight basis)

Cyclohexylamine  
Not more than 10 mg/kg (expressed on dry weight basis)

Dicyclohexylamine  
Not more than 1 mg/kg (expressed on dry weight basis)

Aniline  
Not more than 1 mg/kg (expressed on dry weight basis)
<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Mannitol</td>
<td>Not more than 3 %</td>
</tr>
<tr>
<td>D-Sorbitol</td>
<td>Not more than 6 %</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.3 % (expressed as glucose on dry weight basis)</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>

E 954 SACCHARIN AND ITS Na, K AND Ca SALTS

(i) SACCHARIN

**Synonyms**

**Definition**

Einecs 201-321-0

Chemical name  3-Oxo-2,3dihydrobenzo(d)isothiazol-1,1-dioxide

Chemical formula  C$_7$H$_5$NO$_3$S

Molecular weight  183.18

Assay  Not less than 99 % and not more than 101 % of C$_7$H$_5$NO$_3$S on the anhydrous basis

**Description**

White crystals or a white crystalline powder, odourless or with a faint, aromatic odour. Approximately between 300 and 500 times as sweet as sucrose

**Identification**

Solubility  Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol

**Purity**

Loss on drying  Not more than 1 % (105 °C, 2 hours)

Melting range  226 to 230 °C

Sulphated ash  Not more than 0.2 % (expressed on dry weight basis)

Benzoic and salicylic acid  To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

o-Toluenesulphonamide  Not more than 10 mg/kg (expressed on dry weight basis)

p-Toluenesulphonamide  Not more than 10 mg/kg (expressed on dry weight basis)

Benzoic acid p-sulphonamide  Not more than 25 mg/kg (expressed on dry weight basis)

Readily carbonisable substances  Absent

Arsenic  Not more than 3 mg/kg (expressed on dry weight basis)

Selenium  Not more than 30 mg/kg (expressed on dry weight basis)

Lead  Not more than 1 mg/kg (expressed on dry weight basis)
(ii) SODIUM SACCHARIN

Synonyms
Saccharin; Sodium salt of saccharin

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>204-886-1</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium o-benzosulphimide; sodium salt of 2,3-dihydro-3-oxobenziso-</td>
</tr>
<tr>
<td></td>
<td>sulphonazole; oxobenzisosulphonazole; 1,2-benzisothiazolin-3-one-1,</td>
</tr>
<tr>
<td></td>
<td>1-dioxide sodium salt dihydrate</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C$_7$H$_4$NNaO$_3$S·2H$_2$O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>241.19</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 99 % and not more than 101 % of C$_7$H$_4$NNaO$_3$S on</td>
</tr>
<tr>
<td></td>
<td>the anhydrous basis</td>
</tr>
</tbody>
</table>

Description
White crystals or a white crystalline efflorescent powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions

Identification

| Solubility             | Freely soluble in water, sparingly soluble in ethanol               |

Purity

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 15 % (120 °C, 4 hours)</td>
</tr>
<tr>
<td>Benzoic and salicylic acid</td>
<td>To 10 ml of a 1 in 20 solution, previously acidified with five drops</td>
</tr>
<tr>
<td></td>
<td>of acetic acid, add three drops of an approximately molar solution of</td>
</tr>
<tr>
<td></td>
<td>ferric chloride in water. No precipitate or violet colour appears</td>
</tr>
<tr>
<td>o-Toluenesulphonamide</td>
<td>Not more than 10 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>p-Toluenesulphonamide</td>
<td>Not more than 10 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Benzoic acid p-sulphonamide</td>
<td>Not more than 25 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Readily carbonisable substances</td>
<td>Absent</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Selenium</td>
<td>Not more than 30 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>

(iii) CALCIUM SACCHARIN

Synonyms
Saccharin; Calcium salt of saccharin

Definition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>229-349-9</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium o-benzosulphimide; calcium salt of 2,3-dihydro-3-oxobenziso-</td>
</tr>
<tr>
<td></td>
<td>sulphonazole; 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt</td>
</tr>
<tr>
<td></td>
<td>hydrate (2:7)</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C$_{14}$H$_8$CaN$_2$O$_6$S$_2$·3½H$_2$O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>467.48</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 95 % of C$_{14}$H$_8$CaN$_2$O$_6$S$_2$ on the anhydrous</td>
</tr>
<tr>
<td></td>
<td>basis</td>
</tr>
</tbody>
</table>

Description
White crystals or a white crystalline powder, odourless or with a faint odour. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
POTASSIUM SACCHARIN

Synonyms
Saccharin; Potassium salt of saccharin

Definition
Einecs
Chemical name: Potassium o-benzosulphimide; potassium salt of 2,3-dihydro-3-oxobenzisozosulphonazole; potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate
Chemical formula: C_{7}H_{4}KNO_{3}S·H_{2}O
Molecular weight: 239,77
Assay: Not less than 99 % and not more than 101 % of C_{7}H_{4}KNO_{3}S on the anhydrous basis

Description
White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose

Identification

Solubility
Freely soluble in water, sparingly soluble in ethanol

Purity
Loss on drying
Not more than 8 % (120 °C, 4 hours)
Benzoic and salicylic acid
To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

o-Toluenesulphonamide
Not more than 10 mg/kg (expressed on dry weight basis)
p-Toluenesulphonamide
Not more than 10 mg/kg (expressed on dry weight basis)
Benzoic acid p-sulphonamide
Not more than 25 mg/kg (expressed on dry weight basis)
Readily carbonisable substances
Absent
Arsenic
Not more than 3 mg/kg (expressed on dry weight basis)
Selenium
Not more than 30 mg/kg (expressed on dry weight basis)
Lead
Not more than 1 mg/kg (expressed on dry weight basis)
<table>
<thead>
<tr>
<th>E 955 SUCRALOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
</tr>
<tr>
<td>4,1',6'-Trichlorogalactosucrose</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
</tr>
<tr>
<td>Einecs 259-952-2</td>
</tr>
<tr>
<td>Chemical name</td>
</tr>
<tr>
<td>Chemical formula</td>
</tr>
<tr>
<td>Molecular weight</td>
</tr>
<tr>
<td>Assay</td>
</tr>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>White to off-white, practically odourless, crystalline powder.</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
</tr>
<tr>
<td>Solubility</td>
</tr>
<tr>
<td>Slightly soluble in ethyl acetate</td>
</tr>
<tr>
<td>Infrared absorption spectrum</td>
</tr>
<tr>
<td>Thin layer chromatography</td>
</tr>
<tr>
<td>Specific rotation</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
</tr>
<tr>
<td>Water content</td>
</tr>
<tr>
<td>Sulphated ash</td>
</tr>
<tr>
<td>Other chlorinated disaccharides</td>
</tr>
<tr>
<td>Chlorinated monosaccharides</td>
</tr>
<tr>
<td>Triphenylphosphine oxide</td>
</tr>
<tr>
<td>Methanol</td>
</tr>
<tr>
<td>Lead</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E 957 THAUMATIN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
</tr>
<tr>
<td><strong>Definition</strong></td>
</tr>
<tr>
<td>Einecs 258-822-2</td>
</tr>
</tbody>
</table>
**Chemical name**

Thaumatin is obtained by aqueous extraction (pH 2.5 to 4) of the arils of the fruit of strains of *Thaumatococcus daniellii* (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material.

**Chemical formula**

Polypeptide of 207 amino acids

**Molecular weight**

Thaumatin I 22209

Thaumatin II 22293

**Assay**

Not less than 15.1 % nitrogen on the dried basis equivalent to not less than 93 % proteins (N × 6.2)

**Description**

Odourless, cream-coloured powder. Approximately 2 000 to 3 000 times as sweet as sucrose.

**Identification**

Solubility

Very soluble in water, insoluble in acetone.

**Purity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 9 % (105 °C to constant weight)</td>
</tr>
<tr>
<td>Carbohydrates</td>
<td>Not more than 3 % (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 2 % (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Aluminium</td>
<td>Not more than 100 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>

**Microbiological criteria**

<table>
<thead>
<tr>
<th>Property</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total aerobic microbial count</td>
<td>Not more than 1 000 colonies per gram</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent in 1 g</td>
</tr>
</tbody>
</table>

**E 959 NEOHESPERIDINE DIHYDROCHALCONE**

**Synonyms**

Neohesperidin dihydrochalcone; NHDC; Hesperetin dihydrochalcone-4′-β-neohesperidoside; Neohesperidin DC

**Definition**

It is obtained by catalytic hydrogenation of neohesperidin.

**Einecs**

243-978-6

**Chemical name**

2-O-α-L-rhamnopyranosyl-4′-β-D-glucopyranosyl hesperetin dihydrochalcone.

**Chemical formula**

C_{28}H_{36}O_{15}

**Molecular weight**

612.6

**Assay**

Content not less than 96 % on the dried basis

**Description**

Off-white, odourless, crystalline powder. Approximately between 1 000 and 1 800 times as sweet as sucrose.

**Identification**

Solubility

Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene.

Ultraviolet absorption maximum

282 to 283 nm for a solution of 2 mg in 100 ml methanol.
Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1 % 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced.

**Purity**

- **Loss on drying**: Not more than 11 % (105 °C, 3 hours)
- **Sulphated ash**: Not more than 0,2 % (expressed on dry weight basis)
- **Arsenic**: Not more than 3 mg/kg expressed on dry weight basis
- **Lead**: Not more than 2 mg/kg (expressed on dry weight basis)

### E 960 STEVIOL GLYCOSIDES

**Synonyms**

**Definition**

The manufacturing process comprises two main phases: the first involving water extraction of the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract by employing ion exchange chromatography to yield a steviol glycoside primary extract, and the second involving recrystallisation of the steviol glycosides from methanol or aqueous ethanol resulting in a final product consisting mainly (at least 75 %) of stevioside and/or rebaudioside A.

The additive may contain residues of ion-exchange resins used in the manufacturing process. Several other related steviol glycosides that may be generated as a result of the production process, but do not occur naturally in the *Stevia rebaudiana* plant have been identified in small amounts (0,10 to 0,37 % w/w).

**Chemical name**

- Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester
- Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

**Chemical formula**

<table>
<thead>
<tr>
<th>Trivial name</th>
<th>Formula</th>
<th>Conversion factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steviol</td>
<td>C₂₀H₃₀O₃</td>
<td>1,00</td>
</tr>
<tr>
<td>Stevioside</td>
<td>C₃₈H₆₀O₁₈</td>
<td>0,40</td>
</tr>
<tr>
<td>Rebaudioside A</td>
<td>C₄₄H₇₀O₂₃</td>
<td>0,33</td>
</tr>
<tr>
<td>Rebaudioside C</td>
<td>C₄₄H₇₀O₂₂</td>
<td>0,34</td>
</tr>
<tr>
<td>Dulcoside A</td>
<td>C₄₈H₆₀O₁₇</td>
<td>0,40</td>
</tr>
<tr>
<td>Rubusoside</td>
<td>C₃₂H₅₀O₁₃</td>
<td>0,50</td>
</tr>
<tr>
<td>Steviolbioside</td>
<td>C₅₂H₅₀O₁₃</td>
<td>0,50</td>
</tr>
<tr>
<td>Rebaudioside B</td>
<td>C₃₈H₆₀O₁₈</td>
<td>0,40</td>
</tr>
<tr>
<td>Rebaudioside D</td>
<td>C₅₀H₆₀O₂₈</td>
<td>0,29</td>
</tr>
<tr>
<td>Rebaudioside E</td>
<td>C₄₄H₇₀O₂₃</td>
<td>0,33</td>
</tr>
<tr>
<td>Rebaudioside F</td>
<td>C₄₄H₆₈O₂₂</td>
<td>0,34</td>
</tr>
</tbody>
</table>

**Molecular weight and CAS No**

<table>
<thead>
<tr>
<th>Trivial name</th>
<th>CAS Number</th>
<th>Molecular weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stevioside</td>
<td>57817-89-7</td>
<td>804,87</td>
</tr>
</tbody>
</table>
Rebaudioside A  58543-16-1  967,01

Assay
Not less than 95 % stevioside, rebaudiosides A, B, C, D, E and F, steviolbioside, rubusoside and dulcoside on the dried basis.

Description
White to light yellow powder, approximately between 200 and 300 times sweeter than sucrose

Identification
Solubility
Freely soluble to slightly soluble in water
Stevioside and rebaudioside A
The main peak in the chromatogram obtained following the procedure in Method of Assay corresponds to either stevioside or rebaudioside A
pH
Between 4,5 and 7,0 (1 in 100 solution)

Purity
Total ash
Not more than 1 %
Loss on drying
Not more than 6 % (105 °C, 2h)
Residual solvents
Not more than 200 mg/kg methanol
Not more than 5 000 mg/kg ethanol
Arsenic
Not more than 1 mg/kg
Lead
Not more than 1 mg/kg

E 961 NEOTAME

Synonyms
N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester;
N(3,3-dimethylbutyl)-L-aspartyl-L-phenylalanine methyl ester.

Definition
Neotame is manufactured by reaction under hydrogen pressure of aspartame with 3,3-dimethylbutyraldehyde in methanol in presence of a palladium/carbon catalyst. It is isolated and purified by filtration, where diatomaceous earth may be used. After solvent removal via distillation, neotame is washed with water, isolated by centrifugation and finally vacuum dried.

CAS Nr. 165450-17-9

Chemical name
N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester

Chemical formula
C_{20}H_{30}N_{2}O_{5}

Molecular weight
378,47

Description
White to off-white powder

Assay
Not less than 97,0 % on the dried basis

Identification
Solubility
4,75 % (w/w) at 60 °C in water, soluble in ethanol and ethyl acetate

Purity
Water content
Not more than 5 % (Karl Fischer, sample size 25 ± 5mg)

pH
5,0-7,0 (0,5 % aqueous solution)

Melting range
81 °C to 84 °C
N-[(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine

Not more than 1.5 %

Lead

Not more than 1 mg/kg

E 962 SALT OF ASPARTAME-ACESULFAME

Synonyms
Aspartame-acesulfame; Aspartame-acesulfame salt

Definition
The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.

Einecs

Chemical name 6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-α-aspartic acid

Chemical formula C_{18}H_{23}O_{9}N_{3}S

Molecular weight 457.46

Assay 63.0 % to 66.0 % aspartame (dry basis) and 34.0 % to 37.0 % acesulfame (acid form on a dry basis)

Description
A white, odourless, crystalline powder

Identification
Solubility Sparingly soluble water; slightly soluble in ethanol

Transmittance The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0.95, equivalent to an absorbance of not more than approximately 0.022.

Specific rotation [α]_{D}^{20} + 14.5° to + 16.5°

Determine at a concentration of 6.2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0.646 to correct for the aspartame content of the salt of aspartame-acesulfame

Purity
Loss on drying Not more than 0.5 % (105 °C, 4 hours)

5-Benzyl-3,6-dioxo-2-piperazineacetic acid

Not more than 0.5 %

Lead

Not more than 1 mg/kg

E 965 (i) MALTITOL

Synonyms
D-Maltitol; Hydrogenated maltose

Definition
Maltitol is obtained by hydrogenation of D-maltose. It is mainly composed of D-maltitol. It may contain small amounts of sorbitol and related polyhydric alcohols.

Einecs

Chemical name (α)-D-Glucopyranosyl-1,4-D-glucitol

Chemical formula C_{12}H_{24}O_{11}

Molecular weight 344.3
### E 965 (ii) MALTITOL SYRUP

**Synonyms**
- Hydrogenated high-maltose-glucose syrup; Hydrogenated glucose syrup; Maltitol liquid

**Definition**
A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product.

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assay</strong></td>
<td>Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Colourless and odourless, clear viscous liquids or white crystalline masses</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>Very soluble in water, slightly soluble in ethanol</td>
</tr>
<tr>
<td><strong>HPLC test</strong></td>
<td>Comparison with an appropriate reference standard of Maltitol shows that the principle peak in the chromatogram of the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution (ISO 10504:1998).</td>
</tr>
</tbody>
</table>

---

### Assay
Content not less than 98 % D-maltitol C\(_{12}\)H\(_{24}\)O\(_{11}\) on the anhydrous basis

### Description
White crystalline powder

### Identification
- **Solubility**: Very soluble in water, slightly soluble in ethanol
- **Melting range**: 148 to 151 °C
- **Specific rotation**: \([\alpha]_D^{20} + 105,5^\circ \text{ to } + 108,5^\circ \) (5 % w/v solution)

### Purity
- **Appearance of the aqueous solution**: The solution is clear and colourless
- **Water content**: Not more than 1 % (Karl Fischer method)
- **Sulphated ash**: Not more than 0,1 % (expressed on an anhydrous basis)
- **Reducing sugars**: Not more than 0,1 % (expressed as glucose on an anhydrous basis)
- **Chlorides**: Not more than 50 mg/kg (expressed on anhydrous basis)
- **Sulphates**: Not more than 100 mg/kg (expressed on anhydrous basis)
- **Nickel**: Not more than 2 mg/kg (expressed on anhydrous basis)
- **Arsenic**: Not more than 3 mg/kg (expressed on anhydrous basis)
- **Lead**: Not more than 1 mg/kg (expressed on anhydrous basis)

---
### E 966 LACTITOL

**Synonyms**
- Lactit; Lactositol; Lactobiosit

**Definition**
Lactitol is manufactured via catalytic hydrogenation of lactose

<table>
<thead>
<tr>
<th>EINECS</th>
<th>209-566-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>4-O-β-D-Galactopyranosyl-D-glucitol</td>
</tr>
<tr>
<td>Chemical formula</td>
<td>C(<em>{12})H(</em>{22})O(_{11})</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>344.3</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 95 % on the dry weight basis</td>
</tr>
</tbody>
</table>

**Description**
Crystalline powder or colourless solution. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst.

**Identification**
Solubility: Very soluble in water

Specific rotation: \([\alpha]_D^{20} = +13^\circ \text{ to } +16^\circ\) calculated on the anhydrous basis (10 % w/v aqueous solution)

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Crystalline products; not more than 10.5 % (Karl Fischer method)</td>
</tr>
<tr>
<td>Other polyols</td>
<td>Not more than 2.5 % (on the anhydrous basis)</td>
</tr>
<tr>
<td>Reducing sugars</td>
<td>Not more than 0.2 % (expressed as glucose on dry weight basis)</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Not more than 100 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Sulphates</td>
<td>Not more than 200 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 % (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Nickel</td>
<td>Not more than 2 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg (expressed on dry weight basis)</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg (expressed on dry weight basis)</td>
</tr>
</tbody>
</table>

### E 967 XYLITOL

**Synonyms**
- Xylitol

**Definition**
Xylitol is mainly composed of D-xylitol. The part which is not D-xylitol is composed of related substances such as L-arabinitol, galactitol, mannitol, sorbitol
### D-xylitol

**Chemical name**  
D-xylitol

**Chemical formula**  
$\text{C}_5\text{H}_{12}\text{O}_5$

**Molecular weight**  
152.2

**Assay**  
Not less than 98.5 % as xylitol on the anhydrous basis

**Description**  
White, crystalline powder, practically odourless.

**Identification**

- **Solubility**  
Very soluble in water, sparingly soluble in ethanol

- **Melting range**  
92 to 96 °C

- **pH**  
5 to 7 (10 % w/v aqueous solution)

- **Infrared absorption spectroscopy**  
Comparison with a reference standard e.g. EP or USP.

**Purity**

- **Water content**  
Not more than 1% (Karl-Fischer method)

- **Sulphated ash**  
Not more than 0.1 % (expressed on dry weight basis)

- **Reducing sugars**  
Not more than 0.2 % (expressed as glucose on dry weight basis)

- **Other polyhydric alcohols**  
Not more than 1 % (expressed on dry weight basis)

- **Nickel**  
Not more than 2 mg/kg (expressed on dry weight basis)

- **Arsenic**  
Not more than 3 mg/kg (expressed on dry weight basis)

- **Lead**  
Not more than 1 mg/kg (expressed on dry weight basis)

- **Chlorides**  
Not more than 100 mg/kg (expressed on dry weight basis)

- **Sulphates**  
Not more than 200 mg/kg (expressed on dry weight basis)

---

### E 968 ERYTHRITOL

**Synonyms**  
Meso-erythritol; Tetrahydroxybutane; Erythrite

**Definition**  
Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as *Moniliella pollinis* or *Moniliella megachilensis*, followed by purification and drying

**Assay**  
Not less than 99 % after drying

**Description**  
White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.

**Identification**

- **Solubility**  
Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.

- **Melting range**  
119-123 °C
**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 0.2 % (70 °C, 6 hours, in a vacuum desiccator)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Reducing substances</td>
<td>Not more than 0.3 % expressed as D-glucose</td>
</tr>
<tr>
<td>Ribitol and glycerol</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 0.5 mg/kg</td>
</tr>
</tbody>
</table>

**E 999 QUILLAIA EXTRACT**

**Synonyms**

Soapbark extract; Quillay bark extract; Panama bark extract; Quillai extract; Murillo bark extract; China bark extract

**Definition**

Quillaia extract is obtained by aqueous extraction of *Quillaia saponaria* Molina, or other *Quillaia* species, trees of the family Rosaceae. It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components

**Description**

Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution

**Identification**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Between 3.7 and 5.5 (4 % solution)</td>
</tr>
</tbody>
</table>

**Purity**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 6.0 % (Karl Fischer method) (powder form only)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1103 INVERTASE**

**Synonyms**

**Definition**

Invertase is produced from *Saccharomyces cerevisiae*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einecs</td>
<td>232-615-7</td>
</tr>
<tr>
<td>Enzyme Commission No</td>
<td>EC 3.2.1.26</td>
</tr>
<tr>
<td>Systematic name</td>
<td>β-D-Fructofuranoside fructohydrolase</td>
</tr>
</tbody>
</table>
**Molecular weight**
Assay

**Description**

**Identification**

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 0.5 mg/kg</td>
</tr>
</tbody>
</table>

**Microbiological criteria**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total bacterial count</td>
<td>Not more than 50 000 colonies per gram</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>Absent in 25 g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>Not more than 30 colonies per gram</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absent in 25 g</td>
</tr>
</tbody>
</table>

**E 1105 LYSOZYME**

**Synonyms**
Lysozyme hydrochloride; Muramidase

**Definition**
Lysozyme is a linear polypeptide obtained from hens’ egg whites consisting of 129 amino acids. It possesses enzymatic activity in its ability to hydrolyse the \( \beta \)-(1-4) linkages between N-acetylmuramic acid and N-acetylglucosamine in the outer membranes of bacterial species, in particular gram-positive organisms. Is usually obtained as the hydrochloride.

**Einecs**
232-620-4

**Enzyme Commission No**
EC 3.2.1.17

**Chemical name**
Chemical formula
Molecular weight
About 14 000

**Assay**
Content not less than 950 mg/g on the anhydrous basis

**Description**
White, odourless powder having a slightly sweet taste

**Identification**
Isoelectric point
10.7
pH
Between 3.0 and 3.6 (2 % aqueous solution)
Spectrophotometry
Absorption maximum of an aqueous solution (25 mg/100 ml) at 281 nm, a minimum at 252 nm

**Purity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water content</td>
<td>Not more than 6.0 % (Karl Fischer method) (powder form only)</td>
</tr>
<tr>
<td>Residue on ignition</td>
<td>Not more than 1.5 %</td>
</tr>
<tr>
<td>Nitrogen</td>
<td>Not less than 16.8 % and not more than 17.8 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 5 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>
Microbiological criteria

- **Total bacterial count**: Not more than $5 \times 10^4$ colonies per gram
- **Salmonella spp.**: Absent in 25 g
- **Staphylococcus aureus**: Absent in 1 g
- **Escherichia coli**: Absent in 1 g

### E 1200 POLYDEXTROSE

**Synonyms**

Modified polydextroses

**Definition**

Randomly bonded glucose polymers with some sorbitol end-groups, and with citric acid or phosphoric acid residues attached to the polymers by mono or diester bonds. They are obtained by melting and condensation of the ingredients and consist of approximately 90 parts D-glucose, 10 parts sorbitol and 1 part citric acid and/or 0.1 part phosphoric acid. The 1,6-glucosidic linkage predominates in the polymers but other linkages are present. The products contain small quantities of free glucose, sorbitol, levoglucosan (1,6-anhydro-D-glucose) and citric acid and may be neutralised with any food grade base and/or decolourised and deionised for further purification. The products may also be partially hydrogenated with Raney nickel catalyst to reduce residual glucose. Polydextrose-N is neutralised polydextrose.

<table>
<thead>
<tr>
<th>EINECS</th>
<th>Chemical name</th>
<th>Chemical formula</th>
<th>Molecular weight</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Content not less than 90 % of polymer on the ash free and anhydrous basis</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Description**

White to light tan-coloured solid. Polydextroses dissolve in water to give a clear, colourless to straw coloured solution.

**Identification**

- **Test for sugar**: Passes test
- **Test for reducing sugar**: Passes test
- **pH**: Between 2.5 and 7.0 for polydextrose (10 % solution) Between 5.0 and 6.0 for polydextrose-N (10 % solution)

**Purity**

- **Water content**: Not more than 4.0 % (Karl Fischer method)
- **Sulphated ash**: Not more than 0.3 % (polydextrose) Not more than 2.0 % (polydextrose N)
- **Nickel**: Not more than 2 mg/kg for hydrogenated polydextroses
- **1,6-Anhydro-D-glucose**: Not more than 4.0 % on the ash-free and the dried basis
- **Glucose and sorbitol**: Not more than 6.0 % combined on the ash-free and the dried basis; glucose and sorbitol are determined separately
- **Molecular weight limit**: Negative test for polymers of molecular weight greater than 22 000
5-Hydroxy-methylfurfural Not more than 0,1 % (polydextrose) Not more than 0,05 % (polydextrose-N)

Lead Not more than 0,5 mg/kg

**E 1201 POLYVINYLPYRROLIDONE**

**Synonyms**

Povidone; PVP; Soluble polyvinylpyrrolidone

**Definition**

Einecs

Chemical name Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]

Chemical formula (C₆H₉NO)n

Average molecular weight Not less than 25 000

Assay Content not less than 11,5 % and not more than 12,8 % of nitrogen (N) on the anhydrous basis

**Description**

White or nearly white powder

**Identification**

Solubility Soluble in water and in ethanol. Insoluble in ether

pH Between 3,0 and 7,0 (5 % solution)

**Purity**

Water content Not more than 5 % (Karl Fischer)

Total ash Not more than 0,1 %

Aldehyde Not more than 500 mg/kg (as acetaldehyde)

Free-N-vinylpyrrolidone Not more than 10 mg/kg

Hydrazine Not more than 1 mg/kg

Lead Not more than 2 mg/kg

**E 1202 POLYVINYLPOLYPYRROLIDONE**

**Synonyms**

Crosipovidone; Cross-linked polyvidone; Insoluble polyvinylpyrrolidone

**Definition**

Polyvinylpyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination

Einecs

Chemical name Polyvinylpyrrolidone; poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]

Chemical formula (C₆H₉NO)n

Molecular weight

Assay Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
<table>
<thead>
<tr>
<th>Description</th>
<th>A white hygroscopic powder with a faint, non-objectionable odour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water, ethanol and ether</td>
</tr>
<tr>
<td>pH</td>
<td>Between 5.0 and 8.0 (1 % suspension in water)</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
<tr>
<td>Water content</td>
<td>Not more than 6 % (Karl Fischer)</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.4 %</td>
</tr>
<tr>
<td>Water-soluble matter</td>
<td>Not more than 1 %</td>
</tr>
<tr>
<td>Free-N-vinylpyrrolidone</td>
<td>Not more than 10 mg/kg</td>
</tr>
<tr>
<td>Free-N,N'-divinyl-imidazolidone</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg</td>
</tr>
</tbody>
</table>

**E 1203 POLYVINYL ALCOHOL**

**Synonyms**

Vinyl alcohol polymer, PVOH

**Definition**

Polyvinyl alcohol is a synthetic resin prepared by the polymerisation 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 polymerisation and the degree of hydrolysis.

**Chemical name**

Ethenol homopolymer

**Chemical formula**

\((\text{C}_2\text{H}_3OR)\_n\) where \(R = \text{H} \) or \(\text{COCH}_3\)

**Description**

Odourless, tasteless, translucent, white or cream-coloured granular powder

**Identification**

**Solubility**

Soluble in water; sparingly soluble in ethanol

**Precipitation reaction**

Dissolve 0.25 g 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 0.01 g 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 test solution (TS) and a few drops of boric acid solution

Dissolve 0.5 g 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.s (4 % solution at 20 °C) corresponding to an average molecular weight of 26 000-30 000 Da

**Purity**

**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, 3 hours)
Residue in ignition  Not more than 1,0 %
Lead  Not more than 2 mg/kg

**E 1204 PULLULAN**

**Synonyms**

**Definition**
Linear, neutral glucan consisting mainly of maltotriose units connected by -1,6 glycosidic bonds. It is produced by fermentation from a food-grade hydrolysed starch using a non-toxin-producing strain of *Aureobasidium pullulans*. After completion of the fermentation, the fungal cells are removed by microfiltration, the filtrate is heat-sterilised and pigments and other impurities are removed by adsorption and ion exchange chromatography.

**Einecs**  232-945-1
**Chemical name**
**Chemical formula**  \((C_6H_{10}O_5)_n\)
**Molecular weight**
**Assay**  Not less than 90 % of glucan on the dried basis

**Description**
White to off-white odourless powder

**Identification**
Solubility  Soluble in water, practically insoluble in ethanol
pH  5,0 to 7,0 (10 % solution)
Precipitation with polyethylene glycol 600  Add 2 ml of polyethylene glycol 600 to 10 ml of a 2 % aqueous solution of pullulan. A white precipitate is formed
Depolymerisation with pullulanase  Prepare two test tubes each with 10 ml of a 10 % pullulan solution. Add 0,1 ml pullulanase solution having activity 10 units/g to one test tube, and 0,1 ml water to the other. After incubation at about 25 °C for 20 minutes, the viscosity of the pullulanase-treated solution is visibly lower than that of the untreated solution
Viscosity  100 to 180 mm²/s (10 % w/w aqueous solution at 30 °C)

**Purity**
Loss on drying  Not more than 6 % (90 °C, pressure not more than 50 mm Hg, 6 hours)
Mono-, di- and oligosaccharides  Not more than 10 % expressed as glucose
Lead  Not more than 1 mg/kg

**Microbiological criteria**
Yeast and moulds  Not more than 100 colonies per gram
Coliforms  Absent in 25 g
Salmonella spp.  Absent in 25 g
E 1205 BASIC METHACRYLATE COPOLYMER

**Synonyms**

Basic butylated methacrylate copolymer; amino methacrylate copolymer; aminoalkyl methacrylate copolymer E; butyl methacrylate, dimethylaminoethyl methacrylate, methyl methacrylate polymer; butyl methacrylate, methyl methacrylate, dimethylaminoethyl methacrylate polymer

**Definition**

Basic methacrylate copolymer is manufactured by thermic controlled polymerisation of the monomers methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate, dissolved in propan-2-ol by using a free radical donor initiator system. An alkyl mercaptane is used as chain modifying agent. The solid polymer is milled (first milling step) and extruded and granulated under vacuum to remove residual volatile components. The granules resulting are commercialised as such or undergo a second milling step (micronisation).

**Chemical name**

Poly[buty1 methacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate] 1:2:1

**Chemical formula**

Poly[(CH\_2:CH(C\_3)CO\_2(CH\_2)\_2N(CH\_3)\_2)-co-(CH\_2:CH(C\_3)CO\_2CH\_3)-co-(CH\_2:C(CH\_3)CO\_2(CH\_2)\_3CH\_3)]

**Weight average molecular weight**

Estimated by gel permeation chromatography

Approximately 47 000 g/mol

**Particle size of powder (when used forms a film)**

< 50 μm more than 50 %

< 0,1 μm 5,1-5,5 %

**Assay**

20,8-25,5 % dimethylaminoethyl (DMAE) groups on dry substance

(according to Ph. Eur. 2.2.20 ‘potentiometric titration’)

**Description**

Granules are colourless to yellow tinged, the powder is white

**Identification**

Infrared absorption spectroscopy

To be identified

Viscosity of a 12,5 % solution in 60:40 (w/w/) propan-2-ol to acetone

3-6 mPa.s

Refractive index

[n]\text{D}^20 \text{ } 1,380-1,385

Solubility

1 g dissolves in 7 g Methanol, Ethanol, propan-2-ol, dichloromethane, aqueous Hydrochloric acid 1N.

Not soluble in petroleum ether.

**Purity**

Loss of drying

Not more than 2,0 % (105 °C, 3H)

alkali value

162-198 mg KOH/g of dried substance

Sulphated ash

Not more than 0,1 %

Residual monomers

Butylmethacrylate < 1 000 mg/kg

Methyl methacrylate < 1 000 mg/kg

Dimethylaminoethyl methacrylate < 1 000 mg/kg

Solvent residues

propan-2-ol < 0,5 %

Butanol < 0,5 %

Methanol < 0,1 %
Arsenic: Not more than 2 mg/kg
Lead: Not more than 2 mg/kg
Mercury: Not more than 2 mg/kg
Copper: Not more than 10 mg/kg

**E 1404 OXIDISED STARCH**

**Synonyms**

**Definition**

Oxidised starch is starch treated with sodium hypochlorite

**Einecs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**

**Description**

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

**Identification**

- Microscopic observation: Passes test (if not pregelatinised)
- Iodine staining: Passes test (dark blue to light red colour)

**Purity**

- Loss on drying: Not more than 15.0 % for cereal starch
  - Not more than 21.0 % for potato starch
  - Not more than 18.0 % for other starches
- Carboxyl groups: Not more than 1.1 % (on an anhydrous basis)
- Sulphur dioxide: Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
- Arsenic: Not more than 1 mg/kg
- Lead: Not more than 2 mg/kg (on an anhydrous basis)
- Mercury: Not more than 0.1 mg/kg

**E 1410 MONOSTARCH PHOSPHATE**

**Synonyms**

**Definition**

Monostarch phosphate is starch esterified with ortho-phosphoric acid, or sodium or potassium ortho-phosphate or sodium tripolyphosphate

**Einecs**

**Chemical name**

**Chemical formula**

**Molecular weight**
**Assay**

**Description**
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

**Identification**
- Microscopic observation: Passes test (if not pregelatinised)
- Iodine staining: Passes test (dark blue to light red colour)

**Purity**
- Loss on drying: Not more than 15.0% for cereal starch
  - Not more than 21.0% for potato starch
  - Not more than 18.0% for other starches

- Residual phosphate: Not more than 0.5% (as P) for wheat or potato starch (on an anhydrous basis)
  - Not more than 0.4% (as P) for other starches (on an anhydrous basis)

- Sulphur dioxide: Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)

- Arsenic: Not more than 1 mg/kg

- Lead: Not more than 2 mg/kg (on an anhydrous basis)

- Mercury: Not more than 0.1 mg/kg

---

**E 1412 DISTARCH PHOSPHATE**

**Synonyms**

**Definition**
Distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride

**Einacs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**

**Description**
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

**Identification**
- Microscopic observation: Passes test (if not pregelatinised)
- Iodine staining: Passes test (dark blue to light red colour)

**Purity**
- Loss on drying: Not more than 15.0% for cereal starch
  - Not more than 21.0% for potato starch
  - Not more than 18.0% for other starches
<table>
<thead>
<tr>
<th>Residual phosphate</th>
<th>Not more than 0,5 % (as P) for wheat or potato starch (on an anhydrous basis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not more than 0,4 % (as P) for other starches (on an anhydrous basis)</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)</td>
</tr>
<tr>
<td></td>
<td>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg (on an anhydrous basis)</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0,1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1413 PHOSPHATED DISTARCH PHOSPHATE**

**Synonyms**

**Definition**

Phosphated distarch phosphate is starch having undergone a combination of treatments as described for monostarch phosphate and for distarch phosphate.

**Einecs**

**Chemical name**

**Chemical formula**

**Molecular weight**

**Assay**

**Description**

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles.

**Identification**

- **Microscopic observation**: Passes test (if not pregelatinised)
- **Iodine staining**: Passes test (dark blue to light red colour)

**Purity**

- **Loss on drying**
  - Not more than 15,0 % for cereal starch
  - Not more than 21,0 % for potato starch
  - Not more than 18,0 % for other starches
- **Residual phosphate**
  - Not more than 0,5 % (as P) for wheat or potato starch (on an anhydrous basis)
  - Not more than 0,4 % (as P) for other starches (on an anhydrous basis)
- **Sulphur dioxide**
  - Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
- **Arsenic**
  - Not more than 1 mg/kg
- **Lead**
  - Not more than 2 mg/kg (on an anhydrous basis)
- **Mercury**
  - Not more than 0,1 mg/kg
E 1414 ACETYLATED DISTARCH PHOSPHATE

Synonyms
Definition
Acetylated distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and esterified by acetic anhydride or vinyl acetate

Einecs
Chemical name
Chemical formula
Molecular weight
Assay

Description
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

Identification
Microscopic observation  Passes test (if not pregelatinised)
Iodine staining  Passes test (dark blue to light red colour)

Purity
Loss on drying  Not more than 15.0 % for cereal starch
Not more than 21.0 % for potato starch
Not more than 18.0 % for other starches
Acetyl groups  Not more than 2.5 % (on an anhydrous basis)
Residual phosphate  Not more than 0.14 % (as P) for wheat or potato starch (on an anhydrous basis)
Not more than 0.04 % (as P) for other starches (on an anhydrous basis)
Vinyl acetate  Not more than 0.1 mg/kg (on an anhydrous basis)
Sulphur dioxide  Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic  Not more than 1 mg/kg
Lead  Not more than 2 mg/kg (on an anhydrous basis)
Mercury  Not more than 0.1 mg/kg

E 1420 ACETYLATED STARCH

Synonyms
Starch acetate

Definition
Acetylated starch is starch esterified with acetic anhydride or vinyl acetate
<table>
<thead>
<tr>
<th>Molecular weight</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles</td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
</tr>
<tr>
<td>Microscopic observation</td>
<td>Passes test (if not pregelatinised)</td>
</tr>
<tr>
<td>Iodine staining</td>
<td>Passes test (dark blue to light red colour)</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 15.0 % for cereal starch</td>
</tr>
<tr>
<td>Not more than 21.0 % for potato starch</td>
<td></td>
</tr>
<tr>
<td>Not more than 18.0 % for other starches</td>
<td></td>
</tr>
<tr>
<td>Acetyl groups</td>
<td>Not more than 2.5 % (on an anhydrous basis)</td>
</tr>
<tr>
<td>Vinyl acetate</td>
<td>Not more than 0.1 mg/kg (on an anhydrous basis)</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)</td>
</tr>
<tr>
<td>Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)</td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 2 mg/kg (on an anhydrous basis)</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
</tbody>
</table>

**E 1422 Acetylated Distarch Adipate**

**Synonyms**

**Definition**

Acetylated distarch adipate is starch cross-linked with adipic anhydride and esterified with acetic anhydride

<table>
<thead>
<tr>
<th>EINECS</th>
<th>Chemical name</th>
<th>Chemical formula</th>
<th>Molecular weight</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microscopic observation</td>
<td>Passes test (if not pregelatinised)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iodine staining</td>
<td>Passes test (dark blue to light red colour)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Not more than 15.0 % for cereal starch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not more than 21.0 % for potato starch</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not more than 18.0 % for other starches</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetyl groups</td>
<td>Not more than 2.5 % (on an anhydrous basis)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adipate groups</td>
<td>Not more than 0.135 % (on an anhydrous basis)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
| Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic | Not more than 1 mg/kg
Lead | Not more than 2 mg/kg (on an anhydrous basis)
Mercury | Not more than 0.1 mg/kg

E 1440 HYDROXYPROPYL STARCH

Synonyms
Definition
Hydroxypropyl starch is starch etherified with propylene oxide
Einecs
Chemical name
Chemical formula
Molecular weight
Assay
Description
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification
Microscopic observation
Passes test (if not pregelatinised)
Iodine staining
Passes test (dark blue to light red colour)
Purity
Loss on drying
Not more than 15.0% for cereal starch
Not more than 21.0% for potato starch
Not more than 18.0% for other starches
Hydroxypropyl groups
Not more than 7.0% (on an anhydrous basis)
Propylene chlorohydrin
Not more than 1 mg/kg (on an anhydrous basis)
Sulphur dioxide
Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
Arsenic
Not more than 1 mg/kg
Lead
Not more than 2 mg/kg (on an anhydrous basis)
Mercury
Not more than 0.1 mg/kg

E 1442 HYDROXYPROPYL DISTARCH PHOSPHATE

Synonyms
Definition
Hydroxypropyl distarch phosphate is starch cross-linked with sodium trimetaphosphate or phosphorus oxychloride and etherified with propylene oxide
<table>
<thead>
<tr>
<th>Description</th>
<th>White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Microscopic observation</td>
<td>Passes test (if not pregelatinised)</td>
</tr>
<tr>
<td>Iodine staining</td>
<td>Passes test (dark blue to light red colour)</td>
</tr>
<tr>
<td>Purity</td>
<td></td>
</tr>
</tbody>
</table>
| Loss on drying | Not more than 15.0 % for cereal starch  
Not more than 21.0 % for potato starch  
Not more than 18.0 % for other starches |
| Hydroxypropyl groups | Not more than 7.0 % (on an anhydrous basis) |
| Residual phosphate | Not more than 0.14 % (as P) for wheat or potato starch (on an anhydrous basis)  
Not more than 0.04 % (as P) for other starches (on an anhydrous basis) |
| Propylene chlorohydrin | Not more than 1 mg/kg (on an anhydrous basis) |
| Sulphur dioxide | Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)  
Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) |
| Arsenic | Not more than 1 mg/kg |
| Lead | Not more than 2 mg/kg (on an anhydrous basis) |
| Mercury | Not more than 0.1 mg/kg |

**E 1450 STARCH SODIUM OCTENYL SUCCINATE**

**Synonyms**

SSOS

**Definition**

Starch sodium octenyl succinate is starch esterified with octenylsuccinic anhydride

| Description | White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles |
**Identification**

- Microscopic observation: Passes test (if not pregelatinised)
- Iodine staining: Passes test (dark blue to light red colour)

**Purity**

- Loss on drying:
  - Not more than 15,0 % for cereal starch
  - Not more than 21,0 % for potato starch
  - Not more than 18,0 % for other starches
- Octenylsuccinyl groups: Not more than 3 % (on an anhydrous basis)
- Octenylsuccinic acid residue: Not more than 0.3 % (on an anhydrous basis)
- Sulphur dioxide:
  - Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)
  - Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)
- Arsenic: Not more than 1 mg/kg
- Lead: Not more than 2 mg/kg (on an anhydrous basis)
- Mercury: Not more than 0.1 mg/kg

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**E 1451 ACETYLATED OXIDISED STARCH**

**Synonyms**

---

**Definition**

Acetylated oxidised starch is starch treated with sodium hypochlorite followed by esterification with acetic anhydride

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**Synonyms**

---

**Description**

White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles

---

**Identification**

- Microscopic observation: Passes test (if not pregelatinised)
- Iodine staining: Passes test (dark blue to light red colour)

---

**Purity**

- Loss on drying:
  - Not more than 15,0 % for cereal starch
  - Not more than 21,0 % for potato starch
  - Not more than 18,0 % for other starches
- Carboxyl groups: Not more than 1.3 % (on an anhydrous basis)
- Acetyl groups: Not more than 2.5 % (on an anhydrous basis)
Sulphur dioxide  
Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)  
Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis)  
Arsenic  
Not more than 1 mg/kg  
Lead  
Not more than 2 mg/kg (on an anhydrous basis)  
Mercury  
Not more than 0,1 mg/kg  

E 1452 STARCH ALUMINIUM OCTENYL SUCCINATE  

Synonyms  

Definition  
Starch aluminium octenyl succinate is starch esterified with octenylsuccinic anhydride and treated with aluminium sulphate  

Einecs  
Chemical name  
Chemical formula  
Molecular weight  
Assay  

Description  
White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles  

Identification  
Microscopic observation  Passes test (if not pregelatinised)  
Iodine staining  Passes test (dark blue to light red colour)  

Purity  
Loss on drying  Not more than 21,0 %  
Octenylsuccinyl groups  Not more than 3 % (on an anhydrous basis)  
Octenylsuccinic acid residue  Not more than 0,3 % (on an anhydrous basis)  
Sulphur dioxide  Not more than 50 mg/kg for modified cereal starches (on an anhydrous basis)  
Not more than 10 mg/kg for the other modified starches, unless otherwise specified (on an anhydrous basis)  
Arsenic  
Not more than 1 mg/kg  
Lead  
Not more than 2 mg/kg (on an anhydrous basis)  
Mercury  
Not more than 0,1 mg/kg  
Aluminium  
Not more than 0,3 % (on an anhydrous basis)  

E 1505 TRIETHYL CITRATE  

Synonyms  

Definition  
Ethyl citrate  

Einecs  
201-070-7
### E 1517 GLYCERYL DIACETATE

**Synonyms**  
Diacetin

**Definition**  
Glyceryl diacetate consist predominantly of a mixture of the 1, 2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters

**Eines**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Glyceryl diacetate; 1, 2, 3-propanetriol diacetate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical formula</td>
<td>C₇H₁₂O₅</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>176,17</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 94,0 %</td>
</tr>
</tbody>
</table>

**Description**  
Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour

**Identification**

- **Solubility**  
  Soluble in water. Miscible with ethanol
- **Test for glycerol**  
  Passes test
- **Test for acetate**  
  Passes test
- **Specific gravity (20° C/20 °C)**  
  1,175-1,195
- **Boiling range**  
  Between 259 and 261 °C

**Purity**

| Total ash | Not more than 0,02 % |
| Acidity | Not more than 0,4 % (as acetic acid) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
### E 1518 GLYCERYL TRIACETATE

**Synonyms**

- Triacetin

**Definition**

- Einecs: 203-051-9
- Chemical name: Glyceryl triacetate
- Chemical formula: \( \text{C}_9\text{H}_{14}\text{O}_6 \)
- Molecular weight: 218.21
- Assay: Content not less than 98.0%

**Description**

- Colourless, somewhat oily liquid having a slightly fatty odour

**Identification**

- Test for acetate: Passes test
- Test for glycerol: Passes test
- Refractive index: \([n]_D^{25}\) between 1.429 and 1.431
- Specific gravity (25 °C/25 °C): Between 1.154 and 1.158
- Boiling range: Between 258 and 270 °C

**Purity**

- Water content: Not more than 0.2% (Karl Fischer method)
- Sulphated ash: Not more than 0.02% (as citric acid)
- Arsenic: Not more than 3 mg/kg
- Lead: Not more than 2 mg/kg

### E 1519 BENZYL ALCOHOL

**Synonyms**

- Phenylcarbinol
- Phenylmethyl alcohol
- Benzenemethanol
- Alpha-hydroxytoluene

**Definition**

- Einecs
- Chemical name: Benzyl alcohol; Phenylmethanol
- Chemical formula: \( \text{C}_7\text{H}_8\text{O} \)
- Molecular weight: 108.14
- Assay: Not less than 98.0%

**Description**

- Colourless, clear liquid with a faint, aromatic odour

**Identification**

- Solubility: Soluble in water, ethanol and ether
- Refractive index: \([n]_D^{20}\) 1.538-1.541
- Specific gravity (25° C/25 °C): 1.042-1.047
- Test for peroxides: Passes test
- Distillation range: Not less than 95% v/v distils between 202 and 208 °C
### E 1520 PROPANE-1,2-DIOL

**Synonyms**
- Propylene glycol

**Definition**
- **Einecs**: 200-338-0
- **Chemical name**: 1,2-dihydroxypropane
- **Chemical formula**: \( \text{C}_3\text{H}_8\text{O}_2 \)
- **Molecular weight**: 76.10
- **Assay**: Content not less than 99.5 % on the anhydrous basis

**Description**
- Clear, colourless, hygroscopic, viscous liquid

**Identification**
- **Solubility**: Soluble in water, ethanol and acetone
- **Specific gravity (20° C/20 °C)**: 1.035-1.040
- **Refractive index**
  - \( [n]_D^{20} \): 1.431-1.433

**Purity**
- **Distillation test**: 99.5% of the product distils between 185-189 °C. The remaining 0.5% consists mainly of dimers and traces of trimers from propylene glycol.
- **Sulphated ash**: Not more than 0.07 %
- **Water content**: Not more than 1.0 % (Karl Fischer method)
- **Lead**: Not more than 2 mg/kg

### E 1521 POLYETHYLENE GLYCOL

**Synonyms**
- PEG; Macrogol; Polyethylene oxide

**Definition**
- Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight.
- **Chemical name**: alpha-Hydro-omega-hydroxy(poly(oxy-1,2-ethanediol)
- **Chemical formula**
  - \( \text{C}_2\text{H}_4\text{O}_n \cdot \text{H}_2\text{O} \) (\( n = \) number of ethylene oxide units corresponding to a molecular weight of 6000, about 140)
- **Average molecular weight**: 380 to 9000 Da
- **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 %
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.

**Identification**

**Melting range**

- 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: 105 to 130 mPa.s at 20 °C
- PEG 3000: 75 to 100 mPa.s at 20 °C
- PEG 3350: 83 to 120 mPa.s at 20 °C
- PEG 4000: 110 to 170 mPa.s at 20 °C
- PEG 6000: 200 to 270 mPa.s at 20 °C
- PEG 8000: 260 to 510 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.

**Purity**

**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
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