The Draft Amendment of Standards for Specification, Scope, Application and Limitation of Food Additives

Appendix 1: Standards for Scope, Application and Limitation of Food Additives

### 03. Antioxidants

<table>
<thead>
<tr>
<th>Code</th>
<th>Food Additive Items</th>
<th>Scope and Application Standards</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>03026</td>
<td>$\alpha$– Glycosyl–isoquercitrin</td>
<td>1. Beverages, fruit juices, vegetable juices, frozen dairy, gelatins, puddings, jams, jellies, soft candy, cakes, cookies, pastries, pies, powdered or canned soup: not more than 150 mg/kg. 2. Chewing gum: not more than 1500 mg/kg.</td>
<td></td>
</tr>
</tbody>
</table>

### 07. Food quality improvement, fermentation and food processing agents

<table>
<thead>
<tr>
<th>Code</th>
<th>Food Additive Items</th>
<th>Scope and Application Standards</th>
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<tbody>
<tr>
<td>07048</td>
<td>Sodium Ferrocyanide</td>
<td>Edible salt: not more than 13 mg/kg calculated as anhydrous sodium ferrocyanide.</td>
<td>For manufacturing or processing purpose.</td>
</tr>
<tr>
<td>07084</td>
<td>Potassium Ferrocyanide</td>
<td>Edible salt: not more than 13 mg/kg calculated as anhydrous sodium ferrocyanide.</td>
<td>For manufacturing or processing purpose.</td>
</tr>
<tr>
<td>07085</td>
<td>Calcium Ferrocyanide</td>
<td>Edible salt: not more than 13 mg/kg calculated as anhydrous sodium ferrocyanide.</td>
<td>For manufacturing or processing purpose.</td>
</tr>
</tbody>
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### 08. Nutritional Additives

<table>
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<tr>
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<th>Food Additive Items</th>
<th>Scope and Application Standards</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| 08139 | Calcium Gluconate | 1. General foods: not more than 1,800 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling.  
2. Infant (supplementary) foods: not more than 750 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling. | For supplementing purpose. |
| 08140 | Calcium 3–Hydroxy–3–Methyl Butyrate Monohydrate | Special dietary foods: as practically needed. | Not suitable for pregnant women and people under 18 years of age. |
| 08141 | Synthetic Genistein | Foods in capsule or tablet forms, labeled with daily dosage: not more than 30 mg of genistein in daily intake. | 1. For supplementing purpose.  
2. Require label advisory statements on the products that this product may not be suitable for children, infants, and pregnant or lactating women. |
Appendix 2: Standards for Specification of Food Additives

03. Antioxidants

§ 03026  \( \alpha \)–Glycosyl–isoquercitrin

Synonyms  Enzymatically modified isoquercitrin : isoquercetin : EMIQ

Formula weight  \( \sim 800 \)

Structural formula

![Structural formula image]

The number of glucose units may vary from 1 (\( \alpha = 0 \)) to 11.

Definition  The starting product, rutin, first enzymatically converted to isoquercitrin. Subsequently, an aqueous solution of isoquercitrin and dextrin is treated with cyclodextrin glucanotransferase to add glucose units, forming \( \alpha \)–glycosyl–isoquercitrin.

Assay  After drying, it should contain no less than 60 % (as rutin, \( \text{C}_{27}\text{H}_{30}\text{O}_{16} \)).

Description  Yellow to yellowish brown powder with a slight characteristic scent

Identification

1. 5 mg of the sample is dissolved in 10 mL of water. When 1~2 drops of ferric chloride solution (1\( \rightarrow \)50) are added to this solution, it becomes brown in color.

2. 5 mg of the sample is dissolved in 5 mL of water, where 2 ml of hydrochloric acid and 0.05 g of magnesium powder are added. The color of the solution changes to orange~red color.

3. 0.1 g of the sample is dissolved in 100 mL of 1 N sulfuric acid. When this solution is boiled for 2 hours and cooled, yellow precipitates are formed.

4. Spectrophotometry: 10 mg of the sample dissolved in 500 mL of phosphoric acid solution (1\( \rightarrow \)1,000) shows an absorption maximum at approximately 255 nm and
350 nm.

5. Thin layer chromatography: the main spot in the test solution has the bigger Rf value than that of the main spot of lutin solution.

**Quercetin**  
Not more than 1 %

**Heavy metals**  
Not more than 10 mg/kg (as Pb)

**Lead**  
Not more than 5 mg/kg

**Arsenic**  
Not more than 2 mg/kg (as As₂O₃)

**Loss on drying**  
Not more than 50 % (135 °C, 2 hr)

**Category**  
Food additives category (3)

**Functional uses**  
Antioxidants
07. Food quality improvement, fermentation and food processing agents

§ 07048  Sodium Ferrocyanide

Chemical name  Sodium ferrocyanide; Sodium hexacyanoferrate (II)
Synonyms  Yellow prussiate of soda; hexacyanoferrate of sodium; INS No. 535; CAS No. 13601-19-9

Chemical formula  \( \text{Na}_4\text{Fe(\text{CN})}_6 \cdot 10\text{H}_2\text{O} \)
Formula weight  484.1
Assay  Not less than 99.0%

Description  Yellow crystals or crystalline powder

Solubility  Soluble in water; insoluble in ethanol

Identification  1. Test for ferrocyanide: To 10 mL of a 1 % solution of the sample add 1 mL of ferric chloride TS. A dark blue precipitate is formed.
   2. Test for sodium: Passes test

Cyanide  Not detectable
Ferricyanide  Not detectable
Arsenic  Not more than 3 mg/kg
Lead  Not more than 5 mg/kg
Category  Food additives category (7)

Functional uses  Food quality improvement, fermentation and food processing agents
§ 07084  Potassium Ferrocyanide

**Chemical name**  
Potassium ferrocyanide; Potassium hexacyanoferrate (II)

**Synonyms**  
Yellow prussiate of potash; hexacyanoferrate of potassium; INS No. 536; CAS No. 13943-58-3

**Chemical formula**  
K₄Fe(CN)₆ · 3H₂O

**Formula weight**  
422.4

**Assay**  
Not less than 99.0 %

**Description**  
Yellow crystals or crystalline powder

**Solubility**  
Soluble in water; insoluble in ethanol

**Identification**  
1. Test for ferrocyanide: To 10 mL of a 1 % solution of the sample add 1 mL of ferric chloride TS. A dark blue precipitate is formed.

2. Test for potassium: Passes test

**Cyanide**  
Not detectable

**Ferricyanide**  
Not detectable

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

**Lead**  
Not more than 5 mg/kg

**Category**  
Food additives category (7)

**Functional uses**  
Food quality improvement, fermentation and food processing agents
### § 07085  Calcium Ferrocyanide

**Chemical name**  
Calcium ferrocyanide; Calcium hexacyanoferrate (II)

**Synonyms**  
Yellow prussiate of lime; hexacyanoferrate of calcium; INS No. 538; CAS No. 1327-39-5

**Chemical formula**  
$\text{Ca}_2\text{Fe(CN)}_6 \cdot 12\text{H}_2\text{O}$

**Formula weight**  
508.3

**Assay**  
Not less than 99.0 %

**Description**  
Yellow crystals or crystalline powder

**Solubility**  
Soluble in water

**Identification**

1. Test for ferrocyanide: To 10 mL of a 1 % solution of the sample add 1 mL of ferric chloride TS. A dark blue precipitate is formed.

2. Test for calcium: Passes test

**Cyanide**  
Not detectable

**Ferricyanide**  
Not detectable

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

**Lead**  
Not more than 5 mg/kg

**Category**  
Food additives category (7)

**Functional uses**  
Food quality improvement, fermentation and food processing agents
08. Nutritional Additives
§ 08139   Calcium Gluconate

Same as § 07004
§ 08141  Synthetic Genistein

**Chemical name**  5, 7-dihydroxy-3-(4-hydroxyphenyl)chromen-4-one

**Synonyms**  4’,5,7-trihydroxyisoflavone; genisteol; sophoricol; CAS No. 446-72-0

**Chemical formula**  $\text{C}_{15}\text{H}_{10}\text{O}_{5}$

**Formula weight**  270.2

**Structural formula**

![Structural formula image]

**Assay**  Not less than 98.5 %

**Description**  Off-white to slightly yellowish fine powder

**Water content**  Not more than 0.2 %

**Sulfated ash**  Not more than 0.1 %

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

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

**Heavy metals**  Not more than 10 mg/kg (as Pb)

**Category**  Food additives category (8)

**Functional uses**  Nutritional Additive
16. Emulsifiers

§ 16011 Polysorbate 80 (Polyoxyethylene (20) Sorbitan Monooleate)

Assay

Not less than 65.0 and not more than 69.5% of oxyethylene groups, equivalent to not less than 96.5 and not more than 103.5% of polysorbate 80, calculated on the anhydrous basis.

Description

Polysorbate 80 is a mixture of oleate partial esters of sorbitol and sorbitol anhydride condensed with approximately 20 moles of ethylene oxide (C₂H₄O) for each mole of sorbitol and its mono- and dianhydrides. It is a yellow- to orange-colored, oily liquid having a faint, characteristic odor and a warm, somewhat bitter taste. It is very soluble in water, producing an odorless, nearly colorless solution, and is soluble in alcohol, in fixed oils, in ethyl acetate, and in toluene.

Identification

1. To 5 mL of a 1 in 20 solution add 5 mL of solution hydroxide TS, boil for a few min, cool, and acidify with diluted hydrochloric acid TS. The solution is strongly opalescent.
2. To a 1 in 20 solution add bromine TS, dropwise. The bromine is decolorized.
3. A mixture of 60 volumes of polysorbate 80 with 40 volumes of water at 25°C or below yields a gelatinous mass.

Acid value

Not more than 2.

Hydroxy value

Between 65 and 80.

Saponification value

Between 45 and 55.

Oleic Acid

Between 22 and 24 %.

Water content

Not more than 3 %.

1,4-Dioxane

Not more than 10 mg/kg.

Arsenic

Not more than 3 ppm (as As).

Heavy metals

Not more than 10 ppm (as Pb).

Residue on Ignition

Not more than 0.25 %.
<table>
<thead>
<tr>
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<tr>
<td><strong>Functional uses</strong></td>
<td>Emulsifiers</td>
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