

## Appendix 2 Food additives specifications

### Category 1 Preservatives

§ 01001

#### Sorbic Acid

<b>Synonyms</b>	INS No. 200
<b>Definition</b>	
Chemical names	Sorbic acid, 2,4-hexadienoic acid, 2-propenylacrylic acid
CAS NUMBER	110-44-1
Molecular formula	C <sub>6</sub> H <sub>8</sub> O <sub>2</sub>
Molecular weight	112.12
Assay	Not less than 99.0% on the dried basis.
<b>Appearance</b>	Colorless needle-shaped or white liquid powder with a characteristic odor.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Slightly soluble in water, soluble in ethanol.
Melting range	132~135°C
Spectral analysis	The product's isopropanol solution (2.5 µg/mL) has a maximum absorbance at a wavelength of 254 ± 2 nm.
Double bond test	Take 0.02 g of this product and shake it with 1 mL of bromine test solution. The color of the solution disappears.
<b>Purity</b>	
Water	Not more than 0.5% (Karl Fischer Method).
Sulfated ash	Not more than 0.2%.
Aldehydes	Not more than 0.1% as formaldehyde
Lead	Not more than 2 mg/kg.
<b>Category</b>	Food Additives Category 1
<b>Uses</b>	Preservative

## Potassium Sorbate

**Synonyms**

INS No. 202

**Definition**

Chemical names Potassium sorbate, potassium salt of trans, trans-2,4-hexadienoic acid

CAS NUMBER 24634-61-5

Molecular formula  $C_6H_7KO_2$ 

Molecular weight 150.22

Assay Not less than 98% and not more than 102% on the dried basis.

**Appearance**

White or yellowish-white crystals or crystalline powder or granules.

**Characteristics****Identification**

Solubility Soluble in water, slightly soluble in ethanol.

Test for potassium Passes test

Melting range of sorbic acid 132~135°C

derived from the sample

Test for unsaturation To 2 mL of a 1 in 10 solution of the sample, add a few drops of bromine TS.  
The color of the bromine disappears.

**Purity**

Loss on drying Not more than 1% (105°, 3 h).

Acidity or alkalinity Not more than 1% (as sorbic acid or potassium carbonate)

Aldehydes Not more than 0.1% as formaldehyde

Lead Not more than 2 mg/kg.

**Category**

Food Additives Category 1

**Uses**

Preservative

## Sodium Sorbate

Chemical formula:  $C_6H_7O_2Na$ 

Molecular weight: 134.11

1. Assay : 98~102% (vacuum desiccator over sulfuric acid, 4 h)
2. Appearance : White to light yellow brown scaly crystal or crystalline powder, odorless or slightly stinky.
3. Melting range of sorbic acid derived from the sample : 132°C~135°C.  
Acidify a solution of the sample with dilute hydrochloric acid TS. Collect the precipitated sorbic acid on a filter paper, wash free of chloride with water and dry.
4. Solution : When 0.2 g of this product is dissolved in 5 mL water, the liquid color should not be thicker than the Matching Fluid F.
5. Free alkali : 1 g of this product is dissolved in 20 mL of fresh boiled cooling water, red should appear when adding 2 drops of phenolphthalein test solution. However, when 0.1 mL of 0.1 N sulfuric acid is added, the red color should disappear.
6. Chloride : Not more than 0.015% (as Cl).
7. Sulfate : Not more than 0.04% (as  $SO_4$ ).
8. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 10 ppm of (as Pb).
10. Loss on drying : Not more than 1% (vacuum desiccator over sulfuric acid, 4 h)
11. Residue on ignition : 52.0~53.5%.
12. Category : Food Additives Category 1
13. Uses : Preservative

	Calcium Propionate
<b>Synonyms</b>	Calcium propanoate, INS No. 282
<b>Definition</b>	
Chemical names	Calcium propionate
CAS NUMBER	4075-81-4
Molecular formula	C <sub>6</sub> H <sub>10</sub> CaO <sub>4</sub>
Molecular weight	186.22
Assay	Not less than 98.0% on the dried basis
<b>Appearance</b>	White crystals, powder or granules with not more than a faint odor of propionic acid.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Freely soluble in water, soluble in ethanol.
Positive test for calcium	Passes test
Positive test for propionate	Warm the sample with sulfuric acid. The propionic acid evolved may be recognized by its odor.
Positive test for alkali salt of organic acid	Ignite the sample at a relatively low temperature. The alkaline residue effervesces with acid.
<b>Purity</b>	
Loss on drying	Not more than 4% (105°, 2h)
pH	7.5~10.5 (1 in 10 soln)
Water-insoluble matter	Not more than 0.3%.
Fluoride	Not more of 30 mg/kg.
Iron	Not more than 50 mg/kg.
Lead	Not more than 5 mg/kg.
<b>Category</b>	Food Additives Category 1
<b>Uses</b>	Preservative

	Sodium Propionate
<b>Synonyms</b>	Sodium propanoate, INS No. 281
<b>Definition</b>	
Chemical names	Sodium propionate
CAS NUMBER	137-40-6
Molecular formula	$C_3H_5NaO_2$
Molecular weight	96.06
Assay	Not less than 99.0% on the dried basis.
<b>Appearance</b>	White or colorless, hygroscopic crystals with not more than a faint characteristic odor.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Freely soluble in water, soluble in ethanol.
Positive test for sodium	Passes test
Positive test for propionate	Warm the sample with sulfuric acid. The propionic acid evolved may be recognized by its odor.
Positive test for alkali salt of organic acid	Ignite the sample at a relatively low temperature. The alkaline residue effervesces with acid.
<b>Purity</b>	
Loss on drying	Not more than 4% (105°, 2h)
pH	7.5~10.5 (1 in 10 soln)
Water-insoluble matter	Not more than 0.1%.
Iron	Not more than 50 mg/kg.
Lead	Not more than 5 mg/kg.
<b>Category</b>	Food Additives Category 1
<b>Uses</b>	Preservative

## Dehydroacetic Acid

Chemical formula:  $C_8H_8O_4$ 

Molecular weight: 168.15

1. Assay : Not less than 98.0%
2. Appearance : Colorless to white needle, plate crystal or crystalline powder; odorless, or slightly stinky.
3. Identification : (1) 0.1 g of this product is added with 1 mL water, 3 to 5 drops of salicylaldehyde-alcohol solution (salicylaldehyde 1 mL dissolved in alcohol 5 mL) and 0.5 mL of sodium hydroxide solution (sodium hydroxide 1 g dissolved in water 2 mL).  
When heated in a water, the solution appears red.  
(2) The 1 mL alcohol solution (1 g of this product dissolved in 100 mL alcohol), water 1 mL, 3 drops of potassium sodium tartrate solution (7 g of potassium sodium tartrate dissolved in 50 mL water) and 2 drops of strong copper acetate test solution are mixed to form a purple precipitate with white color.
4. Melting range : 109~112°C.
5. Color of the solution : When 0.5 g of this product is dissolved in 10 mL of acetone, the solution should be colorless.
6. Arsenic : Not more than 4 ppm(as  $As_2O_3$ ).
7. Heavy metals : Not more than 10 ppm of Pb.
8. Readily carbonizable substance : When 0.30 g of this product is dissolved in 5 mL of sulfuric acid, the color of the solution can not be deeper than the matching fluid C.
9. Residue on ignition : Not more than 0.10%.
10. Loss on drying : Not more than 1%.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Sodium Dehydroacetate

Chemical formula:  $C_8H_7O_4 Na \cdot H_2O$ 

Molecular weight: 208.15

1. Assay : Not less than 98.0% on the dried basis.
2. Appearance : Colorless crystalline powder, odorless or with a slightly characteristic odor.
3. Identification : (1) 0.1 g of this product is added with 1 mL water, 3 to 5 drops of salicylaldehyde-alcohol solution (salicylaldehyde 1 mL dissolved in alcohol 5 mL) and 0.5 mL of sodium hydroxide solution (sodium hydroxide 1 g dissolved in water 2 mL).  
When heated in a water, the solution appears red.  
(2) The 1 mL alcohol solution (1 g of this product dissolved in 100 mL alcohol), water 1 mL, 3 drops of potassium sodium tartrate solution (7 g of potassium sodium tartrate dissolved in 50 mL water) and 2 drops of strong copper acetate test solution are mixed to form a purple precipitate with white color.  
(3) Passes test for sodium.
4. Color of the solution : When 0.5 g of this product is dissolved in water 10 mL, the solution should be colorless or almost clear.
5. Dehydroacetic acid : Acidify a solution of the sample (0.5 g in 10 mL of water) with 1 mL of dilute hydrochloric acid TS (1 mL of hydrochloric acid to 4 mL). Collect the precipitation on a filter paper, wash free of chloride with water and dry at 105°C for an hour. The melting range of the filtrate is 109~112°C.
6. Free alkali : Dissolve 1.0 g of the sample in 20 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS. If the solution is red, the red color is discharged by adding 0.30 mL of 0.1 N sulfuric acid.
7. Chloride : Not more than of 0.01% (as Cl).
8. Sulfate : Not more than 0.015% of (as  $SO_4$ ).
9. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
10. Heavy metals : Not more than 10 ppm of Pb.
11. Readily carbonizable substance : When 0.30 g of this product is dissolved in 5 mL of sulfuric acid, the color of the solution can not be deeper than the matching fluid C.
12. Water : 8.3~10.0% (Karl Fischer Method).
13. Category : Food Additives Category 1
14. Uses : Preservative

## Benzoic Acid

**Synonyms**

INS No. 210

**Definition**

Chemical names

Benzoic acid, benzenecarboxylic acid, phenylcarboxylic acid

CAS NUMBER

65-85-0

Molecular formula

 $C_7H_6O_2$ 

Molecular weight

122.12

Assay

Not less than 99.5% (on the dried basis).

**Appearance**

White crystalline solid, usually in the form of scales or needles, having not more than a faint characteristic odor.

**Characteristics****Identification**

Solubility

Slightly soluble in water, freely soluble in ethanol.

Melting range

121~123°C

Test for benzoate

Passes test (Use 0.1 g of the sample with 0.1 g of calcium carbonate and 5 mL of water)

pH of the solution

About 4.0 (solution in water)

**Purity**

Loss on drying

Not more than 0.5% (over sulfuric acid, 3 h)

Sublimation test

Place a small amount of the sample in a dry test tube. Wrap the test tube about 4 cm from the bottom with moistened filter paper. Heat the test tube over a low flame. Benzoic acid sublimes and crystals deposit in the colder part of the test tube leaving no residue at the bottom.

Sulfated ash

Not more than 0.05%.

Lead

Not more than 2 mg/kg.

Readily carbonizable  
substance

Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 mL of sulfuric acid TS (94.5~95.5%). The color produced should not be darker than the Matching Fluid Q.

Readily oxidizable matter

Add 1.5 mL of sulfuric acid to 100 mL of water, heat to boiling and add 0.1N potassium permanganate in drops, until the pink color persists for 30 sec. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1N potassium permanganate to a pink color that persists for



	15 sec. Not more than 0.5 mL should be required.
Organochloride	Not more than 0.07% (as Cl <sub>2</sub> ).
<b>Category</b>	Food Additives Category 1
<b>Uses</b>	Preservative

## Sodium Benzoate

**SYNONYMS**

INS No. 211

**DEFINITION**

Chemical names

Sodium benzoate, sodium salt of benzenecarboxylic acid, sodium salt of phenylcarboxylic acid

C.A.S. number

532-32-1

Chemical formula

 $C_7H_5O_2Na$ 

Formula weight

144.11

Assay

Not less than 99.0% on the dried basis

**DESCRIPTION**

White, almost odourless, crystalline powder, flakes or granules

**CHARACTERISTICS**

## IDENTIFICATION

Solubility

Freely soluble in water, sparingly soluble in ethanol

Test for benzoate

Passes test

Use a 10% solution of the sample

Test for sodium

Passes test

**PURITY**

Loss on drying

Not more than 1.5% (105°C, 4 h) °

Acidity or alkalinity

Dissolve 2 g of the sample, weighed to the nearest mg, in 20 ml of freshly boiled water. Not more than 0.5 ml of either 0.1N sodium hydroxide or 0.1N hydrochloric acid should be required for neutralization, using phenolphthalein TS as indicator.

Lead

Not more than 2 mg/kg

Readily carbonizable substances

Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 ml of sulfuric acid TS. The color produced should not be darker than a light pink ("Matching Fluid Q")

Readily oxidizable substances

Add 1.5 ml of sulfuric acid to 100 ml of water, heat to boiling and add 0.1N potassium permanganate, dropwise, until the pink color persists for 30 sec. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1N potassium permanganate to a pink color that persists for 15 sec.

Chlorinated organic  
compounds

Not more than 0.5 ml should be required.

Not more than 0.07% (as chlorine)

**Category**

Food additives category (1).

**Functional uses**

Preservatives.

## Ethyl p-Hydroxybenzoate

Chemical formula:  $C_9H_{10}O_3$ 

Molecular weight: 166.18

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Identification : (1) To 0.5 g of the sample add 10 mL of sodium hydroxide TS (1 g of sodium hydroxide dissolved in 25 mL of water). Boil for 30 min and concentrate to about 5 mL. Cool, acidify with dilute sulfuric acid TS, collect the precipitate on a filter, and wash thoroughly with water. Dry in a desiccator over sulfuric acid. Determine the melting range of p-hydroxybenzoic acid so obtained. Melting range of p-hydroxybenzoic acid derived from the sample is 213~217°C.  
(2) Add 2 drops of acetic acid and 5 drops of sulfuric acid to 0.05 g of the sample, and the odor of ethyl acetate will be produced after heating for 5 minutes.
4. Melting range : 115~118°C.
5. Free acid : Not more than 0.55% (as 4-Hydroxybenzoic acid).
6. Sulfate : Not more than 0.024% (as  $SO_4$ ).
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm of Pb.
9. Loss on drying : Not more than 0.5% (80°C, 2 h)
10. Residue on ignition : Not more than 0.05%.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Propyl p-Hydroxybenzoate

Chemical formula:  $C_{10}H_{12}O_3$ 

Molecular weight: 180.20

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Identification : (1) To 0.5 g of the sample add 10 mL of sodium hydroxide TS (1 g of sodium hydroxide dissolved in 25 mL of water). Boil for 30 min and concentrate to about 5 mL. Cool, acidify with dilute sulfuric acid TS, collect the precipitate on a filter, and wash thoroughly with water. Dry in a desiccator over sulfuric acid. Determine the melting range of p-hydroxybenzoic acid so obtained. Melting range derived from the sample is 213~217°C.  
(2) Add 2 drops of acetic acid and 5 drops of sulfuric acid to 0.05 g of the sample. The odor of propyl acetate will be produced after heating for 5 minutes.
4. Melting range : 95~98°C.
5. Free acid : Not more than 0.55% (as 4-Hydroxybenzoic acid).
6. Sulfate : Not more than 0.024% (as  $SO_4$ ).
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Not more than 0.5% (Silicone dryer, 5 h).
10. Residue on ignition : Not more than 0.05%.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Butyl p-Hydroxybenzoate

Chemical formula:  $C_{11}H_{14}O_3$ 

Molecular weight: 194.23

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Identification : (1) To 0.5 g of the sample add 10 mL of sodium hydroxide TS (1 g of sodium hydroxide dissolved in 25 mL of water). Boil for 30 min and concentrate to about 5 mL. Cool, acidify with dilute sulfuric acid TS (1 mL of sulfuric acid dissolved in water 20 mL), collect the precipitate on a filter, and wash thoroughly with water. Dry in a desiccator over sulfuric acid. Determine the melting range of p-hydroxybenzoic acid so obtained. Melting range derived from the sample is 213~217°C.  
(2) Add 2 drops of acetic acid and 5 drops of sulfuric acid to 0.05 g of the sample. The odor of butyl acetate will be produced after heating for 5 minutes.
4. Melting range : 69~72°C.
5. Free acid : Not more than 0.55% (as 4-Hydroxybenzoic acid).
6. Sulfate : Not more than 0.024% (as  $SO_4$ ).
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Not more than 0.5% (Silicone dryer, 5 h)
10. Residue on ignition : Not more than 0.10%.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Isopropyl p-Hydroxybenzoate

Chemical formula:  $C_{10}H_{12}O_3$ 

Molecular weight: 180.20

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Identification : (1) To 0.5 g of the sample add 10 mL of sodium hydroxide TS (1 g of sodium hydroxide dissolved in 25 mL of water). Boil for 30 min and concentrate to about 5 mL. Cool, acidify with dilute sulfuric acid TS (1 mL of sulfuric acid dissolved in water 20 mL), collect the precipitate on a filter, and wash thoroughly with water. Dry in a desiccator over sulfuric acid. Determine the melting range of p-hydroxybenzoic acid so obtained. Melting range derived from the sample is 213~217°C.  
(2) Add 2 drops of acetic acid and 5 drops of sulfuric acid to 0.05 g of the sample, and the odor of isopropyl acetate will be produced after heating for 5 minutes.
4. Melting range : 84~86°C.
5. Free acid : Not more than 0.55% (as 4-Hydroxybenzoic acid).
6. Sulfate : Not more than 0.024% (as  $SO_4$ ).
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Not more than 0.5% (Silicone dryer, 5 h).
10. Residue on ignition : Not more than 0.10%.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Isobutyl p-Hydroxybenzoate

Chemical formula:  $C_{11}H_{14}O_3$ 

Molecular weight: 194.23

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Identification : (1) To 0.5 g of the sample add 10 mL of sodium hydroxide TS (1 g of sodium hydroxide dissolved in 25 mL of water). Boil for 30 min and concentrate to about 5 mL. Cool, acidify with dilute sulfuric acid TS (1 mL of sulfuric acid dissolved in water 20 mL), collect the precipitate on a filter, and wash thoroughly with water. Dry in a desiccator over sulfuric acid. Determine the melting range of p-hydroxybenzoic acid so obtained. Melting range derived from the sample is 213- 217°C.  
(2) Add 2 drops of acetic acid and 5 drops of sulfuric acid to 0.05 g of the sample, and the taste of isobutyl acetate will be produced after heating for 5 minutes.
4. Melting range : 75~77°C.
5. Free acid : Not more than 0.55% (as 4-Hydroxybenzoic acid).
6. Sulfate : Not more than 0.024% (as  $SO_4$ ).
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Not more than 0.5% (Silicone dryer, 5h).
10. Residue on ignition : Not more than 0.10%.
11. Category : Food Additives Category 1
12. Uses : Preservative



Sodium Diacetate  
(Sodium Hydrogen Diacetate)

Chemical formula:  $C_4H_7NaO_4K \cdot xH_2O$

Molecular weight (Anhydrous): 142.09

1. Description : A molecular compound of sodium acetate and acetic acid. White, hygroscopic crystalline solid with an acetic odor. The pH of 1 in 10 solution of this sample is 4.5 to 5.0.
2. Identification : The 1 in 10 solution of this sample passes the test for acetate and test for sodium.
3. Assay :  $CH_3COOH$  39.0~41.0%;  $CH_3COONa$  58.0~60.0%.
4. Water : Not more than 2%.
5. Readily oxidizable substances : Not more than 0.2% (as formic acid).
6. Arsenic : Not more than 3 ppm (as As).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 1
9. Uses : Preservative

## Potassium Benzoate

Chemical formula:  $C_7H_5O_2 K$ 

Molecular weight: 160.11

1. Assay : Not less than 99% (drying at 110°C for 4 hours)
2. Appearance : White granular or crystalline powder, odorless.
3. Solution : When 1 g of the sample is dissolved in 5 mL of water, the solution should be clear.
4. Free alkali : Dissolve 2 g of the sample in 20 mL of hot water, and add 2 drops of phenolphthalein TS. If the solution is red, the red color is discharged by adding 0.2 mL of 0.1 N sulfuric acid.
5. Chloride compound : Not more than 0.014% (as Cl).
6. Sulfate : Not more than 0.30% of (as  $SO_4$ ).
7. Benzenedicarboxylic acid : The test for benzoic acid test of benzenedicarboxylic acid is applicable.
8. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 10 ppm of (as Pb).
10. Loss on drying : Not more than 1% (110°C, 4 hr).
11. Category : Food Additives Category 1
12. Uses : Preservative

## Nisin

1. Description : Nisin is a mixture of closely related antimicrobial polypeptides produced by *Streptococcus lactis* Lancefield Group N. White powder. Soluble in water and insoluble in non-polar solvents.
2. Assay : Not less than 900 IU/mg.
3. Arsenic : Not more than 1 ppm.
4. Lead : Not more than 2 ppm.
5. Zinc : Not more than 25 ppm.
6. Total amount of zinc and copper : Not more than 50 ppm.
7. Total plate count : Not more than 10 CFU m.
8. *E. coli* : Negative by test/eg g.
9. *Salmonella* : Negative by test/eg g.
10. Coagulase-positive *Staphylococcus aureus* : Negative by test/eg g.
11. Category : Food Additives Category 1
12. Uses : Preservative

## Thiamine Dilaurylsulfate

Chemical formula:  $C_{36}H_{68}N_4O_9 \cdot S_3 \cdot H_2O$ 

Molecular weight: 815.17

1. Assay : Not less than 98.0% and not more than 102.0%.
2. Appearance : Colorless to white crystal or white crystalline powder, odorless or slightly smelly.
3. Identification : (1) Dissolve 0.1 g of the sample in 20 mL of potassium chloride and hydrochloric acid TS, and boil slowly for 30 minutes. After cooling and filtration, add 1 mL of lead acetate TS and 1 mL sodium hydroxide solution to 1 mL of filtrate. The solution is yellow. Then heat in water bath. The solution turns brown, and after a period of time the dark brown precipitate appears.  
 (2) Take 1 mL of the filtrate obtained from test (1), add 2 g of sodium hydroxide TS 5 mL and 0.5 mL of potassium ferricyanide solution, then add 5 mL of isobutanol TS, shake hard after 2 minutes. When observed under UV light, blue-purple fluorescence appears on isobutanol liquid layer. When the solution is acidified, the fluorescence disappears; when the solution is alkaline, the fluorescence reappears.  
 (3) Add 30 mL of water and 15 mL of hydrochloric acid to 1 g of the sample, connect with a flow cooler, and cool down after boiling for 4 hours. Extract with 15 mL of ether twice. After the both extraction solution is combined and washed with water, the ether is removed by heating and evaporating in the water bath. The residue is dried at 100°C for 15 minutes and cooled, and its melting point should be 20°C to 28°C.
4. Chloride : Not more than 0.56% (as Cl).
5. Heavy metals : Not more than 20 ppm of (as Pb).
6. Loss on drying : Not more than 2.0% (Silicone dryer, 24 hr).
7. Residue on ignition : Not more than 0.30%.
8. Category : Food Additives Category 1
9. Uses : Preservative

## Propionic Acid

**Synonyms** INS No. 280; Propanoic acid, ethylformic acid, methylacetic acid

**Definition**

Chemical names Propionic acid

CAS NUMBER 79-09-4

Molecular formula  $C_3H_6O_2$

Molecular weight 74.08

Assay Not less than 99.5% (on the dried basis)

**Appearance** An oily liquid with a slightly pungent odor

**Characteristics****Identification**

Solubility Miscible with water and ethanol

Specific gravity  $D_{20}^{20}$ : 0.993~0.997

**Purity**

Distillation range 138.5~142.5°C

Non-volatile residue Not more than 0.01% when dried at 140°C to constant weight.

Formic acid Not more than 0.1%.

Aldehydes Not more than 0.2% (as propionaldehyde)

Lead Not more than 2 mg/kg.

**Category** Food Additives Category 1

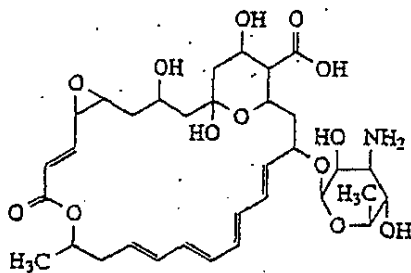
**Uses** Preservative

Natamycin (Pimaricin)

Chemical names : 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<sup>5,7</sup> ] octacos-8,14,16,18,20-pentaene-25-carboxylic acid.

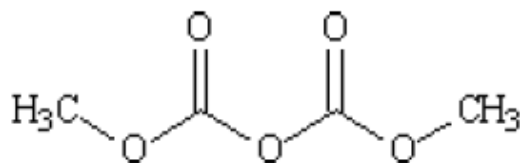
Chemical formula: C<sub>33</sub>H<sub>47</sub>NO<sub>13</sub>

Molecular weight: 665.74



1. Description : White to ivory crystalline powder, almost tasteless, odorless. May contain up to three mole of water. Melts and discomposes at about 280°C. Insoluble in water, fat and mineral oil; slightly soluble in methanol; soluble in acetic acid and dimethylformamide.
2. Identification : Transfer 50 mg, accurately weighed, to a 200 mL volumetric flask, add 5.0 mL of water, and moisten the specimen. Add 100 mL of a 1 in 1000 solution of glacial acetic in methanol, and shake by mechanical means in the dark until dissolved. Dilute with the acetic acid-methanol solution to volume, and mix. Transfer 2.0 mL of this solution to a 100 mL volumetric flask, dilute with the acetic acid-methanol solution to volume, and mix; the UV absorption spectrum of the solution so obtained exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Natamycin RS, concomitantly measured.
3. Assay : Not less than 97.0% and not more than 102.0% of C<sub>33</sub>H<sub>47</sub>NO<sub>13</sub> on the dried basis.
4. Heavy metals : Not more than 20 mg/kg of Pb.
5. pH : 5.0~7.5.
6. Specific rotation :  $[\alpha]_D^{20}$ : +276°~+280°.
7. Water : 6.0%~9.0%.
8. Category : Food Additives Category 1
9. Uses : Preservative

Dimethyl Dicarbonate



Synonyms : DMDC, Dimethyl Pyrocarbonate

INS No. 242

CAS No. 004-525-33-1

Chemical formula: C<sub>4</sub>H<sub>6</sub>O<sub>5</sub>

Molecular weight: 134.09

1. Assay : Not less than 99.8%.
2. Appearance : Colorless liquid.
3. Solubility : Soluble in water; miscible with toluene.
4. Identification : The infrared spectrum of the sample corresponds with the reference infrared spectrum and standard spectrum.
5. Dimethyl carbonate : Not more than 0.2%.
6. Lead : Not more than 2 mg/kg.
7. Category : Food Additives Category 1
8. Uses : Preservative

## Category 2 Sanitizing Agents

§ 02003

### Hydrogen Peroxide

Chemical formula:  $\text{H}_2\text{O}_2$

Molecular weight: 34.01

1. Description : Colorless, nearly odorless liquid. Miscible with water. Concentration suitable for food use is 30 ~ 50%.
2. Identification : Add 10 mL of water containing 1 drop of dilute sulfuric acid to 1 mL of the sample, shake. Add 2 mL of ether, then add 1 drop of potassium dichromate TS to the water layer to form a dissipative blue color. After being shaken and placed, the blue color will enter the ether layer.
3. Assay : Not less than the labelled concentration or within the range stated on the label.
4. Acidity : Not more than 0.03% of  $\text{H}_2\text{SO}_4$ .
5. Phosphate : Not more than 0.005%.
6. Iron : Not more than 0.5 ppm.
7. Tin : Not more than 10 ppm.
8. Arsenic : Not more than 3 ppm (as As).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Non-volatile residue : Not more than 0.006%.
11. Category : Food Additives Category 2
12. Uses : Sanitizing Agents



### Category 3 Antioxidants

§ 03001

#### Dibutyl Hydroxy Toluene

Chemical formula: C<sub>15</sub>H<sub>24</sub>O

Molecular weight: 220.35

1. Assay : Not less than 99.0%.
2. Appearance : Colorless crystal or white crystalline powder or particle, odorless or with a slightly characteristic odor.
3. Identification : To 10 mL of a 1 in 100,000 solution of the sample in methanol add 10 mL of water, 2 mL of sodium nitrite solution (3 in 1000) and 5 mL of dianisidine dihydrochloride solution (200 mg of 3,3-dimethoxy-benzidine dihydrochloride dissolved in a mixture of 40 mL of methanol and 60 mL of 1 N hydrochloric acid). An orange red color develops within 3 min. Add 5 mL of chloroform, and shake. The chloroform layer exhibits a purple or magenta color that fades when exposed to light.
4. Melting range : 69~72°C.
5. Turbidity : When 1.0 g of the sample is dissolved in 10 mL of ethanol, the solution should be clear.
6. p-Cresol : Not more than 0.1%.
7. Sulfate : Not more than 0.02% (as SO<sub>4</sub>).
8. Arsenic : Not more than 3 ppm(as As).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Residue on ignition : Not more than 0.05%.
11. Category : Food Additives Category 3
12. Uses : Antioxidants.

## Butyl Hydroxy Anisole

Chemical formula:  $C_{11}H_{16}O_2$ 

Molecular weight: 180.25

1. Assay : Not less than 98.5% (as  $C_{11}H_{16}O_2$ )
2. Description : Mixture mainly consists of 3-tert-butyl-4-hydroxyanisole(3-BHA), and, secondly, 2-tert-butyl-4-hydroxyanisole(2-BHA). White or slightly yellow crystals or waxy solid, with a faint characteristic odor. Insoluble in water; freely soluble in ethanol and propane-1,2-diol.
3. Identification : To 5 mL of a 1 in 10,000 solution of the sample in 72% ethanol, add 2 mL of sodium borate TS and 1 mL of a 1 in 10,000 solutions of 2,6- dichloroquinonechlorimide in absolute ethanol, and mix. A blue color appears.
4. Melting range : 57~65°C
5. Turbidity : When 0.5 g of the sample is dissolved in 10 mL of ethanol, the solution should be clear.
6. Sulfate : Not more than 0.02% (as  $SO_4$ ).
7. Arsenic : Not more than 3 ppm (as As).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Residue on ignition : Not more than 0.05%.
10. Category : Food Additives Category 3
11. Uses : Antioxidants.

## L-Ascorbic Acid (Vitamin C)

Chemical formula:  $C_6H_8O_6$ 

Molecular weight: 176.13

1. Assay : Not less than 99.0%.
2. Description : White to slightly yellow, odorless crystalline powder; having a sour taste. Soluble in water and ethanol; insoluble in chloroform, ether and benzene.
3. Identification : (1) Dissolve 0.1 g of the sample in 100 mL of metaphosphoric acid TS (1 in 50 solution of metaphosphoric acid). Add iodine TS dropwise to 5 mL of this solution until the solution was slightly yellow. Then, add a drop of copper sulfate solution (1 in 1000 solution of copper sulphate) and a drop of pyrrole and heat in 50 ~ 60 °C water bath for 5 minutes. The solution should be blue or green.  
(2) Add 1 to 2 drops of Sodium 2,6-dichlorophenolindophenol TS to 10 mL of 1 in 100 solution of the sample. The blue color should disappear immediately.
4. Melting range : 187~192°C.
5. Specific rotation :  $[\alpha]_D^{20}$ : +20.5°~+21.5° (10% (w/v) aqueous solution)
6. Arsenic : Not more than 4 ppm(as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 0.4% (reduced pressure, silica gel, 3 h)
9. Residue on ignition : Not more than 0.10%.
10. Category : Food Additives Category 3, 8.
11. Uses : Antioxidants; Nutritional additives

## Sodium L-Ascorbate

Chemical formula:  $C_6H_7O_6Na$ 

Molecular weight: 198.11

1. Assay : Not less than 99.0%.
2. Appearance : White or yellowish-white, odorless and salty crystalline powder.
3. Identification : (1) Solubility: Soluble in water; sparingly soluble in ethanol  
(2) Passes test for ascorbate.  
(3) Passes test for sodium.  
(4) A solution of the sample will decolorize a solution of 2,6-dichlorophenolindophenol TS.
4. pH : 6.5 ~ 8.0 (1 in 10 soln)
5. Specific rotation :  $[\alpha]_D^{20}$ : +103.0° ~ +108.0° (10% (w/v) aqueous solution)
6. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 0.25% (vacuum desiccator over sulfuric acid, 24 h)
9. Category : Food Additives Category 3, 8.
10. Uses : Antioxidants; Nutritional additives

## L-Ascorbyl Stearate

Chemical formula:  $C_{24}H_{42}O_7$ 

Molecular weight: 442.59

1. Assay : Not less than 95%
2. Appearance : White or yellowish-white crystalline powder or powder.
3. Identification : (1) Dissolve 0.1 g of the sample in 100 mL of metaphosphoric acid TS (1 in 50 solution of metaphosphoric acid) by heating. Cool and add iodine TS dropwise to 5 mL of this solution until the solution was slightly yellow. Then, add a drop of copper sulfate solution (1 in 1000 solution of copper sulphate) and a drop of pyrrole and heat at 50 ~ 60 °C for 5 minutes. The solution should be blue or green.  
(2) 10 mL of the 1 in 100 solution of the sample in ethanol will decolorize a blue solution of 2,6- dichlorophenol-indophenol TS.
4. Melting range : 114~119°C.
5. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Residue on ignition : Not more than 0.10%.
8. Category : Food Additives Category 3, 8.
9. Uses : Antioxidants; Nutritional additives

## L-Ascorbyl Palmitate

Chemical formula:  $C_{22}H_{38}O_7$ 

Molecular weight: 414.54

1. Assay : Not less than 95% (vacuum oven, 56 - 60°C, 1 h)
2. Appearance : White or yellowish-white powder, with a citrus-like odor.
3. Melting range : 107~117°C.
4. Specific rotation :  $[\alpha]_D^{25} = +21^\circ \sim +24^\circ$  (vacuum oven, 56 - 60°C, 1 h, then make 10% (w/v) methanol solution)
5. Arsenic : Not more than 3 ppm (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Not more than 2% (vacuum oven, 56 - 60°C, 1 h)
8. Residue on ignition : Not more than 0.1%.
9. Category : Food Additives Category 3, 8.
10. Uses : Antioxidants; Nutritional additives

## Erythorbic Acid

Chemical formula:  $C_6H_8O_6$ 

Molecular weight: 176.13

1. Assay : Not less than 99.0%.
2. Description : White or yellowish-white, odorless, sour powder. Soluble in water and in ethanol, slightly soluble in glycerin.
3. Identification : (1) Dissolve 0.1 g of the sample in 100 mL of metaphosphoric acid TS (1 in 50 solution of metaphosphoric acid). Add iodine TS dropwise to 5 mL of this solution until the solution was slightly yellow. Then, add a drop of copper sulfate solution (1 in 1000 solution of copper sulphate) and a drop of pyrrole and heat in 50 ~ 60 °C water bath for 5 minutes. The solution should be blue or green.  
(2) Add 10 mL of potassium permanganate TS (1 g of potassium permanganate dissolved in 300 mL of water) to 10 mL of the 1 in 100 solution of the sample, and the pink color of the solution disappears immediately.
4. Melting range : 166~172°C.
5. Specific rotation :  $[\alpha]_D^{20} = -16.2^\circ \sim -18.2^\circ$  (10% (w/v) aqueous solution).
6. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 0.40% (reduced pressure, silica gel, 3 h)
9. Residue on ignition : Not more than 0.30%.
10. Category : Food Additives Category 3
11. Uses : Antioxidants.

## Sodium Erythorbate

**Synonyms**

INS No. 316; Sodium isoascorbate

**Definition**

## Chemical names

Sodium isoascorbate, sodium D-isoascorbic acid, sodium salt of 2,3-didehydro-D-erythro-hexono-1,4-lactone, 3-keto-D-gulofurano-lactone sodium enolate monohydrate

## CAS NUMBER

6381-77-7

## Molecular formula

 $C_6H_7O_6Na \cdot H_2O$ 

## Molecular weight

216.13

## Assay

Not less than 98.0% on the dried basis

**Appearance**

White crystalline powder, almost odorless.

**Characteristics****Identification**

## Solubility

Freely soluble in water, very slightly soluble in ethanol.

## Reducing activity

A solution of the sample will decolorize a solution of 2,6-dichlorophenolindophenol TS.

## Test for ascorbate

Passes test

## Test for sodium

Passes test

**Purity**

## Loss on drying

Not more than 0.25% (in vacuum over sulfuric acid, 24 h)

## Specific rotation

[ $\alpha$ ] 25, D: +95.5°~+98.0° (10% (w/v) solution)

## pH

5.5~8.0 (10% solution)

## Oxalate

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.

## Lead

Not more than 2 mg/kg.

**Category**

Food Additives Category 3

**Uses**

Antioxidants.



dl- $\alpha$ -Tocopherol (Vitamin E)Chemical formula: C<sub>29</sub>H<sub>50</sub>O<sub>2</sub>

Molecular weight: 430.71

1. Assay : Not less than 96.0%
2. Description : Slightly yellow to amber, nearly odorless, clear, viscous oil. Insoluble in water, freely soluble in ethanol, miscible with acetone, chloroform, ether and vegetable oils.
3. Identification : Dissolve about 10 mL of the sample in 10 mL of absolute ethanol. Add 2 mL of nitric acid and heat at about 75°C for 15 min. A bright red to orange color develops.
4. Spectrophotometry : E (1%, 1 cm) (292 nm): 71.0~76.0 (Dilute 5 mL of 0.1 g in 100 mL of absolute ethanol to 100 mL by absolute ethanol.)
5. Index of refraction :  $n_D^{20} = 1.503 \sim 1.507$ .
6. Turbidity : When 0.10 g of the sample is dissolved in 10 mL of ethanol, the solution should be clear.
7. Arsenic : Not more than 4 ppm (as As<sub>2</sub>O<sub>3</sub>).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Category : Food Additives Category 3, 8.
10. Uses : Antioxidants; Nutritional additives

## Propyl Gallate

Chemical formula:  $C_{10}H_{12}O_5$ 

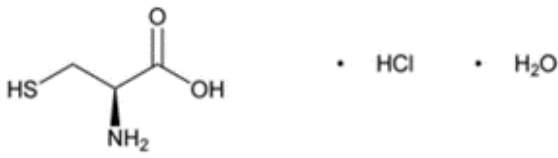
Molecular weight: 212.20

1. Assay : 98.0~102.0%.
2. Description : White or creamy-white, crystalline odorless powder. Odorless, with little bitter taste.  
Slightly soluble in water; freely soluble in ethanol, ether and propane-1,2- diol.
3. Identification : (1) Dissolve 0.5 g of the sample in 10 mL of sodium hydroxide solution (1 in 25 solution of sodium hydroxide). After distillation, take 4 mL of the initial distillation, which should be clear. The odor of propanol should be produced after heating.  
(2) Add 1 drop of ferric chloride solution (1 g of ferric chloride in 500mL of water) to 5 mL of 1 in 50 ethanol solution of the sample. The solution is purple.
4. Melting range : 146~150°C (after drying at 105°C for 2 hr).
5. Color of the solution : Dissolve 0.5 g of the sample in 10 mL of ethanol, and the color of the solution shall not be darker the Matching Fluid C.
6. Chloride : Not more than 0.028% (as Cl).
7. Sulfate : Not more than 0.048% ( $SO_4$ ).
8. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Not more than 1.5% (105°C, 2 h)
11. Residue on ignition : Not more than 0.10%.
12. Category : Food Additives Category 3
13. Uses : Antioxidants.

## Guaiac Resin

1. Description : The resin from the wood of *Guajacum officinale* L., or of *Guajacum sanctum* L.  
Externally, it is brownish black to dusky brown, acquiring a greenish color on long exposure, the fractured surface having a glassy lustre, the thin pieces being transparent and varying in color from brown to yellowish orange; the powder is moderate yellow brown, becoming olive brown on exposure to air. It has a mild balsamic odor. Dissolves readily but incompletely in ethanol, ether, chloroform and solutions of alkalis; slightly soluble in carbon disulfide and benzene.
2. Identification : (1) Add 1 drop of ferric chloride TS to 5 mL of an ethanolic solution of the sample (1 in 100). A blue color is produced which gradually changes to green, finally becoming greenish yellow.  
(2) A mixture of 5 mL of an ethanolic solution of the sample (1 in 100) and 5 mL of water becomes blue upon shaking with 20 mg of lead peroxide. Filter the solution, and boil a portion of the filtrate. The color disappears but may be restored by the addition of lead peroxide and shaking. Add a few drops of diluted hydrochloric acid TS to a second portion of the filtrate. The color is immediately discharged.
3. Melting range : 85~90°C.
4. Alcohol-insoluble solid : Not more than 15%.
5. Acid-insoluble ash : Not more than 15%.
6. Total ash : Not more than 5%.
7. Lead : Not more than 10 ppm.
8. Arsenic : Not more than 3 ppm(as As).
9. Heavy metals : Not more than 40 ppm (as Pb).
10. Category : Food Additives Category 3
11. Uses : Antioxidants.

## L-Cysteine Monohydrochloride

Chemical names	L-2-Amino-3-mercaptopropanoic Acid Monohydrochloride
C.A.S. number	Monohydrate: 7048-04-6 Anhydrous: 52-89-1
Chemical formula	Monohydrate: $C_3H_7NO_2S \cdot HCl \cdot H_2O$ Anhydrous: $C_3H_7NO_2S \cdot HCl$
Structural formula	
Formula weight	Monohydrate: 175.63 Anhydrous: 157.62
Assay	98.0% - 101.5% $C_3H_7NO_2S \cdot HCl$ , on the dried basis
<b>Description</b>	White, crystalline powder. It is freely soluble in water and in alcohol. The anhydrous form melts with decomposition at about 175°C.
<b>Identification</b>	The spectrum of the sample exhibits maxima at the same wavelengths as those in the spectrum of the Reference standard.
Lead	Not more than 5 mg/kg
Loss on drying	8.0%~12.0%  Room temperature for 24 h in a vacuum desiccator using a suitable desiccant and maintaining a pressure of not more than 5 mmHg
Specific rotation	$[\alpha]_D^{20} = +5.0^\circ \sim +8.0^\circ$ , calculated on the dried basis $[\alpha]_D^{25} = +4.9^\circ \sim +7.9^\circ$ , calculated on the dried basis
Residue on ignition	Not more than 0.1%
<b>Category</b>	Food additives category (03) (07) (10)
<b>Functional uses</b>	Antioxidants; Food quality improvement, fermentation and food processing agents; Flavoring Agents.

## Tertiary-Butyl Hydroquinone

Chemical formula:  $C_{10}H_{14}O_2$ 

Molecular weight: 166.22

1. Assay : Not less than 99.0%.
2. Description : White, crystalline solid having a characteristic odor. Practically insoluble in water; soluble in ethanol and ether.
3. Identification : Dissolve several mg of the sample in 1 mL of methanol, and add several drops of dimethylamine solution (1 in 4). A red to pink color is produced.
4. Melting range : 126.5~128.5°C.
5. Toluene : Not more than 25 ppm.
6. Hydroxyquinone : Not more than 0.1%.
7. 2,5-Di-t-butyl hydroquinone : Not more than 0.2%.
8. t-Butyl-p-benzoquinone : Not more than 0.2%.
9. Arsenic : Not more than 3 ppm(as As).
10. Heavy metals : Not more than 10 ppm (as Pb).
11. Polycyclic :  
aromatic  
hydrocarbons

When measured at a wavelength of 280 ~ 289 nm, its UV absorbance should be below 0.15.

When measured at a wavelength of 290 ~ 299 nm, its UV absorbance should be below 0.12.

When measured at a wavelength of 300 to 359 nm, the UV absorbance should be below 0.08.

When measured at a wavelength of 360 ~ 400 nm, its UV absorbance should be below 0.02.

12. Category : Food Additives Category 3.
13. Uses : Antioxidants.

## Calcium Ascorbate

Chemical formula:  $C_{12}H_{14}CaO_{12} \cdot 2H_2O$ 

Molecular weight: 426.25

1. Assay :  $C_{12}H_{14}CaO_{12} \cdot 2H_2O$  Not less than 98.0%
2. Description : White to slightly yellow odorless crystalline powder. Soluble in water; slightly soluble in ethanol and insoluble in ether.
3. Identification : The 1 in 10 solution of the sample passes the test for calcium. A solution of the sample will decolorize a solution of dichlorophenol-indophenol TS.
4. pH : 6.8~7.4 (1 in 10 soln)
5. Specific rotation :  $[\alpha]_D^{25} = +95^\circ \sim +97^\circ$  (5% (w/w) soln)
6. Oxalate : Dissolve 1 g of the sample in 10 mL of water, add 2 drops of glacial acetic acid and 5mL of calcium acetate solution (1 in 10 solution of calcium acetate). The solution will remain clear after placed for 5 minutes.
7. Fluoride : Not more than 10 ppm.
8. Arsenic : Not more than 3 ppm (as As).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Category : Food Additives Category 3, 8.
11. Uses : Antioxidants; Nutritional additives

## Tocopherols Concentrate, Mixed

1. Description : Mixed Tocopherol Concentrate contains 2 types: high- $\alpha$  type and low- $\alpha$  type. Both are obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols of different assay. High- $\alpha$  type contains relatively higher content of d-alpha-tocopherols, so it can be deemed as a form of Vitamin E and an antioxidant. Low- $\alpha$  type contains higher content of d- $\beta$ -, d-gamma-, d-delta-tocopherols and less of d-alpha-tocopherols, so it can only be considered as an antioxidant but not a form of Vitamin E. Both types may contain an edible vegetable oil added to adjust the required amount of total tocopherols, and the tocopherol forms may be adjusted by suitable physical and chemical means. Brownish red to red, clear, viscous oil having a mild, characteristic odor; may show a slight separation of wax like constituents in microcrystalline form. It oxidizes and darkens slowly in air and on exposure to light, particularly when in alkaline media. Insoluble in water; soluble in ethanol; miscible in acetone, chloroform, ether and vegetable oil.
2. Identification
  - A. Dissolve about 50 mg of the sample in 10 mL of absolute ethanol. Add, with swirling, 2 mL of nitric acid and heat at about 75°C for 15 min. A bright red to orange color develops.
  - B. High- $\alpha$  type: The retention time of the major peak in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.  
 Low- $\alpha$  type: The retention time of the third major peak (i.e. the peak occurring just before that of the internal standard) in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.
3. Assay : High- $\alpha$  type: Not less than 50.0% of total tocopherols. d-alpha-tocopherols (C<sub>29</sub>H<sub>50</sub>O<sub>2</sub>) should be not less than 50.0% of total tocopherols. Total of d- $\beta$ -, d-gamma- (C<sub>28</sub>H<sub>48</sub>O<sub>2</sub>), d-delta-tocopherols (C<sub>27</sub>H<sub>46</sub>O<sub>2</sub>) should not be less than 20.0% of total tocopherols.  
 Low- $\alpha$  type: Not less than 50.0% of total tocopherols. Total of d- $\beta$ -, d-gamma- (C<sub>28</sub>H<sub>48</sub>O<sub>2</sub>), d-delta-tocopherols (C<sub>27</sub>H<sub>46</sub>O<sub>2</sub>) should not be less than 80.0% of total tocopherols.
4. Acidity : Moderate.

5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.004% (as Pb).
7. Specific rotation :  $[\alpha]_D^{25}$ : Not less than +24° for high- $\alpha$  type; not less than +20° for low- $\alpha$  type.
8. Category : High- $\alpha$  type: Food Additives Category 3, 8.  
Low- $\alpha$  type: Food Additives Category 3.
9. Uses : High- $\alpha$  type: Antioxidants; Nutritional additives  
Low- $\alpha$  type: Antioxidants



*d*- $\alpha$ -Tocopherol Concentrate

1. Description : d-Alpha-Tocopherol, concentrate is a form of Vitamin E obtained by the vacuum steam distillation of edible vegetable oil products, comprising a concentrated form of d-alpha-tocopherol. It may contain an edible vegetable oil added to adjust the required amount of total tocopherols, and the content of d-alpha-tocopherol may be adjusted by suitable physical and chemical means.  
  
Brownish red, nearly odorless, clear viscous oil, which oxidizes and darkens slowly in air and on exposure to light.  
  
Insoluble in water; soluble in ethanol; miscible with ether, acetone, chloroform and vegetable oil.
2. Identification
  - A. Dissolve about 50 mg of the sample in 10 mL of absolute ethanol. Add, with swirling, 2 mL of nitric acid and heat at about 75°C for 15 min. A bright red to orange color develops.
  - B. The retention time of the major peak in the chromatogram of the sample solution is the same as that of the standard solution, both relative to the internal standard, as obtained in the assay preparation.
3. Assay : Not less than 40.0% of total tocopherols, of which not less than 95.0% consists of d-alpha-tocopherol (C<sub>29</sub>H<sub>50</sub>O<sub>2</sub>).
4. Acidity : Moderate.
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.004% (as Pb).
7. Specific rotation : Not less than  $[\alpha]_D^{25} : +24^\circ$
8. Category : Food Additives Category 3, 8.
9. Uses : Antioxidants; Nutritional additives

Disodium Ethylenediaminetetraacetate (EDTA Na<sub>2</sub>)

Chemical formula: C<sub>10</sub>H<sub>14</sub>N<sub>2</sub>Na<sub>2</sub>O<sub>8</sub>·2H<sub>2</sub>O

Molecular weight: 372.24

1. Description : White crystalline powder. Miscible with water.
2. Identification
  - A. The 1 in 20 solution of this sample passes test for sodium.
  - B. To 5 mL of water in a test tube add 2 drops of ammonium to thiocyanate TS and 2 drops of ferric chloride TS. A deep red solution develops. Add about 50 mg of the sample and mix. The deep red color disappears.
3. Assay : C<sub>10</sub>H<sub>14</sub>N<sub>2</sub>Na<sub>2</sub>O<sub>8</sub>·2H<sub>2</sub>O not less than 99.0%.
4. pH of 1% solution : 4.3~4.7.
5. Nitrilotriacetic acid : Passes test
6. Cyanide : Not more than 1 ppm(as CN).
7. Arsenic : Not more than 3 ppm (as As).
8. Lead : Not more than 10 ppm.
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Category : Food Additives Category 3, 7.
11. Uses : Antioxidants; Food quality improvement, fermentation and food processing agents

Calcium Disodium Ethylenediaminetetraacetate (EDTA CaNa<sub>2</sub>)Chemical formula: C<sub>10</sub>H<sub>12</sub>CaN<sub>2</sub>Na<sub>2</sub>O<sub>8</sub>·2H<sub>2</sub>O

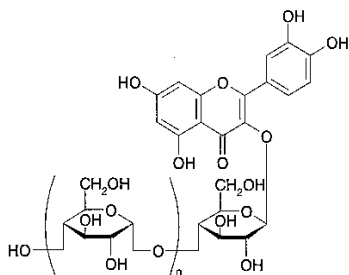
Molecular weight: 410.30

1. Description : White, odorless crystalline granules or a white to nearly white powder; slightly hygroscopic and salty. Stable in air. Freely soluble in water.
2. Identification : A. The 1 in 20 solution of this sample passes test for calcium and test for sodium.  
B. To 5 mL of water in a test tube add 2 drops of ammonium thiocyanate TS and 2 drops of ferric chloride TS. A deep red solution develops. Add about 50 mg of the sample and mix. The deep red color disappears.
3. Assay : Not less than 97% and not more than the equivalent of 102% calculated on the anhydrous basis.
4. pH : 6.5~7.5 (1 in 100 soln)
5. Water : Not more than 13%.
6. Magnesium chelating substances : Transfer 1 g of the sample, accurately weighed, to a small beaker, and dissolve it in 5 mL of water. Add 5 mL of buffer solution prepared by dissolving 67.5 g of ammonium chloride in 200 mL of water, adding 570 mL of strong ammonia TS, and diluting with water to 1000 mL. To the buffered solution add 5 drops of eriochrome black TS, and titrate with 0.1 M magnesium acetate to the appearance of a deep wine-red color. Not more than 2.0 mL should be required.
7. Arsenic : Not more than 3 ppm (as As).
8. Lead : Not more than 10 ppm.
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Category : Food Additives Category 3, 7.
11. Uses : Antioxidants, Food quality improvement, fermentation and food processing agents

$\alpha$ -Glycosyl-isoquercitrin

**Synonyms** : Enzymatically modified isoquercitrin; isoquercetin; EMIQ

Molecular weight: Approximately 800



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

**Definition** : Isoquercitrin is obtained by enzymatic hydrolysis of rutin. After mixed with starch or dextrin, it is reacted with cyclodextrin glucanotransferase.

**Assay** : Not less than 60% of rutin ( $C_{27}H_{30}O_{16}$ ) on the dried basis.

**Appearance** : Yellow to orange powder, lumps or mush, with a slightly special odor.

**Identification** : (1) Dissolve 5 mg of the sample in 10 mL of water and add 1 to 2 drops of 1 in 50 ferric chloride solution. A dark brown color appears.

(2) Dissolve 5 mg of the sample in 5 mL of water, add 2 mL of hydrochloric acid and 0.05 g of magnesium powder. The solution is orange to red.

(3) Dissolve 0.1 g of the sample in 100 mL of 1 N sulfuric acid, boil for 2 hours. Yellow precipitates appear after cooling.

(4) Spectrophotometry: Dissolve 10 mg of the sample in 500 mL of 1 in 1,000 phosphoric acid solution. The solution has the maximum absorption value around the wavelength of 255 nm and 350 nm.

(5) TLC: Analyze the test solution and control solution(rutin for assay)in methanol by TLC. Several brown spots are observed: one having an  $R_f$  value greater than that of the main spot of rutin for assay and others having  $R_f$  values the same as or smaller than that of the main spot of rutin for assay.

**Quercetin** : Not more than 1%.

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

**Arsenic** : Not more than 1.5 mg/kg

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

**Category** : Food Additives Category 3

**Functional uses** : Antioxidants

### Extracts of Rosemary

#### SYNONYMS

Extracts 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. Rosemary leaf extract antioxidant is prepared by extraction of the leaves of *Rosmarinus officinalis* using a food approved solvent system. Extracts may then be deodorized, decolorized and standardized.

#### Chemical names

Rosemary extract (*Rosmarinus officinalis*)

#### CHARACTERISTICS

##### IDENTIFICATION

Reference antioxidative  
compounds: phenolic  
diterpenes

: 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)

Acetone extraction: not less than 10% w/w, expressed as the total of carnosic acid and carnosol

Supercritical carbon dioxide extraction: not less than 13% w/w, expressed as the total of carnosic acid and carnosol

Deodorized ethanolic extract: not less than 5% w/w, expressed as the total of carnosic acid and carnosol

Two-step extraction using hexane and ethanol: not less than 5% w/w, expressed as the total of carnosic acid and carnosol

Antioxidants/Volatiles  
Ratio

Total % of carnosic acid and carnosol / Total % of reference volatiles: (-)-borneol, (-)-bornyl acetate, (-)-camphor, 1,8-Cineole (eucalyptol) and verbenone: not less than 15

Density

not less than 0.25 g/mL

Solubility

Insoluble in water

Residual solvents

Acetone extraction: Acetone: not more than 500 mg/kg

Supercritical carbon dioxide extraction: Ethanol: not more than 2%

Deodorized ethanolic extract: Ethanol: not more than 500 mg/kg

Two-step extraction using hexane and ethanol: Hexane: not more than 25 mg/kg, Ethanol: not more than 500 mg/kg

<b>Purity</b>	
Loss on drying	: Not more than 5%
Arsenic	: Not more than 3 mg/kg
Lead	: Not more than 2 mg/kg
<b>Category</b>	: Food additives category (03)
<b>Functional uses</b>	: Antioxidants

§ 04001

Potassium Sulfite

Chemical formula:  $K_2SO_3$

Molecular weight: 158.25

1. Assay : Not less than 90.0%.
2. Description : White, odorless, granular powder. Easily oxidize in air. Freely soluble in water; slightly soluble in ethanol.
3. Identification : The solution of this sample (1 in 20) passes test for potassium and test for sulfite.
4. Alkalinity : Between 0.25 and 0.45% as  $K_2CO_3$ .
5. Selenium : Not more than 30 ppm.
6. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 4
9. Uses : Bleaching agents.

### Sodium Sulfite

Chemical formula:  $\text{Na}_2\text{SO}_3 \cdot 7\text{H}_2\text{O}$

Molecular weight: 252.16

1. Assay : Not less than 95% on the dried basis.
2. Description : White or colorless, odorless powder. Easily oxidizes in air. Freely soluble in water; sparingly soluble in ethanol.
3. Identification : The solution of this sample (1 in 20) passes test for sodium and test for sulfite.
4. Solution : Dissolve 0.5g of the sample in 10 mL of water. The solution should be "almost clear" and alkaline.
5. Selenium : Not more than 30 ppm (calculated as Se on the anhydrous basis)
6. Arsenic : Not more than 4 ppm (calculated as  $\text{As}_2\text{O}_3$  on the anhydrous basis)
7. Heavy metals : Not more than 10 ppm (calculated as Pb on the anhydrous basis)
8. Category : Food Additives Category 4
9. Uses : Bleaching agents.



Sodium Sulfite, Anhydrous

Chemical formula:  $\text{Na}_2\text{SO}_3$

Molecular weight: 126.04

1. Assay : Not less than 95%
2. Description : Colorless, white or light pink and odorless. Easily oxidizes in air. Freely soluble in water; sparingly soluble in ethanol.
3. Identification : The solution of this sample (1 in 20) passes test for sodium and test for sulfite.
4. Solution : Dissolve 0.5 g of the sample in 10 mL of water. The solution should be less than "almost clear" and colorless.
5. Selenium : Not more than 30 ppm.
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 4
9. Uses : Bleaching agents.

### Sodium Bisulfite

1. Assay : Between 58.5 to 67.4% of SO<sub>2</sub>.
2. Description : A mixture of NaHSO<sub>3</sub> and Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub>. White or yellowish-white crystals or granular powder having an odor of sulfur dioxide. Unstable in air. Freely soluble in water; slightly soluble in ethanol.
3. Identification : The solution of this sample (1 in 10) passes test for sodium and test for sulfite.
4. Iron : Not more than 50 ppm.
5. Selenium : Not more than 30 ppm.
6. Arsenic : Not more than 4 ppm (as As<sub>2</sub>O<sub>3</sub>).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 4
9. Uses : Bleaching agents.

## Sodium Hydrosulfite

Chemical formula:  $\text{Na}_2\text{S}_2\text{O}_4$ 

Molecular weight: 174.11

1. Assay : Not less than 85.0%.
2. Description : White or off-white crystals or granular powder, odorless or having an odor of sulfur dioxide.
3. Identification : (1) Add 2 mL of 1 in 20 copper sulfate to 10 mL of 1 in 100 solution of the sample. The solution is grayish black.  
(2) Add 10 mL of potassium permanganate TS (1 g of potassium permanganate dissolved in 300 mL of water) to 10 mL of the 1 in 100 solution of the sample, and the color of the solution disappears immediately.  
(3) Passes test for sodium.
4. Solution : Add 10 mL of water to 10 mL of formaldehyde solution, neutralize it with 1 in 25 sodium hydroxide solution. Dissolve 0.5 g of the sample in 10 mL of the previous solution, and then put it for 5 minutes. Its turbidity should be below "slightly turbid".
5. Sodium diamine vinyl acetate : Dissolve 0.5 g of the sample in 5 mL of water, add 2 mL of 1 in 200 solution of potassium chromate and 2 mL of arsenite acid TS. After heated in a water bath for 2 minutes, color purple does not appear.
6. Formate : Not more than 0.05% of  $\text{HCHO}$ .
7. Zinc : Not more than 80 ppm.
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Category : Food Additives Category 4
11. Uses : Bleaching agents.

## Potassium Metabisulfite

Chemical formula:  $K_2S_2O_5$ 

Molecular weight: 222.33

1. Assay : Not less than 93.0%.
2. Description : Colorless free-flowing crystals, crystalline powder, or granules, usually having an odor of sulfur dioxide. Easily oxidizes in air. Soluble in water; insoluble in ethanol.
3. Identification : The solution of this sample (1 in 10) passes test for potassium and test for sulfite.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be clear with only a trace of suspended matter while the solution being acid.
5. Iron : Not more than 10 ppm.
6. Selenium : Not more than 30 ppm.
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 4
10. Uses : Bleaching agents.

## Sodium Metabisulfite

Chemical formula:  $\text{Na}_2\text{S}_2\text{O}_5$ 

Molecular weight: 190.11

1. Assay : Not less than 93.0%.
2. Appearance : White or light yellow crystals or crystalline powder having an odor of sulfur dioxide.  
Freely soluble in water; slightly soluble in ethanol.
3. Identification : The solution of this sample (1 in 20) passes test for sodium and test for sulfite.
4. Solution : Dissolve 0.5g of the sample in 10 mL of water. The solution should be "almost clear" and acidic.
5. Iron : Not more than 20 ppm.
6. Selenium : Not more than 30 ppm.
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Lead : Not more than 10 ppm.
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Category : Food Additives Category 4
11. Uses : Bleaching agents.

§ 04009

§ 07079

### Benzoyl Peroxide

Chemical formula:  $C_{14}H_{10}O_4$

Molecular weight: 242.23

1. Assay : Not less than 96.0%.
2. Description : Colorless, crystalline solid having a faint odor of benzaldehyde. Insoluble in water, slightly soluble in ethanol and soluble in benzene, chloroform and ether. 1 g of this product can be dissolved in 40 mL of carbon disulfide. Melts between 103°C and 106°C with decomposition. (Caution: Benzoyl peroxide, especially in the dry form, is a dangerous, highly reactive, oxidizing material and has been known to explode spontaneously)
3. Identification : To 500 mg of the sample add 50 mL of 0.5 N ethanolic potassium hydroxide, heat gradually to boiling and continue boiling for 15 min. Cool and dilute with 200 mL of water. Add sufficient 0.5 N hydrochloric acid to make strongly acidic and extract with ether. Dry the ether solution over anhydrous sodium sulfate, and then evaporate to dryness on a steam bath. The benzoic acid so obtained melts between 121°C and 123°C.
4. Arsenic : Not more than 3 ppm (as As).
5. Heavy metals : Not more than 0.004% (as Pb).
6. Lead : Not more than 10 ppm.
7. Category : Food Additives Category 4
8. Uses : Bleaching agents.

## Category 5 Color Fasting Agents

§ 05001

### Potassium Nitrite

Chemical formula:  $\text{KNO}_2$

Molecular weight: 85.10

1. Assay : Not less than 90.0% on the dried basis
2. Description : White or slightly yellow, deliquescent granules or rods. Freely soluble in water, sparingly soluble in ethanol. The 1 in 10 solution is alkaline on litmus paper.
3. Identification : The solution of this sample (1 in 10) passes test for potassium and test for nitrite.
4. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Category : Food Additives Category 5
8. Uses : Color Fasting Agents.

# Sodium Nitrite

Chemical formula:  $\text{NaNO}_2$

Molecular weight: 69.00

1. Assay : Not less than 97.0% on the dried basis.
2. Description : Clear, colorless, odorless, transparent crystals, or white granules or powder; deliquescent in air. The solution is alkaline on litmus paper. Freely soluble in water; slightly soluble in ethanol.
3. Identification : Passes test for sodium and test for nitrate.
4. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Loss on drying : Not more than 3.0% (100°C, 5 h).
8. Category : Food Additives Category 5
9. Uses : Color Fasting Agents.



## Potassium Nitrite

Chemical formula:  $\text{KNO}_3$ 

Molecular weight: 101.10

1. Assay : Not less than 99.0% on the dried basis.
2. Description : White, odorless, transparent prisms, or white granular or crystalline powder, salty and having a cool taste. Slightly deliquescent in moist air. The aqueous solution was neutral on litmus paper. 1 g of the sample is soluble in 3 mL of water at 25°C, 0.5 mL of boiling water, 620 mL, or in ethanol.
3. Identification : The solution of this sample (1 in 10) passes test for potassium and test for nitrite.
4. Chloride : Not more than 0.021% (as Cl).
5. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Lead : Not more than 10 ppm.
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 1.0% (105°C, 4 h).
9. Category : Food Additives Category 5
10. Uses : Color Fasting Agents.

# Sodium Nitrite

Chemical formula:  $\text{NaNO}_3$

Molecular weight: 84.99

1. Assay : Not less than 99.0% on the dried basis.
2. Description : White crystal or white crystalline powder, odorless, salty. Deliquescent in moist air.  
The aqueous solution was neutral on litmus paper. Soluble in water; sparingly soluble in ethanol.
3. Identification : The solution of this sample (1 in 5) passes test for potassium and test for nitrite.
4. Chloride : Not more than 0.02% (as Cl).
5. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Loss on drying : Not more than 1.0% (105°C, 4 h).
8. Category : Food Additives Category 5
9. Uses : Color Fasting Agents.

## Category 6 Leavening agents

§ 06001

### Potassium Alum (Aluminum Potassium Sulfate)

Chemical formula:  $\text{AlK}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$

Molecular weight: 474.38

1. Assay : Not less than 99.5% of  $\text{AlK}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$ .
2. Description : Colorless, transparent crystals or crystalline fragments, or white crystalline powder; odorless and slightly sweet and astringent. 1 g of the sample is soluble in 7.5 mL of 25°C of water or 0.3 mL of boiling water, soluble in glycerin; insoluble in ethanol. The aqueous solution is acidic on litmus paper.
3. Identification : The solution of this sample (1 in 20) passes test for potassium, test for aluminum and test for nitrite.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be "almost clear" and colorless.
5. Fluoride : Not more than 30 ppm.
6. Ammonium salt : Heat 1 g of the sample with 10 mL of sodium hydroxide TS on a steam bath for 1 min. The odor of ammonia is not perceptible.
7. Iron : Not more than 190 ppm (as Fe on anhydrous basis)
8. Lead : Not more than 10 ppm.
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$  on anhydrous basis)
10. Selenium : Not more than 30 ppm.
11. Heavy metals : Not more than 40 ppm (as Pb on anhydrous basis)
12. Category : Food Additives Category 6
13. Uses : Leavening agents

# Sodium Alum

Chemical formula:  $\text{AlNa}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$

Molecular weight: 458.26

1. Assay : Not less than 99.5% of  $\text{AlNa}(\text{SO}_4)_2$  on the dried basis.
2. Description : Colorless crystals, white particles or powder. Odorless, slightly salty and astringent.  
Soluble in water; insoluble in ethanol.
3. Identification : Passes test for aluminum, test for sulfate and sodium flame test.
4. Fluoride : Not more than 30 ppm (Fluoride, on anhydrous basis)
5. Ammonium salt : Heat 1 g of the sample with 10 mL of sodium hydroxide TS on a steam bath for 1 min.  
The odor of ammonia is not perceptible.
6. Selenium : Not more than 30 ppm (Se, on anhydrous basis)
7. Lead : Not more than 10 ppm.
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ , on anhydrous basis)
9. Heavy metals : Not more than 20 ppm (as Pb, on anhydrous basis)
10. Loss on drying : Not more than 47.2%.
11. Category : Food Additives Category 6
12. Uses : Leavening agents

Burnt Potassium Alum  
(Aluminum Potassium Sulfate, Anhydrous)

Chemical formula:  $\text{AlK}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$

Molecular weight: 258.21

1. Assay : Not less than 96.5% on the dried basis (200°C, 4 h)
2. Description : Large, transparent crystals or crystalline fragments, or white crystalline powder; odorless with a slightly sweet and astringent taste.
3. Identification : The solution of the sample (1 in 20) passes test for potassium, test for aluminum and test for sulfate.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be “almost clear” and colorless.
5. Water-insoluble matter : Not more than 2%.
6. Fluoride : Not more than 30 ppm.
7. Iron : Not more than 190 ppm (as Fe).
8. Lead : Not more than 10 ppm.
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Selenium : Not more than 30 ppm.
11. Heavy metals : Not more than 40 ppm (as Pb).
12. Category : Food Additives Category 6
13. Uses : Leavening agents

Ammonium Alum  
(Aluminum Ammonium Sulfate)

Chemical formula:  $\text{AlNH}_4(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$ 

Molecular weight: 453.32

1. Assay : Not less than 99.5% of  $\text{AlNH}_4(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$ .
2. Description : Large, colorless crystals, white granules, or a powder; odorless. Sweet and very astringent. 1 g of the sample is soluble in 7.0 mL of 25°C of water or 0.3 mL of boiling water, slowly soluble in glycerin; insoluble in ethanol. The aqueous solution is acidic on litmus paper.
3. Identification : The solution of the sample (1 in 20) passes test for aluminum, test for ammonium and test for sulfate.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be “almost clear” and colorless.
5. Fluoride : Not more than 30 ppm.
6. Alkalis and alkaline earths : Completely precipitate the aluminum from a boiling solution of 1 g of the sample in 100 mL of water by the addition of enough ammonia TS to render the solution distinctly alkaline to methyl red TS, and filter with 10 mL of hot water. Evaporate the filtrate to dryness, and ignite. The weight of the residue does not exceed 5 mg.
7. Iron : Not more than 190 ppm of (as Fe, on anhydrous basis)
8. Lead : Not more than 10 ppm.
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ , on anhydrous basis)
10. Selenium : Not more than 30 ppm.
11. Heavy metals : Not more than 40 ppm (as Pb, on anhydrous basis)
12. Category : Food Additives Category 6
13. Uses : Leavening agents

Burnt Ammonium Alum  
(Aluminum Ammonium Sulfate, Anhydrous)

Chemical formula:  $\text{AlNH}_4(\text{SO}_4)_2$

Molecular weight: 237.15

1. Assay : Not less than 96.5% on the dried basis (200°C, 4 h)
2. Description : White powder or porous mass, odorless, slightly sweet, and with a strong astringent taste.
3. Identification : The 1 in 20 solution of the sample passes test for ammonium, test for aluminum and test for sulfate.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be “almost clear” and colorless.
5. Water-insoluble matter : Not more than 2%.
6. Fluoride : Not more than 30 ppm.
7. Iron : Not more than 190 ppm (as Fe).
8. Lead : Not more than 10 ppm.
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Selenium : Not more than 30 ppm.
11. Heavy metals : Not more than 40 ppm (as Pb).
12. Category : Food Additives Category 6
13. Uses : Leavening agents

# Ammonium Chloride

Chemical formula:  $\text{NH}_4\text{Cl}$

Molecular weight: 53.49

1. Assay : Not less than 99.0% on the dried basis.
2. Description : Colorless crystal or white crystalline powder or crystallized masses, salty and cool.  
Slightly deliquescent. 1 g of the sample is soluble in 100 mL of alcohol, 8 mL of glycerin, 2.6 mL of water at 25°C or 1.4 mL of boiling water.
3. Identification : The 1 in 10 solution of the sample passes test for ammonium and test for chloride.
4. Solution : Dissolve 2 g of the sample in 20 mL of water. The solution should be "almost clear".
5. pH : 4.5~6.0 (1 in 20 soln)
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 2.0% (Silicone dryer, 4 hr).
9. Residue on ignition : Not more than 0.5%.
10. Category : Food Additives Category 6
11. Uses : Leavening agents



Potassium *dl*-Bitartrate

Chemical formula: C<sub>4</sub>H<sub>5</sub>O<sub>6</sub>K

Molecular weight: 188.18

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : Colorless crystal or white crystalline powder, with a cool and sour odor.
3. Solution : Dissolve 0.5 g of the sample in 3 mL of water. The solution should be less than "almost clear" and colorless.
4. Sulfate : Not more than 0.02% of SO<sub>4</sub>.
5. Ammonium salt : Heat 0.5 g of the sample with 5 mL of sodium hydroxide TS. The odor of ammonia is not perceptible.
6. Calcium : Test for calcium of "d-potassium tartrate" is applicable.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Readily oxidizable matter : Dissolve 2 g of the sample in 20 mL of water 30 mL of dilute sulphuric acid. When 4 mL of 0.1 N potassium permanganate solution is added at 20°C, the solution color should not disappear within 3 minutes.
9. Loss on drying : Not more than 0.5% (105°C, 3 h).
10. Category : Food Additives Category 6
11. Uses : Leavening agents

Potassium *d*-BitartrateChemical formula: C<sub>4</sub>H<sub>5</sub>O<sub>6</sub>K

Molecular weight: 188.18

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : Colorless crystal or white crystalline powder, having a cool and sour odor.
3. Solution : Dissolve 0.5 g of the sample in 3 mL of water. The solution should be less than "almost clear" and colorless.
4. Specific rotation :  $[\alpha]_D^{20} = +32.5^\circ \sim +35.5^\circ$  [ dried at 105°C for 3hours (Add 10 mL of ammonia TS and water to 5 g of the sample to make a 50 mL solution) ]
5. Sulfate : Not more than 0.02% of SO<sub>4</sub>.
6. Ammonium salt : Heat 0.5 g of the sample with 5 mL of sodium hydroxide TS. The odor of ammonia is not perceptible.
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Calcium : Add 1 g of the sample in 5 mL of acetic acid and vibrated constantly. After placed for 30 minutes, add 25 mL of water. After standing, the solution is filtered with absorbent cotton. The filtrate should not be turbid when 8 drops of ammonium oxalate TS are added.
9. Loss on drying : Not more than 0.5% (105°C, 3 h).
10. Category : Food Additives Category 6
11. Uses : Leavening agents

## Sodium Bicarbonate

Chemical formula:  $\text{NaHCO}_3$ 

Molecular weight: 84.01

1. Assay : Not less than 99.0% on the dried basis.
2. Description : Colorless, white, crystalline masses or crystalline powder. Stable in dry air and slowly decompose in moist air. The freshly prepared cold solution of the sample is alkaline on litmus paper before shaking. When the solution is placed, stirred or heated, alkalinity increases. 1 g of the sample is soluble in 10 mL of water, but not in ethanol.
3. Identification : The 1 in 10 solution of the sample passes test for sodium and test for carbonate.
4. Solution : When 1 g of the sample is dissolved in 20 mL of water, the solution should be clear.
5. Chloride : Not more than 200 ppm (as Cl).
6. Carbonate : Carefully add 20 mL of freshly boiled and cooled water to 1 g of the sample. After shaking at a temperature below 15°C, add 2.0 mL of 0.1 N hydrochloric acid. Then add 2 drops of phenolphthalein TS, no pink color should appear immediately.
7. Ammonium salt : Heat 1 g of the sample in the tube. The odor of ammonia is not perceptible.
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Loss on drying : Not more than 0.25% (Silicone dryer, 4 hr).
11. Category : Food Additives Category 6
12. Uses : Leavening agents

# Ammonium Carbonate

1. Assay : Not less than 30.0% and not more than 34.0% of  $\text{NH}_3$ .
2. Description : Consists of  $\text{NH}_4\text{HCO}_3$  and  $\text{NH}_2\text{COONH}_4$  in varying proportions. White powder or hard, white or translucent masses of crystals with an odor of ammonia. On exposure to air it becomes opaque and is finally converted into white porous lumps or powder (of ammonium bicarbonate) due to loss of ammonia and carbon dioxide. 1 g of the sample is slowly soluble in 4 mL of water.
3. Identification : (1) When heated, it volatilizes without charring and the vapor is alkaline to moist litmus.  
(2) Dissolve 1 g of the sample in 20 mL of water, and bubbles will be formed when adding acid.  
(3) Passes test for ammonia and test for carbonate.
4. Solution : Dissolve 2.0 g of the sample in 20 mL of water. The solution should be "almost clear".
5. Chloride : Not more than 40 ppm (as Cl).
6. Sulfide : Not more than 50 ppm.
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Residue on ignition : Not more than 0.01%.
10. Non-volatile residue : Not more than 0.05%.
11. Category : Food Additives Category 6, 7.
12. Uses : Leavening Agents; Food quality improvement, fermentation and food processing agentss.

# Ammonium Bicarbonate

Chemical formula:  $\text{NH}_4\text{HCO}_3$

Molecular weight: 79.06

1. Assay : Not less than 99.0%.
2. Description : White crystals or a crystalline powder with a slight odor of ammonia. At 60°C or above, it evaporates quickly and decomposes into ammonia, carbon dioxide and water. Stable at room temperature. 1 g of the sample can be dissolved in 6 mL of water; insoluble in ethanol.
3. Identification : Passes test for ammonium and test for carbonate.
4. Solution : Dissolve 2.0 g of the sample in 20 mL of water. The solution should be "almost clear".
5. Chloride : Not more than 40 ppm (as Cl).
6. Sulfates : Not more than 70 ppm.
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Residue on ignition : Not more than 0.01%.
10. Non-volatile residue : Not more than 0.05%.
11. Category : Food Additives Category 6
12. Uses : Leavening agents

## Potassium Carbonate

Chemical formula:  $K_2CO_3$ 

Molecular weight: 138.21

1. Assay : Not less than 99.0% on the dried basis.
2. Description : This product includes anhydrous form and hydrated form containing 1.5 molecules of water. Anhydrous form is white granular powder, hydrated form is small white transparent crystal or particles. Odorless, with strong alkali taste, easily deliquescent. Its aqueous solution is alkaline. 1 g of the sample is soluble in 1 mL of 25 °C water or 0.7 mL of boiling water, but insoluble in alcohol.
3. Identification : The 1 in 10 solution of the sample passes test for potassium and test for carbonate.
4. Solution : Dissolve 1 g of the sample in 20 mL of water. The solution should be "almost clear" and colorless.
5. Insoluble matter : Dissolve 1 g of the sample in 20 mL of water, no residue should appear.
6. Chloride : Not more than 530 ppm (as Cl).
7. Lead : Not more than 10 ppm.
8. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Anhydrous: Not more than 1%  
Hydrated forms: Between 10% and 16.5% (180°C , 4 h)
11. Category : Food Additives Category 6, 7 and 14.
12. Uses : Leavening agents; Food quality improvement, fermentation and food processing agentss; chemicals for food industry.

# Baking Powder

1. Appearance : White to off-white powder or fragile powder.
2. Solution : Dissolve 1 g of the sample in 50 mL of water, heat in water bath until no foam appears, then cool and test the pH. pH of the one dosage type and two dosage type is 5.0 ~ 8.5, and the pH of ammonium dosage type is 6.0 ~ 9.0.
3. Nitric acid : Not more than 2%.  
insoluble matter
4. Arsenic : Not more than 4 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 40 ppm (as Pb).
6. Gas relief : 2 g of the sample shall produce more than 70 mL of gas.
7. Category : Food Additives Category 6
8. Uses : Leavening agents

## Sodium Aluminum Phosphate, Acidic

Chemical formula:  $\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$  or

Molecular weight: 949.88 or

 $\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$ 

Molecular weight: 897.82

1. Assay : Not less than 95.0% of  $\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$   
Not less than 95.0% of  $\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$
2. Description : White, odorless powder. Insoluble in water; soluble in hydrochloric acid.
3. Identification : Passes test for aluminum, test for sodium and test for phosphate. Test a 1 in 10 solution in dilute hydrochloric acid (1 in 2).
4. Fluoride : Not more than 25 ppm.
5. Lead : Not more than 10 ppm.
6. Arsenic : Not more than 3 ppm (as As).
7. Heavy metals : Not more than 40 ppm (as Pb).
8. Residue on :  $\text{NaAl}_3\text{H}_{14}(\text{PO}_4)_8 \cdot 4\text{H}_2\text{O}$  19.5%~21%.  
ignition  $\text{Na}_3\text{Al}_2\text{H}_{15}(\text{PO}_4)_8$  15%~16%.
9. Category : Food Additives Category 6
10. Uses : Leavening agents



## Burnt Sodium Alum

Chemical formula:  $\text{AlNa}(\text{SO}_4)_2$ 

Molecular weight: 242.09

1. Assay : Not less than 96.5%
2. Description : Colorless crystals, white particles or powder. Odorless, slightly salty and astringent.  
Soluble slowly in water but insoluble in alcohol.
3. Identification : Passes sodium flame test, test for aluminum and test for sulfate.
4. Fluoride : Not more than 30 ppm(as F).
5. Ammonium salt : Heat 1 g of the sample with 10 mL of sodium hydroxide TS on a steam bath for 1 min.  
The odor of ammonia is not perceptible.
6. Selenium : Not more than 30 ppm(as Se)
7. Lead : Not more than 10 ppm.
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Not more than 10%.
11. Category : Food Additives Category 6
12. Uses : Leavening agents

§ 07001

## Calcium Chloride

**Synonyms** INS No. 509

### Definition

Chemical names Calcium chloride

CAS number 10043-52-4

Chemical formula Anhydrous:  $\text{CaCl}_2$

Dehydrate:  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

Hexahydrate:  $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$

Molecular weight Anhydrous: 110.99

Dehydrate: 147.02

Hexahydrate: 219.08

Assay Anhydrous: Not less than 93%

Dehydrate: Not less than 99.0% and not more than the equivalent of 107.0% of  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

Hexahydrate: Not less than 98.0% and not more than the equivalent of 110% of  $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$

### Description

Anhydrous: White, deliquescent lumps or porous masses

Dehydrate: White, hard, deliquescent fragments or granules Hexahydrate:

Colorless, very deliquescent crystals

### Characteristics

#### Identification

Solubility Anhydrous: Freely soluble in water and ethanol

Dehydrate: Freely soluble in water; soluble in ethanol

Hexahydrate: Very soluble in water and ethanol

Test for chloride Passes test

Test for calcium Passes test

#### Purity

Free alkali Not more than 0.15% as  $\text{Ca}(\text{OH})_2$

Dissolve 1 g of the sample in 20 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS. If the solution is pink, the pink color is

discharged by adding 2 mL of 0.02 N hydrochloric acid.

Magnesium and alkali      Not more than 5%

salts

Fluoride      Not more than 40 mg/kg

Lead      Not more than 2 mg/kg

**Category**      Food Additives Category 7

**Uses**      Food quality improvement, fermentation and food processing agents

# Calcium Hydroxide

Chemical formula:  $\text{Ca(OH)}_2$

Molecular weight: 74.09

1. Assay : Not less than 95.0%
2. Description : Alkaline, white, bitter powder.  
1 g of this product is soluble in 630 mL of 25°C water or 1300 mL of boiling water.  
Insoluble in ethanol, soluble in glycerol and saturated sucrose solution.
3. Identification : (1) Mix the product with water 3 to 4 times of its weight, a muddy solution will be produced and its suspension is alkaline on litmus paper.  
(2) Add 1 g of the sample in 20 mL of water and add sufficient acetic acid to dissolve it.  
The solution passes test for calcium.
4. Hydrochloric acid : Not more than 0.5%.  
insoluble matter
5. Carbonate : No bubbles shall be generated when 2 g of the sample in 50 mL of water is added with 5 mL of dilute hydrochloric acid.
6. Fluoride : Not more than 50 ppm.
7. Magnesium and : The weight of the residue does not exceed 12 mg.  
alkali salts
8. Barium : Not more than 300 ppm
9. Lead : Not more than 10 ppm.
10. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
11. Heavy metals : Not more than 40 ppm (as Pb).
12. Category : Food Additives Category 7
13. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Sulfate

**Synonyms** : INS No. 516

**Definition**

CAS NUMBER 7778-18-9

Chemical formula Anhydrous:  $\text{CaSO}_4$   
Dehydrate:  $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$

Molecular weight Anhydrous: 136.14  
Dehydrate: 172.18

Assay : Not less than 99.0% after drying

**Appearance** : Fine, white to slightly yellow-white, odorless powder.

**Characteristics****Identification**

Solubility Slightly soluble in water; insoluble in ethanol.

Test for : Passes test.

calcium

Test for : Passes test.

sulfate

**Purity**

Loss on Anhydrous: Not more than 1.5% (250° to constant weight).

drying Dihydrate: 19 ~ 23% (250° to constant weight).

Fluorine : Not more than 30 mg/kg

Selenium : Not more than 30 mg/kg

Lead : Not more than 2 mg/kg

**Category** : Food Additives Category 7

**Uses** : Food quality improvement, fermentation and food processing agents

## Calcium Gluconate

Chemical formula:  $C_{12}H_{22}CaO_{14} \cdot H_2O$ 

Molecular weight: 448.39

1. Assay : Not less than 98% and not more than 104% (as  $Cl_2H_{22}CaO_{14} \cdot H_2O$  on the dried basis.
2. Description : Odorless and tasteless, white, crystalline granules or powder, stable in air. The solution was tested neutral on litmus paper. 1 g of this sample is slowly soluble in 30 mL of 25°C water of 5 mL of boiling water; insoluble in ethanol and other organic solvents.
3. Identification : (1) Add 1 drop of ferric chloride solution (1 g of ferric chloride dissolved in 10 g of water) to 1 mL of calcium gluconate solution (1 g of calcium gluconate dissolved in 40 g of water). The solution is dark yellow.  
(2) Add 0.7 mL of glacial acetic acid and 1 mL of freshly distilled phenylhydrazine to 5 mL of warm calcium gluconate solution (1 g of calcium gluconate dissolved in 10 g of warm water) in a test tube. Heat on a steam bath for 30 minutes and cool. Scrape the inner wall of the tube with glass bar to induce crystallization and collect the crystal by filtration. Dissolve the crystal in 10 mL of hot water, add a small amount of activated carbon. The crystal is dissolved in 10 mL of hot water. Add a small amount of activated, mix and cool. Collect the crystal in the same way again. The melting point of crystal is between 192 ~ 202 °C.  
(3) The 1 in 40 solution of the sample passes the test for calcium.
4. Solution : Dissolve 1 g of the sample in 20 mL of water at 60°C. The solution should be less than “almost clear”.
5. pH : 6.0~8.0 (1 in 20 soln)
6. Chloride : Not more than 0.07% of Cl.
7. Sulfate : Not more than 0.05% of  $SO_4$ .
8. Lead : Not more than 10 ppm.
9. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Sucrose and reducing sugar : Add 10 mL of hot water and 2 mL of dilute hydrochloric acid TS and boil for 2 minutes. Cool and add 5 mL of sodium carbonate TS, stand for 5 minutes, add water to make a 20 mL solution. Filter, then add 2 mL of Feringin TS to 5 mL of clear filtrate and boil for 1 minute. Orange-yellow to red precipitates shall not be generated immediately.
12. Loss on drying : Dry it at 80° for 2 hours: it loses not more than 0.5% of its weight.

- 13. Category : Food Additives Category 7
- 14. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Citrate

<b>Synonyms</b>	INS No. 333(iii)
<b>Definition</b>	
Chemical names	Tricalcium citrate, tricalcium salt of 2-hydroxy-1,2,3- propanetricarboxylic acid, tricalcium salt of β-hydroxy-tricarballic acid
C.A.S. number	813-94-5
Chemical formula	$C_{12}H_{10}Ca_3O_{14} \cdot 4H_2O$
Structural formula	$\left[ \begin{array}{c} \text{CH}_2\text{COO}^\ominus \\   \\ \text{HO}-\text{C}-\text{COO}^\ominus \\   \\ \text{CH}_2\text{COO}^\ominus \end{array} \right]_2 \text{Ca}_3 \cdot 4\text{H}_2\text{O}$
Formula weight	570.51
Assay	Not less than 97.5% after drying
<b>Description</b>	Odourless, fine white powder
<b>Characteristics</b>	
Identification	
Solubility	Very slightly soluble in water. Insoluble in ethanol.
Test for citrate	Passes test
Test for calcium	Passes test
Purity	
Loss on drying	Not less than 10% and not more than 14% (150°C, 4 h)
Fluorides	Not more than 30 mg/kg
Free acid and alkali	Passes test
Oxalate	Dissolve 1 g of the sample in 5 ml of warm dilute hydrochloric acid TS and filter the solution if necessary.
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (7) (8)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Nutritional additives.



§ 07006

§ 08113

### Calcium Dihydrogen Phosphate

**SYNONYMS** : Monobasic calcium phosphate, monocalcium orthophosphate, monocalcium phosphate, calcium biphosphate, acid calcium phosphate, INS No. 341(i)

#### DEFINITION

**Chemical names** : Calcium dihydrogen phosphate

**C.A.S. number** : Anhydrous: 7758-23-8  
Monohydrate: 10031-30-8

**Chemical formula** : Anhydrous:  $\text{Ca}(\text{H}_2\text{PO}_4)_2$   
Monohydrate:  $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$

**Formula weight** : Anhydrous: 234.05  
Monohydrate: 252.07

**Assay** Anhydrous: Not less than 16.8% and not more than 18.3% of Ca  
Monohydrate: Not less than 15.9% and not more than 17.7% of Ca

**DESCRIPTION** Hygroscopic white crystals or granules, or granular powder

#### CHARACTERISTICS

##### IDENTIFICATION

**Solubility** : Sparingly soluble in water, insoluble in ethanol

**Test for calcium** : Passes test

**Test for phosphate** : Passes test

##### PURITY

**Loss on drying** : Monohydrate: Not more than 1% (60°C , 3 h)

**Loss on ignition** : Anhydrous: Between 14.0 and 15.5% (800°C , 30 min)

**Fluoride** : Not more than 50 mg/kg

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

**Lead** : Not more than 4 mg/kg

**Category** : Food additives category (7); (8).

**Functional uses** : Food quality improvement, fermentation and food processing agents; Nutritional additives.

## Calcium Phosphate, Dibasic

<b>Synonyms</b>	: INS No. 341(ii); Dibasic calcium phosphate; dicalcium phosphate
<b>Definition</b>	
Chemical names	: Calcium monohydrogen phosphate, calcium hydrogen orthophosphate, secondary calcium phosphate
CAS NUMBER	: 7757-93-9
Chemical formula	Anhydrous: $\text{CaHPO}_4$ Dihydrate: $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$
Molecular weight	Anhydrous: 136.06 Dihydrate: 172.09
Assay	: 98.0 ~ 102.0% after drying
<b>Appearance</b>	: A white, odorless powder.
<b>Characteristics</b>	
Identification	
Solubility	Practically insoluble in water; insoluble in ethanol.
Test for phosphate	Passes test.
Test for calcium	Passes test.
Purity	
Loss on drying	Anhydrous: Not more than 2% (200°C, 3 hr). Dihydrate: 18% ~ 22% (200°C, 3 hr).
Fluorine	: Not more than 50 mg/kg.
Arsenic	: Not more than 3 mg/kg.
Lead	: Not more than 4 mg/kg.
<b>Category</b>	: Food Additives Category 7, 8.
<b>Uses</b>	: Food quality improvement, fermentation and food processing agents; Nutritional additives

## Calcium Phosphate, Tribasic

<b>Synonyms</b>	: INS No. 341(iii); Tricalcium phosphate; precipitated calcium phosphate
<b>Definition</b>	: Consists of a variable mixture of calcium phosphates having and approximate composition of $10 \text{ CaO} \cdot 3\text{P}_2\text{O}_5 \cdot \text{H}_2\text{O}$ .
<b>Assay</b>	: Not less than the equivalent of 90% of $\text{Ca}_3(\text{PO}_4)_2$ , calculated on the ignited basis
<b>Appearance</b>	: White, odorless and tasteless powder which is stable in air.
<b>Characteristics</b>	
Identification	
Solubility	Practically insoluble in water; insoluble in ethanol, soluble in dilute hydrochloric and nitric acid.
Test for phosphate	Passes test.
Test for calcium	Passes test.
Purity	
Loss on ignition	: Not more than 10% (825° to constant weight).
Fluorine	: Not more than 50 mg/kg.
Lead	: Not more than 4 mg/kg.
<b>Category</b>	: Food Additives Category 7, 8.
<b>Uses</b>	: Food quality improvement, fermentation and food processing agents; Nutritional additives

## Calcium Dihydrogen Pyrophosphate

Chemical formula:  $\text{CaH}_2\text{P}_2\text{O}_7$ 

Molecular weight: 216.04

1. Assay : Not less than 90%
2. Description : A white powder or granules.
3. Identification : (1) Shake 0.5 g of the sample and 10 mL of water evenly. The solution is acid.  
(2) Heat and dissolve 5 mL of dilute nitric acid (1 mL of nitric acid dissolved in 9 mL of water) to 0.2 g of the sample. Add 2 mL of ammonium molybdate TS. After heating, yellow precipitate forms.  
(3) Dissolve 9 mL of water and 1 mL of dilute hydrochloric acid (1 mL of hydrochloric acid in 3 mL of water) to 0.3 of the sample by heating. Cool and filter. Add 3 mL of ammonium oxalate solution (1 g of ammonium oxalate in 30 mL of water) to the filtrate, and white precipitate forms. Add 5 mL of dilute hydrochloric acid (1 mL of hydrochloric acid in 30 mL of water), and the precipitate dissolves.
4. Hydrochloric acid insoluble matter : Not more than 0.4%.
5. Test for orthophosphate : Add 2 to 3 drops of silver nitrate TS (1 in 50 solution of silver nitrate) to 1.0 g of the sample. An obvious yellow color should not appear.
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Dry it at  $150^\circ$  for 4 hours: it loses not more than 5% of its weight.
9. Category : Food Additives Category 7
10. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Glycerophosphate

Chemical formula:  $C_3H_7CaO_6P$ 

Molecular weight: 210.14

1. Assay : Not less than 98.0%
2. Description : White odorless, powder. Almost tasteless or slightly bitter, slightly hygroscopic. At low temperature, it is more soluble in water and citric acid increases its water solubility. Insoluble in alcohol.
3. Identification : (1) Mix and heat 100 mg of the sample with 500 mg of potassium bisulfate, and irritant propylene aldehyde gas will be produced.  
(2) Mix 1 g of the sample with 10 mL of cold water at 5°C or below. After shaking evenly, perform the following tests:  
(a) When the test solution is boiled, white scaly crystals form.  
(b) Add 2 to 3 drops of lead acetate TS to 3 mL of the sample, and a white curd-like precipitate appears. Add 3 mL of nitric acid, and the precipitate disappears.  
(c) Saturated solution of the sample passes the test for calcium.
4. Solution : Add 1 g of this product is to 50 mL of water, and the solution should be below "slightly turbid".
5. Ethanol-soluble substances : Not more than 1%.
6. Free alkali : Add 5 drops of phenolphthalein TS to 1 in 60 solution of the sample. Not more than 1.5 mL of 0.1 N sulfuric acid should be required to titration.
7. Chloride : Not more than 0.07% of Cl.
8. Sulfate : Not more than 0.048% of  $SO_4$ .
9. Phosphate : Not more than 0.04% of  $PO_4$ .
10. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
11. Heavy metals : Not more than 40 ppm (as Pb).
12. Lead : Not more than 10 ppm.
13. Loss on drying : Dry it at 150° for 4 hours: it loses not more than 13.0% of its weight.
14. Category : Food Additives Category 7
15. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Lactate

Chemical formula:  $\text{C}_6\text{H}_{10}\text{CaO}_6 \cdot 0 \sim 5\text{H}_2\text{O}$ 

Molecular weight: 218.22

1. Assay : Not less than 97.0% and not more than 101.0% of on the dried basis as  $\text{C}_6\text{H}_{10}\text{CaO}_6$ .
2. Description : White to cream colored, almost odorless, crystalline powder or granules. The pentahydrate is somewhat efflorescent. Soluble in water, practically insoluble in ethanol.
3. Identification : Dissolve 1 g of this product in 20 mL of water. The solution passes the test for calcium and lactate.
4. Solution : Dissolve 1 g of the sample in 20 mL of water in water bath. The solution should be clear.
5. pH : 6.0~8.0. 6.0-8.0 (1 in 20 soln)
6. Lead : Not more than 10 ppm (as Pb).
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Magnesium and alkali salts : Not more than 1% .
10. Volatile fatty acid : Add 0.5 g of the sample in 1 mL of sulfuric acid. When heated in a water bath, butyric acid-like odor should not occur.
11. Acidity : Not more than 0.55% of lactic acid.
12. Fluoride : Not more than 15 ppm.
13. Loss on drying : Dry it at 120° for 4 hours: it loses not more than 30.0% of its weight.
14. Category : Food Additives Category 7
15. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Stearyl 2-Lactylate

1. Description : White or slightly yellowish powder or brittle solid with a characteristic odor. Slightly soluble in hot water.
2. Identification : (1) Ignite 1 g of the sample at 500°C for 1 hour and dissolve it in 5 mL of dilute hydrochloric acid (1+3). The solution passes test for calcium.  
(2) Add 10 mL of dilute hydrochloric acid TS to 2 g of the sample, heat for 5 min in a water bath, filter and neutralize the filtrate with ammonia TS. Dissolve the residue from the filter in 30 mL of sodium hydroxide solution (1+25) and heat in 95°C or hotter water bath for 30 min. Add 20 mL of dilute hydrochloric acid (1+3) to it after cooling, extract twice with 30 mL of diethyl ether, wash the ether solution with 20 mL of water, dry with anhydrous sodium sulfate and evaporate the ether. The residue melts between 54 and 69°C.  
(3) Passes the test for lactate.
3. Acid value : 50~86.
4. Ester value : 125~164.
5. Arsenic : Not more than 4 ppm (as As<sub>2</sub>O<sub>3</sub>).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Total lactic acid : 32~38%.
8. Calcium content : 4.2~5.2%
9. Residue on ignition : 14.3~17.7% (800°C).
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Carbonate

Chemical formula:  $\text{CaCO}_3$ 

Molecular weight: 100.09

1. Assay : Not less than 98.0% after drying at 200°C for 4 hours.
2. Description : An odorless, tasteless powder or crystal. Stable in air. Practically insoluble in water and in alcohol.
3. Identification : Dissolve 1.0 g of the sample in 10 mL of water and 7 mL of dilute acetic acid (1 mL of acetic acid in 3 mL of water). Neutralize the solution with ammonia after boiling. The solution passes test for calcium.
4. Hydrochloric acid : Not more than 0.2%.  
insoluble matter
5. Free alkali : Add 3 g of the sample to 30 mL of freshly boiled and cooled water, stir for 3 min. and filter. To 20 mL of the filtrate add 2 drops of phenolphthalein TS. Though a red color is produced, it should disappear when 0.2 mL of 0.1 N hydrochloric acid is added.
6. Heavy metals : Not more than 30 ppm (as Pb).
7. Magnesium and : Not more than 1%.  
alkali salts
8. Barium : Not more than 0.03%.
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Fluoride : Not more than 0.005%.
11. Lead : Not more than 10 ppm.
12. Loss on drying : Dry it at 200° for 4 hours: it loses not more than 2.0% of its weight.
13. Category : Food Additives Category 7
14. Uses : Food quality improvement, fermentation and food processing agents



§ 07015

Ammonium Carbonate

The same as § 06009

§ 07016

Potassium Carbonate

The same as § 06011

## Sodium Carbonate; Sodium Carbonate, Anhydrous

Chemical names : Sodium carbonate; sodium salt of carbonic acid

Synonyms : Soda ash; INS No. 500 (i); CAS No. 497-19-8.

Chemical formula	: $\text{Na}_2\text{CO}_3$ (anhydrous)	Molecular weight:
	$\text{Na}_2\text{CO}_3 \cdot x\text{H}_2\text{O}$ (hydrated)	106.00

1. Assay : Not less than 99.0% after drying.
2. Appearance : Colorless crystals or white, granular or crystalline powder; the anhydrous form is hygroscopic; hydrated forms available include the monohydrate and the decahydrate; the latter is efflorescent.
3. Solubility : Freely soluble in water; insoluble in ethanol.
4. Identification : Passes test for sodium and test for carbonate.
5. Loss on drying : Anhydrous: Not more than 2%  
 Monohydrate: Not more than 15%  
 Decahydrate: 55 - 65%  
 For all forms, heat the sample first at about 70o, then gradually raise the temperature and finally dry at 250-300°C to constant weight.
6. Lead : Not more than 2 mg/kg.
7. Heavy metals : 10 mg/kg (as Pb).
8. Category : Food Additives Category 7, 14.
9. Uses : Food quality improvement, fermentation and food processing agents; chemicals for food industry.

## Magnesium Carbonate

<b>SYNONYMS</b>	:INS No. 504(i), Magnesium subcarbonate (light or heavy), hydrated basic magnesium carbonate, magnesium carbonate hydroxide; INS No. 504(ii)
<b>DEFINITION</b>	A basic hydrated or a normal hydrated magnesium carbonate or a mixture of the two
Chemical names	: Magnesium carbonate, Magnesium carbonate hydroxide hydrated
C.A.S. number	: Magnesium Carbonate : 546-93-0
Assay	Magnesium Carbonate : 24.0% ~ 26.4% (As Mg) Magnesium Hydroxide Carbonate : 40.0% ~ 45.0% (As MgO)
<b>DESCRIPTION</b>	Odourless, light, white friable masses or as a bulky white powder
<b>CHARACTERISTICS</b>	
<b>IDENTIFICATION</b>	
Solubility	: Practically insoluble in water; insoluble in ethanol
Test for carbonate	Magnesium Carbonate: Passes test Magnesium Hydroxide Carbonate: -
Test for magnesium	Passes test
Alkalinity	Magnesium Carbonate: - Magnesium Hydroxide Carbonate: Slurry shows slight alkalinity
<b>PURITY</b>	
Acid insoluble substances	Not more than 0.05%
Water insoluble substances	Magnesium Carbonates: Not more than 1% Magnesium Hydroxide Carbonate: -
Soluble salts	Magnesium Carbonates: - Magnesium Hydroxide Carbonate: Not more than 1.0%

<u>Calcium</u>	<u>Magnesium Carbonates: Not more than 0.4%</u>
	<u>Magnesium Hydroxide Carbonate : 1.0%以下</u>
<u>Lead</u>	<u>Not more than 2 mg/kg</u>
Arsenic	Not more than 4 <u>mg/kg</u> (As As <sub>2</sub> O <sub>3</sub> )
<b>Category</b>	: Food additives category (7).
<b>Functional uses</b>	: Food quality improvement, fermentation and food processing agents.

## Ammonium Sulfate

Chemical formula:  $(\text{NH}_4)_2\text{SO}_4$ 

Molecular weight: 132.14

1. Assay : Not less than 99.0%.
2. Description : Colorless crystals, white granule; odorless. Decomposes above 280 °C. Freely soluble in water; insoluble in ethanol.
3. Identification : Passes test for ammonium and test for sulfate.
4. Solution : Dissolve 1 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
5. pH : 4.5 - 6.0 (0.1 M solution)
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Selenium : Not more than 4 ppm.
9. Residue on ignition : Not more than 0.25%.
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents

## Sodium Sulfate

Chemical formula:  $\text{Na}_2\text{SO}_4 \cdot n\text{H}_2\text{O}$  ( $n=10$  or  $0$ )

Molecular weight: 322.20 (Decahydrate); 142.04

(Anhydrous)

1. Assay : Not less than 99.0% on the dried basis
2. Description : Colorless crystal or white, fine crystalline powder. The hydrated form is deliquescent. Freely soluble in water; practically insoluble in ethanol. The 1 in 20 solution of the sample is neutral or weak base on litmus paper.
3. Identification : Passes test for sodium and test for sulfate.
4. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be less than "almost clear" and colorless.
5. Chloride : Not more than 0.11% of Cl.
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Selenium : Not more than 0.003%.
9. Loss on drying :  $\text{Na}_2\text{SO}_4 \cdot 10\text{H}_2\text{O}$ : 51.0~57.0% (105°C, 4hr).  
 $\text{Na}_2\text{SO}_4$ : 5.0% (105°C, 4hr).
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents

## Magnesium Stearate

### SYNONYMS

: Magnesium distearate, dibasic magnesium stearate, INS No. 470(iii)

### DEFINITION

: Magnesium stearate is a mixture of magnesium salts of fatty acids obtained from edible fats and oils. The product consists mainly of magnesium stearate and palmitate in varying proportions. It is manufactured by one of the two following processes: a) direct process wherein fatty acids are directly reacted with a magnesium source, such as magnesium oxide to form magnesium salts of the fatty acids; b) indirect process where a sodium soap is produced by the reaction of fatty acids with sodium hydroxide in water and the product is precipitated by adding magnesium salts to the soap.

### Chemical names

: Magnesium stearate, magnesium octadecanoate, fatty acids C<sub>16</sub>-C<sub>18</sub> magnesium salts

### C.A.S number

: 557-04-0 (magnesium stearate)  
91031-63-9 (fatty acids C<sub>16-18</sub> magnesium salts)

### Chemical formula

: Mg(C<sub>18</sub>H<sub>35</sub>O<sub>2</sub>)<sub>2</sub> (magnesium distearate)

### Formula weight

: 591.27 (magnesium distearate)

### Assay

: Magnesium: Not less than 4.0% and not more than 5.0%, on dried basis.

Fatty acids: Not less than 40.0% stearic acid in the fatty acid fraction; and not less than 90.0% as the sum of stearic acid and palmitic acid in the fatty acid fraction.

### DESCRIPTION

Off-white to white, very fine powder; greasy to the touch

### CHARACTERISTICS

#### IDENTIFICATION



Solubility Practically insoluble in water

Magnesium Presence of magnesium in the sample

Fatty acid composition Identify the individual fatty acids in the sample

### **PURITY**

Loss on drying Not more than 6% (105°C, constant weight, use 1 g of sample)

Acidity or alkalinity Passes test

Unsaponifiable matter Not more than 2%

Cadmium Not more than 1 mg/kg

Lead Not more than 2 mg/kg

Nickel Not more than 3 mg/kg

**Category** : Food additives category (7).

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

## Magnesium Sulfate

<b>Synonyms</b>	Epsom salt (heptahydrate) ; INS No. 518
<b>Definition</b>	Magnesium sulfate occurs naturally in sea water, mineral springs and in minerals such as kieserite and epsomite. It is recovered from them or by reacting sulfuric acid and magnesium oxide. It is produced with one or seven molecules of water of hydration or in a dried form containing the equivalent of between 2 and 3 waters of hydration.
Chemical names	Magnesium sulfate
C.A.S. number	Monohydrate: 14168-73-1 Heptahydrate: 10034-99-8 Dried: 15244-36-7
Chemical formula	Monohydrate: $\text{MgSO}_4 \cdot \text{H}_2\text{O}$ Heptahydrate: $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ Dried: $\text{MgSO}_4 \cdot x\text{H}_2\text{O}$ , where x is the average hydration value (between 2 and 3)
Formula weight	Monohydrate: 138.38 Heptahydrate: 246.47
Assay	Not less than 99.0 % and not more than 100.5% on the ignited basis
<b>Description</b>	Colourless crystals, granular crystalline powder or white powder. Crystals effloresce in warm, dry air.
<b>Characteristics</b>	
Identification	
Solubility	Freely soluble in water, very soluble in boiling water, and sparingly soluble in ethanol.
Test for magnesium	Passes test
Test for sulfate	Passes test
Purity	
Loss on ignition	Monohydrate: between 13.0 and 16.0 %, Heptahydrate: between 40.0 and 52.0 %, Dried: between 22.0 and 32.0 % (105°C, 2 h, then 400°C to constant weight)

pH	Between 5.5 and 7.5 (1 in 20 solution)
Chloride	Not more than 0.03%
Arsenic	Not more than 3 mg/kg
Iron	Not more than 20 mg/kg
Selenium	Not more than 30 mg/kg
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (07) (08)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Nutritional additives.

## Magnesium chloride

Chemical formula:  $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$ 

Molecular weight: 203.30

1. Assay : Not less than 95.0% of  $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$
2. Description : Colorless, odorless flakes, granules, lumps or crystals; very soluble in water; freely soluble in ethanol.
3. Identification : Passes the test for magnesium and test for chloride.
4. Solution : 1 g of this product is dissolved in water 10 mL, and the solution should be below "slightly turbid".
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Zinc : Not less than 0.07 mg/g
7. Calcium : 0.5 g of the sample is dissolved in water to make a 50 mL solution. Take 5 mL of the sample, add 1 mL of ammonium oxalate test solution (1 in 25 solution of ammonium oxalate) and place it for 5 minutes. The turbidity of the solution should be below "slightly turbid".
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Ammonium salt : Not more than 0.005%.
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents

## Ammonium Phosphate, Monobasic

Chemical formula:  $\text{NH}_4\text{H}_2\text{PO}_4$ 

Molecular weight: 115.03

1. Assay : 96.0~102.0%.
2. Description : Colorless to white crystal or white crystalline powder or granules; odorless. Very soluble in water.
3. Identification : The 1 in 20 solution of this product passes the test for ammonium and test for phosphate.
4. Solution : Dissolve 1 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
5. pH : 4.1~5.0 (1 in 100 soln)
6. Chloride : Not more than 0.035% of Cl.
7. Fluoride : Not more than 10 ppm.
8. Sulfate : Not more than 0.039% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

## Ammonium Phosphate, Dibasic

Chemical formula:  $(\text{NH}_4)_2\text{HPO}_4$ 

Molecular weight: 132.06

1. Assay : 96.0~102.0%.
2. Description : Colorless to white crystal or white crystalline powder or granule, having an odor of ammonium. Soluble in water.
3. Identification : The 1 in 20 solution of this product passes the test of ammonium and test of phosphate.
4. Solution : Dissolve 1.0 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
5. pH : 7.6~8.4 (1 in 100 soln)
6. Chloride : Not more than 0.035% of Cl
7. Fluoride : Not more than 10 ppm.
8. Sulfate : Not more than 0.039% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

## Potassium Dihydrogen Phosphate

<b>Synonyms</b>	Monobasic potassium phosphate, monopotassium monophosphate potassium acid phosphate, potassium biphosphate; INS No. 340(i)
<b>Definition</b>	
Chemical names	Potassium dihydrogenphosphate, monopotassium dihydrogenorthophosphate, monopotassium dihydrogen monophosphate
C.A.S. number	7778-77-0
Chemical formula	$\text{KH}_2\text{PO}_4$
Formula weight	136.09
Assay	Not less than 98.0% after drying
<b>Description</b>	Odourless, colourless crystals or white granular or crystalline powder
<b>Characteristics</b>	
Identification	
Solubility	Freely soluble in water; insoluble in ethanol
pH	4.2 - 4.7 (1 in 100 soln)
Test for potassium	Passes test
Test for phosphate	Passes test
Test for orthophosphate	To 5 ml of a 1 in 100 soln of the sample, add silver nitrate TS. A yellow precipitate is obtained.
Purity	
Loss on drying	Not more than 2% (105°C, 4 h)
Water insoluble substances	Not more than 0.2%
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
<b>Category</b>	Food additives category (7) (8) (13)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Nutritional additives; Coagulating Agents.

## Potassium Phosphate, Dibasic

Chemical formula:  $K_2HPO_4$ 

Molecular weight: 174.18

1. Assay : Not less than 98.0% on the dried basis (105°C, 4 h)
2. Description : Colorless or white granular powder, crystals or masses; deliquescent. 1 g of this product is soluble in 3 mL of water, insoluble in ethanol.
3. Identification : The 1 in 20 solution of this product passes the test for potassium and test for phosphate.
4. Solution : Dissolve 1.0 g of the sample in 20 mL of water. The solution should be colorless and the turbidity is below "slightly turbid".
5. pH : 8.7~9.3 (1 in 100 soln)
6. Chloride : Not more than 0.011% of Cl.
7. Fluoride : Not more than 10 ppm.
8. Sulfate : Not more than 0.019% of  $SO_4$ .
9. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Lead : Not more than 5 ppm.
12. Water-insoluble matter : Not more than 0.2%.
13. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 5% of its weight.
14. Category : Food Additives Category 7, 13.
15. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent



## Potassium Phosphate, Tribasic

Chemical formula:  $K_3PO_4 \cdot 0 \sim 3H_2O$ 

1. Assay : Not less than 97.0% of  $K_3PO_4$ , calculated on the ignited basis.
2. Description : Colorless or white, odorless hygroscopic crystals or granules; freely soluble in water; insoluble in ethanol.
3. Identification : The 1 in 20 solution of this product passes the test for potassium and test for phosphate.
4. Solution : Dissolve 1.0 g of the sample in 20 mL of water. The solution should be colorless and the turbidity is below “slightly turbid”.
5. pH : 11.5~12.5 (1 in 100 soln)
6. Chloride : Not more than 0.011% of Cl
7. Fluoride : Not more than 10 ppm.
8. Sulfate : Not more than 0.019% of  $SO_4$ .
9. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Lead : Not more than 5 ppm.
12. Water-insoluble matter : Not more than 0.2%.
13. Loss on ignition : Not more than 23.0% (120°C, 2 h, then 800°C, 1 h)
14. Category : Food Additives Category 7, 13.
15. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Dihydrogen Phosphate

<b>Synonyms</b>	Monobasic sodium phosphate, monosodium monophosphate sodium acid phosphate, sodium biphosphate; INS No. 339(i)
<b>Definition</b>	
Chemical names	Sodium dihydrogenphosphate, monosodium dihydrogenortho- phosphate, monosodium dihydrogen monophosphate
C.A.S. number	7558-80-7
Chemical formula	Anhydrous: $\text{NaH}_2\text{PO}_4$ Monohydrate: $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ Dihydrate: $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$
Formula weight	Anhydrous: 119.98 Monohydrate: 138.00 Dihydrate: 156.01
Assay	Not less than 97% after drying
<b>Description</b>	White odourless, slightly deliquescent powder, crystals, or granules
<b>Characteristics</b>	
Identification	
Solubility	Freely soluble in water; insoluble in ethanol, ether or chloroform
pH	4.2 - 4.6 (1 in 100 soln)
Test for sodium	Passes test
Test for phosphate	Passes test
Test for orthophosphate	To a 1% solution of the sample add silver nitrate TS; the yellow precipitate formed is soluble in dilute nitric acid TS.
Purity	
Loss on drying	Anhydrous: Not more than 2% (60°, 1 h, then 105°, 4 h) Monohydrate: Not more than 15% (60°, 1 h, then 105°, 4 h) Dihydrate: Not more than 25% (60°, 1 h, then 105°, 4 h)

Free acid and disodium phosphate	2.00 g of the sample dissolved in 40 ml of water require for neutralization not more than 0.3 ml of either N sodium hydroxide or N sulfuric acid, using methyl orange TS as indicator.
Fluoride	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
<b>Category</b>	Food additives category (07) (08) (13)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Nutritional additives; Coagulating Agents.

## Sodium Phosphate, Monobasic, Anhydrous

Chemical formula:  $\text{NaH}_2\text{PO}_4$ 

Molecular weight: 119.98

1. Assay : Not less than 98.0% and not more than 103.0% of  $\text{NaH}_2\text{PO}_4$  after drying at 105°C for 4 hours.
2. Description : White odorless, slightly deliquescent powder, crystals, or granules. Freely soluble in water; insoluble in ethanol.
3. Identification : The 1 in 20 solution of this product passes the test for sodium and test for phosphate.
4. Solution : Dissolve 2.0 g of the sample in 20 mL of water. The solution should be colorless and the turbidity is below “slightly turbid”.
5. pH : 4.3~4.9 (1 in 100 soln)
6. Chloride : Not more than 0.11% of Cl
7. Fluoride : Not more than 0.005%.
8. Sulfate : Not more than 0.048% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Water-insoluble matter : Not more than 0.2%.
12. Loss on drying : Not more than 2.0% (60°C, 1 h, then 105°C, 4h)
13. Category : Food Additives Category 7, 13.
14. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Phosphate, Dibasic

Chemical formula:  $\text{Na}_2\text{HPO}_4 \cdot 2 \sim 12\text{H}_2\text{O}$ 

1. Assay : Not less than 98.0% of  $\text{Na}_2\text{HPO}_4$  after drying at 105°C for 4 hours.
2. Description : White to colorless, odorless powder, crystals, or granules. Freely soluble in water; insoluble in ethanol.
3. Identification : The 1 in 20 solution of this product passes the test for sodium and test for phosphate.
4. Solution : Dissolve 0.5 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
5. pH : 9.0~9.6 (1 in 100 soln)
6. Chloride : Not more than 0.21% of Cl
7. Fluoride : Not more than 0.005%.
8. Sulfate : Not more than 0.039% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Water-insoluble matter : Not more than 0.2%.
12. Loss on drying : Not more than 61.0%. (40°C, 3h, then 120°C, 4 h).
13. Category : Food Additives Category 7, 13.
14. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Phosphate, Dibasic, Anhydrous

Chemical formula:  $\text{Na}_2\text{HPO}_4$ 

Molecular weight: 141.96

1. Assay : Not less than 98.0% of  $\text{Na}_2\text{HPO}_4$  after drying at 105°C for 4 hours.
2. Description : White, hygroscopic powder Freely soluble in water; insoluble in ethanol.
3. Identification : The 1 in 20 solution of the sample passes the test for sodium and the test for phosphate.
4. Solution : Dissolve 0.5 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
5. pH : 9.0~9.6 (1 in 100 soln)
6. Chloride : Not more than 0.21% of Cl
7. Fluoride : Not more than 0.005%.
8. Sulfate : Not more than 0.039% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Water-insoluble matter : Not more than 0.2%.
12. Loss on drying : Dry it at 120° for 4 hours: it loses not more than 5% of its weight.
13. Category : Food Additives Category 7, 13.
14. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Trisodium Phosphate

<b>Synonyms</b>	Tribasic sodium phosphate, sodium phosphate; INS No. 339(iii)
<b>Definition</b>	
Chemical names	Trisodium orthophosphate, trisodium phosphate, trisodium monophosphate
C.A.S. number	7601-54-9
Chemical formula	Anhydrous: $\text{Na}_3\text{PO}_4$ Hydrated: $\text{Na}_3\text{PO}_4 \cdot x\text{H}_2\text{O}$
Formula weight	Anhydrous: 163.94
Assay	Anhydrous, hemihydrate and monohydrate: Not less than 97.0% calculated on the dried basis  Dodecahydrate: Not less than 92.0% calculated on the ignited basis
<b>Description</b>	White odourless crystals, granules or a crystalline powder; hydrated forms available include hemi- and monohydrates, hexahydrate, octahydrate, decahydrate and dodecahydrate; the dodecahydrate contains 1/4 mol of sodium hydroxide.
<b>Characteristics</b>	
Identification	
Solubility	Freely soluble in water; insoluble in ethanol
pH	11.5 - 12.5 (1 in 100 soln)
Test for sodium	Passes test.
Test for phosphate	To 5 ml of a 1 in 100 solution of the sample add 1 ml of concentrated nitric acid and 5 ml of ammonium molybdate TS and warm. A bright canary-yellow precipitate is obtained.
Test for orthophosphate	Dissolve 0.1 g of the sample in 10 ml water, acidify slightly with dilute acetic acid TS, and add 1 ml of silver nitrate TS. A yellow precipitate is formed.
Purity	
Loss on ignition	Anhydrous: Not more than 2% (120°C, 2 h, then 800°C, 30 min)  Monohydrate: Not more than 11% (120°C, 2 h, then 800°C, 30 min)  Dodecahydrate: 45-58% (120°C, 2 h, then 800°C, 30 min)

Water insoluble substances	Not more than 0.2%
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 4 mg/kg
<b>Category</b>	Food additives category (07) (13)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Coagulating Agents.



## Sodium Phosphate, Tribasic, Anhydrous

Chemical formula:  $\text{Na}_3\text{PO}_4$ 

Molecular weight: 163.94

1. Assay : Not less than 97.0% of  $\text{Na}_3\text{PO}_4$  on the dried basis.
2. Description : White, odorless powder or granules. Freely soluble in water; insoluble in ethanol .
3. Identification : The 1 in 20 solution of this product passes the test for sodium and test for phosphate.
4. Solution : Dissolve 0.5 g of the sample in 20 mL of water. The solution should be colorless and the turbidity is below “slightly turbid”.
5. pH : 11.5~12.5 (1 in 100 soln)
6. Chloride : Not more than 0.71% of Cl
7. Fluoride : Not more than 0.005%.
8. Sulfate : Not more than 0.058% of  $\text{SO}_4$ .
9. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Water-insoluble matter : Not more than 0.2%.
12. Loss on drying : Not more than 5.0% (200°C, 5hr).
13. Category : Food Additives Category 7, 13.
14. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Potassium Metaphosphate

1. Assay : 56~80% of  $P_2O_5$  on the dried basis (110°C, 4 h)
2. Appearance : Odorless, colorless or white glassy masses, fragments, crystals or powder.
3. Solution : Heat 1 g of the sample with 50 mL of water in water bath, stir and add 50 mL of sodium hydroxide TS slowly. After 10 min, when the solution is cooled to 35~45°C, it should be colorless and the turbidity should be below “slightly turbid”.
4. Chloride : Not more than 0.1% of Cl.
5. Sulfate : Not more than 0.1% of  $SO_4$ .
6. Phosphate : Add 2 to 3 drops of silver nitrate TS to 1 g of the sample. An obvious yellow color should not appear.
7. Carbonate : Boil 2 g of the sample in 5 mL of water, cool, and add 2 mL of hydrochloric acid. No bubbles are generated.
8. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at 110° for 4 hours: it loses not more than 5% of its weight.
11. Category : Food Additives Category 7, 13.
12. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Metaphosphate

1. Assay : Not less than 65% and not more than 83% of  $P_2O_5$  on the dried basis (110°C, 4 h)
2. Appearance : Colorless or white glassy masses, fragments, crystals or powder.
3. Solution : Dissolve 1 g of the sample in 20 mL of water, and the solution should be below "slightly turbid".
4. Chloride : Not more than 0.2% of Cl.
5. Sulfate : Not more than 0.03% of  $SO_4$ .
6. Phosphate : Add 2 to 3 drops of silver nitrate TS to 1 g of the sample. An obvious yellow color should not appear.
7. Carbonate : Boil 2 g of the sample in 5 mL of water, cool, and add 2 mL of hydrochloric acid. No bubbles are generated.
8. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at 110° for 4 hours: it loses not more than 5% of its weight.
11. Category : Food Additives Category 7, 13.
12. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Potassium Polyphosphate

1. Assay :  $P_2O_5 = 43 \sim 76\%$  on the dried basis ( $110^\circ\text{C}$ , 4 h)
2. Appearance : Colorless or white glassy masses, fragments, crystals or powder.
3. Solution : Dissolve 1 g of the sample in 4 g of sodium acetate and 100 mL of water. The solution should be colorless and the turbidity is below “slightly turbid”.
4. Chloride : Not more than 0.1% of Cl.
5. Sulfate : Not more than 0.1% of  $SO_4$ .
6. Test for orthophosphate : Add 2 to 3 drops of silver nitrate TS to 1 g of the sample. An obvious yellow color should not appear.
7. Carbonate : Boil 2 g of the sample in 5 mL of water, cool, and add 2 mL of hydrochloric acid. Not more than a few bubbles are generated.
8. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at  $110^\circ$  for 4 hours: it loses not more than 5% of its weight.
11. Category : Food Additives Category 7, 13.
12. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Polyphosphate

1. Assay :  $P_2O_5 = 53 \sim 80\%$  on the dried basis ( $110^\circ\text{C}$ , 4 h)
2. Appearance : Colorless or white glassy masses, fragments, crystals or powder.
3. Solution : Heat and dissolve 1 g of the sample in 20 mL of water. The solution should be colorless and the turbidity should be below “slightly turbid”.
4. Chloride : Not more than 0.2% of Cl.
5. Sulfate : Not more than 0.05% of  $SO_4$ .
6. Test for orthophosphate : Add 2 to 3 drops of silver nitrate TS to 1 g of the sample. An obvious yellow color should not appear.
7. Carbonate : Boil 2 g of the sample in 5 mL of water, cool, and add 2 mL of hydrochloric acid. Not more than a few bubbles are generated.
8. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at  $110^\circ$  for 4 hours: it loses not more than 5% of its weight.
11. Category : Food Additives Category 7, 13.
12. Uses : Food quality improvement, fermentation and food processing agents; coagulating agent

## Sodium Acetate

Chemical formula:  $\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$ 

Molecular weight: 136.08

1. Assay : Not less than 98.5% of  $\text{C}_2\text{H}_3\text{NaO}_2$  on the dried basis.
2. Identification : (1) The 1 in 20 solution of the sample passes test for sodium and test for acetate.  
(2) When heating the sample slowly, it liquefies. Then water evaporates and later decomposes evolving an odor of acetone. A solution of the residue gives alkaline reaction with litmus paper.
3. Description : Colorless, transparent crystals or a granular crystalline powder, odorless or with a faint, acetic odor. Effloresces in warm, dry air. Very soluble in water; soluble in ethanol.
4. Solution : When 1.0 g of the sample is dissolved in 20 mL of water, the solution should be clear and colorless.
5. Free Acid and free alkali : Dissolve 2.0 g of the sample in 20 mL of freshly boiled and cooled water. Add 2 drops of phenolphthalein TS, and keep the solution at 10°C. If a colorless solution is produced, not more than 0.1 mL of 0.1 N sodium hydroxide should be required to give a red color. If a red color is produced, not more than 0.1 mL of 0.1 N hydrochloric acid should be required to discharge it.
6. Alkalinity : Not more than 0.05% of  $\text{Na}_2\text{CO}_3$ .
7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Test for potassium : Mix 5 mL of the saturated solution of the sample with a few drops of acid sodium hydrogen tartrate TS. No turbidity occurs within 5 minutes.
10. Loss on drying : 36.0~42.0% (120°C, 4 h).
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

## Sodium Acetate (Anhydrous)

Chemical formula:  $C_2H_3NaO_2$ 

Molecular weight: 82.03

1. Assay : Not less than 98.5% of  $C_2H_3NaO_2$  on the dried basis.
2. Identification : (1) Dissolve 1 g of the sample in 20 mL of water. The solution passes the test for sodium and test for acetate.  
(2) When heating the sample slowly, it first fuses gradually and boils, and later decomposes evolving an unpleasant odor of acetone. A solution of the residue gives alkaline reaction with litmus paper.
3. Description : White, odorless, granular, hygroscopic powder. Miscible with water.
4. Solution : When 1.0 g of the sample is dissolved in 20 mL of water, the solution should be clear.
5. Free acid and free alkali : Dissolve 1.2 g of the sample in 20 mL of freshly boiled and cooled water. Add 2 drops of phenolphthalein TS, and keep the solution at 100. If a colorless solution is produced, not more than 0.1 mL of 0.1 N sodium hydroxide should be required to give a pink color. If a pink color is produced, not more than 0.1 N hydrochloric acid should be required to discharge it.
6. Alkalinity : Not more than 0.05% of  $Na_2CO_3$ .
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Test for potassium : Mix 5 mL of the saturated solution of the sample with a few drops of acid sodium hydrogen tartrate TS. No turbidity occurs within 5 minutes.
10. Loss on drying : Dry it at 120° for 4 hours: it loses not more than 2.0% of its weight.
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

## Glycerol

Chemical formula:  $C_3H_8O_3$ 

Molecular weight: 92.10

1. Assay : Not less than 95%
2. Identification : Add 2 to 3 drops of the sample to 0.5 g of potassium hydrogen sulfate. After heating, a pungent acrolein odor is produced.
3. Description : Clear, colorless, hygroscopic, syrupy liquid, having a not more than a slight characteristic odor, which is neither harsh nor disagreeable. Miscible with water and with ethanol; immiscible with chloroform, ether and grease.
4. pH : The aqueous solution of the sample should be neutral.
5. Density : 1.250~1.264.
6. Chloride : Not more than 0.003% of Cl.
7. Arsenic : Not more than 4 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 5 ppm (as Pb).
9. Fatty acids and esters : Not more than 0.1% (as butyric acid)
10. Acrolein, glucose and ammonium salt : Mix and heat 5mL of the sample and 5 mL of potassium hydroxide TS (1 g of potassium hydroxide dissolved in 10 mL of water) at 60°C for 5 minutes. No yellow color or an odor of ammonia is produced.
11. Residue on ignition : Not more than 0.01% (800±25° to constant weight).
12. Category : Food Additives Category 7, 15.
13. Uses : Food quality improvement, fermentation and food processing agents; carrier.



## Sodium Stearyl 2-Lactylate

1. Description : A mixture of sodium salts of stearyl lactic acids and minor proportions of other salts of related acids, formed by the esterification of stearic acid with lactic acid and neutralized to the sodium salts. White or slightly yellowish powder or brittle solid with a characteristic odor. Slightly hygroscopic, having a mild, caramel-like odor. Soluble in hot grease or dispersed in warm water. The fatty acids used should comply with the food additives specifications.

2. Identification : A. Add 1 g of the sample to the mixture of 25 mL of water and 5 mL of hydrochloric acid. When heated, the fatty acids are released and a layer of oil appears on the surface of the liquid.

The water layer passes test for sodium.

B. Take 25 g of the sample to triangular flask, add 15% potassium hydroxide alcohol solution 50g. The mixture was heated to a minimum of 1 hour or until saponification was completed. After cooling, add 150 mL of water and mix.

After the soap dissolves completely, add 60 mL dilute sulfuric acid TS. Heat the mixture and keep stirring until the fatty acids separate completely to form a transparent layer. The fatty acids were washed with boiling water until there was no sulfate reaction. Collect the fatty acid in a small beaker. Heat the water in a steam bath until the fatty acid is separated from the water. After fatty acid is cooled and solidified, dispose water, and then dissolve fatty acid. Filter to a dry beaker, and dry at 105°C for 20 minutes. The fatty acids obtained has a freezing point that is above 54 °C.

3. Acid value : 60~80.

4. Ester value : 150~190.

5. Sodium content : 3.5~5.0%.

6. Total lactic acid : 31.0~34.0%.

7. Arsenic : Not more than 3 ppm (as As).

8. Heavy metals : Not more than 10 ppm (as Pb).

9. Category : Food Additives Category 7

10. Uses : Food quality improvement, fermentation and food processing agents

## Aluminum silicate

1.     Synonyms               : Kaolin
2.     Definition            : A native hydrated aluminum silicate, freed from most of its impurities by elutriation and dried.
3.     Appearance           : A soft, whitish powder free from gritty particles; odorless.
4.     Identification         : (1) Test for silicate: Mix about 500 mg of the sample with about 200 mg of anhydrous sodium carbonate and 2 g of anhydrous potassium carbonate, and heat the mixture in a platinum or nickel crucible until it melts completely. Cool, add 5 mL of water, and allow to stand for 3 min. Heat the bottom of the crucible gently, detach the melt, and transfer it to a beaker with the aid of about 50 mL of water. Add gradually hydrochloric acid until no effervescence is observed, then add 10 mL more of the acid, and evaporate the mixture on a steam bath to dryness. Cool, add 20 mL of water, boil and filter the mixture through an ash-free filter paper. An insoluble residue of silica remains. (Note: Retain the filtrate for the test for aluminum). Transfer the gelatinous residue into a platinum dish, and cautiously add 5 mL of hydrofluoric acid (Warning: toxic, corrosive, must not contact skin; work under fume hood). The precipitate dissolves. (If it does not dissolve, repeat the evaporation with hydrofluoric acid.) Heat and hold in the vapors a glass stirring rod with a drop of water on the tip. The drop becomes turbid.  
  
(2) Test for aluminum: Add ammonia TS to the filtrate obtained in the test for silicate. A white gelatinous precipitate is formed which is insoluble in excess ammonia but dissolves in sodium hydroxide TS.
5.     Solubility             : Insoluble in water, ethanol and mineral acids.
6.     Plasticity            : To 8 g of the sample add 5 mL of water and mix well. The mixture is plastic.
7.     Water soluble  
       substances            : Not more than 13%.
8.     Acid-soluble  
       matter                 : Not more than 2%.
9.     Asbestos             : Absent
10.    Lead                  : Not more than 5 mg/kg.
11.    Category             : Food Additives Category 7
12.    Uses                  : Food quality improvement, fermentation and food processing agents

## Diatomaceous Earth

1. Identification : (1) Place 0.2 g of the sample in a platinum crucible, and add 5 mL of hydrofluoric acid.  
The sample is dissolved. When the solution is heated, almost all of it volatilizes.  
(2) When examined with 100x to 200x microscope, typical diatom shapes are observed.
2. Description : White, light grey or reddish brown powder. Insoluble in water, in acids (except hydrofluoric), and in dilute alkalis.
3. Water soluble substances and pH : Boil 10 g of sample with 100 mL of water for 2 h and filter through a fineporosity sintered-glass filter (aperture: 0.45 µm, diameter: 47mm). Dilute filtrate to 100 mL. pH range of the solution is 5.0 to 11.0. Take 50 mL of the filtrate and evaporate it. Dry the residue is dried at 105 °C for 2 hours, and the amount of residue should be less than 25 mg.
4. Hydrochloric acid-soluble substances : Not more than 3%.
5. Arsenic : Not more than 4 ppm (as As).
6. Heavy metals : Not more than 50 ppm (as Pb).
7. Lead : Not more than 10 ppm.
8. Hydrofluoric acid-insoluble substances : Not more than 25%.
9. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 10% of its weight.
10. Loss on ignition : Not more than 7.0% on the dry basis (1000°C, 30 min)
11. Category : Food Additives Category 7, 17.
12. Uses : Food quality improvement, fermentation and food processing agents; others.

## Talc

1. Identification : Mix 0.2 g sample with 0.9 g of anhydrous sodium carbonate and 1.3 g of anhydrous potassium carbonate, and heat the mixture in a platinum crucible until fusion is complete. Cool, and transfer the fused mixture to a dish or beaker with the aid of about 5 mL of hot water. Add hydrochloric acid to the liquid until effervescence ceases, then add 20 mL more of the acid, and evaporate the mixture on a steam bath to dryness. Cool, add 20 mL of water, boil and filter the mixture, an insoluble residue of gel remains. The filtrate passes test for magnesium.
2. Description : Odorless, very fine, white or grayish white, crystalline powder. Do not dissolve in water and alkali metal hydroxide solution, but slightly soluble in dilute mineral acid.
3. Water-soluble substances : Boil a 10 g sample with 100 mL of water for 2 hours and from time to time, add water to maintain approximately the original volume, and filter through a fineporosity sintered-glass filter (aperture: 0.45  $\mu\text{m}$ , diameter: 47mm). Dilute filtrate to 100 mL. pH range of the solution is 6.0 to 8.0. Take 50 mL of the filtrate and evaporate it. Dry the residue is dried at 105 °C for 2 hours, and the amount of residue should be less than 10 mg. (less than 0.2%)
4. Hydrochloric acid-soluble substances : Not more than 2.5% of  $\text{SO}_4$ .
5. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Heavy metals : Not more than 40 ppm (as Pb).
7. Lead : Not more than 10 ppm.
8. Free alkali : Not more than 1% (as NaOH)
9. Extractable amount of fluorine : Not more than 0.002%.
10. Water-soluble iron : Slightly acidify with hydrochloric acid the remaining half of the 20 mL filtrate obtained in the test for water-soluble substances (3.) and add 1 mL of potassium ferrocyanide TS. The solution does not turn blue.
11. Water-soluble substances : Not more than 0.2%.
12. Loss on drying : Not more than 0.5% (105°C, 1 h).

- 13. Loss on ignition : Not more than 6.0% (550°C, to a constant weight).
- 14. Category : Food Additives Category 7
- 15. Uses : Food quality improvement, fermentation and food processing agents

§ 07047

L-Cystein Monohydrochloride

The same as § 03012.

## Sodium Ferrocyanide

Chemical names : Sodium ferrocyanide, Sodium hexacyanoferrate (II)

Synonyms : Yellow prussiate of soda; hexacyanoferrate of sodium; INS No. 535; CAS No. 13601-19-9

Chemical formula :  $\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10\text{H}_2\text{O}$  Molecular weight : 484.1

1. Assay : Not less than 99.0%.
2. Appearance : Yellow crystalline powder.
3. Solubility : Soluble in water, insoluble in ethanol.
4. 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) Passes test for calcium.
5. Cyanide : Not detectable.
6. Prussiate : Not detectable.
7. Arsenic : Not more than 3 mg/kg.
8. Lead : Not more than 5 mg/kg.
9. Category : Food Additives Category 7
10. Uses : Food quality improvement, fermentation and food processing agents

§ 07051

Disodium Ethylenediaminetetraacetate (EDTA Na<sub>2</sub>)

The same as § 03017.



§ 07051

Calcium Disodium Ethylenediaminetetraacetate (EDTA  $\text{CaNa}_2$ )

The same as § 03017.

## Silicon Dioxide (Synthetic Amorphous Silica)

Chemical formula:  $\text{SiO}_2$ 

Molecular weight: 60.08

1. Description : Silicon dioxide is an amorphous substance when scanned with Xray diffraction, which is produced synthetically by either a thermal process, yielding pyrogenic (fumed) silica, or by a wet process, yielding hydrated silica, precipitated silica and silica gel. Pyrogenic silica is produced in an essentially anhydrous state, whereas the wet process products are obtained as hydrates or contain surface absorbed water.  
Pyrogenic (fumed) silica: A pyrogenic silicon dioxide occurring as a fine, white amorphous powder or granules. Hydrated silica (precipitated silica and silica gel): A precipitated, hydrated silicon dioxide occurring as a fine, white amorphous powder or granules. Deliquescent or capable of adsorbing unequal amounts of moisture from the air. All cerium oxide products are insoluble in water and in organic solvents, but soluble in hydrofluoric acid and in high concentration of hot lye.
2. Identification : A. Mix about 5 mg of the sample with 200 mg of anhydrous potassium carbonate in a platinum crucible. Ignite for 10 minutes until red and hot, cool down. Dissolve the melt in 2 mL of fresh distilled water (heat if necessary). Then slowly add 2 mL of ammonium molybdate TS. The solution is dark yellow.  
B. Take 1 drop of the solution of the Test A on the filter paper. After evaporation of the solvent, add 1 drop of o-toluidine/ent, add 1 drop of o-toluidineththen put the filter paper on the ammonia TS. Blue-green spots will appear.
3. Assay : Pyrogenic (fumed) silica: Not less than 99.0% of  $\text{SiO}_2$  on the ignited basis.  
Hydrated silica (precipitated silica and silica gel): Not less than 94.0% of  $\text{SiO}_2$  on the ignited basis.
4. Arsenic : Not more than 3 ppm (as As).
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.003% (as Pb).
7. Loss on drying : Pyrogenic (fumed) silica: Not more than 2.5%.  
Precipitated silica and silica gel: Not more than 7%  
Hydrated silica Not more than 70%
8. Loss on ignition : Pyrogenic (fumed) silica: Not more than 2.5% (on dried sample)  
Hydrated silica (precipitated silica and silica gel): Not more than 8.5% (on dried sample)
9. Dissolvable salts : Precipitated silica, silica geland hydrated silica: Not more than 5% (as  $\text{Na}_2\text{SO}_4$ ).

- 10. Category : Food Additives Category 7
- 11. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Oxide

Chemical formula: CaO

Molecular weight: 56.08

1. Description : Odorless, white or greyish white masses or granules, or white to greyish white powder.  
1 g of the sample is soluble in 840 mL of 25°C water and 1740 mL of boiling water; insoluble in ethanol, soluble in glycerol.
2. Identification : Shake 1 g of the sample with 20 mL of water, add acetic acid until it dissolves. The solution passes test for calcium.
3. Assay : Not less than 95.0% after ignition.
4. Acid insoluble matter : Not more than 1%.
5. Magnesium and alkali salts : Not more than 3.6%.
6. Fluoride : Not more than 0.005%.
7. Arsenic : Not more than 3 ppm (as As).
8. Lead : Not more than 10 ppm (as Pb).
9. Heavy metals : Not more than 0.004%.
10. Loss on ignition : Not more than 10%.
11. Category : Food Additives Category 7, 8.
12. Uses : Food quality improvement, fermentation and food processing agents; Nutritional additives

## Potassium Bicarbonate

Chemical formula:  $\text{KHCO}_3$ 

Molecular weight: 100.12

1. Description : Odorless, colorless crystals or white powder or granules, stable in air. 1 g of the sample is soluble in 2.8 mL of water; insoluble in ethanol. The solution has a neutral or alkaline reaction to the phenolphthalein TS. 1 g of the sample is soluble in 2.8 mL of water and is insoluble in alcohol.
2. Identification : The 1 in 10 solution of the sample passes test for potassium and test for carbonate.
3. Assay : Not less than 99.0% and not more than 101% calculated on the dried basis.
4. Normal carbonate : Moderate.
5. Arsenic : Not more than 3 ppm (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Not more than 0.25%.
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents

## Glycerol Ester of Wood Rosin

1. Description : The sample is obtained by esterifying of wood rosin with food grade glycerin, and then purifying it by steam distillation (when used as chewing gum and bubble gum base) or steam convection distillation (when used as beverage stabilizer). Hard, yellow to pale amber-colored solid. (If measured by ASTM D509, the chroma is N or slightly lighter)  
Soluble in acetone and benzene, but insoluble in water.
2. Identification : The infrared absorbance spectrum of the sample melted and prepared on a caesium or potassium bromide plate corresponds to the infrared absorption spectrum and the standard map.
3. Acid value : 3~9.
4. Drop Softening Point : 88~96°C.
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 3 ppm.
7. Heavy metals : Not more than 0.004% (as Pb).
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents

## Patroleum Wax (Refined Paraffin Wax, Microcrystalline Wax)

1. Description : This product is a paraffin solid hydrocarbon mixture from refined paraffin, including refined paraffin and microcrystalline paraffin. The refined paraffin wax is usually obtained from the low molecular weight of petroleum. The molecular weight, ignition point and melting point are lower than that of microcrystalline paraffin, and the viscosity is smaller after melting. The refined paraffin wax is usually obtained from the low molecular weight of petroleum. The molecular weight, ignition point and melting point are lower than that of microcrystalline paraffin, and the viscosity is smaller after melting. Colorless or white, translucent, tasteless and odorless wax. Melting point is between 48 ~ 93°C (120 ~ 200°F). The melting point and color are used as the basis for classification commercially.
2. Identification : The infrared absorbance spectrum of the sample melted and prepared on a caesium or potassium bromide plate corresponds to the infrared absorption spectrum and the standard map.
3. Ultraviolet absorbance limits : 280~289 nm, not more than 0.15.  
290~299 nm, not more than 0.12.  
300~359 nm, not more than 0.08.  
360~400 nm, not more than 0.02.
4. Arsenic : Not more than 3 ppm (as As).
5. Lead : Not more than 3 ppm.
6. Heavy metals : Not more than 0.002% (as Pb).
7. Color, melting point and odor : Should meet the specifications set by the seller.
8. Category : Food Additives Category 7, 17.
9. Uses : Food quality improvement, fermentation and food processing agents; others.

## Rice Bran Wax

1. Description : Refined wax from rice bran. Yellowish brown to light tan, hard and having microcrystalline. Soluble in chloroform and benzene, but insoluble in water.
2. Identification : The infrared absorbance spectrum of the sample melted and prepared on a caesium or potassium bromide plate corresponds to the infrared absorption spectrum and the standard map.
3. Free fatty acid : Not more than 10%.
4. Iodine value : Not more than 20.
5. Saponification : 75~120.  
value
6. Melting range : 75~80°C.
7. Arsenic : 3 ppm (As)
8. Lead : Not more than 3 ppm.
9. Heavy metals : Not more than 0.004% (as Pb).
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents



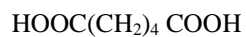
## Stearic Acid (Octadecanoic Acid)

Chemical formula:  $C_{18}H_{36}O_2$ 

Molecular weight: 284.48

1. Description : Mixture of solid organic acids obtained from fat, mainly containing stearic acid ( $C_{18}H_{36}O_2$ ) and palmitic acid ( $C_{16}H_{32}O_2$ ). White or yellow, hard and slightly smooth crystal solid or powder that has a characteristic odor of butter. Insoluble in water. 1 g of the sample is soluble in about 20 mL of ethanol, in 2 mL of chloroform or in 3 mL of ether.
2. Acid value : 196~211.
3. Iodine value : Not more than 7
4. Saponification value : 197~212.
5. Unsaponifiable matter : Not more than 1.5%.
6. Water : Not more than 0.2%.
7. Titer : 54.5~69°C.
8. Arsenic : 3 ppmu (as As).
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Residue on ignition : Not more than 0.1%.
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

Adipic Acid  
(Hexanedioic Acid; 1,4–Butanedicarboxylic Acid)



Chemical formula:  $\text{C}_6\text{H}_{10}\text{O}_4$

Molecular weight: 146.14

1. Description : White crystals or crystalline powder that is not deliquescent; slightly soluble in water; freely soluble in ethanol; soluble in acetone.
2. Assay : Not less than 99.6% and not more than 101.0%.
3. Water : Not more than 0.2%.
4. Melting range : 151.5~154.0°C.
5. Arsenic : 3 ppmu (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Residue on ignition : Not more than 0.002%.
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents

## Aluminum Sulfate

Chemical formula:  $\text{Al}_2(\text{SO}_4)_3 \cdot x\text{H}_2\text{O}$ 

Molecular weight (anhydrous): 342.14

1. Description : Odorless, white powder, shining plates, or crystalline fragments, with a slightly astringent taste. The molecular structure can be in anhydrous form or hydrated form that contains 18 molecules of water. Due of the weathering of the hydrated sample, its molecular formula may be  $\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}$ . 1 g of hydrated form is soluble in about 2 mL of water. The solubility of anhydrous sample is similar to that of hydrated sample. However, the dissolution rate is slow that it seems insoluble at the beginning. The pH of 1 in 20 solution of the sample is 2.9 or higher.
2. Identification : The 1 in 10 solution of the sample passes the test for aluminum and test for sulfate.
3. Assay :  $\text{Al}_2(\text{SO}_4)_3$  (anhydrous) — Not less than 99.5% on the ignited basis  
 $\text{Al}_2(\text{SO}_4)_3 \cdot 18\text{H}_2\text{O}$  (hydrated) — 99.5 ~ 114.0%. If calculate by  $\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}$ , the limit is about 101.7%.
4. Alkali metal and alkaline earth metal : Moderate.
5. Ammonium salt : Moderate.
6. Fluorine ion : Not more than 0.003%.
7. Selenium : Not more than 0.003%.
8. Arsenic : 3 ppm (as As)
9. Lead : Not more than 10 ppm.
10. Heavy metals : Not more than 0.004% (as Pb).
11. Loss on ignition  $\text{Al}_2(\text{SO}_4)_3$  (anhydrous) : Not more than 5%.  
 [ Note: Not applicable to  $\text{Al}_2(\text{SO}_4)_3 \cdot 18\text{H}_2\text{O}$  ]
12. Category : Food Additives Category 7
13. Uses : Food quality improvement, fermentation and food processing agents

## Perlite (Expanded Perlite)

1. Description : Natural perlite is gray to brown, thick, glassy igneous rock. Primary component is sodium potassium aluminum silicate. The sample contains 3% to 5% of water. After being crushed and heated to a temperature of 900 to 1100°C, it pops like a popcorn (due to the sorption of water inside), and the volume expands more than 20 times. This product is white and non-hygroscopic powder obtained by crushing this expanded material. The bulk density is 32~400 kg/m<sup>3</sup> (2~25 lb/ft<sup>3</sup>). The particle size ranges from less than 1 µm to hundreds of µm. The sample is used as a filter aid in food processing. Slightly soluble in water and almost insoluble in dilute acids and bases.
2. Identification : A. Take about 1 g of the sample and place it in a beaker. Mix with 25 mL of dilute hydrochloric acid TS, cover the mouth of the cup with a surface glass. After filtration, the filtrate was neutralized by ammonia solution until it is neutral on litmus paper. The neutralized filtrate passes test for aluminum, test for potassium and test for sodium.  
  
B. Place some ammonium phosphate crystal on the platinum ring, and dissolve into beads with flame. Contact this hot, transparent bead with the sample, reheat it with flame to dissolve. The silica will float inside the bead. When cooled, it a reticular, opaque bead forms.
3. pH : 5~9 (filtrate of 10% suspension)
4. Arsenic : Not more than 3 ppm (as As).
5. Lead : Not more than 10 ppm.
6. Loss on drying : Not more than 3% (powder)
7. Loss on ignition : Not more than 7% (glass)
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents

### Hydroxypropyl Cellulose

1. Description : The sample contains hydroxypropyl cellulose ether compound. White powder. Soluble in water and some organic solvents. May contain some anti-adhesive.
2. Identification : A. Prepare a 0.1% solution of the sample. A layer of foam appears after oscillation.  
(distinguished from sodium carboxymethyl cellulose)  
B. Take an appropriate amount of the sample to prepare a 0.5% aqueous solution. Add 5 mL of 5% copper sulfate or aluminum sulfate solution to 5 mL of the solution.  
No precipitation appears. (distinguished from sodium carboxymethyl cellulose)
3. Assay : Not more than 80.5% of hydroxypropyl ( $-\text{OCH}_2\text{CHOHCH}_3$ ) on the dried basis, which is equivalent to 4.6 hydroxypropyl/anhydrous glucose units or less.
4. pH : 5.0~8.0 (1% solution)
5. Viscosity of 10% solution : Not less than 145 centipoises
6. Arsenic : Not more than 3 ppm (as As).
7. Lead : Not more than 10 ppm.
8. Heavy metals : Not more than 0.004% (as Pb).
9. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 5% of its weight..
10. Residue on ignition : Not more than 0.5%.
11. Category : Food Additives Category 7, 12, 16.
12. Uses : Food quality improvement, fermentation and food processing agents; pasting (binding) agent.; emulsifier

Hydroxypropyl Methylcellulose  
(Propylene Glycol Ether of Methylcellulose)

1. Description : The sample is propylene glycol methyl cellulose, in which both hydroxypropyl and methyl ether bond on anhydrous glucose ring of cellulose. There are several types depending on the content and combination of methoxyl and hydroxypropyl. Hygroscopic white or off-white powder, or granules or fine fibers. Swells in water and some organic solvent, producing a clear to opalescent, viscous colloidal solution; insoluble in ethanol.
2. Identification : A. When 1 g of this product is added to 100 mL water, it absorbs water and expands to form a clear milky adhesive solution (depending on its inherent viscosity), which can coexist with most electrolytes.  
B. Add 1 g of the sample into 100 mL of boiling water, which appears mushy after stirring. When cooled to 20°C, the solution becomes a clear or milky viscous solution.  
C. If the solution prepared in the above identification test B is put on the glass plate for the moisture to vaporize, a self-sustaining thin film forms.
3. Assay : Not less than 19.0% and not more than 30.0% of methyl groups (-OCH<sub>3</sub>) and not less than 3.0% and not more than 12.0% hydroxypropoxy groups (-OCH<sub>2</sub>CHOHCH<sub>2</sub>).
4. Viscosity : For products with a viscosity value of 100 centipoises or less, when 2 g is dissolved into a 100 g solution, the viscosity should be between 80% and 120% of the indicated value. For those with a value greater than 100 centipoises, the viscosity of the above solution should be between 75% and 140% of the indicated value.
5. Arsenic : Not more than 3 ppm (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 5% of its weight.
8. Residue on ignition : Not more than 1.5% for products with viscosities of 50 centipoise or above, and not more than 3.0% for products with viscosities below 50 centipoise.
9. Category : Food Additives Category 7, 12, 16.
10. Uses : Food quality improvement, fermentation and food processing agents; pasting (binding) agent.; emulsifier

## Polydextrose

1. Description : Polydextrose is obtained by melting and condensation of the ingredients which consist of approximately 89 parts D-glucose, 10 parts sorbitol and up to 1-part citric acid. White to light tan-colored solid, odorless and a little sour. Very soluble in water but slightly soluble or insoluble in most organic solvents.
2. Polymer of molecular weight greater than : Negative  
22,000
3. Arsenic : Not more than 3 ppm (as As).
4. Heavy metals : Not more than 10 ppm (as Pb).
5. Residue on : Not more than 13%.  
ignition
6. Category : Food Additives Category 7, 12.
7. Uses : Food quality improvement, fermentation and food processing agents; pasting (binding) agent.

## Food Gypsum

Chemical formula:  $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$ 

Molecular weight: 172.18

1. Assay : Not less than 93% on the dried basis.
2. Description : This product is made from bittern. White powder.
3. Solution : 0.2 g of the sample is heated and dissolved in 10 mL of dilute hydrochloric acid, and solution turbidity should be below "almost clear".
4. Free alkali : Dissolve 0.5 g of the sample in 100 mL of freshly boiled and cooled water, mix and filter. Take 10 mL of the solution and add a drop of phenolphthalein TS. The red color should not appear.
5. Chloride : Not more than 3% of Cl.
6. Carbonate : No bubbles shall be generated when 0.5 g of the sample is added with 5 mL of dilute hydrochloric acid.
7. Arsenic : Not more than 1 ppm (as As).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on ignition : Not more than 40%.
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents



## Acid Clay

<b>Definition</b>	Acid Clay is obtained by purifying clay(such as montmorillonite clay, bentonite clay, etc.) . It consists mainly of hydrous aluminum silicate.
<b>Description</b>	Acid Clay occurs as a grayish-white to yellow-brown powder or as granules.
<b>Identification</b>	<p>(1) Mix 1.0 g of Acid Clay with 3.0 g of sodium carbonate and 0.4 g of boric acid, and heat the mixture in a platinum or nickel crucible until it melts completely. Cool, and then add hydrochloric acid until no effervescence is observed. Add an additional 10 mL of hydrochloric acid, heat on a water bath until the mixture becomes gelatinous, cool, and then filter. The filtrate obtained responds to all the tests for Aluminum Salt as directed in the Qualitative Tests.</p> <p>(2) To a 100 mL measuring cylinder containing 100 mL of water, add 2.0 g of Acid Clay in small portions, and allow to stand for 24 hours. The precipitate formed is not more than 15 mL.</p>
pH	4.0 ~ 10.0
<b>Purity</b>	
Water-soluble substances	Not more than 0.50%
Lead	Not more than 40 mg/kg
Arsenic	Not more than 3 mg/kg
Loss on Ignition	Not more than 35.0% (at 110°C for 3 hours, then at 550°C for 3 hours).
<b>Category</b>	Food additives category 7
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents

## Disodium Dihydrogen Pyrophosphate

Chemical formula:  $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ 

Molecular weight: 221.95

1. Assay : Not less than 95% (110°C, 4 h)
2. Appearance : White crystalline powder .
3. Water-insoluble matter : Dissolve 5 g of the sample in 100 mL of water, shake occasionally for an hour, and filter through a tared filtering crucible (1G4). Wash the insoluble residue with 30 mL of water, dry at 110°C for 2 h, cool and weigh. The weight should not be more than 40 mg.
4. pH : 3.8~4.5 (1 in 100 soln)
5. Chloride : Not more than 0.057% (as Cl).
6. Sulfate : Not more than 0.038% of  $\text{SO}_4$ .
7. Test for orthophosphate : Add 2 to 3 drops of 2% silver nitrate TS to 1 g of the sample. An obvious yellow color should not appear.
8. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at 110° for 4 hours: it loses not more than 5% of its weight.
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

## Carnauba Wax

1. Description : The refined wax obtained from the fronds of the Brazilian tropical palm tree *Copernicia cerifera* (Arruda) Mart. A pale yellow to light brown, hard and brittle solid, having a clean fracture. The density is around 0.997. Insoluble in water; partially soluble in boiling ethanol; soluble in ether.
2. Acid value : 2~7.
3. Arsenic : Not more than 3 ppm (as As).
4. Ester value : Between 75 and 85.
5. Heavy metals : Not more than 40 ppm (as Pb).
6. Lead : Not more than 10 ppm.
7. Melting range : 82~86°C.
8. Unsaponifiable matter : Between 50 % and 55 %.
9. Category : Food Additives Category 7
10. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Chloride Anhydrous

Chemical formula:  $\text{CaCl}_2$ 

Molecular weight: 110.99

1. Assay : Not less than 93.0%.
2. Description : White, deliquescent, odorless lumps or porous masses. Freely soluble in water and ethanol.
3. Identification : The 1 in 20 solution of the sample passes test for calcium and test for chloride.
4. Solution : The turbidity of the 1 in 20 solution of the sample should be “slightly turbid”.
5. pH : 4.5~8.5 (1 in 20 soln)
6. Free Acid and free alkali : Dissolve 1 g of the sample in 20 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS. If the solution is colorless, the pink color appears after adding 2.0 mL of 0.02 N sodium hydroxide. If the solution is pink, the pink color is discharged by adding 2 mL of 0.02 N hydrochloric acid.
7. Fluoride : Not more than 40 ppm.
8. Magnesium and alkali salts : The weight of the residue does not exceed 25 mg.
9. Lead : Not more than 10 ppm.
10. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
11. Heavy metals : Not more than 20 ppm (as Pb).
12. Category : Food Additives Category 7
13. Uses : Food quality improvement, fermentation and food processing agents

## Sodium Trimetaphosphate

Chemical formula:  $(\text{NaPO}_3)_3$ 

Molecular weight: 305.92

1. Assay : Not less than 68.0% and not more than 70.0% of  $\text{P}_2\text{O}_5$ .
2. Description : White crystal or crystalline powder. Soluble in water, The 1 in 100 solution of the sample is around 6.0.
3. Identification : (1) The 1 in 20 solution of the sample passes test for sodium.  
(2) Dissolve 100 mg of the sample in 5 mL of hot dilute nitric acid TS, heat the solution in a steam bath for 10 minutes, then cool, and add sodium hydroxide TS to make it a neutral on litmus paper. Then add silver nitrate TS, a yellow precipitate forms. This precipitate can be dissolved in dilute nitric acid TS.
4. Fluoride : Not more than 0.005%.
5. Arsenic : Not more than 3 ppm (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Insoluble substances : Not more than 0.1%.
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents

## Azodicarbonamide

Chemical formula:  $C_2H_4N_4O_2$ 

Molecular weight: 116.08

1. Assay : Not less than 98.6% on the dried basis.
2. Description : Yellow to orange-red, odorless, crystalline powder. Practically insoluble in water and in most organic solvents; slightly soluble in dimethyl sulfoxide. Melts with decomposition when the temperature is above 180°C.
3. Identification : Dissolve 35 mg of the sample in 1000 mL of water. The solution has the maximum absorption value of 245 nm.
4. Arsenic : Not more than 3 ppm (as As).
5. Heavy metals : Not more than 0.003% (as Pb).
6. Lead : Not more than 10 ppm.
7. Loss on drying : Not more than 0.5%.
8. Nitrogen : 47.2% ~ 48.7%.
9. pH : Not less than 5.0 (1 in 50 suspension)
10. Residue on ignition : Not more than 0.15%.
11. Category : Food Additives Category 7
12. Uses : Maturing agent for flour

§ 04009

§ 07079

### Benzoyl Peroxide

Chemical formula:  $C_{14}H_{10}O_4$

Molecular weight: 242.23

1. Assay : Not less than 96.0%.
2. Description : Colorless, crystalline solid having a faint odor of benzaldehyde. Insoluble in water, slightly soluble in ethanol and soluble in benzene, chloroform and ether. Melts with decomposition between 103°C and 106°C. (Caution: Benzoyl peroxide, especially in the dry form, is a dangerous, highly reactive, oxidizing material and has been known to explode spontaneously. Please read the safety instructions on the package before use.)
3. Identification : To 500 mg of the sample add 50 mL of 0.5 N ethanolic potassium hydroxide, heat gradually to boiling and continue boiling for 15 min. Cool and dilute with 200 mL of water. Add sufficient 0.5 N hydrochloric acid to make strongly acidic and extract with ether. Dry the ether solution over anhydrous sodium sulfate, and then evaporate to dryness on a steam bath. The benzoic acid so obtained melts between 121°C and 123°C.
4. Arsenic : Not more than 3 ppm (as As).
5. Heavy metals : Not more than 0.004% (as Pb).
6. Lead : Not more than 10 ppm.
7. Category : Food Additives Category 4, 7
8. Uses : Bleaching agents; Food quality improvement, fermentation and food processing agents.

## Cross-Linked Sodium Carboxymethyl Cellulose

Synonyms: Cross-linked sodium CMC, croscarmellose sodium, INS No.468

Chemical formula:  $-\left[ \text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3) \right]_n-$

where  $\text{R}_1$ ,  $\text{R}_2$ , and  $\text{R}_3$  represent the following groups, present in varying proportions:

-H

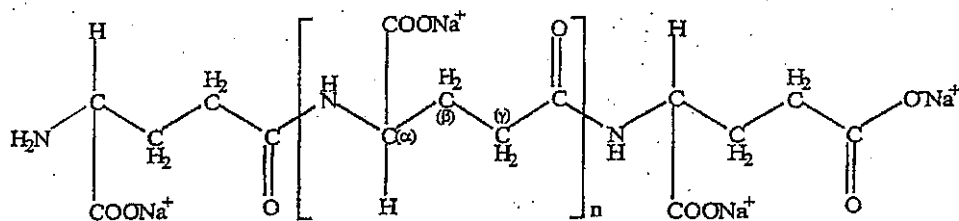
-CH<sub>2</sub>COONa

-CH<sub>2</sub>COOH

1. **Definition** : Cross-linked sodium carboxymethyl cellulose is the sodium salt of thermally cross-linked partly O-carboxymethylated cellulose. It is manufactured by acidifying an aqueous suspension of sodium carboxymethyl cellulose and heating the suspension to achieve cross-linking. The product is then washed and dried. It is also produced during the manufacture of sodium carboxymethyl cellulose by lowering the pH and heating to achieve crosslinking.
2. **Description** : A slightly hygroscopic, white to greyish-white, odorless powder.
3. **Identification** : (1) Solubility: Practically insoluble in acetone, in ethanol and in toluene.  
 (2) Color reaction: Add 0.5 g of the powdered sample to 50 mL water, while stirring to produce a uniform dispersion. Dilute 1 mL of this mixture with 1 mL of water in a small test tube and add 5 drops of 1-naphthol TS. Incline the test tube, and carefully introduce down the side of the tube 2 mL of sulfuric acid so that it forms a lower layer. A red-purple color develops at the interface.  
 (3) Precipitate formation: Mix 1 g of the powdered sample with 100 mL of solution containing 4 mg/kg of methylene blue in water and allow to settle. The substance absorbs methylene blue and settles as a blue, fibrous mass.  
 (4) Test for sodium: Passes test
4. **pH** : Not less than 5.0 and not more than 7.0 (1 in 100 suspension in water).
5. **Loss on drying** : Dry it at 105°C for 3 hours: it loses not more than 6% of its weight.
6. **Sulfated ash** : Not less than 14.0 % and not more than 28.0 % on the dried basis (2 g of sample).
7. **Water soluble substances** : Not more than 10%.
8. **Degree of substitution** : Not less than 0.2 and not more than 1.50 carboxymethyl groups (CH<sub>2</sub>COOH) per anhydroglucose unit on the dried basis.



9. Sodium chloride and sodium glycolate : Not more than 0.5%, in combination (on the dried basis)
10. Lead : Not more than 2 mg/kg.
11. Category : Food Additives Category 7
12. Uses : Food quality improvement, fermentation and food processing agents

Sodium  $\gamma$ -PolyglutamateChemical formula:  $(C_5H_6NNaO_3)_n$ 

1. Extent of polymerization : About 100 to 20,000 glutamic acid molecules.
2. Assay : Not less than 70% on the dried basis.
3. Description : White or off-white granular or powder, odorless, tasteless. Soluble in water; insoluble in alcohol or other organic solvents. 1 g of the sample is soluble in 5 mL of water.
4. Identification : (1) Add 6 mol/L hydrochloric acid to 5 mL of sodium polyglutamate aqueous solution (1 g of sodium polyglutamate dissolved in 200 mL of water), heat at 110°C for 24 hours for acid hydrolysis, and adjust the solution to neutral with NaOH. Add 1 mL of ninhydrin reagent (1 in 1000 solution). After heating for 5 minutes, the solution is blue-purple.  
(2) The FT-IR analysis of sodium glutamate 1–2 mg showed a weak absorption near 1600  $\text{cm}^{-1}$  and a strong absorption near 1410  $\text{cm}^{-1}$ .
5. pH : 4.0~7.0.
6. Heavy metals : Not more than 15 ppm (as Pb).
7. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Loss on drying : Not more than 5% (Infrared moisture analyzer, 105°C, to constant weight)
9. Ash : Not more than 30% (2~3 g of sample, 650°C).
10. Category : Food Additives Category 7
11. Uses : Food quality improvement, fermentation and food processing agents

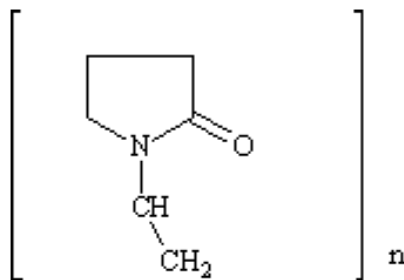
## Polyvinylpyrrolidone

General name : Povidone, PVP

Chemical names : Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidiny)-ethylene]

Chemical formula:  $(C_6H_9NO)_n$

Molecular weight: About 40,000 for low molecular weight product, and about 360,000 for high molecular weight product.



1. Assay : Not less than 12.2 % and not more than 13.0% nitrogen calculated on the anhydrous basis.
2. Appearance : White to tan powder.
3. Solubility : Soluble in water, alcohol and chloroform; insoluble in ether.
4. pH : 3.0-7.0 (5% soln)
5. 沉澱物形態 : (1) Add 5 mL of dilute hydrochloric acid liquid, 5 mL of water and 2 mL of potassium dichromate solution (1 g of potassium dichromate dissolved in 10 mL of water) to 5 mL of solution of the sample (1 g of the sample in 50 mL of water). Yellow sediment forms.  
 (2) Add 2 mL of cobalt nitrate and ammonium rhodanide solution (75 mg of cobalt nitrate and 0.3 g of ammonium rhodanide dissolved in 2 mL of water) to 5 mL of the solution of the sample (1 g of the sample dissolved in 50 mL of water). After mixing, acidify the solution with dilute hydrochloric acid, generating light blue precipitate.  
 (3) Add 1 mL of 25% hydrochloric acid, 5 mL of 5% of lanthanum chloride aqueous solution and 1 mL of 5% phosphonium acid aqueous solution to 5 mL of the solution of the sample (1 g of the sample dissolved in 50 mL of water). Bulky white precipitate forms and gradually turns blue under sunlight. The characteristics of the becoming blue under illumination can be used to distinguish polyvinylpyrrolidone and polyethylene oxide. The latter becomes white by the same treatment.

6. Water : Not more than 5% (Karl Fischer Method)
7. Relative viscosity : Low molecular weight products: 1.188-1.325; High molecular weight products:  
3.225-5.662 (Measured by Cannon-Fenske capillary viscometer)
8. Total ash : Not more than 0.02% (Test 10 g of the sample)
9. Aldehydes : Not more than 0.2% (as aldehydes)
10. Monomer content : Not more than 1% of vinylpyrrolidone.
11. Hydrazine : Not more than 1 mg/kg.
12. Lead : Not more than 2 mg/kg (Determine using an atomic absorption technique)
13. Category : Food Additives Category 7
14. Uses : Food quality improvement, fermentation and food processing agents

Calcium Stearate

1. Assay : Not less than 95% on the dried basis.
2. Description : White or white-yellow, slightly glossy crystalline solid, semi-solid or powder.
3. Solubility : Insoluble in water, ethanol and ether.
4. Identification : Passes test for cation and test for fatty acid.
5. Free fatty acid : Not more than 3%.
6. Unsaponifiable matter : Not more than 2%.
7. Lead : Not more than 2 mg/kg.
8. Loss on drying : Not more than 4.0% (105°, constant weight, then 2 h)
9. Category : Food Additives Category 7
10. Uses : Food quality improvement, fermentation and food processing agents

## Potassium Ferrocyanide

Chemical names : Potassium ferrocyanide, Potassium hexacyanoferrate (II)

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

Chemical formula :  $K_4Fe(CN)_6 \cdot 3H_2O$  Molecular weight : 422.4

1. Assay : Not less than 99.0%.
2. Appearance : Yellow crystalline powder.
3. Solubility : Soluble in water, insoluble in ethanol.
4. 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) Passes test for potassium.
5. Cyanide : Not detectable.
6. Prussiate : Not detectable.
7. Arsenic : Not more than 3 mg/kg.
8. Lead : Not more than 5 mg/kg.
9. Category : Food Additives Category 7
10. Uses : Food quality improvement, fermentation and food processing agents

## Calcium Ferrocyanide

Chemical names	: Calcium ferrocyanide, Calcium hexacyanoferrate (II)		
Synonyms	: Yellow prussiate of lime; hexacyanoferrate of calcium; INS No. 538; CAS No. 1327-39-5		
Chemical formula	: $\text{Ca}_2\text{Fe}(\text{CN})_6 \cdot 12\text{H}_2\text{O}$	Molecular weight	: 508.3
1. Assay	: Not less than 99.0%.		
2. Appearance	: Yellow crystalline powder.		
3. Solubility	: Miscible with water.		
4. 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) Passes test for calcium.		
5. Cyanide	: Not detectable.		
6. Prussiate	: Not detectable.		
7. Arsenic	: Not more than 3 mg/kg.		
8. Lead	: Not more than 5 mg/kg.		
9. Category	: Food Additives Category 7		
10. Uses	: Food quality improvement, fermentation and food processing agents		

§ 07087

§ 11-1-001

### D-Sorbitol

**Synonyms**

INS No. 420(i); D-Glucitol, D-sorbitol, sorbit, sorbol

**Definition**

Chemical names

D-Sorbitol

CAS NUMBER

50-70-4

Molecular formula

$C_6H_{14}O_6$

Molecular weight

182.17

Assay

Not less than 97.0% of  $C_6H_{14}O_6$  of total glycitols and not less than 91.0% of D-sorbitol on the anhydrous basis. The term glycitols refers to compounds with the structural formula  $CH_2OH-(CHOH)_n-CH_2OH$ , where n is an integer less than or equal to 4.

**Appearance**

White hygroscopic powder, crystalline powder, flakes or granules.

**Characteristics****Identification**

Solubility

Very soluble in water, slightly soluble in ethanol.

Melting range

88~102°C

Thin layer chromatography

Passes test

**Purity**

Water

Not more than 1% (Karl Fischer Method).

Sulfated ash

Not more than 0.1%.

Chloride

Not more than 50 mg/kg.

Sulfate

Not more than 100 mg/kg.

Nickel

Not more than 2 mg/kg.

Reducing sugar

Not more than 0.3%.

Total sugars

Not more than 1% (as glucose).

Lead

Not more than 1 mg/kg.

**Category**

Food Additives Category 11-1, 7.

**Uses**

Sweetener, Food quality improvement, fermentation and food processing agents



§ 07089

Xylitol

The same as § 11-1-003

§ 07090

D-Mannitol

The same as § 11-1-006

§ 07091

Maltitol

The same as § 11-1-017

§ 07092

Maltitol Syrup

The same as § 11-1-018

§ 07093

Isomalt (Hydrogenated Palatinose)

The same as § 11-1-019

§ 07094

Lactitol

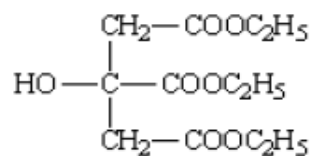
The same as § 11-1-020

§ 07095

Erythritol

The same as § 11-1-023

## Triethyl citrate



Synonyms : Ethyl citrate;

INS No. 1505;

CAS No 77-93-0

Chemical names Triethyl 2-hydroxypropan-1,2,3-tricarboxylate

Chemical formula:  $\text{C}_{12}\text{H}_{20}\text{O}_7$

Molecular weight: 276.29

1. Description : Odorless, practically colorless, oily liquid. Slightly soluble in water; miscible with ethanol and ether.
2. Assay : Not less than 99% w/w.
3. Index of refraction :  $n_D^{20} = 1.439-1.441$ .
4. Density : 1.135-1.139.
5. Water : Not more than 0.25% (Karl Fischer Method).
6. Acidity : Not more than 0.02% w/w (as citric acid)
7. Lead : Not more than 2 mg/kg.
8. Category : Food Additives Category 7
9. Uses : Food quality improvement, fermentation and food processing agents



**Nitrous oxide****SYNONYMS**

Dinitrogen oxide; Dinitrogen monoxide; INS No. 942

**Definition**

Nitrous oxide, a colourless and non-flammable gas, commonly known as laughing gas, is manufactured by thermal decomposition processes of ammonium nitrate. The hot, corrosive mixture of gases are cooled to condense the steam and filtered to remove higher oxides of nitrogen. The gas is further purified in a train of three gas washes with base, acid and base again. Nitric oxide impurity, if present, is chelated out with ferrous sulfate, or reduced with iron metal, or oxidised and absorbed in a base as a higher oxide.

Chemical names

Nitrous oxide

C.A.S. number

9000-69-5

Chemical formula

N<sub>2</sub>O

Formula weight

44.01

Assay

Not less than 99 % (v/v)

**DESCRIPTION**

Colourless, odourless gas

**Characteristics****IDENTIFICATION**

Solubility

1 volume dissolves in 1.4 volumes of water (20° 760 mm Hg). Freely soluble in alcohol; soluble in ether and in oils.

Infrared absorption or

Corresponds with the nitrous oxide standard

Chromatography

**PURITY**

Carbon dioxide

Not more than 0.03%(v/v)

Carbon monoxide

Not more than 10 µl/l

Nitric oxide

Not more than 1 µl/l

Nitrogen dioxide

Not more than 1 µl/l

Halogens (as Cl)

Not more than 5 µl/l

Ammonia

Not more than 25 µl/l

**Category**

Food additives category (07).

**Functional uses**

Food quality improvement, fermentation and food processing agents.

**Carbon Dioxide**

**SYNONYMS** INS No. 290

**Definition**

C.A.S. number 124-38-9

Chemical formula  $\text{CO}_2$

Formula weight 44.01

Assay Not less than 99.5% (v/v)

**DESCRIPTION**

Colourless, odourless gas, 1 litre of which weighs about 1.98 g at 0°C and 760 mm of mercury. Under a pressure of about 59 atmospheres it may be condensed to a liquid, a portion of which forms a white solid (Dry Ice) upon rapid evaporation. Solid carbon dioxide evaporates without melting upon exposure to air. Commercial carbon dioxide is shipped and handled in pressurized cylinders or low pressure bulk liquid systems, or in solid blocks.

**Characteristics**

The following specifications apply to gaseous carbon dioxide as produced from its condensed liquid or solid phase by evolution to the gas phase at normal environmental conditions.

**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.

Detector tube test Passes test

**PURITY**

Acidity Transfer 50 ml of water, previously boiled and cooled to room temperature, into a Nessler tube. Introduce 1,000 ml of the sample into the water through a tube (1 mm internal diameter) keeping the opening of the tube within 2 mm from the bottom of the vessel. Add 0.1 ml of methyl orange TS. The red colour produced is not darker than the colour of an identical control solution to which has been added 1.0 ml of 0.01 N hydrochloric acid instead of the carbon dioxide.

Phosphine, hydrogen sulfide, and other organic reducing substances, Transfer 25 ml of silver ammonium nitrate TS and 3 ml of ammonia TS into a Nessler tube. In the absence of light, introduce 1,000 ml of the sample in the same manner as in the test of Acidity. No brown colour is produced.

Carbon monoxide Not more than 10 µL/L

Non-volatile hydrocarbons Not more than 10 mg/kg

Volatile hydrocarbons Not more than 50 µL/L

Water Passes test

**Category** Food additives category (07).

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

## Nitrogen

<b>Synonyms</b>	INS No. 941
<b>Definition</b>	
Chemical name	Nitrogen
C.A.S. number	7727-37-9
Chemical formula	N <sub>2</sub>
Formula weight	28.0
Assay	Not less than 99.0% v/v
<b>Description</b>	Colourless, odourless gas or liquid
<b>Characteristics</b>	
<b>Identification</b>	
Flame test	A flame is extinguished in an atmosphere of the sample.
<b>Purity</b>	
Oxygen	Not more than 1% v/v
Carbon monoxide	Not more than 10 µl/l
<b>Category</b>	Food Additives Category 7
<b>Uses</b>	Food quality improvement, fermentation and food processing agents

## Activated Acid Clay

<b>Definition</b>	Activated Acid Clay is obtained by treating acid clay with sulfuric acid. Its principal constituent is hydrous aluminum silicate.
<b>Description</b>	Activated Acid Clay occurs as a whitish to gray powder or as granules.
<b>Identification</b>	Mix 1.0 g of Activated Acid Clay with 3.0 g of sodium carbonate and 0.4 g of boric acid, and heat the mixture in a platinum or nickel crucible until it melts completely. Cool, and add hydrochloric acid until no effervescence is observed. Add an additional 10 mL of hydrochloric acid, and heat on a water bath until the mixture becomes gelatinous, cool, and filter. The filtrate obtained responds to all the tests for Aluminum Salt as directed in the Qualitative Tests.
<b>pH</b>	2.0 ~ 6.0
<b>Purity</b>	
Water-soluble substances	Not more than 1.6%
Lead	Not more than 40 mg/kg
Arsenic	Not more than 3 mg/kg
Loss on Ignition	Not more than 35% (at 110°C for 3 hours, then at 550°C for 3 hours).
<b>Category</b>	Food additives category 7
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents

§ 08001

Dry Formed Vitamin A

1. Assay : Powder processed from vitamin A oil, fatty acid or vitamin A ester oil. 1 g of the sample contains 6 to 150 mg Vitamin A. The content should be 100% to 120% of the indicated content. (Vitamin A 150 mg=500,000 I.U.)
2. Appearance : Light yellow to light auburn powder.
3. Spoilage : This product must not have a strange smell.
4. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Loss on drying : Not more than 5% (vacuum desiccator over sulfuric acid, 4 h)
7. Residue on : Not more than 5%.  
ignition
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

# Vitamin A Oil

1. Assay : 1 g of the sample contains 30 to 300 mg of Vitamin A. The content should be 100% to 110% of the indicated content. (Vitamin A 300 mg = 1,000,000 I.U.)
2. Appearance : Yellow to slightly reddish orange liquid, having a characteristic odor.
3. Acid value : Not more than 2.8
4. Chloroform-insoluble matter : No insoluble matter appears when 0.5 g of the sample is dissolved in 3 mL of chloroform.
5. Category : Food Additives Category 8
6. Uses : Nutritional additives

## Vitamin A Fatty Acid Ester, in Oil

1. Appearance : Colorless to slightly reddish light yellow grease, having a peculiar smell.
2. Acid value : Not more than 1.96
3. Alcohol type Vitamin A : Dissolve 100 mg of the sample in petroleum ether, making 1 mL of it equivalent to 100-200 IU to be used as a test liquid. The coloring layer of about 5 cm is suspended in a chromatography tube with a suspension of petroleum ether. Note that the aluminum glue should be immersed in petroleum ether usually. After a small piece of cotton is placed on the aluminum layer, charge 10 mL of petroleum ether. The petroleum ether is discharged at the rate of 30 drops per minute. When the layer is about 1 cm above the aluminum adhesive layer, add 5~10 mL of the test solution to the chromatographic tube. When the liquid level of the liquid to be tested reaches 1 cm above the aluminum adhesive layer, the ester type vitamin A is discharged at the same speed with petroleum ether containing 5% ether. In the same way, the alcoholic vitamin A was dissolved in petroleum ether containing 50% diethyl ether. The movement and dissolvent of the ester type vitamin A and the alcohol type vitamin A in the coloring layer can be observed by ultraviolet light having a wavelength of about 350 nm in a short time. If the chromatographic layer is cracked or bubbled, the experiment should be re-operated. This test should be carried out below normal temperature.

Continuously distill the alcoholic vitamin A solution obtained by the above method by nitrogen or carbon dioxide gas into a water bath at about 70°C to evaporate the petroleum ether.

Dissolve the residue in isopropanol immediately to formulate a 1 mL, which corresponds to about 10 IU. Measure the absorbance at wavelengths of 310 nm, 325 nm and 334 nm. When the content of alcoholic Vitamin A was calculated according to the following formula, the content should be below 10%.

$$\text{Alcohol type Vitamin A content} = a / b \times 100 (\%)$$

Where a: International unit of alcoholic Vitamin A obtained by quantitative method (I.U.);

b: International unit of total Vitamin A obtained by quantitative method (I.U.).

All the petroleum ether, ether, aluminum gel and isopropyl alcohol used are required to be tested with Vitamin A.



4. Category : Food Additives Category 8
5. Uses : Nutritional additivesNutritional additives

Thiamine Hydrochloride (Vitamin B<sub>1</sub>)Chemical formula: C<sub>12</sub>H<sub>17</sub>ON<sub>4</sub>ClS·HCl

Molecular weight: 337.29

1. Assay : Not less than 98% and not more than 102% on the dried basis (105°C, 2 h)
2. Appearance : Small white to yellowish crystals or crystalline powder; odorless or with a slight characteristic odor.
3. Solution : Dissolve 1 g of the sample in water to make a 10 mL solution, The color of the solution should not be thicker than the solution made from diluting 1.5 mL of 0.1 N potassium dichromate solution to 1,000 mL.
4. pH of the solution : 2.7~3.4.
5. Sulfate : Not more than 0.05% of SO<sub>4</sub>.
6. Nitrate : Dissolve 1 g of the sample in 50 mL of water. Oscillate 2 mL of sulfuric acid with 2 mL of the previous solution. After cool and add 2 mL of horizon ferrous sulfate solution, the interface shall not show a brown ring.
7. Hydrobromide : Dissolve 7 mg of the sample in 0.1 mL of water. Add 1 drop of the fluorescent red TS to 1 drop of the solution made in the previous step, 1 drop of the same amount of glacial acetic acid and hydrogen peroxide, stir and then dry on the water bath. The residue should not be red.
8. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 5% of its weight.
9. Residue on ignition : Not more than 0.2%.
10. Category : Food Additives Category 8
11. Uses : Nutritional additives

Thiamine Mononitrate

Chemical formula:  $C_{12}H_{17}O_4N_5S$

Molecular weight: 327.37

1. Assay : Not less than 98% and not more than 102% on the dried basis (105°C, 2 h)
2. Appearance : White crystalline powder, odorless or with a slight characteristic odor.
3. pH : 6.5~8.0 (1 in 50 soln)
4. Chloride : Not more than 0.05% of Cl.
5. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1% of its weight.
6. Residue on ignition : Not more than 0.2%.
7. Category : Food Additives Category 8
8. Uses : Nutritional additives

Riboflavin (Vitamin B<sub>2</sub>)Chemical formula: C<sub>17</sub>H<sub>20</sub>O<sub>6</sub>N<sub>4</sub>

Molecular weight: 376.37

1. Assay : Not less than 98% after drying at 105°C for 2 hours.
2. Appearance : Yellow to orange-yellow crystalline powder, with slight odor.
3. Specific rotation :  $[\alpha]_D^{20} = -115 \sim -140^\circ$  Dry the sample at 100°C for 4 h. Dissolve 50.0 mg in 0.05 N sodium hydroxide free from carbonate and dilute to 10.0 mL with the same solvent. Measure the optical rotation within 30 min of dissolution.
4. Lumiflavin : Prepare the standard for this test for the absence of lumiflavin by diluting 3 mL of 0.1 N potassium dichromate with water to 1000 mL. Pour some chloroform through an alumina column to remove any ethanol. To 10 mL of this chloroform add 35 mg of the sample, shake for 5 min and filter. The color of the filtrate should be no more intense than that of 10 mL of the standard when viewed in identical containers.
5. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1.5% of its weight.
6. Residue on ignition : Not more than 13%.
7. Category : Food Additives Category 8, 9.
8. Uses : Nutritional additives; Nutritional additives; Colors

## Riboflavin Phosphate Sodium

Chemical formula:  $C_{17}H_{20}O_9N_4NaP \cdot 0 \sim 2H_2O$

1. Assay : Not less than 98% (vacuum desiccator over sulfuric acid, 4 h)
2. Appearance : Yellow to orange crystalline hygroscopic powder, with slight odor and a bitter taste.
3. Solution : When 0.2 g of the sample is dissolved in 10 mL of water, the solution should be clear.
4. Specific rotation :  $[\alpha]_D^{20} = +38.0 \sim +43.0^\circ$  (Dissolve 0.3 g of the sample in 5 N hydrochloric acid to make a 20 mL solution)
5. Absorbance : Dissolve 1 g of the sample in 100,000 mL of solution. The ratio of absorbance at 260 nm to 375 nm is  $2.60 \pm 0.15$ . 260 nm, the ratio to 445 nm is  $2.21 \pm 0.15$ . 375 nm, and the ratio of 445 nm is  $0.85 \pm 0.05$ .
6. Lumiflavin : Prepare the standard for this limit test for the absence of lumiflavin by diluting 3 mL of 0.1 N potassium dichromate with water to 1000 mL. Pour some chloroform through an alumina column to remove any ethanol. To 10 mL of this chloroform add 35 mg of the sample, shake for 5 min and filter. The color of the filtrate should be no more intense than that of 10 mL of the standard when viewed in identical containers.
7. Water : Not more than 12% (Karl Fischer Method)
8. Category : Food Additives Category 8, 9.
9. Uses : Nutritional additives; Nutritional additives; Colors

Pyridoxine Hydrochloride (Vitamin B<sub>6</sub>)

Chemical formula: C<sub>8</sub>H<sub>11</sub>O<sub>3</sub>N·HCl

Molecular weight: 205.64

1. Assay : Not less than 98% (vacuum desiccator over sulfuric acid, 4h)
2. Appearance : White to yellowish crystals or crystalline powder; odorless.
3. Heavy metals : Not more than 30 ppm (as Pb).
4. Loss on drying : Not more than 0.5% (vacuum desiccator over sulfuric acid, 4 h)
5. Residue on ignition : Not more than 0.1%.
6. Category : Food Additives Category 8
7. Uses : Nutritional additivesNutritional additives

Cyanocobalamin (Vitamin B<sub>12</sub>)

1. Assay : Not less than 95% .
2. Appearance : Dark red crystals or crystalline powder; odorless and tasteless.
3. Solubility : Soluble in water and ethanol; insoluble in acetone, chloroform or ether.
4. Loss on drying : Not more than 12% (105°C using vacuum, approx. 5 mm Hg, 2 h)
5. Category : Food Additives Category 8
6. Uses : Nutritional additivesNutritional additives

§ 08012

L-Ascorbic Acid (Vitamin C)

The same as § 03003



§ 08013

Sodium L-Ascorbate

The same as § 03004

§ 08014

L-Ascorbyl Stearate

The same as § 03005

§ 08015

L-Ascorbyl Palmitate

The same as § 03006

Calciferol (Vitamin D<sub>2</sub>)Chemical formula: C<sub>28</sub>H<sub>44</sub>O

Molecular weight: 396.66

1. Appearance : White, odorless crystal.
2. Melting range : 115~118°C (vacuum desiccator over sulfuric acid, 3 h)
3. Specific rotation :  $[\alpha]_D^{20} = +102.0 \sim +107.0^\circ$  (Dissolve 0.3 g of the sample in ethanol to make 20 mL solution.)
4. Specific absorbance : Dissolve the sample in ldehyde-free ethanol. The absorbance at a wavelength of 265 nm, E(1%, 1cm) is 445 to 485.
5. Ergosterol : Dissolve 10 mg of the sample in 2 mL of 90 v/v% ethanol, add the solution that contains 20 mg of and 2 mL of 90 v/v% ethanol. After 18 hours of standing, no precipitation forms.
6. Category : Food Additives Category 8
7. Uses : Nutritional additivesNutritional additives

§ 08018

*dl*- $\alpha$ -Tocopherol (Vitamin E)

The same as § 03009

§ 08020

Tocopherols Concentrate, Mixed

The same as § 03015

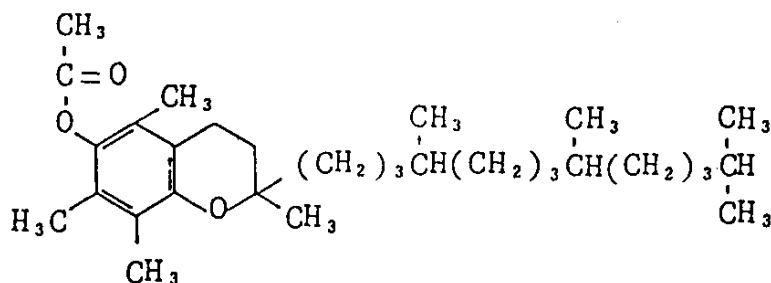
§ 08021

*d*- $\alpha$ -Tocopherol Concentrate

The same as § 03016

*d*- $\alpha$ -Tocopheryl AcetateChemical formula:  $C_{31}H_{52}O_3$ 

Molecular weight: 472.75



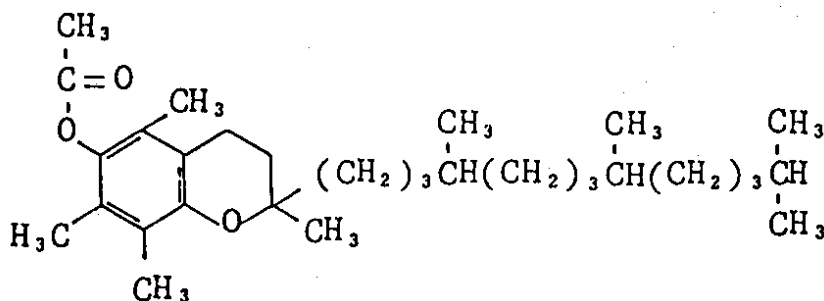
1. Description : A form of Vitamin E that is made from edible vegetable oil by vacuum distillation and acetylation. Colorless to yellow, transparent and viscous oil, almost odorless.  
Coagulate easily when it is standing. Melts at about 25°C. Insoluble in water; soluble in ethanol, and miscible with ether, acetone, chloroform and vegetable oil; instable under alkaline condition.
2. Identification : A. Prepare a test solution of the sample according to "specific optical rotation measurement". Take 10 mL of the solution, add 2 mL of nitric acid while stirring, and heat at about 75°C for 15 minutes. The solution is bright red to orange.  
B. The retention time of the major peak in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.
3. Assay :  $C_{31}H_{52}O_3$  96.0~102.0%.
4. Acidity : Moderate.
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.004% (as Pb).
7. Specific rotation : Not less than  $[\alpha]_D^{25} = +24^\circ$
8. Category : Food Additives Category 8
9. Uses : Nutritional additives



### *dl*- $\alpha$ -Tocopheryl Acetate

Chemical formula: C<sub>31</sub>H<sub>52</sub>O<sub>3</sub>

Molecular weight: 472.75



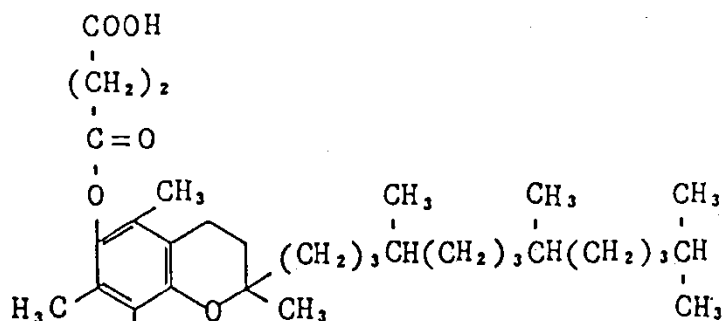
- |    |                |  |
|----|----------------|--|
| 1. | Description    | : A form of Vitamin E. Colorless to yellowish green, transparent and sticky oil, nearly odorless. Insoluble in water; soluble in ethanol, and miscible with ether, acetone, chloroform and vegetable oil; instable under alkaline condition.   |
| 2. | Identification | : A. Prepare a test solution of the sample according to "specific optical rotation measurement". Take 10 mL of the solution, add 2 mL of nitric acid while stirring, and heat at about 75°C for 15 minutes. The solution is bright red to orange.<br>B. The retention time of the major peak in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.<br>C. The specific optical rotation of 1 in 10 chloroform solution of the sample is about $\pm 0.05^\circ$ (almost unmeasurable). |
| 3. | Assay          | : Not less than 96.0% and not more than 102.0% of $C_{31}H_{52}O_3$ .  |
| 4. | Acidity        | : Moderate.  |
| 5. | Lead           | : Not more than 10 ppm.  |
| 6. | Heavy metals   | : Not more than 0.004% (as Pb)   |
| 7. | Category       | : Food Additives Category 8  |
| 8. | Uses           | : Nutritional additives  |

*d*- $\alpha$ -Tocopheryl Acetate Concentrate

1. Description : This product is a form of Vitamin E, which is prepared from edible vegetable oil by vacuum distillation and acidification. The content of *d*- $\alpha$ -tocopheryl acetate can be adjusted by appropriate physical or chemical methods. Light yellowish brown, transparent and viscous oil, almost odorless. Insoluble in water; soluble in ethanol, and miscible with ether, acetone, chloroform and vegetable oil; instable under alkaline condition.
2. Identification : A. Prepare a test solution of the sample according to "specific optical rotation measurement". Take 10 mL of the solution, add 2 mL of nitric acid while stirring, and heat at about 75°C for 15 minutes. The solution is bright red to orange.  
B. The retention time of the major peak in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.
3. Assay : Not less than 40.0% *d*- $\alpha$ -tocopheryl acetate (C<sub>31</sub>H<sub>52</sub>O<sub>3</sub>).
4. Acidity : Moderate.
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.004% (as Pb).
7. Specific rotation : Not less than  $[\alpha]_D^{25} = +24^\circ$
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

*d*- $\alpha$ -Tocopheryl Acid SuccinateChemical formula:  $C_{33}H_{54}O_5$ 

Molecular weight: 530.79



1. Description : A type of Vitamin E, which is made from edible vegetable oil by vacuum distillation and acylation of succinic acid. White to off-white crystalline powder, almost odorless, tasteless. Melts at about 75°C. Insoluble in water; soluble in ethanol, ether, acetone and vegetable oil; very soluble in chloroform. Stable in air, but not stable under alkaline conditions or heating.
2. Identification : A. Prepare a test solution of the sample according to "specific optical rotation measurement". Take 10 mL of the solution, add 2 mL of nitric acid while stirring, and heat at about 75°C for 15 minutes. The solution is bright red to orange.  
B. The retention time of the major peak in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation, both relative to the internal standard.
3. Assay : Not less than 96.0% and 102.0% of  $C_{33}H_{54}O_5$
4. Acidity : Moderate.
5. Lead : Not more than 10 ppm.
6. Heavy metals : Not more than 0.004% (as Pb).
7. Specific rotation : Not less than  $[\alpha]_D^{25} = +24^\circ$
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

## Nicotinic Acid

Chemical formula:  $C_6H_5O_2N$ 

Molecular weight: 123.11

1. Assay : Not less than 99.5% on the dried basis (105°C, 1 h)
2. Appearance : White crystal or crystalline powder, odorless, with slight sour taste.
3. Melting point : 234~237°C.
4. Chloride : Not more than 0.02% of Cl.
5. Sulfate : Not more than 0.02% of  $SO_4$ .
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Loss on drying : Dry it at 105°C for 1 hour: it loses not more than 1% of its weight.
8. Residue on ignition : Not more than 0.1%.
9. Category : Food Additives Category 8
10. Uses : Nutritional additives

## Nicotinamide

Chemical formula:  $C_6H_6ON_2$ 

Molecular weight: 122.13

1. Assay : Not less than 98.5% on the dried basis (over sulfuric acid, 4 h)
2. Appearance : White crystalline powder, odorless, bitter.
3. Melting range : 128~131°C.
4. Heavy metals : Not more than 30 ppm (as Pb).
5. Readily carbonizable substance : When 0.2 g of the sample is tested by readily carbonized substance measurement, the color of the solution should not be thicker than Matching Fluid A.
6. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 hr)
7. Residue on ignition : Not more than 0.1%.
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

# Folic Acid

Chemical formula:  $C_{19}H_{19}O_6N_7$

Molecular weight: 441.40

1. Assay : Not less than 95.0% and not more than 102.0% (By high performance liquid chromatography)
2. Appearance : Yellow to orange crystalline powder, odorless.
3. Water : Not more than 8.5% (Karl Fischer Method)
4. Residue on ignition : Not more than 0.5%.
5. Category : Food Additives Category 8
6. Uses : Nutritional additivesNutritional additives

§ 08030

Calcium Oxide

The same as § 07054

§ 08031

Calcium Carbonate

The same as § 07014



## Iron, Reduced

Chemical formula: Fe

Molecular weight: 55.85

1. Assay : Not less than 96.0%
2. Description : This product is an elemental iron obtained by chemical methods. Grayish black, matt to slightly lustrous powder. Can pass through the 100 mesh screen. When viewed under a microscope at 100x magnification, the sample is an amorphous powder that does not have a crystalline structure.
3. Identification : When dissolved in dilute mineral acid, the sample releases hydrogen chloride and produces corresponding iron salt solution. Passes test for ferrous salts.
4. Acid insoluble matter : Not more than 1.25%
5. Arsenic : Not more than 8 ppm (as As).
6. Lead : Not more than 0.0025%.
7. Mercury : Not more than 5 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

### Ferric Pyrophosphate (Iron Pyrophosphate)

Chemical formula:  $\text{Fe}_4(\text{P}_2\text{O}_7)_3 \cdot x\text{H}_2\text{O}$

Molecular weight: 745.22 (Anhydrous)

1. Description : Tan or yellowish-white, odorless powder. Insoluble in water but soluble in mineral acids.
2. Identification : Dissolve 500 mg of the sample in 5 mL of dilute hydrochloric acid (1→2), add an excess of sodium hydroxide TS to form a reddish brown precipitate. After allowing the solution to stand for a few minutes, filter it and discard the first few milliliters of the filtrate. Take 5 mL of clear filtrate, add 1 drop of bromophenol blue TS, titrate with 1 N hydrochloric acid until it becomes green. Then add 10 mL of zinc sulphate solution (1en aand adjust the pH to 3.8 (green) to form a white precipitate.
3. Assay : Not less than 24.0% and not more than 26.0% of Fe.
4. Arsenic : Not more than 3 ppm (as As).
5. Lead : Not more than 10 ppm.
6. Mercury : Not more than 3 ppm.
7. Loss on ignition : Not more than 20%.
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

## Iron, Carbonyl

Chemical formula: Fe

Molecular weight: 55.85

1. Assay : Not less than 98.0%
2. Description : An elemental iron obtained by decomposition of iron pentacarbonyl. Dark gray powder.  
When viewed under a microscope at a magnification of 500 times or more, it is a spherical particle with a concentric shell. The sample can pass through 200 mesh sieve; more than 95% of the sample can pass 325 mesh sieve. Stable in dry air.
3. Identification : Soluble in dilute mineral acid and releases hydrogen, and generate corresponding ferric salt solution. The solution passes test for ferrous salts.
4. Acid insoluble matter : Not more than 0.2%.
5. Arsenic : Not more than 4 ppm (as As).
6. Lead : Not more than 0.002%.
7. Mercury : Not more than 2 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

## Iron, Electrolytic

Chemical formula: Fe

Molecular weight: 55.85

1. Assay : Not less than 97%
2. Description : The sample is an elemental iron obtained by electrolytic process. Amorphous, matt grayish black powder. The sample can pass through 100 mesh, and more than 95% of the sample can pass through 325 mesh sieve. Stable in dry air.
3. Identification : Soluble in dilute mineral acid and releases hydrogen, generating corresponding ferric salt solution. The solution passes test for ferrous salts.
4. Acid insoluble matter : Not more than 0.2%.
5. Arsenic : Not more than 4 ppm (as As).
6. Lead : Not more than 0.002%.
7. Mercury : Not more than 2 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

Ferric Ammonium Citrate

1. Assay : Not less than 16.5% and not more than 21.1% of iron (Fe).
2. Appearance : Thin, transparent brown, reddish brown, or garnet red scales or granules, or a brownish yellow powder; odorless or has a slight ammonia and salty odor.
3. Solubility : Very soluble in water; insoluble in ethanol.
4. Tartrate : Heat to dissolve 4 mL of potassium hydroxide TS to 10 mL of 1 in 10 solution of the sample and filter. Acidify 5 mL of the filtrate with acetic acid.  
Add 2 mL of glacial acetic acid and stand the solution for 24 hours. No white crystalline precipitate should be formed.
5. Ferric citrate : Add a drop of potassium ferrocyanide TS to 10 mL 1 in 100 solution of the sample. No blue precipitation forms.
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Lead : Not more than 20 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

## Ferric Chloride

Chemical formula:  $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$ 

Molecular weight: 270.32

1. Assay : 98.5~102.0%.
2. Appearance : Deliquescent tan crystal or solid block.
3. Solution : Dissolve 1 g of the sample in 0.1 mL of hydrochloric acid and 10 mL of water by heating. The turbidity should be below "slightly turbid".
4. Free acid : Near a glass rod moistened with ammonia solution to a 2→5 solution of the sample. No smoke forms.
5. Free chlorine : Heat a 2→5 solution of the sample and near a filter paper wetted by the zinc iodide starch TS to it. The filter paper should not be blue.
6. Nitrate : Dissolve 0.5 g of the sample in 25 mL of water, boil, add 50 mL of ammonia TS (1→2), then add water to make a 100 mL solution. Cool and filter. Add 5 mL of water, 0.1 mL of Indigo Carmine TS and 10 mL of sulfuric acid to 5 mL of the filtrate. Color blue should exist for more than 5 minutes.
7. Sulfate : Not more than 0.016% of  $\text{SO}_4$ .
8. Heavy metals : Not more than 30 ppm (as Pb).
9. Lead : Not more than 10 ppm.
10. Zinc : Neutralize 20 mL of the filtrate obtained in "6.Nitrate" with hydrochloric acid, and add water to make it 30 mL. Then add 3 mL of dilute hydrochloric acid and 0.2 mL of potassium ferrocyanide TS. When stood for 15 minutes, the turbidity should not be thicker than that of 3 mL of zinc standard solution (1 mL = Zn 0.01 mg).
11. Arsenic : Not more than 3.3 ppm (as  $\text{As}_2\text{O}_3$ ).
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

Ferric Citrate

1. Assay : Not less than 16.5% and not more than 18.5% of iron (Fe).
2. Appearance : Thin, transparent brown, reddish brown, or garnet red scales, or a brownish yellow powder.
3. Solution : Dissolve 1 g of the sample in water and heat. The turbidity of the solution should be below "almost clear".
4. Ammonium salt : Heat 1 g of the sample with 10 mL of water and 5 mL of sodium hydroxide TS on a steam bath for 1 min. The odor of ammonia is not perceptible.
5. Tartrate : Filter the solution used in the test "4. Ammonium salt". Make 4 mL of the filtrate to make weakly acidic with acetic acid, add 2 mL of glacial acetic acid. After standing for 24 hours, no white crystalline precipitate should be produced.
6. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Lead : Not more than 20 ppm.
8. Alkalis and alkaline earths : Mix 0.5 g of the ignition residue of the sample with 1 mL of water. The solution should not be alkaline.
9. Category : Food Additives Category 8
10. Uses : Nutritional additives

# Ferrous Sulfate

Chemical formula:  $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$

Molecular weight: 278.03

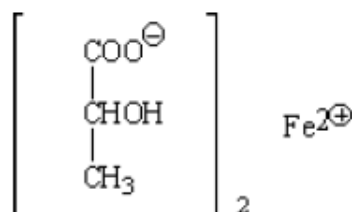
1. Assay : Not less than 98% and not more than 104%.
2. Appearance : Whitish green, odorless crystals, crystalline powder or granules.
3. Solution : Dissolve 1 g of the sample in 20 mL of water and 1 mL of dilute sulfuric acid. The turbidity of the solution should be below "almost clear".
4. pH : Not less than 3.7 (1 in 10 soln)
5. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Heavy metals : Not more than 25 ppm (as Pb).
7. Mercury : Not more than 3 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives



## Ferrous Lactate

Synonyms : INS No. 585.

Chemical formula:  $C_6H_{10}FeO_6 \cdot xH_2O$ , (x = 2 or 3)      Molecular weight: 270.02 (Dihydrate); 288.03 (Trihydrate)



1. Assay : Not less than 96% on the dried basis.
2. Appearance : Greenish white crystals or light green powder having a weak, characteristic smell.
3. Solubility : Soluble in water; practically insoluble in ethanol.
4. pH : 5.0~6.0 (1 in 50 solution)
5. Identification : (1) Test for lactate: Passes test.  
(2) Test for ferrous salts: Passes test.
6. Loss on drying : Not more than 18% (100°C using vacuum, 209pprox.. 700 mm Hg)
7. Sulfate : Not more than 0.1%
8. Chloride : Not more than 0.1%
9. Iron (III) : Not more than 0.6%
10. Lead : Not more than 1 mg/kg.
11. Category : Food Additives Category (8)
12. Uses : Nutritional additives

Sodium Ferrous Citrate  
(Iron and Sodium Succinate Citrate)

1. Assay : 10.0~11.0% of iron.
2. Description : White green to yellowish green powder, odorless, with a weak iron taste.
3. Identification : (1) Add 1 mL of dilute hydrochloric acid (1 g of the sample dissolved in 3 g of water), freshly prepared potassium ferricyanide solution (1 g of this product is 10 g of water) to 5 mL of 1 in 100 solution of the sample. Blue color appears.  
(2) Add 2 mL of ammonia solution to 5 mL of the solution of the sample (1 g of the sample dissolved in 100 g of water). Reddish brown color appears, but no precipitation will occur.  
(3) Ignite 3 g of the sample at 500~600°C for 3 hours. The residue passes test for sodium.  
(4) Add 5 mL of water and 10 mL of potassium hydroxide solution (1 g of potassium hydroxide in 25 g of water) to 0.5 g of the sample. Heat in water bath for 10 minutes, stir, cool and filter. Neutralize a part of filtrate with dilute acetic acid (1 mL of acetic acid in 1 mL of water), add an excess of calcium chloride solution (3 g of calcium chloride in 40 g of water) and boil. White crystalline precipitate appears. Collect the residue. Add sodium hydroxide solution (1 g of sodium hydroxide in 25 g of water) to part of residue. Precipitation will not dissolve. Add dilute hydrochloric acid (1 mL of hydrochloric acid in 3 mL of water) to another part of residue. Precipitate will dissolve.
4. Iron (III) : Place 2.0 g of the sample in a glass bolt triangle flask. Add 5 mL of hydrochloric acid and 30 mL of water, add 4 g of potassium iodide, and place it in dark for 1 minute. Afterward, add 2 mL of starch TS 2, and mix. The color appears. However, if 1 mL of 0.1 N sodium thiosulfate solution is added, the color should disappear immediately.
5. Tartrate : Add 5 mL of water and 10 mL of potassium hydroxide TS (add water to 1 g of potassium hydroxide to make a 15 mL solution) to 1.0 g of the sample, stir in a water bath for 10 minutes, cool and filter. Add dilute acetic acid (add water to 1 mL of acetic acid to make a 4 mL solution) to make 5 mL of the filtrate weakly acidic, then add 2 mL of acetic acid. After standing for 24 hours, no white crystalline precipitate should appear.
6. Sulfate : Not more than 0.48% of SO<sub>4</sub>.

7. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Category : Food Additives Category 8
10. Uses : Nutritional additivesNutritional additives

## Potassium Iodide

Chemical formula: KI

Molecular weight: 166.0

1. Assay : Not less than 99% on the dried basis (105°C, 4 h)
2. Appearance : Colorless transparent, white opaque hexagonal crystal, or white granular or powder, odorless, salty and bitter.
3. Solubility : 1 g of the sample is soluble in 0.7 mL, 0.5 mL of boiling water, 22 mL of ethanol, or 2 mL of glycerol.
4. Alkalinity : Add 0.1 mL of 0.1 N sulfuric acid and 1 drop of phenolphthalein TS to 1 g of the sample in 10 mL of freshly boiled and cooled water. No pink color is produced.
5. Iodate, nitrite, thiosulfate and barium salt : Dissolve 0.5 g of the sample in 10 mL of freshly boiled and cooled water. When adding 2 drops of dilute sulfuric acid, it should not show obvious yellow color in 30 seconds. It should not be turbid in one minute.
6. Nitrate, nitrite or ammonium salt : Place 1 g of the sample in a roughly 40 mL test tube, dissolve the sample with 5 mL of water, add 5 mL of sodium hydroxide TS and about 200 mg of aluminum wire. Fill the test tube with refined cotton, and put a wet red litmus test paper at the nozzle. Heat the test tube in water bath for 15 minutes. The test paper shall not appear blue.
7. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Positive test for sodium : The flame test of the 1 in 20 solution of the sample should not be yellow.
10. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 1% of its weight.
11. Category : Food Additives Category 8
12. Uses : Nutritional additives

### Potassium Iodate

Chemical formula:  $\text{KIO}_3$

Molecular weight: 214.01

1. Appearance : White crystalline powder.
2. Water-insoluble matter : Not more than 50 ppm.
3. Acidity or alkalinity : Dissolve 3 g of the sample in 40 mL of warm water, add 3 drops of phenolphthalein TS. The solution should not be red. Then add 0.25 mL of 0.02 N hydrochloric acid. The red color appears.
4. Chloride and bromide : Not more than 0.02% of Cl.
5. Chlorate : Add 2 mL of sulfuric acid to 2 g of the sample. The sample should stay white and generate no smell or gas.
6. Iodide : Dissolve 1 g of the sample in 20 mL of water, add 1 mL of chloroform and 0.5 mL of 1 N sulfuric acid. The chloroform layer should not appear violet in 1 minute.
7. Nitrogen compound : Not more than 0.025% of N.
8. Sulfate : Not more than 50 ppm of  $\text{SO}_4$ .
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Iron : Not more than 10 ppm.
11. Positive test for sodium : The flame test of 1 in 10 solution of the sample should not show an obvious yellow.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

Methyl Hesperidin (Vitamin P)

1. Assay : Not less than 90% (over sulfuric acid, 24 h)
2. Appearance : Yellow to orange powder, odorless or nearly odorless.
3. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be less than "almost clear".
4. Sulfate : Not more than 0.02% of SO<sub>4</sub>.
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Loss on drying : Not more than 3% (vacuum desiccator over sulfuric acid, 24 h)
7. Residue on : Not more than 0.5%.  
ignition
8. Category : Food Additives Category 8
9. Uses : Nutritional additivesNutritional additives

Menadione (Vitamin K<sub>3</sub>)Chemical formula: C<sub>11</sub>H<sub>8</sub>O<sub>2</sub>

Molecular weight: 172.18

1. Assay : Not less than 98.5% (over sulfuric acid, 4 h)
2. Appearance : Bright yellow crystalline powder, nearly odorless.
3. Melting range : 105~107°C.
4. Solubility : 1 g of the sample is soluble in about 60 mL of ethanol or 10 mL of benzene; less soluble in chloroform, carbon tetrachloride or vegetable oil; almost insoluble in water.
5. Loss on drying : Not more than 0.3% (over sulfuric acid, 4 hr)
6. Residue on ignition : Not more than 0.1%.
7. Category : Food Additives Category 8
8. Uses : Nutritional additives

## L-Histidine Monohydrochloride

Chemical formula:  $\text{C}_6\text{H}_9\text{O}_2\text{N}_3 \cdot \text{HCl} \cdot \text{H}_2\text{O}$ 

Molecular weight: 209.64

1. Assay : Not less than 98% on the dried basis (98°C, 3 h)
2. Appearance : White, odorless crystal or crystalline powder, with a sour and bitter taste.
3. Solution : Dissolve 1 g of the sample in 10 mL of water. The solution should be less than "almost clear" and colorless.
4. pH : 3.5~4.5 (1 in 10 soln)
5. Specific rotation :  $[\alpha]_D^{20} = +8.5 \sim +10.5^\circ$  (Dry at 98°C for 3 hours. Dissolve 5.5 g of the sample in 6 N hydrochloric acid to make a 50 mL solution.)
6. Ammonium salt : Not more than 0.02% of  $\text{NH}_4$ .
7. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Other amino acids : The test method of other amino acid for "L-diaminohexanoic acid hydrochloride" is applicable.
10. Loss on drying : Dry it at 98° for 3 hours: it loses not more than 0.2% of its weight.
11. Residue on ignition : Not more than 0.05%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additivesNutritional additives



## L-Isoleucine

Chemical formula:  $C_6H_{13}O_2N$ 

Molecular weight: 131.18

1. Assay : Not less than 98.5% (105°C, 3 h)
2. Appearance : White crystal or crystalline powder, odorless, with a slight bitter taste.
3. Solution : Dissolve 0.5 g of the sample in 20 mL of water. The solution should be "almost clear" and colorless.
4. pH : 5.5~7.0 (1 in 100 soln)
5. Specific rotation :  $[\alpha]_D^{20} = +39.5 \sim +41.5^\circ$  (Dry at 105 °C for 3 hours. Dissolve 2 g of the sample in 6 N hydrochloric acid to make a 50 mL solution.)
6. Chloride : Not more than 0.02% of Cl.
7. Ammonium salt : Not more than 0.02% of  $NH_4$ .
8. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Other amino acids : Test for other amino acid of "L-aspartate" is applicable.
11. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.2% of its weight.
12. Residue on ignition : Not more than 0.1%.
13. Category : Food Additives Category 8
14. Uses : Nutritional additives

## DL-Tryptophan

Chemical formula:  $C_{11}H_{12}O_2N_2$ 

Molecular weight: 204.23

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : White to slightly yellow crystal or crystalline powder, odorless or slightly smelly, a little sweet.
3. Solution : Dissolve 0.5 g of the sample in 10 mL of 0.5 N sodium hydroxide solution. The color of the solution should not be darker than Matching Fluid C.
4. pH : 5.5~7.0 (1 in 500 soln)
5. Chloride : Not more than 0.02% (as Cl).
6. Ammonium salt : Not more than 0.03% of  $NH_4$ .
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Other amino acids : Test for other amino acid of "L-aspartate" is applicable.
10. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.3% of its weight.
11. Residue on ignition : Not more than 0.1%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

## L-Tryptophan

Chemical formula:  $C_{11}H_{12}O_2N_2$ 

Molecular weight: 204.23

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : White to yellowish white crystal or crystalline powder, odorless or with slight odor, slightly bitter.
3. Solution : Dissolve 0.5 g of the sample in 10 mL of 0.5 N sodium hydroxide solution. The color of the solution should not be darker than Matching Fluid C and the turbidity should be below “almost clear”.
4. pH : 5.5~7.0 (1 in 100 soln)
5. Specific rotation :  $[\alpha]_D^{20} = -30 \sim -33^\circ$  (Dry at 105°C for 3 hours. Dissolve 0.5 g of the sample in water to make a 50 mL solution.)
6. Chloride : Not more than 0.02% of Cl.
7. Ammonium salt : Not more than 0.03% of  $NH_4$ .
8. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Other amino acids : Test for other amino acid of “L-aspartate” is applicable.
11. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.3% of its weight.
12. Residue on ignition : Not more than 0.1%.
13. Category : Food Additives Category 8
14. Uses : Nutritional additives

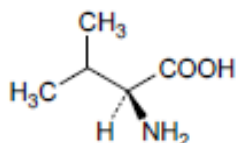
## L—Valine

Chemical names (2S)-2-Amino-3-methylbutanoic acid

C.A.S. number 72-18-4

Chemical formula  $C_5H_{11}NO_2$

Structural formula



Formula weight 117.15

Content L-Valine, when calculated on the dried basis, contains 98.0%–102.0% of L-valine

**Description** L-Valine occurs as white crystals or crystalline powder. It is odorless or has a slight, characteristic odor, and has a slight, characteristic taste.

**Identification** To 5 mL of a solution of L-Valine (1 in 1000), add 1 mL of ninhydrin solution (1 in 1000), and heat for 3 minutes. A purple color develops.

Specific Rotation  $[\alpha]_D^{20}$  : +26.5~+29.0° (Dry at 105 °C for 3 hours. Dissolve 4 g of the sample in 6 N hydrochloric acid to make a 50 mL solution.)

pH 5.5 ~ 7.0 (0.5 g, water 20 mL)

**Purity**

Clarity and color Colorless and clear (0.50 g, water 20 mL)

of solution

Chloride Not more than 0.021% as Cl

Arsenic Not more than 2 mg/kg as  $As_2O_3$

Lead Not more than 2 mg/kg

Loss on Drying Not more than 0.3% (105°C, 3 hours)

Residue on Ignition Not more than 0.1%

**Category** Food additives category 8

**Functional uses** Nutritional additives

## L — Lysine L— Glutamate

Chemical formula:  $C_{11}H_{23}O_6N_3 \cdot 2H_2O$ 

Molecular weight: 329.30

1. Assay : 98~102% (105°C, 5 h).
2. Appearance : White powder, odorless or with a slightly characteristic odor; having a specific taste.
3. Solution : Dissolve 1 g of the sample in 20 mL of water. The solution should be less than "almost clear" and colorless.
4. pH : 6.0~7.5 (1 in 10 soln)
5. Specific rotation :  $[\alpha]_D^{20} = +27.5 \sim +29.5^\circ$  (Dry at 105 °C for 5 hours. Dissolve 4 g of the sample in 6 N hydrochloric acid to make a 50 mL solution.)
6. Chloride : Not more than 0.04% of Cl.
7. Ammonium salt : Not more than 0.02% of  $NH_4$ .
8. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 30 ppm (as Pb).
10. Loss on drying : Dry it at 105°C for 5 hours: it loses not more than 11.4% of its weight.
11. Residue on ignition : Not more than 13%.
12. Other amino acid : Dissolve 0.1 g of the sample in water to make a 50 mL solution. Take 5  $\mu$ l for filter paper chromatography test, and stop when the fluid reach 30 cm from the origin. After drying the filter paper, dry at 100°C for 20 minutes. Spray coloring solution on the filter paper and dry at 100°C for 5 minutes. In addition to spots of the diaminocaproic acid and glutamate, no other spots should appear.  
  
Developing solvent: Mixture of n-butyl, glacial acetic acid and water (5: 1: 2).  
  
Coloring solution: 1 g of ninhydrin is dissolved in 500 mL of n-butanol that is saturated with water.  
  
Filter paper: Chromatography filter paper No.2
13. Category : Food Additives Category 8
14. Uses : Nutritional additivesNutritional additives

## L — Lysine Monohydrochloride

Chemical formula:  $C_6H_{14}O_2N_2 \cdot HCl$ 

Molecular weight: 182.66

1. Assay : Not less than 98.5% (105°C, 3 h).
2. Appearance : White powder, odorless or with a slightly characteristic odor.
3. Solution : When 0.5 g of the sample is dissolved in 10 mL of water, the solution should be clear.
4. pH : 5.0~6.0 (1 in 10 soln)
5. Specific rotation :  $[\alpha]_D^{20} = +19.0 \sim +21.5^\circ$  (Dry at 105 °C for 3 hours. Dissolve 4 g of the sample in 6 N hydrochloric acid to make a 50 mL solution.)
6. Ammonium salt : Test for ammonium salt of "L-aspartate" is applicable.
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Other amino acid : Dissolve 0.3 g of the sample in water to make a 50 mL solution. Take 5  $\mu$ l for filter paper chromatography test, and stop when the fluid reach 30 cm from the origin. After drying the filter paper, dry at 100°C for 20 minutes. Spray coloring solution on the filter paper and dry at 100°C for 5 minutes. Only one spot should appear.  
  
Developing solvent: Mixture of n-butanol, acetone, dicyclohexylamine and water (10: 10: 2: 5).  
  
Coloring solution: Dissolve 0.2 g of ninhydrin in 100 mL of the mixture of n-butanol, glacial acetic acid and water (5: 1: 2)  
  
Filter paper: Chromatography filter paper No.2
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 1% of its weight.
11. Residue on ignition : Not more than 13%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

## DL—Methionine

Chemical formula:  $C_5H_{11}O_2NS$ 

Molecular weight: 149.22

1. Assay : Not less than 98.5% (105°C, 4 h).
2. Appearance : White flake crystals or crystalline powder with characteristic odor and slightly sweet taste.
3. Solution : When 0.5 g of the sample is dissolved in 20 mL of water, the solution should be clear.
4. Chloride : Not more than 0.024% of Cl.
5. Sulfate : Not more than 0.05% of  $SO_4$ .
6. Ammonium salt : Not more than 0.02% of  $NH_4$ .
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Loss on drying : Not more than 0.5% (105°C, 4 h)
10. Residue on ignition : Not more than 0.1%.
11. Category : Food Additives Category 8
12. Uses : Nutritional additives

## L—Methionine

Chemical formula:  $C_5H_{11}O_2NS$ 

Molecular weight: 149.22

1. Assay : Not less than 98.5% on the dried basis (105°C, 4 h)
2. Appearance : White flake crystal or crystalline powder with characteristic odor and slightly bitter taste.
3. Solution : When 0.5 g of the sample is dissolved in 20 mL of water, the solution should be clear.
4. Specific rotation :  $[\alpha]_D^{20} = +21.0 \sim +25.0^\circ$  (Dissolve 1 g of the sample in 6 N hydrochloric acid to make the solution into 50 mL after drying at 105°C for 4 hours.)
5. Chloride : Not more than 0.024% of Cl.
6. Sulfate : Not more than 0.05% of  $SO_4$ .
7. Ammonium salt : Not more than 0.02% of  $NH_4$ .
8. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 0.5% of its weight.
11. Residue on ignition : Not more than 0.1%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives



## L—Phenylalanine

Chemical formula:  $C_9H_{11}O_2N$ 

Molecular weight: 165.20

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : White crystal or crystalline powder, a little bitter.
3. Solution 及溶性 : Dissolve 1 g of the sample in 100 mL of water. The solution should be less than "almost clear" and colorless. The pH should be 5.4~6.0.
4. Specific rotation :  $[\alpha]_D^{20} = -33 \sim -35^\circ$  (Dry at 105°C for 3 hours. Dissolve 1 g of the sample in water to make a 50 mL solution.)
5. Chloride : Not more than 0.02% of Cl.
6. Ammonium salt : Not more than 0.02% of  $NH_4$ .
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Other amino acids : Test for other amino acid of "L-aspartate" is applicable.
10. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.3% of its weight.
11. Residue on ignition : Not more than 0.1%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

## DL—Threonine

Chemical formula:  $C_4H_9O_3N$ 

Molecular weight: 119.12

1. Assay : Not less than 98% on the dried basis (105°C, 3 h)
2. Appearance : White crystalline powder, odorless, with a slight sweet taste.
3. Solution : Dissolve 1 g of the sample in 20 mL of water, and the solution should be less than "almost clear" and colorless.
4. pH : 5.0~6.5 (1 in 20 soln)
5. Chloride : Not more than 0.02% of Cl.
6. Ammonium salt : Not more than 0.02% of  $NH_4$ .
7. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Other amino acids : Not detectable.
10. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.2% of its weight.
11. Residue on ignition : Not more than 0.1%.
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

L—Threonine

Chemical formula:  $C_4H_9O_3N$

Molecular weight: 119.12

1. Assay : Not less than 98% on the dried basis (105°C, 3 h)
2. Appearance : White crystal or crystalline powder, odorless, with a slight sweet taste.
3. Specific rotation :  $[\alpha]_D^{20} = -26 \sim -29^\circ$  (Dry at 105°C for 3 hours. Dissolve 3 g of the sample in water to make a 50 mL solution.)
4. Solubility, liquid, chloride, ammonium, arsenic, heavy : Test 3.~11. of the DL-hydroxybutyric acid is metals, other amino acids, loss on drying, residue on applicable.  
ignition
5. Category : Food Additives Category 8
6. Uses : Nutritional additivesNutritional additives

## Sodium Pantothenate

Chemical formula:  $C_9H_{16}O_5NNa$ 

Molecular weight: 241.23

1. Assay :  $N = 5.6 \sim 6.0\%$ ;  $Na = 9.4 \sim 9.8\%$  (vacuum desiccator over sulfuric acid, 24 h)
2. Appearance : White crystal or crystalline powder, odorless, with a slight sour taste.
3. Specific rotation :  $[\alpha]_D^{25} = +25 \sim +30^\circ$  (Vacuum desiccator over sulfuric acid, 24 h. Dissolve 1.25 g the sample in 25 mL of water)
4. Heavy metals : Not more than 20 ppm (as Pb).
5. Calcium : Dissolve 1 g of the sample in 10 mL of water, add 0.5 mL of dilute acetic acid and 0.5 mL of ammonium oxalate TS. No precipitate occurs.
6. Alkaloid : Dissolve 0.2 g of the sample in 5 mL of water, add 1 mL of dilute hydrochloric acid and 2 drops of mercury iodide TS. No turbidity should be generated within 1 minute.
7. Loss on drying : Not more than 5% (vacuum desiccator over sulfuric acid, 24 h)
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

## Calcium Pantothenate

Chemical formula:  $C_{18}H_{32}O_{10}N_2Ca$ 

Molecular weight: 476.55

1. Assay : N=5.7~6.0%; Ca=8.2~8.6% on the dried basis (105°C, 3 h)
2. Appearance : White, odorless powder, having a bitter taste.
3. Specific rotation :  $[\alpha]_D^{20} = +25.0 \sim +28.5^\circ$  (dried at 105°C for 3 hours, and dissolve 1.25 g of the sample in water to make a 25 mL solution)
4. Heavy metals : Not more than 20 ppm (as Pb).
5. Alkaloid : Dissolve 0.2 g of the sample in 5 mL of water, add 1 mL of dilute hydrochloric acid and 2 drops of mercury iodide TS. No turbidity should be generated within 1 minute.
6. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 5% of its weight.
7. Category : Food Additives Category 8
8. Uses : Nutritional additives

## Potassium Chloride

Chemical formula: KCl

Molecular weight: 74.55

1. Assay : Not less than 99.0% on the dried basis.
2. Description : Colorless, elongated, prismatic, or cubital crystals, or white granular powder; odorless, having a salty taste and stable in the air. Freely soluble in water; insoluble in ethanol. The solution is neutral on litmus paper. 1 g of the sample is soluble in 2.8 mL of 25°C water and 2 mL of boiling water.
3. Identification : The 1 in 20 solution of the sample passes test for potassium and test for chloride.
4. Acidity or alkalinity : To a solution of 5 g of the sample in 50 mL of recently boiled and cooled water add 3 drops of phenolphthalein TS. No pink color is produced. Then add 0.3 mL of 0.02 N sodium hydroxide. A pink color is produced.
5. Iodide or bromide : Dissolve 2 g of the sample in 6 mL of water, add 1 mL of chloroform, and then add, dropwise and with constant agitation, 5 mL of a mixture of equal parts of chlorine TS and water. The chloroform is free from even a transient violet or permanent orange color.
6. Test for sodium : Take the 1 in 20 solution of the with platinum wire, and perform flame test on non-glow flame. No obvious yellow color should appear.
7. Arsenic : Not more than 3 ppm (as As).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1% of its weight.
10. Category : Food Additives Category 8, 9.
11. Uses : Nutritional additives; Nutritional additives; Flavoring Agents agent.

§ 08064

Magnesium Sulfate

The same as § 07022

## Choline Bitartrate

Chemical formula:  $C_9H_{19}NO_7$ 

Molecular weight: 253.25

1. Description : The sample is a white, hygroscopic crystalline powder with a sour taste, odorless or with a slight trimethylamine odor. Completely soluble in water; slightly soluble in alcohol; insoluble in ether, chloroform and benzene.
2. Identification : A. Dissolve 500 mg of the sample in 2 mL of water, add 3 mL of sodium hydroxide TS, heated to boiling. An odor of trimethylamine appears.  
B. Dissolve 500 mg of the sample in 2 mL of iodine TS. Reddish brown precipitate immediately appears. After adding 5 mL of sodium hydroxide TS, the precipitate is dissolved and the solution becomes clear and yellow. This solution is heated to produce a pale yellow precipitate and iodoform odor.  
C. Add 2 mL of cobalt chloride TS and 2 mL of 1 in 50 potassium ferrocyanide solution to 1 mL of 1 in 100 solution of the sample. Color emerald green will appear immediately.
3. Assay : Not less than 98.0% on the dried basis.
4. Arsenic : Not more than 3 ppm (as As).
5. 1,4—Dioxane : Passes test
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Lead : Not more than 10 ppm.
8. Residue on ignition : Not more than 0.1%.
9. Water : Not more than 0.5%.
10. Category : Food Additives Category 8
11. Uses : Nutritional additives



## Choline Chloride

Chemical formula:  $C_5H_{14}ClNO$ 

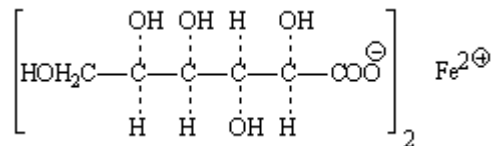
Molecular weight: 139.62

1. Description : Colorless or white, hygroscopic crystals or crystalline powder, usually with an odor of trimethylamine. Very soluble in water and alcohol.
2. Identification : A. The sample passes Test A, B and C for choline bitartrate.  
B. The 1 in 20 solution of the sample passes test for chloride.
3. Assay : Not less than 98% on the dried basis.
4. Arsenic : Not more than 3 ppm (as As).
5. 1,4—Dioxane : Passes test
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Lead : Not more than 10 ppm.
8. Residue on ignition : Not more than 0.05%.
9. Water : Not more than 0.5%.
10. Category : Food Additives Category 8
11. Uses : Nutritional additives

## Ferrous Gluconate

Chemical formula:  $C_{12}H_{22}FeO_{14} \cdot 2H_2O$ 

Molecular weight: 482.17



1. Assay : Not less than 95% on the dried basis.
2. Appearance : Fine yellowish-grey or pale greenish-yellow powder or granules having a slight odor resembling that of burnt sugar.
3. Solubility : Soluble with slight heating in water; practically insoluble in ethanol.
4. Loss on drying : 6.5~10.0% (105°C, 16 h).
5. Reducing sugar : Dissolve 0.5 g of the sample in 10 mL of water; warm, and make the solution alkaline with 1 mL of ammonia TS. Pass hydrogen sulfide gas into the solution to precipitate the iron, and allow the mixture to stand for 30 min to coagulate the precipitate. Filter, and wash the precipitate with two successive 5 mL portions of water. Acidify the combined filtrate and washings with hydrochloric acid, and add 2 mL of dilute hydrochloric acid TS in excess. Boil the solution until the vapors no longer darken lead acetate paper, and continue to boil, if necessary, until concentrated to about 10 mL. Allow to cool, add 5 mL of sodium carbonate TS and 20 mL of water; filter, and adjust the volume of the filtrate to 100 mL. To 5 mL of the filtrate add 2 mL of alkaline cupric tartrate TS and boil for 1 min. No red precipitate should be formed within 1 min.
6. Iron : Not more than 2%.
7. Lead : Not more than 2 ppm.
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

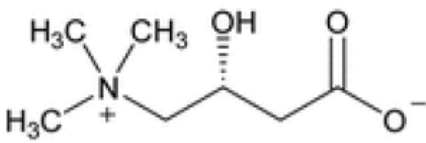
## Magnesium Oxide

Chemical formula: MgO

Molecular weight: 40.31

1. Assay : Not less than 96.0% after ignition at about 800°C.
2. Description : Very bulky white powder, known as light magnesium oxide, or as a relatively dense, white powder, known as heavy magnesium oxide. 5 g of light magnesium oxide occupy a volume of 40 to 50 mL, while 5 g of heavy magnesium oxide occupy a volume of 10 to 20 mL. The sample is alkaline to moistened litmus paper.
3. Solubility : Practically insoluble in water; insoluble in ethanol.
4. Loss on drying : Not more than 5% after ignition at 800°C to 825°C to constant weight.
5. Alkali (free) and soluble salts : Boil 2 g of the sample, weighed to the nearest mg, with 100 mL of water for 5 min in a covered beaker and filter while hot. Add methyl red TS and titrate 50 mL of the cooled filtrate with 0.1 N sulfuric acid. Not more than 2 mL of the acid should be consumed. Evaporate 25 mL of the filtrate to dryness and dry at 105°C for 1 h. Not more than 10 mg of residue should remain.
6. Calcium oxide : Not more than 1.5%  
(Weigh 400 mg of the sample to the nearest 0.1 mg, and dissolve in a mixture of 3 mL of sulfuric acid and 22 mL of water. Add 50 mL of ethanol, and allow the mixture to stand overnight. If crystals of magnesium sulfate separate, warm the mixture to about 50°C to dissolve. Filter through a tared, previously ignited, porcelain filter crucible, and wash the precipitate several times with a mixture of 2 volumes of ethanol and 1 volume of dilute sulfuric acid TS. Ignite the crucible and contents at a dull red heat, cool and weigh. The weight of calcium sulfate obtained, multiplied by 0.4119, gives the equivalent of calcium oxide in the sample taken for the test.)
7. Arsenic : Not more than 3 ppm.
8. Lead : Not more than 10 ppm.
9. Heavy metals : Not more than 40 ppm (as Pb).
10. Category : Food Additives Category 8
11. Uses : Nutritional additives

## L-Carnitine

Chemical names	4-Amino-3-hydroxybutyric Acid Trimethylbetaine ; Levocarnitine ; 4-Trimethylamino-3-hydroxybutyrate ; (R)-3-Carboxy-2-hydroxy-N,N,N-trimethyl-1-propanaminium Hydroxide, Inner Salt
C.A.S. number	541-15-1
Chemical formula	C <sub>7</sub> H <sub>15</sub> NO <sub>3</sub>
Structural formula	
Formula weight	161.20
Assay	97.0% ~ 103.0%, calculated on the anhydrous basis
Description	L-Carnitine occurs as white crystals or as a white, crystalline, hygroscopic powder.
Identification	Dissolve 1 g of sample in 10 mL of water and 10 mL of 1 N hydrochloric acid, and add 5 mL of sodium tetraphenylborate test solution. It forms a white precipitate.
Solubility	It is freely soluble in water, in alcohol, in alkaline solutions, and in dilute mineral acids. It is practically insoluble in acetone and in ethyl acetate. It decomposes without melting at about 185°C to 195°C.
Specific Rotation	$[\alpha]_D^{20}$ : -29.0 ~ -32.0°, calculated on the anhydrous basis
pH	5.5 ~ 9.5
Chloride	Not more than 0.4%
Water	Not more than 4.0%
Lead	Not more than 1 mg/kg
Potassium	Not more than 0.2%
Sodium	Not more than 0.1%
Residue on Ignition	Not more than 0.5%
Category	Food additives category 8
Functional uses	Nutritional additives

Manganese Sulfate

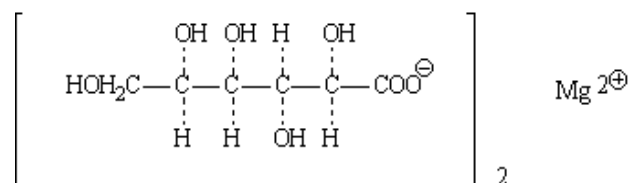
Synonym : CAS No. 7785-87-7

Chemical formula :  $\text{MnSO}_4 \cdot \text{H}_2\text{O}$

Molecular weight : 169.02

1. Assay : 98.0 ~ 102.0% °
2. Description : Light pink granular powder
3. Solubility : Freely soluble in water, insoluble in ethanol
4. Arsenic : Not more than 3 mg/kg
5. Lead : Not more than 4 mg/kg
6. Selenium : Not more than 0.003%
7. Loss on drying : 10.0 ~ 13.0% (400 ~ 500°C , heat to constant weight)
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

## Magnesium Gluconate

Chemical formula:  $C_{12}H_{22}MgO_{14}$ Formula weight: 414.60 (Anhydrous); 450.63  
(Dihydrate)

- |    |                     |  |
|----|---------------------|--|
| 1. | Assay               | : Not less than 98.0% and not more than 102.0% on the anhydrous basis. |
| 2. | Description         | : White to off-white, odorless, fine powder.                           |
| 3. | Solubility          | : Soluble in water; sparingly soluble in ethanol.                      |
| 4. | Water               | : Between 3.0% and 12.0% (Karl Fischer Method).                        |
| 5. | Reducing substances | : Not more than 1.0% calculated as D-glucose.                          |
| 6. | Lead                | : Not more than 2 ppm.   |
| 7. | Category            | : Food Additives Category 8  |
| 8. | Uses                | : Nutritional additives  |

## Magnesium Hydroxide

Chemical formula:  $\text{Mg}(\text{OH})_2$ 

Molecular weight: 58.32

1. Assay : Not less than 95%
2. Description : Odorless, white bulky powder. The sample is alkaline to moistened litmus paper.
3. Solubility : Practically insoluble in water and in ethanol.
4. Loss on drying : Not more than 2% (105°C, 2 h)
5. Loss on ignition : Not more than 30 - 33% (approx. 800°C to constant weight)
6. Alkalis (free) and soluble salts : Boil 2 g of the sample with 100 mL of water for 5 min in a covered beaker and filter while hot. Add methyl red TS and titrate 50 mL of the cooled filtrate with 0.1 N sulfuric acid. Not more than 2 mL of the acid is required to reach the endpoint. Evaporate 25 mL of the filtrate to dryness and dry at 105°C for 3 h. Not more than 10 mg of residue remains.
7. Calcium oxide : Not more than 1.5%  
(Dissolve about 500 mg of the sample, accurately weighed, in a mixture of 3 mL of concentrated sulfuric acid and 22 mL of water. Add 50 mL of ethanol and allow the mixture to stand overnight. If crystals of magnesium sulfate separate, warm the mixture to about 50°C to dissolve. Filter through a Gooch crucible containing an asbestos mat previously washed with dilute sulfuric acid TS, water, and ethanol and ignited and weighed. Wash the crystals on the mat several times with a mixture of 3 volumes of ethanol and 1 volume of water. Ignite the crucible and contents at a dull red heat, cool and weigh. The weight of calcium sulfate obtained, multiplied by 0.4119, gives the equivalent of calcium oxide in the sample taken for the test.)
8. Arsenic : Not more than 3 ppm.
9. Lead : Not more than 10 ppm.
10. Heavy metals : Not more than 40 ppm.
11. Category : Food Additives Category 8
12. Uses : Nutritional additives

## Lactoferrin

Description	Obtained by degreasing, separating and refining the milk. White to pink powder.
Crude protein	Not less than 93% (TN×6.38, on the dried basis).
Lactoferrin	Not less than 95% on the protein basis.
Iron	30 mg/100 g
Water	Not more than 4.5%.
Solubility	Dissolve 2 g of the sample in 100 mL of water. The solution should be “transparent”.
pH	5.2-7.2 (20°C) (2% soln)
Ash	Not more than 1%
Heavy metals	Not more than 20 mg/kg as Pb
Arsenic	Not more than 2 mg/kg as As
Category	Food Additives Category 8
Uses	Nutritional additives



§ 08113

Calcium Dihydrogen Phosphate

The same as § 07006

§ 08114

Calcium Phosphate, Dibasic

The same as § 07007

§ 08116

Calcium Phosphate, Tribasic

The same as § 07009

Iron Lactate

1. Assay : Not less than 15.5% and not more 20.0% of Fe.
2. Appearance : 帶綠白至黃褐色粉末或塊狀，略具特異臭。
3. Identification : (1)本品 0.5 g 在 450~550°C高溫下加熱一小時，取其殘渣，加入稀釋鹽酸(鹽酸 1 mL 溶於水 1 mL)3 mL，並加熱溶解之，其溶液之鐵離子試驗呈陽性反應。  
(2) Passes test for lactate.
4. Solution : Dissolve 1 g of the sample in 20 mL of water in water bath. The solution should be "almost clear".
5. Chloride : Not more than 0.07% of Cl.
6. Sulfate : Not more than 0.48% of SO<sub>4</sub>.
7. Arsenic : Not more than 4 ppm (as As<sub>2</sub>O<sub>3</sub>).
8. Heavy metals : Not more than 50 ppm (as Pb).
9. 易碳化物及酪酸鹽 : 本品 0.5 g 加硫酸 1 mL 混合時，不得產生顏色或類似酪酸之臭味。
10. Category : Food Additives Category 8
11. Uses : Nutritional additivesNutritional additives

§ 08118

Calcium Lactate

The same as § 07012

## Calcium Gluconolactate

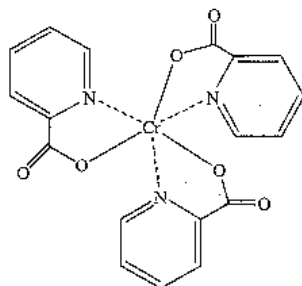
Chemical formula:  $\text{Ca}_5(\text{C}_3\text{H}_5\text{O}_3)_6(\text{C}_6\text{H}_{11}\text{O}_7)_4 \cdot 2\text{H}_2\text{O}$       Molecular weight: 1551.5

1. Assay : Not less than 98.0% and not more than 101.0%.
2. Description : White or slightly gray or yellow powder.
3. Identification : The 100 mg in 10 mL solution of the sample passes the test for calcium. In the thin layer chromatography analysis, the sample passes test for lactic acid and test for gluconic acid.
4. Total sugars : No red precipitate exists.
5. pH : Dissolve about 10 g of the sample in 1000 mL of boiled water, and the pH of the solution is 5.6 ~ 8.6.
6. Heavy metals : Not more than 5 ppm (as Pb).  
The total amount of Fe, Ni, Cu, Zn, Pb and Cd is not more than 50 ppm.  
Not more than 40 ppm of Fe.  
The total amount of Ni, Cu, Zn, Pb and Cd is not more than 10 ppm.  
Not more than 1 ppm (as Pb) and Cd.
7. Arsenic : Not more than 1 ppm (as  $\text{As}_2\text{O}_3$ ).
8. Chloride : Not more than 400 ppm of  $\text{Cl}^-$ .
9. Sulfate : Not more than 600 ppm of  $\text{SO}_4^{-2}$ .
10. Phosphate : Not more than 400 ppm of  $\text{PO}_4^{-3}$ .
11. Loss on drying : Not more than 4.0% (85°C, more than 30 min)
12. Category : Food Additives Category 8
13. Uses : Nutritional additives

# Chromium Picolinate

Chemical formula:  $C_{18}H_{12}N_3O_6Cr$

Molecular weight: 418.31



1. Assay : Not less than 98% and not more than 102% on the dried basis.
2. Appearance : Red to pink powder.
3. Identification : The infrared absorption spectrum measured by the sample should be consistent with the standard product.
4. Chromium : 12~12.6%.
5. Chloride : Not more than 0.06%.
6. Bulk density : Not less than 0.45 g/mL.
7. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 4% of its weight.
8. Sulfate : Not more than 0.2%.
9. Arsenic : Not more than 1 ppm.
10. Lead : Not more than 10 ppm.
11. Mercury : Not more than 1 ppm.
12. Particle size : Not more than 60 Mesh.
13. Category : Food Additives Category 8
14. Uses : Nutritional additives

## Synthetic Zeaxanthin

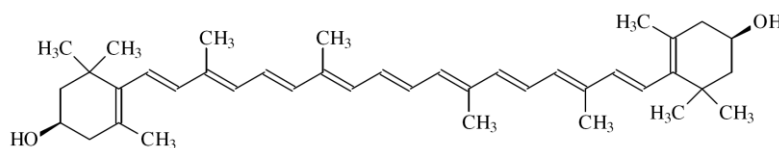
Chemical names : (all-E)-1,1'-(3,7,12,16-Tetramethyl-1,3,5,7,9,11,13,15,17- octadecanonaene-1,18-diyl)bis[2,6,6-trimethylcyclohexene-3-ol]; 3R,3'R-β, β -Carotene-3,3'-diol

Synonyms : Zeaxanthol; anchovyxanthin; INS 161h(i); CAS No. 144-68-3

Chemical formula : C<sub>40</sub>H<sub>56</sub>O<sub>2</sub>

Molecular weight:

568.9



1. Assay : Not less than 96%.
2. Description : Orange-red crystalline powder, with little or no odor.
3. Solubility : Sparingly soluble in chloroform, practically insoluble in water and ethanol.
4. Test for carotenoid : The color of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulfuric acid.
5. Spectrophotometry : An ethanol solution of the sample shows maximum absorption between 450 and 454 nm.
6. Loss on drying : Not more than 0.2%.
7. Sulfated ash : Not more than 0.1%.
8. cis-Zeaxanthins : Not more than 2.0%.
9. 12' -Apo-zeaxanthinal, diatoxanthin, parasiloxanthin : Not more than 1.1 % combined.
10. Triphenyl phosphine oxide (TPPO) : Not more than 0.01%.
11. Heavy metals : Not more than 20 mg/kg (as Pb).
12. Lead : Not more than 2 mg/kg.
13. Category : Food Additives Category 8
14. Uses : Nutritional additives



§ 08133

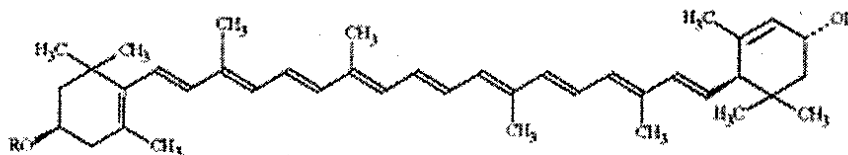
§ 09033

### Lutein

Chemical names : 3,3'-dihydroxy-d-carotene

Chemical formula:  $C_{40}H_{56}O_2$

Molecular weight: 568.88



Lutein: R = H

1. Definition : Crystalline lutein is obtained by extracting with solvent, saponifying, centrifuging marigold flower. The crystal contains a small amount of zeaxanthin.
2. Assay : Not less than 75% of lutein.
3. Description : Yellowish brown crystalline powder.
4. Identification : (1) Solubility: Insoluble in water; soluble in hexane.  
(2) Positive carotenoid test: The color disappears after continuously adding 5% sodium nitrite solution and 0.5 M sulfuric acid to the acetone solution of the sample.
5. Residual solvent : Hexane: Not more than 50 mg/kg.
6. Lead : Not more than 2 mg/kg.
7. Category : Food Additives Category 8
8. Uses : Nutritional additives

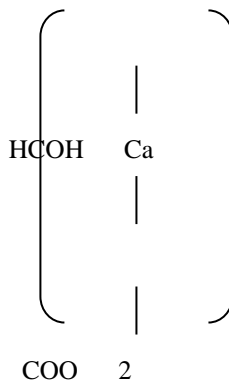
## Calcium L-Threonate

Chemical formula:  $(C_4H_7O_5)_2Ca$ 

Molecular weight: 310.27

CH<sub>2</sub>OH

HOCH



1. Assay : Not less than 95% on the dried basis.
2. Appearance : White powder
3. Melting range : Not less than 265°C.
4. Solubility : Soluble in water. The solution is colorless and clear.
5. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 0.40% of its weight.
6. Water : 0.15~0.25%.
7. pH : 8.0~9.0 (saturated solution)
8. Ascorbic acid : Not more than 18 ppm.
9. Arsenic : 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
10. Heavy metals : Not more than 20 ppm (as Pb).
11. Ascorbic acid : Not detectable.
12. Sulfate : Not more than 0.05%.
13. Chloride : Not more than 0.05%.
14. Category : Food Additives Category 8
15. Uses : Nutritional additives

## Calcium Citrate

<b>Synonyms</b>	INS No. 333(iii)
<b>Definition</b>	
Chemical names	Tricalcium citrate, tricalcium salt of 2-hydroxy-1,2,3- propanetricarboxylic acid, tricalcium salt of β-hydroxy-tricarballic acid
C.A.S. number	813-94-5
Chemical formula	$C_{12}H_{10}Ca_3O_{14} \cdot 4H_2O$
Structural formula	$\left[ \begin{array}{c} \text{CH}_2\text{COO}^\ominus \\   \\ \text{HO}-\text{C}-\text{COO}^\ominus \\   \\ \text{CH}_2\text{COO}^\ominus \end{array} \right]_2 \text{Ca}_3 \cdot 4\text{H}_2\text{O}$
Formula weight	570.51
Assay	Not less than 97.5% after drying
<b>Description</b>	Odourless, fine white powder
<b>Characteristics</b>	
Identification	
Solubility	Very slightly soluble in water. Insoluble in ethanol.
Test for citrate	Passes test
Test for calcium	Passes test
Purity	
Loss on drying	Not less than 10% and not more than 14% (150°C, 4 h)
Fluorides	Not more than 30 mg/kg
Free acid and alkali	Passes test
Oxalate	Dissolve 1 g of the sample in 5 ml of warm dilute hydrochloric acid TS and filter the solution if necessary.
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (7) (8)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Nutritional additives.

## Zinc Citrate Trihydrate

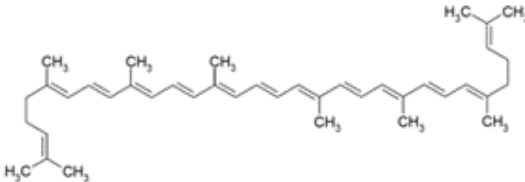
Chemical formula:  $C_{12}H_{10}O_{14}Zn_3 \cdot 3H_2O$ 

Molecular weight: 628.4

1. Assay : Not less than 99.0% and not more than 102.5%.
2. Description : White powder. Insoluble in alcohol, slightly soluble in water, and soluble in diluted inorganic acid.
3. Identification : Solution S: Dissolve 2.5 g of the sample in dilute nitric acid and adjust the volume to 50 mL using dilute nitric acid.  
 Appearance of solution S: Transparent, clear, colorless.
  - A. Test for citrate: Add 0.5 mL of sulphuric acid and 1 mL of potassium permanganate to 5 mL of solution S. Heat until the color of the potassium permanganate remain unchanged. Add 0.5 mL of sodium nitroferic hydride/diluted sulfuric acid (100 g/L) solution and 4 g of sulfuric acid. Slowly add concentrated ammonia to alkalinize the solution until sulfuric acid is dissolved. Add an excess of concentrated ammonia to make the solution purple, then turn violet.
  - B. Test for zinc: Add 0.2 mL of sodium hydroxide solution to 5 mL of solution S. A white precipitate forms. After adding 2 mL of sodium hydroxide solution, the precipitate will completely dissolve and the solution will be clear. After adding 0.1 mL of sodium sulfide solution, a fluffy white precipitate forms.
4. Chloride : Not more than 200 ppm.  
 Dilute 5 mL of solution S with water to 15 mL According to the limit test of chloride in Ph. Eur.
5. Sulfate : Not more than 200 ppm.  
 Dilute 5 mL of solution S with water to 15 mL According to the limit test of sulfate in Ph. Eur.  
 Preparation of standard solution: Mix 5 mL of sulphate standard solution (10 ppm  $SO_4$ ) and 10 mL of distilled water.
6. Iron : Not more than 100 ppm.  
 Dilute 2 mL of solution S with water to 10 mL. According to the limit test of iron in Ph. Eur.
7. Arsenic : Not more than 3 ppm.  
 Take 0.33 g of the sample, according to the test method for arsenic in Ph. Eur (A).

8.     Lead                                 : Not more than 20 ppm.
- Interpret using Ph. Eur atomic absorption spectrometry (Method II). Use a lead hollow cathode lamp as the radiation source and air-acetylene flame. Absorption wavelength is 283.3 nm (or 217.0 nm, depending on the instrument).
- Test solution: Dissolve 5.0 g of the sample in 24 mL of a solution of water and nitric acid (lead-free) in equal proportions, then dilute to 100.0 mL with water.
- Standard solution: Dilute lead standard solution (containing 0.1% of lead) with lead-free nitric acid solution (3.5%).
9.     Assay                                 : Dissolve 0.500 g of the sample in 5 mL of dilute acetic acid solution for complex metric determination                                 titration of zinc. 1 mL Sodium Edetate 0.1 M is equivalent to 20.95 mg (as  $\text{Cl}_2\text{H}_{10}\text{O}_{14}\text{Zn}_3 \cdot 3\text{H}_2\text{O}$ ).
10.    Category                            : Food Additives Category 8
11.    Uses                                 : Nutritional additivesNutritional additives

## Lycopene (Synthetic)

<b>Synonyms</b>	INS 160d(i)
<b>Definition</b>	Synthetic lycopene 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- <i>trans</i> -lycopene together with 5- <i>cis</i> -lycopene and minor quantities of other isomers.
Chemical names	ψ,ψ-carotene; all- <i>trans</i> -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
C.A.S. number	502-65-8
Chemical formula	C <sub>40</sub> H <sub>56</sub>
Structural formula	 <p>The structural formula of lycopene is a long, linear hydrocarbon chain consisting of 11 conjugated double bonds in the all-trans configuration. The chain is terminated by methyl groups at both ends. The double bonds are located at positions 2, 6, 10, 14, 18, 22, 26, 30, 34, 38, and 42, with methyl groups attached at positions 1, 5, 9, 13, 17, 21, 25, 29, 33, 37, and 41.</p>
Formula weight	536.9
Assay	Not less than 96% total lycopenes; not less than 70% all- <i>trans</i> -lycopene
<b>Description</b>	Red crystalline powder
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water, freely soluble in chloroform
Test for carotenoids	The color of the solution of the sample in acetone disappears after successive additions of a 5% solution of sodium nitrite and 1N sulfuric acid
Solution in chloroform	A 1% solution is clear and has intensive red-orange color
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Purity	
Loss on drying	Not more than 0.5% (40°C, 4 h at 10 mmHg)
Lead	Not more than 1 mg/kg
Apo-12'-lycopenal	Not more than 0.15%
Triphenyl phosphine oxide	Not more than 0.01%

(TPPO)

**Category** Food additives category (08) (09)

**Functional uses** Nutritional additive; Colors.

§ 08140

Calcium Gluconate

The same as § 07004



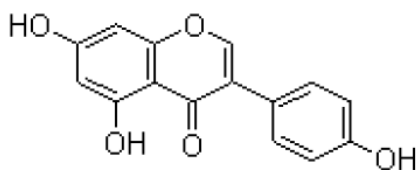
## Synthetic Genistein

Chemical names : 5, 7-dihydroxy-3-(4-hydroxyphenyl)chromen-4-one

Synonyms : Genistein; genisteol; sophoricol; CAS No. 446-72-0

Chemical formula :  $C_{15}H_{10}O_5$

Molecular weight : 270.2



1. Assay : Not less than 98.5%
2. Appearance : White or yellowish powder.
3. Water : Not more than 0.2%.
4. Sulfated ash : Not more than 0.1%.
5. Arsenic : Not more than 1 mg/kg.
6. Lead : Not more than 2 mg/kg.
7. Heavy metals : Not less than 10 mg/kg (as Pb).
8. Category : Food Additives Category 8
9. Uses : Nutritional additives

§ 08143

$\beta$ - Carotene

The same as § 09014.

## Ferrous Sulfate, Dried

<b>Definition</b>	Ferrous sulfate, dried consists primarily of the monohydrate with smaller amounts of the tetrahydrate.
Molecular formula	: $\text{FeSO}_4 \cdot \text{H}_2\text{O}$ $\text{FeSO}_4 \cdot 4\text{H}_2\text{O}$
Formula weight	: Monohydrate: 169.91 Tetrahydrate: 223.91
Assay	: Not less than 86% and not more than 89% of $\text{FeSO}_4$ .
<b>Appearance</b>	: A greyish-white to buff-colored powder.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	: Dissolves slowly in water; insoluble in ethanol.
Iron	: Passes test
Sulfate	: Passes test
<b>Purity</b>	
Acid insoluble matter	: Not more than 0.05%.
Lead	: Not more than 2 mg/kg.
Mercury	: Not more than 1 mg/kg.
<b>Category</b>	: Food Additives Category 8
<b>Uses</b>	: Nutritional additivesNutritional additives

## Sodium Molybdate (VI)

Synonyms : Sodium Molybdate Dihydrate,  
Disodium Molybdate Dihydrate

CAS NO. 10102-40-6

Chemical formula:  $\text{Na}_2\text{MoO}_4 \cdot 2\text{H}_2\text{O}$

Molecular weight: 241.9 (dihydrate)

1. Purity : Not less than 98.0% and not more than 100.5% on the dried basis.
2. Appearance : Whit or off-white powder or colorless crystal.
3. Solubility : Soluble in water.
4. Identification : Dissolve 0.2 g of the sample in 5 mL of nitric acid aqueous solution (nitrogen is mixed with water in equal volume). Add 0.1 g of ammonium chloride, 0.3 mL of disodium hydrogen phosphate solution and heat slowly at 50-60°C to produce a yellow precipitate.
5. Chloride : Not more than 50 ppm of Cl.
6. Phosphate : Not more than 200 ppm of  $\text{PO}_4$ .
7. Ammonium salt : Not more than 10 ppm, tested as 0.10 g (as  $\text{NH}_4$ )
8. Heavy metals : Not more than 10 ppm (as Pb).
- Loss on drying : 14.0%~16.0%. (1.000g, 140°C, 3hr)
- 10 Category : Food Additives Category 8
- 11 Uses : Nutritional additives; Nutritional additives; Colors

§ 08284

Potassium Dihydrogen Phosphate

The same as § 07026

§ 08286

Sodium Dihydrogen Phosphate

The same as § 07029

## L-Carnitine Tartrate

Synonyms : L-carnitine-L-tartrate (2: 1);

Vitamin BT-L-tartrate

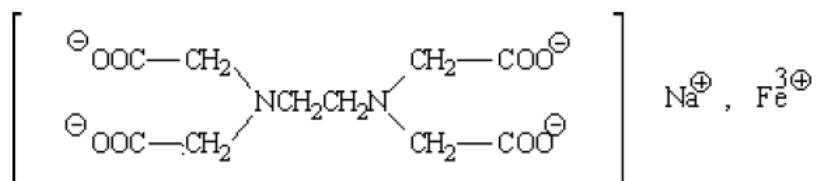
CAS No. 36687-82-8

Chemical formula:  $C_{18}H_{36}N_2O_{12}$

Molecular weight: 472.49

1. Assay : 67.2~69.2% (as L-carnitine)  
30.8~32.8% (as L-tartaric acid)
2. Appearance : White crystalline powder .
3. Water : Not more than 0.5%
4. Solubility : Soluble in water, not less than 1000 g/L (at 20°C).
5. Specific rotation :  $[\alpha]_{20D} = -11.0 \sim -9.5^\circ$ .
6. Identification : This product is completely soluble in water, so it can be measured by L-carnitine and L-tartaric acid.
7. Lead : Not more than 1 ppm.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Residue on ignition : Not more than 0.1% (600°C, 2h).
10. Category : Food Additives Category 8
11. Uses : Nutritional additives

## Ferric Sodium EDTA, EDTA FeNa



Synonyms : Ferric Sodium Edetate, Ferric Sodium EDTA Trihydrate, Sodium Feredetate, Sodium Iron EDTA,

Sodium Iron (iii) ethylenediaminetetraacetate, trihydrate

CAS No. 18154-32-0 (CAS anhydrous 15708-41-5)

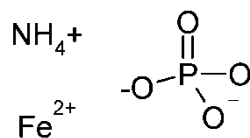
Chemical formula:  $\text{C}_{10}\text{H}_{12}\text{FeN}_2\text{NaO}_8 \cdot 3\text{H}_2\text{O}$

Molecular weight: 421.09 (trihydrate)

1. Assay : Not less than 99% (w/w).
2. Appearance : Odorless, light yellow to tan powder.
3. Solubility : Miscible with water.
4. Assay : 12.5%~13.5% (calculated on trihydrate basis)
5. EDTA : 65.5%~70.5% (calculated on trihydrate basis)
6. pH : 3.5~5.5 (1% solution).
7. Water-insoluble matter : Not more than 0.1%.
8. Nitrilotriacetic acid : Not more than 0.1%.
9. Arsenic : Not more than 1 mg/kg.
10. Lead : Not more than 1 mg/kg.
11. Category : Food Additives Category 8
12. Uses : Nutritional additives



Ferrous ammonium phosphate



Synonyms: Iron(II) ammonium phosphate; Phosphoric acid, ammonium iron (II) salt

CAS No. 10101-60-7

Chemical formula:

$\text{FeNH}_4\text{PO}_4$

Molecular weight: 168.85 (anhydrous)

- |     |            |   |
|-----|------------|---|
| 1.  | Assay      | : Not less than 24% and not more than 30% (as Iron(II))   |
| 2.  | Appearance | : Greyish green powder.                                   |
| 3.  | Solubility | : Insoluble in water, soluble in diluted inorganic acids. |
| 4.  | Fluorine   | : Not more than 50 mg/kg.                                 |
| 5.  | Iron (III) | : Not more than 7%.                                       |
| 6.  | Water      | : Not more than 3%.                                       |
| 7.  | Mercury    | : Not more than 1 mg/kg.                                  |
| 8.  | Cadmium    | : Not more than 1 mg/kg.                                  |
| 9.  | Arsenic    | : Not more than 3 mg/kg.                                  |
| 10. | Lead       | : Not more than 2 mg/kg.                                  |
| 11. | Category   | : Food Additives Category 8                               |

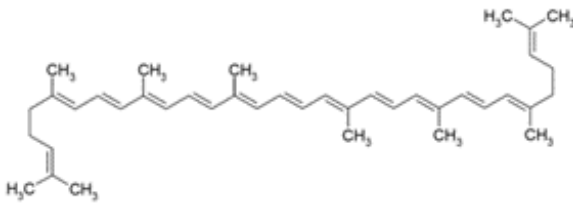
**Potassium Fluoride**

CAS NUMBER	7789-23-3
Chemical formula	KF
Molecular weight	58.1
Assay	Not less than 98.0% on the dried basis.
<b>Appearance</b>	White crystal or powder.
<b>Characteristics</b>	
Solubility	Slightly soluble in water.
Free acid	Not more than 0.1% of HF.
Free alkali	Not more than 0.15% of K <sub>2</sub> CO <sub>3</sub> .
Chloride	Not more than 500 ppm of Cl.
Sulfate	Not more than 100 ppm of SO <sub>4</sub> .
SiF <sub>6</sub>	Not more than 0.1%.
Sodium	Not more than 0.2%.
Iron	Not more than 20 ppm.
Heavy metals	Not more than 30 ppm (as Pb).
Loss on ignition	Not more than 1% (500°C, 1h).
<b>Category</b>	: Food Additives Category 8
<b>Uses</b>	: Nutritional additivesNutritional additives

## Sodium Fluoride

CAS NUMBER	7681-49-4
Chemical formula	NaF
Molecular weight	41.99
Assay	Not less than 98.0% on the dried basis
<b>Appearance</b>	White crystal or powder.
<b>Characteristics</b>	
Water-insoluble matter	Not more than 0.5%.
Free acid	Not more than 0.25% of HF.
Free alkali	Not more than 0.2% of Na <sub>2</sub> CO <sub>3</sub> .
Chloride	Not more than 200 ppm of Cl.
Sulfate	Not more than 300 ppm of SO <sub>4</sub> .
SiF <sub>6</sub>	Not more than 0.1%.
Iron	Not more than 50 ppm.
Heavy metals	Not more than 30 ppm (as Pb).
Loss on drying	Not more than 1% (150°C, 4 hr).
<b>Category</b>	Food Additives Category 8
<b>Uses</b>	Nutritional additivesNutritional additives

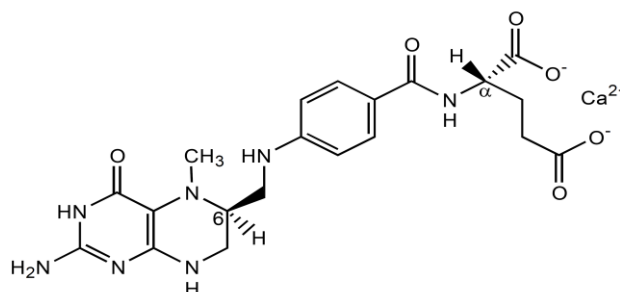
Lycopene from *Blakeslea trispora*

<b>Synonyms</b>	INS 160d(iii)
<b>Definition</b>	<p>Lycopene from <i>Blakeslea trispora</i> is extracted from the fungal biomass and purified by crystallization and filtration. It consists predominantly of all-<i>trans</i>-lycopene. It also contains minor quantities of other carotenoids.</p> <p>Isopropanol and isobutyl acetate are the only solvents used in the manufacture.</p>
Chemical names	<p>ψ,ψ-carotene; all-<i>trans</i>-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</p>
C.A.S. number	502-65-8
Chemical formula	C <sub>40</sub> H <sub>56</sub>
Structural formula	
Formula weight	536.9
Assay	Not less than 95% total lycopenes; not less than 90% all- <i>trans</i> -lycopene
<b>Description</b>	Red crystalline powder
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water, freely soluble in chloroform
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 sulfuric acid
Solution in chloroform	A 1% solution is clear and has intensive red-orange colour
Spectrophotometry	A solution in hexane shows an absorption maximum at approximately 470 nm
Purity	

Other carotenoids	Not more than 5%
Loss on drying	Not more than 0.5% (40°C, 4 h at 20 mmHg)
Lead	Not more than 1 mg/kg
Residual solvents	Isopropanol: Not more than 0.1% Isobutyl acetate: Not more than 1.0%
<b>Category</b>	Food additives category (08) (09)
<b>Functional uses</b>	Nutritional additive; Colors.

§ 08323

	Calcium L-5-Methyltetrahydrofolate
Synonyms	L-5-Methyltetrahydrofolic acid, calcium salt L-Methyltetrahydrofolate, calcium salt L-Methylfolate, calcium L-5-MTHF-Ca
Definition	Calcium L-5-methyltetrahydrofolate (L-5-MTHF-Ca) is a synthetic derivative of folic acid, the predominant, naturally occurring form of folate. It is synthesized by reduction of folic acid to tetrahydrofolic acid followed by methylation and diastereoselective crystallization (in water) of L-5-MTHF as its calcium salt. The product contains variable amounts of water of crystallization.
Chemical name	N-{4-[[[(6S)-2-amino-3,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridiny]methyl]amino]benzoyl}-L-glutamic acid, calcium salt
C.A.S. number	151533-22-1
Chemical formula	C <sub>20</sub> H <sub>23</sub> CaN <sub>7</sub> O <sub>6</sub> (anhydrous form)
Structural formula	(anhydrous form)



Formula weight	497.5 (anhydrous form)
Assay	95.0 – 102.0% (anhydrous basis)
Description	White to light yellowish, almost odourless, crystalline powder.
Characteristics	
Identification	
Solubility	Sparingly soluble in water and very slightly soluble or insoluble in most organic solvents; soluble in alkaline solutions.
Infrared absorption	The infrared absorption spectrum of a potassium bromide dispersion of the sample corresponds to that of a L-5-MTHF-Ca standard.

Calcium	Dilute 30 g of acetic acid (glacial) to 100 mL with water. Dissolve 5.3 g of $K_4Fe(CN)_6$ in 100 mL of water. To 5 mL of the acetic acid solution, add 20 mg of the sample and then 0.5 mL of the potassium ferrocyanide solution. Mix and add 50 mg of ammonium chloride. A white crystalline precipitate is formed.
Liquid chromatography	Retention time matches that of a L-5-MTHF-Ca standard used in test.
Purity	
Water	Not more than 17.0% (Karl Fischer method)  (Note: Allow sufficient time (15 min) for release of bound water.)
Calcium	7.0 - 8.5% (anhydrous basis)
Other folates and related substances	Not more than 2.5%
D-5-Methylfolate	Not more than 1.0%
Lead	Not more than 1 mg/kg
Cadmium	Not more than 0.5 mg/kg
Mercury	Not more than 1 mg/kg
Arsenic	Not more than 1.5 mg/kg
Category	Food Additives Category 8
Uses	Nutritional additives

## Category 9 Colors

§ 09001

### Ponceau 4R

**Synonyms** CI Food Red 7; Cochineal Red A; New Coccine; Brilliant Scarlet; CI (1975) No. 16255; INS No. 124

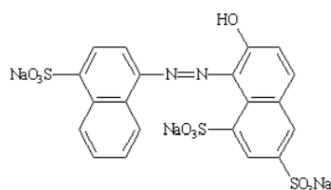
**Definition** Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo)-6,8-naphthalenedisulfonate, and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components.  
May be converted to the corresponding aluminium lake.

**Chemical names** Trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo)-6,8-naphthalenedisulfonate

**C.A.S. number** 2611-82-7

**Chemical formula**  $C_{20}H_{11}N_2Na_3O_{10}S_3$

**Structural formula**



**Formula weight** 604.48

**Assay** Not less than 80% total colouring matters

**Description** Reddish powder or granules

### Characteristics

**Identification**

**Solubility** Soluble in water; sparingly soluble in ethanol

**Spectrophotometry** Maximum wave length: Between 505 and 510 nm

**Purity**

**Loss on drying** Not more than 20% at 135° together with chloride and sulfate calculated as sodium salts

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

**Subsidiary colouring matters** Not more than 1%



Organic compounds other than colouring matters	4-amino-1-naphthalenesulfonic acid 、 7-hydroxy-1,3-naphthalenedisulfonic acid 、 3-hydroxy-2,7-naphthalenedisulfonic acid 、 6-hydroxy-2-naphthalenesulfonic acid 、 7-hydroxy-1,3,6-naphthalenetrisulfonic acid: Not more than 0.5%
Unsulphonated primary aromatic amines	Not more than 0.01% calculated as aniline
Ether-extractable matter	Not more than 0.2%
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (09)
<b>Functional uses</b>	Colors

## Erythrosine (Food Red No.7)

General name : Erythrosion

Chemical names : Disodium salt of 9– (o– carboxyphenyl)– 6– hydroxy– 2, 4, 5, 7– tetraiodo– 3– isoxanthone

Chemical formula:  $C_{20}H_6O_5I_4Na_2 \cdot H_2O$

Molecular weight: 897.91

1. Assay : Not less than 85%.
2. Appearance : Red to red-brown powder or granules. Odorless.
3. Solution : When 0.1 g of the sample is dissolved in 100 mL of water, the solution should be clear.
4. Water-insoluble matter : Not more than 13%.
5. pH : 6.5~10 (1 in 100 soln)
6. Chloride and sulfate : Not more than 2% in total (as Cl,  $SO_4$ ).
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 500 ppm of iron.  
Not more than 25 ppm of chromium.  
Not more than 200 ppm of zinc.  
Not more than 20 ppm (as Pb).
9. Subsidiary coloring matter content : Not more than 3%.
10. Loss on drying : Dry it at 135° for 6 hours: it loses not more than 12% of its weight.
11. Category : Food Additives Category 9
12. Uses : Colors

## Erythrosine Aluminum Lake

**Definition** Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.

Assay Not less than 10% of Erythrosine

**Characteristics****Identification**

Solubility Insoluble in water

**Purity**

Water-soluble chlorides and sulfates Not more than 2.0% calculated as sodium salts

Hydrochloric acid-insoluble matters Not more than 0.5%

Ether-extractable matter Not more than 0.2%

Arsenic Not more than 3 mg/kg

Lead Not more than 5 mg/kg

**Category** Food additives category 9

**Functional uses** Colors

## Tartrazine (Food Yellow No.4)

General name : Tartrazine

Chemical names : Trisodium salt of 3- carboxy- 5- hydroxy- 1- (p- sulfophenyl)- 4- (p- sulfophenylazo)-  
pyrazole

Chemical formula:  $C_{16}H_9O_9N_4S_2Na_3$

Molecular weight: 534.38

1. Assay : Not less than 85%.
2. Appearance : Yellowish orange to orange powder or granules, odorless.
3. Solution : When 0.1 g of the sample is dissolved in 100 mL of water, the solution should be clear.
4. Water-insoluble : Not more than 13%.  
matter
5. Chloride and sulfate : Not more than 6% in total (as Cl,  $SO_4$ ).
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 500 ppm of iron.  
Not more than 25 ppm of chromium.  
Not more than 200 ppm of zinc.  
Not more than 20 ppm (as Pb).
8. Subsidiary : Not more than 3%.  
coloring matter  
content
9. Loss on drying : Not more than 10% (135°C, 6 h).
10. Category : Food Additives Category 9
11. Uses : Colors

## Tartrazine Aluminum Lake

<b>Definition</b>	Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.
Assay	Not less than 10% of Tartrazine
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water
<b>Purity</b>	
Water-soluble chlorides and sulfates	Not more than 2.0% calculated as sodium salts
Hydrochloric acid-insoluble matters	Not more than 0.5%
Ether-extractable matter	Not more than 0.2%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
<b>Category</b>	Food additives category 9
<b>Functional uses</b>	Colors

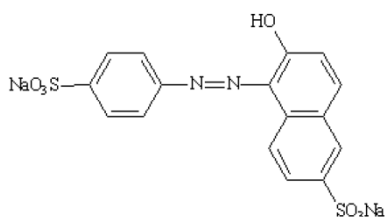
Sunset Yellow FCF (Food Yellow No.5)

Chemical names : Disodium 6-hydroxy-5-(4-sulfonatophenylazo)-2-naphthalene- sulfonate

Synonyms : CI Food Yellow 3; FD&C Yellow No. 6; Crelborange S; CI (1975) No. 15985; INS No. 110;  
CAS No. 2783-94-0.

Chemical formula :  $C_{16}H_{10}N_2Na_2O_7S_2$

Molecular weight: 452.38



1. Definition : Sunset Yellow FCF consists principally of the disodium salt of 6- hydroxy-5-[(4- sulfophenyl)azo]-2-naphthalenesulfonic acid and subsidiary coloring matters together with sodium chloride and/or sodium sulfate as the principal uncolored components.
2. Assay : Not less than 85% total coloring matters.
3. Appearance : Orange-red powder or granules
4. Solubility : Soluble in water; sparingly soluble in ethanol
5. Loss on drying : Not more than 15% together with chloride and sulfate calculated as sodium salts
6. Water-insoluble matter : Not more than 0.2%.
7. Subsidiary coloring matter : Not more than 5%.  
Not more than 2% shall be colors other than trisodium 2-hydroxy-1- (4- sulfonatophenylazo)naphthalene-3,6-disulfonate.
8. Organic compounds other than coloring matters : Not more than 0.5%, sum of the: monosodium salt of 4- aminobenzenesulfonic acid, disodium salt of 3-hydroxy-2,7- naphthalenedisulfonic acid, monosodium salt of 6-hydroxy-2- naphthalenesulfonic acid, disodium salt of 7-hydroxy-1,3- naphthalenedisulfonic acid, disodium salt of 4,4'-diazoaminobis- benzenesulfonic acid, and disodium salt of 6,6'-oxybis-2- naphthalenesulfonic acid.
9. Unsulfonated primary aromatic amines : Not more than 0.01%, calculated as aniline.
10. Ether-extractable : Not more than 0.2%.

matter

11. Lead : Not more than 2 mg/kg.
12. Arsenic : Not more than 2 mg/kg.
13. Category : Food Additives Category 9
14. Uses : Colors

## Sunset Yellow FCF Aluminum Lake

**Definition** Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.

Assay Not less than 10% of Sunset Yellow FCF

**Characteristics****Identification**

Solubility Insoluble in water

**Purity**

Water-soluble chlorides and sulfates Not more than 2.0% calculated as sodium salts

Hydrochloric acid-insoluble matters Not more than 0.5%

Ether-extractable matter Not more than 0.2%

Arsenic Not more than 3 mg/kg

Lead Not more than 5 mg/kg

**Category** Food additives category 9

**Functional uses** Colors



Fast Green FCF (Food Green No.3)

General name : Fast Green FCF

Chemical names : Disodium salt of 4- {[4- (N- ethyl- m- sulfobenzyl- amino)- phenyl]- (4- hydroxyl- 2- sulfophenyl)- methylene}- [1- (N- ethyl- N- m- sulfoniumbenzyl)- $\Delta^{2,5}$ - cyclohexadienimine]

Chemical formula:  $C_{37}H_{34}O_{10}N_2S_3Na_2$

Molecular weight: 808.88

1. Assay : Not less than 85%.
2. Appearance : Dark green powder or granules with metallic glossy, odorless.
3. Solution : When 50 mg of the sample is dissolved in 100 mL of water, the solution should be clear.
4. Water-insoluble matter : Not more than 13%.
5. Chloride and sulfate : Not more than 5% in total (as Cl,  $SO_4$ ).
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 500 iron.  
Not more than 50 ppm of chromium.  
Not more than 200 ppm of zinc.  
Others: Not more than 20 ppm (as Pb).
8. Subsidiary coloring matter content : Not more than 5%.
9. Loss on drying : Not more than 10% (135°C, 6 h).
10. Category : Food Additives Category 9
11. Uses : Colors

## Fast Green FCF Aluminum Lake

**Definition** Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.

Assay Not less than 10% of Fast Green FCF

**Characteristics****Identification**

Solubility Insoluble in water

**Purity**

Water-soluble chlorides and sulfates Not more than 2.0% calculated as sodium salts

Hydrochloric acid-insoluble matters Not more than 0.5%

Ether-extractable matter Not more than 0.2%

Arsenic Not more than 3 mg/kg

Lead Not more than 5 mg/kg

**Category** Food additives category 9

**Functional uses** Colors

## Brilliant Blue FCF

Chemical names : Disodium salt of 4- {[4- (N- ethyl- m- sulfobenzyl- amino)- phenyl]- (2- sulfoniumphenyl)- methylene}- [1- (N- ethyl- N- m- sulfobenzyl)- $\Delta^{2,5}$ - cyclo- hexadienimine]

Chemical formula: C<sub>37</sub>H<sub>34</sub>N<sub>2</sub>Na<sub>2</sub>O<sub>9</sub>S<sub>3</sub>

Molecular weight: 792.87

- |     |                                    |   |
|-----|------------------------------------|---|
| 1.  | Assay                              | : Not less than 85%.  |
| 2.  | Appearance                         | : Purple powder or granular with metallic luster, odorless.   |
| 3.  | Solution                           | : When 50 mg of the sample is dissolved in 100 mL of water, the solution should be clear.   |
| 4.  | Water-insoluble matter             | : Not more than 13%.  |
| 5.  | Chloride and sulfate               | : Not more than 4% in total.  |
| 6.  | Arsenic                            | : Not more than 2 ppm (as As <sub>2</sub> O <sub>3</sub> ).   |
| 7.  | Heavy metals                       | : Not more than 500 ppm of iron.<br>鉻 Not more than 50 ppm..<br>Not more than 200 ppm of zinc.<br>Others: Not more than 20 ppm (as Pb). |
| 8.  | Subsidiary coloring matter content | : Not more than 5%.   |
| 9.  | Loss on drying                     | : Not more than 10% (135°C, 6 h).   |
| 10. | Category                           | : Food Additives Category 9   |
| 11. | Uses                               | : Colors  |

## Brilliant Blue FCF Aluminum Lake

<b>Definition</b>	Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.
Assay	Not less than 10% of Brilliant Blue FCF
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water
<b>Purity</b>	
Water-soluble chlorides and sulfates	Not more than 2.0% calculated as sodium salts
Hydrochloric acid-insoluble matters	Not more than 0.5%
Ether-extractable matter	Not more than 0.2%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
<b>Category</b>	Food additives category 9
<b>Functional uses</b>	Colors

Food Blue No.2

General name : Indigotine (Indigo Carmine)

Chemical names : Disodium salt of 5– 5',– indigotin– disulfonic acid

Chemical formula:  $C_{16}H_8O_8N_2S_2Na_2$

Molecular weight: 466.37

1. Assay : Not less than 85%.
2. Appearance : Dark purple to dark purplish brown powder or granules, odorless.
3. Solution : When 50 mg of the sample is dissolved in 100 mL of water, the solution should be clear.
4. Water-insoluble matter : Not more than 13%.
5. Chloride and sulfate : Not more than 7% in total (as Cl and  $SO_4$ )
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 1,000 ppm of iron.  
Not more than 25 ppm of chromium.  
Not more than 200 ppm of zinc.  
Others: Not more than 20 ppm (as Pb).
8. Subsidiary coloring matter content : Not more than 3%.
9. Loss on drying : Not more than 10% (135°C, 6 h).
10. Category : Food Additives Category 9
11. Uses : Colors

## Indigo Carmine Aluminum Lake

<b>Definition</b>	Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.
Assay	Not less than 10% of indigo carmine
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water
<b>Purity</b>	
Water-soluble chlorides and sulfates	Not more than 2.0% calculated as sodium salts
Hydrochloric acid-insoluble matters	Not more than 0.5%
Ether-extractable matter	Not more than 0.2%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
<b>Category</b>	Food additives category 9
<b>Functional uses</b>	Colors

## β- Carotene

**Synonyms**

From *Blakeslea trispora*: CI Food Orange 5; INS No. 160a(iii)

Other sources: CI Food Orange 5; INS No. 160a(i); CI (1975) No. 40800

**Definition**

These specifications consist predominantly of all-*trans*-β-carotene and may also contain minor amounts of *cis*-isomers and other carotenoids. Commercial preparations of β-carotene intended for use in food are prepared from β-carotene meeting these specifications and are formulated as suspensions in edible oils or water-dispersible powders. These preparations may have different ratio of trans/cis isomers. The colour is also obtained by a fermentation process using the fungus *Blakeslea trispora*.

**Chemical names**

From *Blakeslea trispora*: β-Carotene, β, β-carotene

Other sources: β-Carotene, β, β-carotene

1,1'-(3,7,12,16-tetramethyl-1,3,5,7,9,11,13,15,17-octadecanonaene-1,18-diyl)bis[2,6,6-trimethylcyclohexene]

**C.A.S. number**

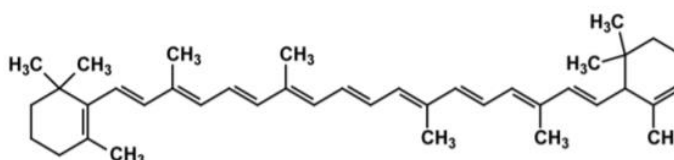
7235-40-7

**Chemical formula**

C<sub>40</sub>H<sub>56</sub>

**Structural formula**

All-*trans*-β-carotene (main compound)

**Formula weight**

536.88

**Assay**

Not less than 96.0% of total colouring matter (expressed as β-carotene)

**Description**

Red to brownish-red crystals or crystalline powder; sensitive to oxygen and light and should therefore be kept in a light-resistant container under inert gas.

**Characteristics****Identification****Solubility**

Insoluble in water; practically insoluble in ethanol; slightly soluble in vegetable oils.

Test for carotenoids	The colour of a solution of the sample in acetone disappears after successive additions of a 5% solution of sodium nitrite and 0.5 M sulfuric acid.
Spectrophotometry	<p>From <i>Blakeslea trispora</i>:</p> <p>Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 483 nm. The ratio is between 1.14 and 1.19.</p> <p>Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 340 nm. The ratio is not lower than 0.75.</p> <p>Other sources:</p> <p>Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 483 nm. The ratio <math>A_{455}/A_{483}</math> is between 1.14 and 1.19.</p> <p>Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 340 nm. The ratio <math>A_{455}/A_{340}</math> is not lower than 15.</p>
Purity	
Sulfated ash	<p>From <i>Blakeslea trispora</i>: Not more than 0.2%</p> <p>Other sources: Not more than 0.1%</p>
Subsidiary colouring matters	Carotenoids other than $\beta$ -carotene: Not more than 3% of total colouring matters.
Residual solvent	<p>From <i>Blakeslea trispora</i>:</p> <p>Ethanol and Ethyl acetate: Not more than 0.8% singly or in combination</p> <p>Isopropanol: Not more than 0.1%</p> <p>Isobutyl acetate: Not more than 1.0%</p> <p>Other sources:-</p>
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (08) (09)
<b>Functional uses</b>	Nutritional additive; Colors.



$\beta$ -Apo-8'-CarotenalChemical formula:  $C_{30}H_{40}O$ 

Molecular weight: 416.65

1. Assay : Not less than 98% (vacuum desiccator over sulfuric acid, 4 h)
2. Appearance : Grayish purple to purple black crystalline powder, with a characteristic aroma.
3. Solution : When 0.1 g of the sample is dissolved in 20 mL of chloroform, the solution should be clear.
4. Decomposition : 136~140°C.  
temperature
5. Absorbance : The maximum absorption band of the cyclohexane solution of the sample is around 461 nm and 488 nm.
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 1% (vacuum desiccator over sulfuric acid, 4 h).
9. Residue on : Not more than 0.1%.  
ignition
10. Category : Food Additives Category 9
11. Uses : Colors

$\beta$ -Apo-8'-Carotenoate, EthylChemical formula:  $C_{32}H_{44}O_2$ 

Molecular weight: 460.70

1. Assay : Not less than 98% (vacuum desiccator over sulfuric acid, 4 h)
2. Appearance : Zinc brown crystalline powder.
3. Solution : When 0.1 g of the sample is dissolved in 10 mL of chloroform, the solution should be clear.
4. Decomposition : 134~138°C  
temperature
5. Absorbance : The maximum absorption band of the cyclohexane solution of the sample is around 449 nm and 475 nm.
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 1% (vacuum desiccator over sulfuric acid, 4 h).
9. Residue on : Not more than 0.1%.  
ignition
10. Category : Food Additives Category 9
11. Uses : Colors

## Canthaxanthin

Chemical formula:  $C_{40}H_{52}O_2$ 

Molecular weight: 564.86

1. Assay : Not less than 98% (vacuum desiccator over sulfuric acid, 4 h)
2. Appearance : Deep violet crystals or crystalline powder; slightly aromatic.
3. Solution : When 0.1 g of the sample is dissolved in 10 mL of chloroform, the solution should be clear.
4. Decomposition : 210°C  
temperature
5. Absorbance : Canthaxanthin in cyclohexane has an absorbance maximum of 470 nm.
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Not more than 1% (vacuum desiccator over sulfuric acid, 4 h).
9. Residue on : Not more than 0.1%.  
ignition
10. Category : Food Additives Category 9
11. Uses : Colors

## Laccaic Acid

1. Appearance : Red powder
2. Solution : Dissolve 0.1g of the sample in 30ml of 1% sodium carbonate, and the solution should be "clear".
3. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
4. Heavy metals : Not more than 30 ppm (as Pb).
5. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 14% of its weight.
6. Residue on ignition : Not more than 0.8%
7. Absorbance : Dissolve 50 mg of the sample in 5 to 10 mL of 1% sodium carbonate solution, and add water to make it 50 mL. Take 10 mL of the solution, add water and dilute hydrochloric acid to make a pH 4 and 20 mL solution. When the absorbance is measured at a wavelength of 485 nm, its  $E_{1\%}^{1\text{cm}}$  could be 107.5 or more.

$$E_{1\text{ cm}}^{1\%} = \frac{\text{波長 } 485 \text{ nm 測得之吸光度}}{\text{檢體量}(g)} \times 10$$

8. Category : Food Additives Category 9
9. Uses : Colors

## Copper Chlorophyll

1. Appearance : Dark green flakes, scale, powder or viscous fluid, with a characteristic odor.
2. Specific absorbance : Dissolve 10 mg of the sample, accurately weighed, in 50 mL of ether. Mix and shake with sodium hydroxide, 2 mL of 1 in 100 methanol solution. Heat in water bath for 30 minutes with a reflux condenser. After cooling, extract three times with 10 mL of water each time, and add phosphate buffer (pH 7.5) to 200 mL. When the absorbance is measured at a wavelength of 405 nm, its  $E_{1\text{ cm}}^{1\%}$  should be 62 or more.
3. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
4. Salt-based coal tar colors : Mix 5 mL of 1 in 100 ether solution of the sample with 1 mL of acetic acid and 5 mL of water, filter with filter paper wetted by water. When the ether layer is left on the filter paper, the filtrate should be colorless.
5. Acidic coal tar dye, inorganic iron and copper salt : The test methods of "acid coal tar dye" and "inorganic iron salt and copper salt" of "sodium copper chlorophyllin" are applicable. Test with 0.01 mL of 1 in 300 acetone solution of the sample.
6. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1.5% of its weight.
7. Residue on ignition : Dry it at 105°C for 2 hours: it loses not more than 2.2% of its weight.
8. Category : Food Additives Category 9
9. Uses : Colors

## Sodium Copper Chlorophyllin

1. Appearance : Blue/black powder, odorless or having not more than a slight characteristic odor.
2. pH : 9.5~10.7 (1 in 100 soln)
3. Specific absorbance : Dry the sample at 105°C for 1 hour. Dissolve 0.1 g of the sample, accurately weighed, in water to make a 1000 mL solution. Add phosphate buffer (pH 7.5) to 10 mL of the solution to make a 100 mL solution. When the absorbance is measured at a wavelength of 405 nm, its  $E_{1\text{ cm}}^{1\%}$  should be 508 to 568.
4. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Sodium Copper Chlorophyllin : Add 1 mL of sodium hydroxide solution (1→50) and 50 mL of ether to 5 mL of the 1 in 200 solution of the sample, shake and mix to remove the water layer. Wash the ether layer twice with 15 mL of sodium hydroxide solution (1 50), and mix with 5 mL of acetic acid solution (150) and the aqueous layer should be colorless.
6. Acidic coal tar dye : Test 0.01 mL of the aqueous solution (1→300) of the sample by the second method of filter paper chromatography. Use No. 1 filter paper, and a mixture of n-butanol, glacial acetic acid and water (4: 1: 2). Expand to 5 cm from the center point, take the filter paper off and dry it. When observed under natural light, there must be no other spot than a single circular ribbon.
7. Inorganic iron and copper salt : When the dried filter paper obtained by the acidic coal tar dye test is sprayed with potassium ferrocyanide solution (1→1,000) and sodium diethyldithiocarbamate solution (1→1,000). No blue or light brown spot should appear.
8. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 5% of its weight.
9. Residue on ignition : Dry it at 105°C for 1 hour: it loses not more than 37% of its weight.
10. Category : Food Additives Category 9
11. Uses : Colors

### Sodium Iron Chlorophyllin

1. Appearance : Dark green crystalline powder, odorless or with a slightly characteristic odor.
2. pH : 9.6~10.0 (1 in 100 soln)
3. Specific absorbance : Dissolve 0.1 g of the sample in water to make a 1,000 mL solution. Add phosphate buffer (pH 7.5) to 10 mL of the solution to make a 100 mL solution. When the absorbance is measured at a wavelength of 398 nm, its  $E_{1\text{ cm}}^{1\%}$  should be 400 to 465.
4. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Salt-based coal tar colors : The test method of "salt-based coal tar colors" of "copper chlorophyll sodium" is applicable.
6. Acidic coal tar dye : The test method of "acidic coal tar dye" of "copper chlorophyll sodium" is applicable.
7. Inorganic iron and copper salt : The test method of "inorganic iron and copper salt " of "copper chlorophyll sodium" is applicable.
8. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 5% of its weight.
9. Residue on ignition : Not more than 30% (for material used as an anticaking agent) (105°, 1 h)
10. Category : Food Additives Category 9
11. Uses : Colors

## Iron Oxides

Chemical formula:  $\text{FeO}(\text{OH}) \cdot x\text{H}_2\text{O}$       Color: Yellow      Molecular weight: 88.85 (anhydrous)

$\text{Fe}_2\text{O}_3$       Ed to red-brown      159.70

$\text{FeO} \cdot \text{Fe}_2\text{O}_3$       Black      231.55

1. Assay : Not less than 60% of Fe.
2. Description : The sample is an anhydrous or hydrated form of iron oxide. Yellow, red, brown, or black powder. Insoluble in water and organic solvents, soluble in concentrated inorganic acids.
3. Water soluble substances : Not more than 1.0%.
4. Arsenic : Not more than 3 ppm (as As).
5. Lead : Not more than 10 ppm.
6. Mercury : Not more than 1 ppm.
7. Barium : Not more than 50 ppm.
8. Cadmium : Not more than 10 ppm.
9. Chromium : Not more than 100 ppm.
10. Copper : Not more than 50 ppm.
11. Nickel : Not more than 100 ppm.
12. Zinc : Not more than 100 ppm.
13. Category : Food Additives Category 9
14. Uses : Colors



Iron Sesquioxide

Chemical formula:  $\text{Fe}_2\text{O}_3$

Molecular weight: 159.69

1. Assay : Not less than 98%
2. Appearance : Red to red-brown powder
3. Water soluble : Not more than 0.75%.  
substances
4. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Heavy metals : Not more than 30 ppm (as Pb).
6. Category : Food Additives Category 9
7. Uses : Colors

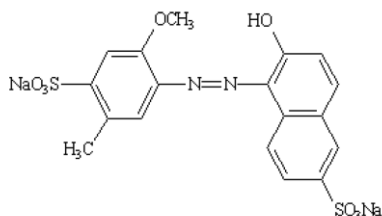
## Allura Red AC(Food Red No. 40)

Chemical names : Disodium 6-hydroxy-5-(2-methoxy-5-methyl-4-sulfonato-phenylazo)-2-naphthalenesulfonate

Synonyms : CI Food Red 17; FD&C Red No.40; CI (1975) No.16035; INS No. 129; CAS No. 25956-17-6.

Chemical formula :  $C_{18}H_{14}N_2Na_2O_8S_2$

Molecular weight: 496.43



1. Definition : Mixture of disodium 6-hydroxy-5-(2-methoxy-5-methyl-4-sulfonato-phenylazo)-2-naphthalene-sulfonate, other coloring matter, sodium chloride and/or sodium sulfate.
2. Assay : Not less than 85% total coloring matters.
3. Appearance : Dark red to red-brown powder.
4. Solubility : Soluble in water, insoluble in ethanol.
5. Loss on drying : Not more than 15% together with chloride and sulfate calculated as sodium salts
6. Water-insoluble matter : Not more than 0.2%.
7. Subsidiary coloring matter content : Not more than 3%.
8. Organic compounds other than coloring matters : Not more than 0.3% of sodium 6-hydroxy-2-naphthalene sulfonate; not more than 0.2% of 4-amino-5-methoxy-2-methyl-benzene-sulfonic acid; not more than 1.0% of disodium 6,6'-oxybis(2-naphthalene-sulfonate).
9. Unsulfonated primary aromatic amines : Not more than 0.01%, calculated as aniline.
10. Ether-extractable matter : Not more than 0.2%.
11. Lead : Not more than 2 mg/kg.
12. Arsenic : Not more than 3 mg/kg.
13. Category : Food Additives Category 9
14. Uses : Colors

§ 09028

Riboflavin (Vitamin B2)

The same as § 08008

§ 09029

Riboflavin Phosphate Sodium

The same as § 08009

## Titanium Dioxide

Synonyms : Titania; CI Pigment white 6; CI (1975) No.77891; INS No. 171; CAS No. 13463-67-7.

Chemical formula :  $\text{TiO}_2$  Molecular weight: 79.88

1. Definition : Titanium dioxide is produced by either the sulfate or the chloride process. Processing conditions determine the form (anatase or rutile structure) of the final product. In the sulfate process, sulfuric acid is used to digest ilmenite ( $\text{FeTiO}_3$ ) or ilmenite and titanium slag. After a series of purification steps, the isolated titanium dioxide is finally washed with water, calcined, and micronized. In the chloride process, chlorine gas is reacted with a titanium-containing mineral under reducing conditions to form anhydrous titanium tetrachloride, which is subsequently purified and converted to titanium dioxide either by direct thermal oxidation or by reaction with steam in the vapor phase. Alternatively, concentrated hydrochloric acid can be reacted with the titanium-containing mineral to form a solution of titanium tetrachloride, which is then further purified and converted to titanium dioxide by hydrolysis. The titanium dioxide is filtered, washed, and calcined. Titanium dioxide may be coated with small amounts of alumina and/or silica to improve the technological Characteristics of the product.
2. Assay : Not less than 99.0% on the dried basis (on an aluminum oxide and silicon dioxide-free basis)
3. Appearance : White to slightly colored powder.
4. Solubility : Insoluble in water, hydrochloric acid, dilute sulfuric acid, and organic solvents. Dissolves slowly in hydrofluoric acid and hot concentrated sulfuric acid.
5. Identification : Add 5 mL sulfuric acid to 0.5 g of the sample, heat gently until fumes of sulfuric acid appear, then cool. Cautiously dilute to about 100 mL with water and filter. To 5 mL of this clear filtrate, add a few drops of hydrogen peroxide; an orange-red color appears immediately.
6. Loss on drying : Not more than 0.5% (105°C, 3 hr).
7. Loss on ignition : Not more than 1.0% (800°C, on the dried basis).
8. Aluminum oxide and/or silicon dioxide : Not more than 2%, either singly or combined.
9. Acid-soluble substances : Not more than 0.5%. Not more than 1.5% for products containing alumina or silica.

10. Water soluble : Not more than 0.5%.  
substances
11. Impurities soluble in 0.5 :  
N hydrochloric acid
- (1) Antimony : Not more than 2 mg/kg.
- (2) Arsenic : Not more than 1 mg/kg.
- (3) Cadmium : Not more than 1 mg/kg.
- (4) Lead : Not more than 10 mg/kg.
12. Mercury : Not more than 1 mg/kg.
13. Category : Food Additives Category 9
14. Uses : Colors

## Allura Red AC Aluminum Lake

<b>Definition</b>	Aluminium lakes are prepared under aqueous conditions by reacting aluminium oxide with colouring matter complying with purity criteria set out in the appropriate specification monograph. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted aluminium oxide may also be present in the final product.
Assay	Not less than 10% of Allura Red AC
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Insoluble in water
<b>Purity</b>	
Water-soluble chlorides and sulfates	Not more than 2.0% calculated as sodium salts
Hydrochloric acid-insoluble matters	Not more than 0.5%
Ether-extractable matter	Not more than 0.2%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
<b>Category</b>	Food additives category 9
<b>Functional uses</b>	Colors

Gold (Metallic)

Synonyms : Pigment Metal 3, Aurum, Au, INS No. 175, Color Index No. 77480

Molecular : 197.0.

weight

1. Assay : Not less than 90%
2. Description : Golden powder or flakes.
3. Silver content : Not more than 7.0% (Determined after complete dissolution)
4. Copper content : Not more than 4.0% (Determined after complete dissolution)
5. Category : Food Additives Category 9
6. Uses : Colors



§ 09033

Lutein

The same as § 08133

§ 09034

Lycopene (Synthetic)

The same as § 08139

## Potassium aluminum silicate-based pearlescent pigments

Synonyms	: Mica-based pearlescent pigments
1. Description	: The sample is obtained by the reaction of mica and titanium salt at high temperature that produces titanium dioxide on mica. Different pearlescent colors can be produced by different particle size and combination with titanium dioxide.
2. Titanium dioxide content	: 10~65% (weight percentage)
3. Aluminum silicate potassium content	: 35~90% (weight percentage)
4. Particle size	: 3~82µm.
5. Loss on drying	: Not more than 0.5% (105°C, 2 hr).
6. pH	: 4-11.
7. Antimony	: Not more than 3 mg/kg.
8. Zinc	: Not more than 25 mg/kg.
9. Barium	: Not more than 25 mg/kg.
10. Chromium	: Not more than 100 mg/kg.
11. Copper	: Not more than 25 mg/kg.
12. Nickel	: Not more than 50 mg/kg.
13. Arsenic	: Not more than 3 mg/kg.
14. Mercury	: Not more than 1 mg/kg.
15. Cadmium	: Not more than 1 mg/kg.
16. Lead	: Not more than 4 mg/kg.
17. Category	: Food Additives Category 9
18. Uses	: Colors

### Caramel Colors

**Synonyms** : Caramel colors are divided into four classes. The synonyms for each class are:

Class I: Plain caramel; INS No.150a

Class II: Sulfite caramel; INS No.150b

Class III: Ammonia caramel; INS No.150c

Class IV: Sulfite ammonia caramel; INS No.150d

**Definition** : Complex mixtures of compounds, some of which are in the form of colloidal aggregates, manufactured by heating carbohydrates either alone or in the presence of food-grade acids, alkalis or salts; classified according to the reactants used in their manufacture as follows:

Class I: Prepared by heating carbohydrates with or without acids or alkalis; no ammonium or sulfite compounds are used.

Class II: Prepared by heating carbohydrates with or without acids or alkalis in the presence of sulfite compounds; no ammonium compounds are used.

Class III: Prepared by heating carbohydrates with or without acids or alkalis in the presence of ammonium compounds; no sulfite compounds are used.

Class IV: Prepared by heating carbohydrates with or without acids or alkalis in the presence of both sulfite and ammonium compounds.

In all cases the carbohydrate raw materials are commercially available food-grade nutritive sweeteners consisting of glucose, fructose and/or polymers thereof. The acids and alkalis are food grade sulfuric or citric acids and sodium, potassium or calcium hydroxides or mixtures thereof.

Where ammonium compounds are used they are one or any of the following: ammonium hydroxide, ammonium carbonate and ammonium hydrogen carbonate, ammonium phosphate, ammonium sulfate, ammonium sulfite and ammonium hydrogen sulfite.

Where sulfite compounds are used they are one or any of the following: sulfurous acid, potassium, sodium and ammonium sulfites and hydrogen sulfites.

Food-grade anti-foaming agents may be used as processing aids during manufacture.

1. **Appearance** : Dark brown to black liquids or solids having an odor of burnt sugar.
2. **Solubility** : Miscible with water.
3. **Classification** : Class I: Not more than 50% of the color is bound by DEAE Cellulose and not more than 50% of the color is bound by Phosphoryl Cellulose.

Class II: More than 50% of the color is bound by DEAE Cellulose and it exhibits an Absorbance Ratio of more than 50.

Class III: Not more than 50% of the color is bound by DEAE Cellulose and more than 50% of the color is bound by Phosphoryl Cellulose.

Class IV: More than 50% of the color is bound by DEAE Cellulose and it exhibits an Absorbance Ratio of not more than 50.

4. Solid content

: Class I: 62-77%

Class II: 65-72%

Class III: 53-83%

Class IV: 40-75%

5. Color intensity

: 0.1% (w/v) caramel pigment solution in 1 cm colorimetric tube. The absorbance value is tested at 610 nm.

Class I: 0.01-0.12

Class II: 0.06-0.10

Class III: 0.08-0.36

Class IV: 0.10-0.60

- |     |                         |  |
|-----|-------------------------|--|
| 6.  | Total nitrogen content  | : Tested by Kjeldahl Method<br>Class I: Not more than 0.1%<br>Class II: Not more than 0.2%<br>Class III: 1.3-6.8%<br>Class IV: 0.5-7.5%                      |
| 7.  | Total sulfur content    | : Class I: Not more than 0.3%<br>Class II: 1.3-2.5%<br>Class III: Not more than 0.3%<br>Class IV: 1.4-10.0%  |
| 8.  | Sulfur Dioxide          | : Class I: -<br>Class II: Not more than 0.2%<br>Class III: -<br>Class IV: Not more than 0.5%   |
| 9.  | 銨鹽氮                     | : Class I: -<br>Class II: -<br>Class III: Not more than 0.4%<br>Class IV: Not more than 2.8%   |
| 10. | 4-Methylimidazole,4-MEI | : Class I: -<br>Class II: -<br>Class III: Not more than 200 mg/kg on equivalent color basis.<br>Class IV: Not more than 250 mg/kg on equivalent color basis. |

Equivalent color basis: Color intensity is expressed in units of 0.1.

11. 2-Acetyl-4-tetrahydroxy-butylimidazole (THI) : Class I: -  
Class II: -  
Class III: Not more than 25 mg/kg on equivalent color basis.  
  
Class IV: -  
Equivalent color basis: Color intensity is expressed in units of 0.1.
12. Arsenic : Not more than 1 mg/kg.
13. Lead : Not more than 2 mg/kg.
14. Category : Food Additives Category 9
15. Uses : Colors

§ 09040

Lycopene from *Blakeslea trispora*

The same as § 08322



§ 10001

## Ethyl Acetate

Chemical formula: C<sub>4</sub>H<sub>8</sub>O<sub>2</sub>

Molecular weight: 88.11

1. Assay : Not less than 98%
2. Appearance : Colorless liquid, with a fruity odor.
3. Density : 0.897~0.906.
4. Index of refraction :  $n_D^{20}=1.370\sim1.375$ .
5. Acid value : Not more than 0.1.
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Readily carbonizable substance : Cool 5 mL of the sample to 10°C, mix with 5 mL of sulfuric acid slowly. Do not raise the temperature. Stand at 10°C for 5 minutes, the color of solution can not be thicker than the colorimetric solution (add water to 0.3 mL of 0.01 N iodine solution to make a 10 mL solution).
8. Distillation range : Not less than 95% v/v distills between 74°C and 78°C.
9. Non-volatile residue : Not more than 2 mg when drying 50 g of the sample at 105°C for 2 hours.
10. Category : Food Additives Category 10
11. Uses : Flavoring Agents

## Butyl Acetate

Chemical formula:  $C_6H_{12}O_2$ 

Molecular weight: 116.16

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.880~0.887.
4. Index of refraction :  $n_D^{20}=1.392\sim1.397$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 122°C and 127°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

Benzyl Acetate

Chemical formula:  $C_9H_{10}O_2$

Molecular weight: 150.18

1. Assay : Not less than 96%.
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 1.055~1.058.
4. Index of refraction :  $n_D^{20}=1.501\sim1.504$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear
6. Acid value : Not more than 1.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Phenylethyl Acetate

Chemical formula:  $C_{10}H_{12}O_2$

Molecular weight: 164.21

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 1.033~1.038.
4. Index of refraction :  $n_D^{20}=1.497\sim1.501$ .
5. Solution : When 1 mL of the sample is dissolved in 6 mL of 60 v/v% ethanol, the solution should be clear
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Terpinyl Acetate

Chemical formula:  $C_{12}H_{20}O_2$

Molecular weight: 196.29

1. Assay : Not less than 97%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.956~0.966.
4. Index of refraction :  $n_D^{20}=1.464\sim1.467$ .
5. Solution : When 1 mL of the sample is dissolved in 7 mL of 70 v/v% ethanol, the solution should be clear
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Cinnamyl Acetate

Chemical formula:  $C_{11}H_{12}O_2$ 

Molecular weight: 176.22

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.053~1.057.
4. Index of refraction :  $n_D^{20}=1.539\sim1.543$ .
5. Solution : When 1 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Geranyl Acetate

Chemical formula:  $C_{12}H_{20}O_2$

Molecular weight: 196.29

1. Assay : Not less than 90%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.900~0.917.
4. Index of refraction :  $n_D^{20}=1.457\sim1.464$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Citronellyl Acetate

Chemical formula:  $C_{12}H_{22}O_2$

Molecular weight: 198.31

1. Assay : Not less than 95% .
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.891~0.897.
4. Index of refraction :  $n_D^{20}=1.442\sim1.450$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents



Linalyl Acetate

Chemical formula:  $C_{12}H_{20}O_2$

Molecular weight: 196.29

1. Assay : Not less than 90%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.902~0.917.
4. Index of refraction :  $n_D^{20}=1.450\sim1.460$ .
5. Solution : When 1 mL of the sample is dissolved in 7 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not less than 2
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Isoamyl Acetate

Chemical formula:  $C_7H_{14}O_2$ 

Molecular weight: 130.19

1. Assay : 98~101%.
2. Appearance : Colorless, clear liquid, having a characteristic fruit-like odor.
3. Density : 0.872~0.878.
4. Index of refraction :  $n_D^{20}=1.397\sim1.402$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 130°C and 143°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Cyclohexyl Acetate

Chemical formula:  $C_8H_{14}O_2$ 

Molecular weight: 142.20

1. Assay : Not less than 96%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.969~0.972.
4. Index of refraction :  $n_D^{20}=1.439\sim1.442$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

*l*-Menthyl AcetateChemical formula:  $C_{12}H_{22}O_2$ 

Molecular weight: 198.30

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow, clear liquid, with a characteristic odor.
3. Density : 0.924~0.928.
4. Index of refraction :  $n_D^{20} = 1.445 \sim 1.448$ .
5. Solution : When 1 mL of the sample is dissolved in 7 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Specific rotation :  $\alpha_D^{20} = -70 \sim -75^\circ$ .
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

Ethyl Vanillin

Chemical formula:  $C_9H_{10}O_3$

Molecular weight: 166.18

1. Appearance : White to light yellow scale crystal or crystalline powder, with vanilla extract odor.
2. Melting range : 75.5~78.0°C.
3. Solution : When 1 g of the sample is dissolved in 10 mL of 60 v/v% ethanol, the solution should be clear.
4. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 h)
5. Residue on ignition : Not more than 0.05%.
6. Category : Food Additives Category 10
7. Uses : Flavoring Agents

## Ethyl Acetoacetate

Chemical formula:  $C_6H_{10}O_3$ 

Molecular weight: 130.15

1. Assay : Not less than 98~102%.
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 1.029~1.032.
4. Index of refraction :  $n_D^{20}=1.415\sim1.422$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 30 v/v% ethanol, the solution should be clear.
6. Free acid : Add 25 mL of fresh boiled and cooled water to 5 g of the sample, stir and mix for 2 minutes, then allow it to stand. Add 2 drops of phenolphthalein TS and 3.4 mL of 0.1 N potassium hydroxide solution to 10 mL of the water layer taken from the solution. Red color should appear.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Eugenol

Chemical formula:  $C_{10}H_{12}O_2$

Molecular weight: 164.21

1. Assay : Not less than 98 v/v%
2. Appearance : Colorless or pale tan, clear liquid; having a specific aroma.
3. Density : 1.065~1.071.
4. Index of refraction :  $n_D^{20}=1.539\sim1.542$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Category : Food Additives Category 10
7. Uses : Flavoring Agents

## Butyric Acid

Chemical formula:  $C_4H_8O_2$

Molecular weight: 88.11

1. Assay : Not less than 98%
2. Appearance : Colorless liquid, with a stimulating odor.
3. Density : 0.958~0.961.
4. Index of refraction :  $n_D^{20} = 1.398 \sim 1.401$ .
5. Sulfate : Not more than 19.2 ppm of  $SO_4$ .
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Distillation range : Not less than 95% v/v distils between 160°C and 165°C.
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents



## Ethyl Butyrate

Chemical formula:  $C_6H_{12}O_2$ 

Molecular weight: 116.16

1. Assay : Not less than 98% and not more than 102%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.874~0.882.
4. Index of refraction :  $n_D^{20}=1.390\sim1.395$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 112°C and 123°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Butyl Butyrate

Chemical formula:  $C_8H_{16}O_2$ 

Molecular weight: 144.21

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.866~0.871.
4. Index of refraction :  $n_D^{20}=1.404\sim1.408$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 160°C and 169°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Isoamyl Butyrate

Chemical formula:  $C_9H_{18}O_2$ 

Molecular weight: 158.24

1. Assay : 98~101%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.863~0.867.
4. Index of refraction :  $n_D^{20}=1.409\sim1.413$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 175°C and 182°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Cyclohexyl Butyrate

Chemical formula:  $C_{10}H_{18}O_2$ 

Molecular weight: 170.25

1. Assay : Not less than 97%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.941~0.945.
4. Index of refraction :  $n_D^{20}=1.441\sim1.444$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Undecalactone

Chemical formula:  $C_{11}H_{20}O_2$ 

Molecular weight: 184.28

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.944~0.948.
4. Index of refraction :  $n_D^{20}=1.450\sim1.455$ .
5. Acid value : Not more than 5.
6. Solution : When 2 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol, the solution should be clear.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Anisaldehyde

Chemical formula:  $C_8H_8O_2$ 

Molecular weight: 136.15

1. Assay : Not less than 95% .
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.123~1.128.
4. Index of refraction :  $n_D^{20}=1.571\sim1.576$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 60 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 10.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Ethyl Caproate

Chemical formula:  $C_8H_{16}O_2$ 

Molecular weight: 144.22

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.869~0.875.
4. Index of refraction :  $n_D^{20}=1.404\sim1.409$ .
5. Solution : When 1 mL of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 163°C and 170°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Allyl Caproate

Chemical formula:  $C_9H_{16}O_2$ 

Molecular weight: 156.23

1. Assay : 98~102%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.887~0.893.
4. Index of refraction :  $n_D^{20}=1.422\sim1.426$ .
5. Solution : When 1 mL of the sample is dissolved in 7 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents



## Nonalactone

Chemical formula:  $C_9H_{16}O_2$ 

Molecular weight: 156.23

1. Assay : Not less than 97%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.965~0.970.
4. Index of refraction :  $n_D^{20}=1.445\sim1.450$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 5.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Geranyl Formate

Chemical formula:  $C_{11}H_{18}O_2$ 

Molecular weight: 182.26

1. Assay : Not less than 80%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.909~0.920.
4. Index of refraction :  $n_D^{20}=1.460\sim1.466$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1 (Titrate under cold water until light red color lasting for 10 seconds).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Isoamyl Formate

Chemical formula:  $C_6H_{12}O_2$ 

Molecular weight: 116.61

1. Assay : Not less than 95% .
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.880~0.886.
4. Index of refraction :  $n_D^{20}=1.395\sim1.400$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1 (Titrate under cold water until light red color lasting for 10 seconds).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 92% v/v distils between 120°C and 124.5°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Citronellyl Formate

Chemical formula:  $C_{11}H_{20}O_2$ 

Molecular weight: 184.28

1. Assay : Not less than 86%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.891~0.900.
4. Index of refraction :  $n_D^{20}=1.444\sim1.450$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1 (Titrate under cold water until light red color lasting for 10 seconds)
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Methyl Salicylate

Chemical formula:  $C_8H_8O_3$ 

Molecular weight: 152.15

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.180~1.187.
4. Index of refraction :  $n_D^{20}=1.534\sim1.538$ .
5. Solution : When 1 mL of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1 (Use phenolphthalein TS as indicator)
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Ethyl Propionate

Chemical formula:  $C_5H_{10}O_2$ 

Molecular weight: 102.14

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.891~0.894.
4. Index of refraction :  $n_D^{20}=1.382\sim1.385$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 50 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 95°C and 100°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Benzyl Propionate

Chemical formula:  $C_{10}H_{12}O_2$ 

Molecular weight: 164.21

1. Assay : Not less than 93%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 1.032~1.037.
4. Index of refraction :  $n_D^{20}=1.495\sim1.501$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Isoamyl Propionate

Chemical formula:  $C_8H_{16}O_2$ 

Molecular weight: 144.22

1. Assay : 98~101%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.868~0.873.
4. Index of refraction :  $n_D^{20}=1.404\sim1.409$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 156°C and 165°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents



## Methylβ-Naphthyl Ketone

Chemical formula: C<sub>12</sub>H<sub>10</sub>O

Molecular weight: 170.21

1. Appearance : White to pale yellow crystals or crystalline powders, with a characteristic aroma.
2. Melting range : 51.5~54°C.
3. Solution : Dissolve 0.1 g of the sample in 10 mL of 70 v/v% ethanol by heating to 30°C, the solution should be clear.
4. Chloride compound : The result of copper mesh flame test shall not be green.
5. Nitrobenzene : Mix 20 mg of the sample with 10 mL of dilute ethanol, add 2 mL of hydrochloric acid, 2 mL of water and 0.5 g of zinc powder. Cover with a glass dish and slightly heat in a water bath. Add 10 mL of water, cool with ice and filter. Mix the filtrate with sodium nitrite solution (1f hydrochlshake for 1 minute. After standing for 10 minutes, add 1 mL of p-aminobenzenesulphonic acid solution (1ding, mix and shake for 10 minutes. Then, add 2 mL of N-(1-naphthyl)-N-(diethyl)-bis-aminoethylene dihydrochloride solution (1→ne d. When placed for 10 minutes, the liquid color should not be thicker than the matching fluid s.
6. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 h)
7. Residue on ignition : Not more than 0.05%.
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Methyl N – Methyl Anthranilate

Chemical formula:  $C_9H_{11}NO_2$

Molecular weight: 165.20

1. Assay : Not less than 98% and not more than 102%.
2. Appearance : Colorless to pale yellow, clear liquid or crystal, with a characteristic aroma. The liquid form has a distinctive violet fluorescence.
3. Density : 1.128~1.135.
4. Index of refraction :  $n_D^{20}=1.577\sim1.582$ .
5. Setting temperature : Not less than 10°C.
6. Solution : When 1 mL of the sample is dissolved in 10 mL of 70 v/v% ethanol, the solution should be clear.
7. Acid value : Not more than 1.
8. Residue on ignition : Not more than 0.05%.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Piperonal(Heliotropin)

Chemical formula:  $C_8H_6O_3$ 

Molecular weight: 150.14

1. Assay : Not less than 99% on the dried basis (over sulfuric acid, 4 h)
2. Appearance : White crystals or masses, having a characteristic aroma.
3. Melting range : 35.5~37°C.
4. Solution : When 1 g of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
5. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 hr).
6. Residue on ignition : Not more than 0.05%.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Ethyl Oenanthate

Chemical formula:  $C_9H_{18}O_2$ 

Molecular weight: 158.24

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.869~0.874.
4. Index of refraction :  $n_D^{20}=1.411\sim1.416$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 185°C and 193°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Octyl Aldehyde

Chemical formula:  $C_8H_{16}O$ 

Molecular weight: 128.22

1. Assay : Not less than 92%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.821~0.833.
4. Index of refraction :  $n_D^{20}=1.417\sim1.426$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 70 v/v% ethanol, the solution should be clear.
6. Free acid : 1 mL of the sample is dissolved in 10 mL of neutral ethanol. When adding 2 drops of phenolphthalein TS and 1.5 mL of 0.1 N sodium hydroxide solution, the solution should be red.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

# Ethyl Caprylate

Chemical formula:  $C_{10}H_{20}O_2$

Molecular weight: 172.27

1. Assay : Not less than 98% and not more than 101%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.867~0.871.
4. Index of refraction :  $n_D^{20}=1.416\sim1.419$ .
5. Solution : When 1 mL of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Linalool

Chemical formula: C<sub>10</sub>H<sub>18</sub>O

Molecular weight: 154.25

1. Assay : Not less than 92%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.864~0.876.
4. Index of refraction :  $n_D^{20}=1.461\sim1.465$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Chloride compound : The result of copper mesh flame test shall not be green.
7. Acid value : Not more than 1.
8. Ester value : Not less than 2
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Distillation range : Not less than 85% v/v distils between 195°C and 205°C.
11. Category : Food Additives Category 10
12. Uses : Flavoring Agents

## Benzyl Alcohol

Chemical formula: C<sub>7</sub>H<sub>8</sub>O

Molecular weight: 108.14

1. Appearance : Colorless, clear liquid, with a faint, aromatic odor.
2. Density : 1.042~1.053.
3. Solution : When 1 mL of the sample is dissolved in 50 mL of water, the oil should not be separated immediately even though the solution is turbid.
4. Chloride compound : The result of copper mesh flame test shall not be green.
5. Free Acid and free alkali : Dissolve 1 g of the sample in 10 mL of neutral ethanol. Add 2 drops of phenolphthalein TS. No red color should appear. Add a drop of 0.1 N sodium hydroxide. A red color should appear.
6. Distillation range : Not less than 90% v/v distils between 202.5 and 206.5°C.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents



## Benzaldehyde

Chemical formula: C<sub>7</sub>H<sub>6</sub>O

Molecular weight: 106.12

1. Assay : Not less than 97%
2. Appearance : Colorless with a characteristic, strong odor.
3. Density : 1.044~1.049.
4. Index of refraction :  $n_D^{20}=1.544\sim1.547$ .
5. Acid value : Not more than 10.
6. Chloride compound : The result of copper mesh flame test shall not be green.
7. Hydrogen cyanide : Add 5 mL of water to 0.5 mL of the sample, shake and mix. Add 0.5 mL of sodium hydroxide TS and 0.1 mL of ferrous sulfate TS, heat slowly. After cooling, make it weakly acidic with dilute hydrochloric acid. The solution should not be greenish blue or produce blue precipitate within 15 minutes.
8. Nitrobenzene : Dissolve 1 mL of the sample in 20 mL of ethanol, add water until it is slightly turbid. Add 3 g of zinc powder and 10 mL of dilute sulfuric acid to have it release hydrogen gas for 1 hour, and filter. After the filtrate is concentrated to 20 mL in water bath, add 2 drops of potassium chromate TS and heat. The solution should not be purple.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Acetophenone

Chemical formula:  $C_8H_8O$ 

Molecular weight: 120.15

1. Assay : Not less than 98%
2. Appearance : Colorless liquid or white crystals with characteristic odor.
3. Melting point :  $18\sim 20^{\circ}C$ .
4. Index of refraction :  $n_D^{20}=1.532\sim 1.534$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 60 v/v% ethanol, the solution should be clear.
6. Chloride compound : The result of copper mesh flame test shall not be green.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Ethyl Phenyl Acetate

Chemical formula:  $C_{10}H_{12}O_2$ 

Molecular weight: 164.21

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 1.031~1.036.
4. Index of refraction :  $n_D^{20}=1.496\sim1.500$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Isobutyl Phenyl Acetate

Chemical formula: C<sub>12</sub>H<sub>16</sub>O<sub>2</sub>

Molecular weight: 192.26

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.987~0.992.
4. Index of refraction :  $n_D^{20}=1.486\sim1.488$ .
5. Solution : When 1 mL of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Isoamyl Phenyl Acetate

Chemical formula:  $C_{13}H_{18}O_2$ 

Molecular weight: 206.29

1. Assay : Not less than 98%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.978~0.980.
4. Index of refraction :  $n_D^{20}=1.485\sim1.487$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Citronellol

Chemical formula:  $C_{10}H_{20}O$ 

Molecular weight: 156.27

1. Assay : Not less than 94%
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.853~0.864.
4. Index of refraction :  $n_D^{20}=1.453\sim1.462$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Ester value : Not more than 4.
8. Aldehydes : Not more than 2% (as Citronellal)
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Category : Food Additives Category 10
11. Uses : Flavoring Agents

## Citronellal

Chemical formula:  $C_{10}H_{18}O$ 

Molecular weight: 154.25

1. Assay : Not less than 85%.
2. Appearance : Colorless liquid with a characteristic odor.
3. Density : 0.852~0.859.
4. Index of refraction :  $n_D^{20}=1.446\sim1.452$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 3.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Geraniol

Chemical formula:  $C_{10}H_{18}O$ 

Molecular weight: 154.25

1. Assay : Not less than 85%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.870~0.885.
4. Index of refraction :  $n_D^{20}=1.469\sim1.478$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Ester value : Not more than 6
8. Aldehydes : Not more than 2.3% (as Citronellal)
9. Heavy metals : Not more than 10 ppm (as Pb).
10. Category : Food Additives Category 10
11. Uses : Flavoring Agents



## Vanillin

Chemical formula:  $C_8H_8O_3$ 

Molecular weight: 152.15

1. Assay : 97~103%.
2. Appearance : White to slightly yellow crystal flakes with a vanilla odor.
3. Melting range : 81~83°C.
4. Solution : When 1 g of the sample is dissolved in 20 mL of water and heated to 80°C, the solution should be clear.
5. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 hr).
8. Residue on ignition : Not more than 0.05%.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Cinnamic Aldehyde

Chemical formula:  $C_9H_8O$ 

Molecular weight: 132.16

1. Assay : Not less than 98%
2. Appearance : Colorless to yellow liquid, with a strong cinnamon odor and stimulating sweet taste.
3. Density : 1.050~1.056.
4. Index of refraction :  $n_D^{20}=1.619\sim1.625$ .
5. Solution : When 1 mL of the sample is dissolved in 10 mL of 60 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 5.
7. Chloride compound : The result of copper mesh flame test shall not be green.
8. Residue on ignition : Not more than 0.02%.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Cinnamyl Alcohol

Chemical formula:  $C_9H_{10}O$ 

Molecular weight: 134.18

1. Assay : Not less than 98%
2. Appearance : Colorless to light yellow liquid or white to light yellow crystal, with special odor.
3. Setting : 28~33°C.  
temperature
4. Solution : Add 3 mL of 50 v/v% ethanol to 1 g of the sample and dissolve it at 35°C. The  
solution should be "clear".
5. Acid value : Not more than 1.
6. Cinnamaldehyde : Not more than 1.5%.
7. Residue on : Not more than 0.03%.  
ignition
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

## Cinnamic Acid

Chemical formula:  $C_9H_8O_2$ 

Molecular weight: 148.16

1. Assay : Not less than 99% (over sulfuric acid, 3 h)
2. Appearance : White crystalline scales, with a characteristic odor.
3. Melting range : 132~135°C.
4. Solution : When 1 g of the sample is dissolved in 7 mL of ethanol, the solution should be clear.
5. Alkaline solution : When 0.2 g of the sample is dissolved sodium carbonate TS and 3 mL of water, the solution should be "clear".
6. Chloride compound : Not more than 14 ppm of Cl.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Loss on drying : Not more than 1% (over sulfuric acid, 3 h).
9. Residue on ignition : Not more than 0.05%.
10. Category : Food Additives Category 10
11. Uses : Flavoring Agents

Methyl Cinnamate

Chemical formula:  $C_{10}H_{10}O_2$

Molecular weight: 162.19

1. Assay : Not less than 98%
2. Appearance : White solid, with a characteristic odor.
3. 凝固點 : Not less than 33.8°C.
4. Solution : When 1 g of the sample is added to 3 mL of 70 v/v% ethanol and heated until dissolved, the solution should be clear.
5. Acid value : Not more than 1.
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Ethyl Cinnamate

Chemical formula:  $C_{11}H_{12}O_2$ 

Molecular weight: 176.22

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.050~1.055.
4. Index of refraction :  $n_D^{20}=1.556\sim1.562$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Decyl Aldehyde

Chemical formula:  $C_{10}H_{20}O$

Molecular weight: 156.27

1. Assay : Not less than 93%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.826~0.835.
4. Index of refraction :  $n_D^{20}=1.427\sim1.435$ .
5. Solution : When 2 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 10.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

## Decyl Alcohol

Chemical formula:  $C_{10}H_{22}O$ 

Molecular weight: 158.29

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Setting : Not less than 5°C.  
temperature
4. Density : 0.826~0.831.
5. Index of :  $n_D^{20}=1.435\sim1.438$ .  
refraction
6. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should  
be clear.
7. Acid value : Not more than 1.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents



## Eucalyptol (Cincol)

Chemical formula:  $C_{10}H_{18}O$ 

Molecular weight: 154.24

1. Assay : Not less than 85%.
2. Appearance : Colorless to pale yellow liquid, with a camphor like odor.
3. Density : 0.915~0.929.
4. Index of refraction :  $n_D^{20}=1.454\sim1.462$ .
5. Solution : When 2 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol, the solution should be clear.
6. Resorcin : Add 5 mL of water to 1 mL of the sample. Add 1 mL of the mixture of 1 mL of mercury nitrate TS and 3 mL of water. Shake and heat in water bath for 2 minutes. Cool, add 1 drop of dilute sulfuric acid and 1 drop of sodium nitrite TS. When heated in water bath for 2 minutes, the water layer shall not appear yellow to tan.
7. Specific rotation :  $\alpha_D^{20}=-3\sim+10^\circ$ .
8. Phellandrene : Dissolve 2.5 mL of the sample in 5 mL of petroleum benzene, then add 10 mL of sodium nitrite solution (1→20). Slowly add 5 mL of glacial acetic acid. No crystals form within 10 minutes.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

Isoeugenol

Chemical formula:  $C_{10}H_{12}O_2$

Molecular weight: 164.21

1. Assay : Not less than 98 v/v%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.083~1.090.
4. Index of refraction :  $n_D^{20}=1.572\sim1.577$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Category : Food Additives Category 10
7. Uses : Flavoring Agents

## Ethyl Isovalerate

Chemical formula:  $C_7H_{14}O_2$ 

Molecular weight: 130.19

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.866~0.870.
4. Index of refraction :  $n_D^{20}=1.393\sim1.398$ .
5. Solution : When 2 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 130°C and 140°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Isoamyl Isovalerate

Chemical formula:  $C_{10}H_{20}O_2$ 

Molecular weight: 172.27

1. Assay : 98~101%.
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.857~0.862.
4. Index of refraction :  $n_D^{20}=1.410\sim1.415$ .
5. Solution : When 1 mL of the sample is dissolved in 8 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Distillation range : Not less than 95% v/v distils between 185°C and 195°C.
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Allyl Isothiocyanate

Chemical formula:  $C_4H_5NS$ 

Molecular weight: 99.16

1. Assay : Not less than 97%
2. Appearance : Colorless to pale yellow oily liquid, with strong characteristic odor.
3. Density : 1.018~1.023.
4. Index of refraction :  $n_D^{20}=1.528\sim1.531$ .
5. Carbon disulfide, petroleum, essential oil and fatty acid : Cool 3 mL of the sample and add 4 mL of sulfuric acid to it slowly. When oscillating and mixing, the solution shall not be red or turbid nor produce colorless oil droplet or oil layer.
6. Phenols and thiocyanate compounds : Dissolve 1 mL of the sample in 5 mL of ethanol. When adding 1 drop of ferric chloride TS, the solution shall not be blue or red.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

Maltol

Chemical formula:  $C_6H_6O_3$

Molecular weight: 126.11

1. Appearance : White to off-white crystalline powder having a characteristic odor.
2. Melting range : 160~163°C.
3. Solution : When 0.1 mL of the sample is dissolved in 5 mL of 70 v/v% ethanol, the solution should be clear.
4. Loss on drying : Not more than 0.5% (over sulfuric acid, 4 hr).
5. Residue on ignition : Not more than 0.05%.
6. Category : Food Additives Category 10
7. Uses : Flavoring Agents

## Methyl Anthranilate

Chemical formula:  $C_8H_9O_2N$ 

Molecular weight: 151.17

1. Assay : Not less than 98%
2. Appearance : Colorless to light yellow liquid or crystalline block. The liquid form has a unique blue-violet fluorescent. With a characteristic aroma.
3. Setting : 22~24°C.  
temperature
4. Solution : When 2 mL of the sample is dissolved in 6 mL of 70 v/v% ethanol at 30°C, the solution should be clear.
5. Index of :  $n_D^{20}=1.580\sim1.585$ .  
refraction
6. Acid value : Not more than 1.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

# Hydroxy Citronellal

Chemical formula:  $C_{10}H_{20}O_2$

Molecular weight: 172.27

1. Assay : Not less than 90%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.921~0.928.
4. Index of refraction :  $n_D^{20}=1.447\sim1.450$ .
5. Solution : When 2 mL of the sample is dissolved in 3 mL of 50 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 10.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents



## Hydroxy Citronellal Dimethylacetal

Chemical formula:  $C_{12}H_{26}O_3$ 

Molecular weight: 218.34

1. Assay : Not less than 95% .
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.928~0.934.
4. Index of refraction :  $n_D^{20}=1.441\sim1.444$ .
5. Solution : When 2 mL of the sample is dissolved in 4 mL of 50 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Hydroxycitronellal : Accurately weigh 5 g of the sample, add 70 mL of hydroxylamine TS, shake, and let it stand for 1 hour. The excess hydroxylamine is titrated with 0.5 N hydrochloric acid. the required 0.5 N hydrochloric acid solution should be below 3 mL.
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

*l*-PerillaldehydeChemical formula: C<sub>10</sub>H<sub>14</sub>O

Molecular weight: 150.22

1. Assay : Not less than 90%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.965~0.980.
4. Index of refraction :  $n_D^{20}=1.502\sim1.510$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 70 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 3.
7. Specific rotation :  $\alpha_D^{20}=-100\sim-150^\circ$ .
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Category : Food Additives Category 10
10. Uses : Flavoring Agents

## Ionone

Chemical formula:  $C_{13}H_{20}O$ 

Molecular weight: 192.30

1. Assay : Not less than 90%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.930~0.948.
4. Index of refraction :  $n_D^{20}=1.497\sim1.522$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 70 v/v% ethanol, the solution should be clear.
6. Residue on ignition : Not more than 0.05%.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

p-Methyl Acetophenone

Chemical formula: C<sub>9</sub>H<sub>10</sub>O

Molecular weight: 134.18

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 1.004~1.008.
4. Index of refraction :  $n_D^{20}=1.532\sim1.535$ .
5. Solution : When 1 mL of the sample is dissolved in 3 mL of 70 v/v% ethanol, the solution should be clear.
6. Chloride compound : The result of copper mesh flame test shall not be green.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

*dl*-MentholChemical formula: C<sub>10</sub>H<sub>20</sub>O

Molecular weight: 156.27

1. Appearance : Colorless columnar or needle-like crystal, or white crystalline powder with a characteristic cool fragrance. Tastes burning at first and becomes cool afterward.
2. Melting range : 32~38°C.
3. Non-volatile matter : Not more than 0.05% (heating and volatilizing on water bath)
4. Thymol : 0.2 g of the sample should not be colored when added to the cold mixture of 2 mL of glacial acetic acid, 6 drops of sulfuric acid and 2 drops of nitrate acid.
5. Nitromethane : Add 1 mL of sodium hydroxide TS to 0.5 g of the sample, heat and boil for about 2 minutes. After the solution cools, add 0.5 mL of sulfanilic acid- $\alpha$ -naphthylamine T.S., it should not be red for 5 minutes.
6. Category : Food Additives Category 10
7. Uses : Flavoring Agents

*l*-MentholChemical formula: C<sub>10</sub>H<sub>20</sub>O

Molecular weight: 156.27

1. Appearance : Colorless columnar or needle-like crystal, or white crystalline powder with a characteristic cool fragrance. Tastes burning at first and becomes cool afterward.
2. Melting range : 42~43°C.
3. Specific rotation :  $[\alpha]_D^{20} = -45 \sim -51^\circ$  (Dissolve 2.5 g of the sample in ethanol to make a 25 mL solution)
4. Non-volatile matter : Not more than 0.05% (heating and volatilizing on water bath)
5. Thymol : 0.2 g of the sample should not be colored when added to the cold mixture of 2 mL of glacial acetic acid, 6 drops of sulfuric acid and 2 drops of nitrate acid.
6. Nitromethane : Add 1 mL of sodium hydroxide TS to 0.5 g of the sample, heat and boil for about 2 minutes. After the solution cools down, add 0.5 mL of sulfanilic acid- $\alpha$ -naphthylamine T.S., the solution should not be red for 5 minutes.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents

$\alpha$ -Amyl Cinnamic AldehydeChemical formula: C<sub>14</sub>H<sub>18</sub>O

Molecular weight: 202.30

1. Assay : Not less than 98%
2. Appearance : Colorless to pale yellow liquid, with a characteristic odor.
3. Density : 0.967~0.972.
4. Index of refraction :  $n_D^{20}=1.554\sim1.559$ .
5. Solution : When 1 mL of the sample is dissolved in 5 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Residue on ignition : Not more than 0.05%.
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

Citral

Chemical formula:  $C_{10}H_{16}O$

Molecular weight: 152.24

1. Assay : Not less than 96%.
2. Appearance : Colorless to pale yellow liquid, having a strong lemon like odor.
3. Density : 0.888~0.894.
4. Index of refraction :  $n_D^{20} = 1.486 \sim 1.490$ .
5. Solution : When 1 mL of the sample is dissolved in 10 mL of 60 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 5.
7. Category : Food Additives Category 10
8. Uses : Flavoring Agents



Allyl Cyclohexyl Propionate

Chemical formula:  $C_{12}H_{20}O_2$

Molecular weight: 196.29

1. Assay : Not less than 98%
2. Appearance : Pale yellow, clear liquid having a characteristic odor.
3. Density : 0.948~0.953.
4. Index of refraction :  $n_D^{20}=1.457\sim1.462$ .
5. Solution : When 1 mL of the sample is dissolved in 4 mL of 80 v/v% ethanol, the solution should be clear.
6. Acid value : Not more than 1.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Category : Food Additives Category 10
9. Uses : Flavoring Agents

*d*-BorneolChemical formula: C<sub>10</sub>H<sub>18</sub>O

Molecular weight: 154.25

1. Appearance : White crystal, crystalline powder or block, with a characteristic aroma.
2. Melting range : 207~210°C.
3. Specific rotation :  $[\alpha]_D^{20} = +16 \sim +37^\circ$  (Dissolve 1 g of the sample in ethanol to make a 10 mL solution)
4. Non-volatile matter : Not more than 0.05% (After heating and sublimating on water bath, dry at 105°C for 1 hour)
5. Category : Food Additives Category 10
6. Uses : Flavoring Agents

§ 10090

L-Cystein Monohydrochloride

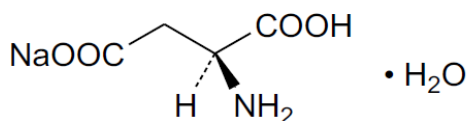
The same as § 03012.

## Category 11 Seasoning Agents

§ 11003

### Monosodium L-Aspartate

Chemical names	Monosodium (2 <i>S</i> )-2-aminobutanedioate monohydrate
C.A.S. number	3792-50-5
Chemical formula	C <sub>4</sub> H <sub>6</sub> O <sub>4</sub> NNa • H <sub>2</sub> O
Structural formula	



Formula weight	173.10
Content	Monosodium L-Aspartate, when calculated on the dried basis, contains not less than 98% of monosodium L-aspartate

**Description** Monosodium L-Aspartate occurs as colorless to white prisms or as a white crystalline powder. It has a characteristic taste.

**Identification**

- (1) To 5 mL of a solution of Monosodium L-Aspartate (1 in 1000), add 1 mL of ninhydrin solution (1 in 1000), and heat for 3 minutes. A purple color develops.
- (2) Monosodium L-Aspartate responds to all tests for Sodium Salt in the Qualitative Tests.

Specific Rotation	$[\alpha]_D^{20} : +18 \sim +21^\circ$
pH	6.0 ~ 7.5 (1.0 g, water 20 mL)

**Purity**

Clarity and color of solution Colorless and clear (1.0 g, water 10 mL)

Chloride	Not more than 0.041% as Cl
Arsenic	Not more than 2 mg/kg as As <sub>2</sub> O <sub>3</sub>
Lead	Not more than 2 mg/kg
Loss on Drying	Not more than 0.3%

**Category** Food additives category 11

**Functional uses** Seasoning Agents

Fumaric Acid

Chemical formula:  $C_4H_4O_4$

Molecular weight: 116.08

1. Assay : Not less than 99%
2. Appearance : Odorless, white crystalline powder or granules, having a characteristic sour taste.
3. Melting range : 287~302°C (closed capillary, rapid heating after drying at 105°C for 3 hours)
4. Solution : When 0.5 g of the sample is dissolved in 10 mL of sodium hydroxide TS, the solution should be clear.
5. Sulfate : Not more than 0.01% of  $SO_4$ .
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Residue on ignition : Not more than 0.05%.
8. Category : Food Additives Category 11
9. Uses : Seasoning Agents.

## Sodium Fumarate

**Synonyms**

Monosodium fumarate; INS No. 365

**Definition**

Chemical names

Monosodium fumarate, monosodium trans-butenedioic acid, monosodium trans-1,2-ethylenedicarboxylate; monosodium trans-1,2-ethylenedicarboxylic acid

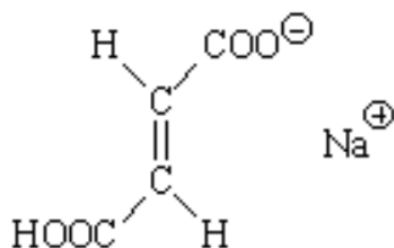
C.A.S. number

7704-73-6

Chemical formula

 $C_4H_3NaO_4$ 

Structural formula



Formula weight

138.06

Assay

Not less than 98.0% and not more than 102.0% on the dried basis

**Description**

Odourless, white crystalline powder

**Characteristics**

Identification

Solubility

Soluble in water

pH

3 - 4 (1 in 30 solution)

1,2-Dicarboxylic acid

Place 50 mg of the sample in a test tube, add 2 to 3 mg of resorcinol and 1 ml of sulfuric acid, shake, heat at 130° for 5 min. and cool. Dilute with water to 5 ml and add sodium hydroxide solution (2 in 5) dropwise to render the solution alkaline, cool and dilute with water to 10 ml. A greenish blue fluorescence is observed under an ultraviolet lamp.

Test for double bond

Add 10 ml of water to 0.5 g of the sample and dissolve by boiling. Add 2 or 3 drops of bromine TS to the hot solution. The colour of bromine TS disappears.

Test for sodium

Passes test

Purity

Loss on drying

Not more than 0.5% (120°, 4 h)

Sulfates	Not more than 0.01%
Maleic acid	Not more than 0.05%
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (11)
<b>Functional uses</b>	Seasoning Agents

## Citric Acid; Citric Acid, Anhydrous

Chemical names : 2-hydroxy-1,2,3-propanetricarboxylic acid

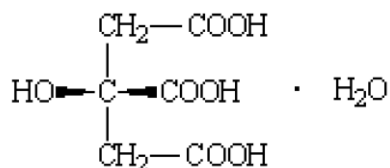
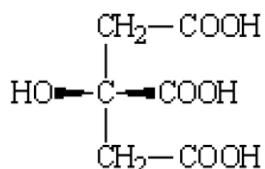
Synonyms : INS No. 330; CAS No. 77-92-9 (anhydrous); CAS No. 5949-29-1 (monohydrate).

Chemical formula : C<sub>6</sub>H<sub>8</sub>O<sub>7</sub> (anhydrous)

Molecular weight: 192.13

formula C<sub>6</sub>H<sub>8</sub>O<sub>7</sub>·H<sub>2</sub>O (monohydrate)

210.14



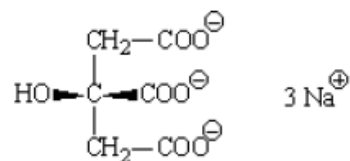
## Anhydrous

## Monohydrate

- |                                   |  |
|-----------------------------------|--|
| 1. Assay                          | : Not less than 99.5% and not more than 100.5% on the anhydrous basis.   |
| 2. Appearance                     | : White or colorless, odorless, crystalline solid. The monohydrate form effloresces in dry air.  |
| 3. Solubility                     | : Very soluble in water; freely soluble in ethanol; slightly soluble in ether.   |
| 4. Water                          | : Anhydrous: Not more than 0.5%.<br>Monohydrate: Not less than 7.5% and not more than 8.8%.  |
| 5. Sulfated ash                   | : Not more than 0.05%.   |
| 6. Oxalate                        | : Not more than 100 mg/kg.   |
| 7. Sulfate                        | : Not more than 150 mg/kg.   |
| 8. Readily carbonizable substance | : Heat 1.0 g of sample with 10 mL of 98% sulfuric acid in a water bath at 90±1°C for 60 min. No color darker than Matching Fluid K (25°C) should be produced (not more than 0.5 absorbance units at 470 nm in a 10 mm cell). |
| 9. Lead                           | : Not more than 0.5 mg/kg.   |
| 10. Heavy metals                  | : Not more than 5 mg/kg (as Pb).   |
| 11. Category                      | : Food Additives Category 11   |
| 12. Uses                          | : Seasoning Agents.  |



## Sodium Citrate



Synonyms: Trisodium citrate; INS No.331(iii)

Chemical names: trisodium salt of 2-hydroxy-1,2,3- propanetricarboxylic acid, trisodium salt of β-hydroxy-tricarballic acid

Chemical formula:

Molecular weight: 258.07 (Anhydrous)

Anhydrous:  $\text{C}_6\text{H}_5\text{Na}_3\text{O}_7$

Hydrated:  $\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot n\text{H}_2\text{O}$  (n=2 or 5)

1. Assay : Not less than 99.0% calculated on the dried basis (180°C, 2 h)
2. Appearance : Colorless crystal or white crystalline powder, odorless.
3. Description : 1. Soluble in water, insoluble in ethanol.  
2. Passes test for citrate and test for sodium.
4. Loss on drying : Anhydrous: not more than 1% (180°C to constant weight) Dihydrate: not more than 13% (180°C to constant weight) Pentahemihydrate: not more than 30% (180°C to constant weight)
5. Alkalinity : A 1 in 20 solution of the sample is alkaline to litmus. After the addition of 0.2 mL of 0.1 N sulfuric acid and 1 drop of phenolphthalein TS to 10 mL of the solution no pink color is produced.
6. Oxalate : To 10 mL of a 1 in 10 solution of the sample add 5 drops of dilute acetic acid TS and 2 mL of calcium chloride TS. No turbidity develops within 1 h.
7. Lead : Not more than 2 mg/kg.
8. Category : Food Additives Category 11
9. Uses : Seasoning Agents.

Succinic Acid

Chemical formula:  $C_4H_6O_4$

Molecular weight: 118.09

1. Assay : Not less than 99%
2. Appearance : Colorless to white crystal or white crystalline powder, odorless, having a characteristic sour taste.
3. Melting range : 184~189°C.
4. Heavy metals : Not more than 20 ppm (as Pb).
5. Readily oxidizable matter : Dissolve 1 g of the sample in 25 mL of water 25 mL of dilute sulphuric acid, and maintain at 20°C. When 4 mL of 0.1 N potassium permanganate solution is added, the solution color should not disappear within 3 minutes.
6. Residue on ignition : Not more than 0.05%.
7. Category : Food Additives Category 11
8. Uses : Seasoning Agents.

## Monosodium Succinate

Chemical formula:  $C_4H_5O_4Na$ 

Molecular weight: 140.08

1. Assay : Not less than 98 and not more than 102%.
2. Appearance : Colorless to white crystal or white crystalline powder, odorless, with a characteristic odor.
3. pH : 4.3~5.3 (1 in 20 soln)
4. Chloride : Not more than 0.1% of Cl.
5. Sulfate : Not more than 0.02% of  $SO_4$ .
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Readily oxidizable matter : Dissolve 2 g of the sample in 25 mL of water 25 mL of dilute sulphuric acid and maintain at 20°C. When 4 mL of 0.1 N potassium permanganate solution is added, the solution color should not disappear within 3 minutes.
9. Residue on ignition : 49.5~51.5%.
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.

## Disodium Succinate

Chemical formula:  $\text{C}_4\text{H}_4\text{O}_4\text{Na}_2 \cdot 6\text{H}_2\text{O}$ 

Molecular weight: 270.15

1. Assay : Not less than 98% and not more than 102% of  $\text{C}_4\text{H}_4\text{O}_4\text{Na}_2$  (120°C, 2 h)
2. Appearance : Colorless to white crystal or white crystalline powder, odorless, with a characteristic odor.
3. pH : 7~9 (1 in 10 soln)
4. Sulfate : Not more than 0.02% of  $\text{SO}_4$ .
5. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Readily oxidizable matter : Dissolve 2 g of the sample in 20 mL of water 30 mL of dilute sulphuric acid and maintain at 20°C. When 4 mL of 0.1 N potassium permanganate solution is added, the solution color should not disappear within 3 minutes.
8. Loss on drying : Not more than 41% (120°C, 2 h)
9. Residue on ignition : 51.5~53.5%.
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.

## L-Glutamic Acid

Chemical formula:  $C_5H_9O_4N$ 

Molecular weight: 147.14

1. Assay : Not less than 99.0% on the dried basis (105°C, 3 h)
2. Appearance : Colorless or white crystals or crystalline powder, with a characteristic sour odor.
3. Solution : When 1 g of the sample is dissolved by heating in 50 mL of water, the solution should be clear.
4. pH : 3.0~3.5 (saturated solution)
5. Specific rotation :  $[\alpha]_D^{20} = +30.7 \sim +32.7^\circ$  (105°C, 3 h, then 10% (w/v) soln in 2N hydrochloric acid)
6. Chloride : Not more than 0.2% of Cl.
7. Ammonium salt : Not more than 0.02% of  $NH_4$ .
8. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Other amino acids : Test for other amino acid of "L-aspartate" is applicable.
11. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.2% of its weight..
12. Residue on ignition : Not more than 0.2%.
13. Category : Food Additives Category 11
14. Uses : Seasoning Agents.

## Monosodium L-Glutamate

**Synonyms** Sodium glutamate, MSG, INS No. 621

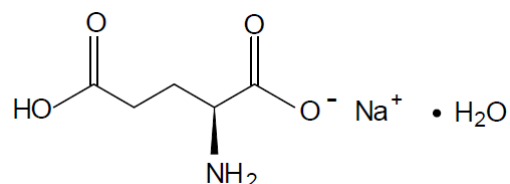
**Definition**

Chemical names Monosodium L-glutamate monohydrate, glutamic acid monosodium salt monohydrate

C.A.S. number 142-47-2

Chemical formula  $C_5H_8NNaO_4 \cdot H_2O$

Structural formula



Formula weight 187.13

Assay Not less than 99.0% on the dried basis

**Description** White, practically odourless crystals or crystalline powder

**Characteristics**

Identification

Solubility Freely soluble in water; sparingly soluble in ethanol; practically insoluble in ether

Test for glutamate Passes test

Test for sodium Passes test

Purity

Loss on drying Not more than 0.5% (98°C, 5 h)

pH 6.7 - 7.2 (1 in 20 soln)

Specific rotation  $[\alpha]_D^{20} = +24.8 \sim +25.3^\circ$  (10% (w/v) solution in 2N hydrochloric acid)

Chlorides Not more than 0.2%

Pyrrolidone carboxylic acid Passes test

Lead Not more than 1 mg/kg

**Category** Food additives category (11)

**Functional uses**

Seasoning agents.

*dl*-Tartaric AcidChemical formula: C<sub>4</sub>H<sub>6</sub>O<sub>6</sub>

Molecular weight: 150.09

1. Assay : Not less than 99.7% on the dried basis (over sulfuric acid, 3 h)
2. Appearance : Colorless crystal or white crystalline powder, odorless, having a smelly sour taste.
3. Melting range : 200~206°C.
4. Sulfate : Not more than 0.05% of SO<sub>4</sub>.
5. Heavy metals : Not more than 10 ppm (as Pb).
6. Calcium : The test for calcium of "d-tartaric acid" is applicable.
7. Readily oxidizable matter : Dissolve 1 g of the sample in 25 mL of water 25 mL of dilute sulphuric acid.  
When 4 mL of 0.1 N potassium permanganate solution is added at 20°C, the solution color should not disappear within 3 minutes.
8. Loss on drying : Not more than 0.5% (over sulfuric acid, 3 hr).
9. Residue on ignition : Not more than 0.1%.
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.



*d*-Tartaric AcidChemical formula: C<sub>4</sub>H<sub>6</sub>O<sub>6</sub>

Molecular weight: 150.09

1. Assay : Not less than 99.7% on the dried basis (over sulfuric acid, 3 h).
2. Appearance : Colorless or translucent crystals, or white, fine to granular, crystalline powder; odorless; having a sour taste.
3. Specific rotation :  $[\alpha]_D^{20} = +11.5 \sim +13.5^\circ$  (over sulfuric acid, 3 h. Then dissolve 10 g of the product to form a 50 mL solution)
4. Sulfate : Not more than 0.05% of SO<sub>4</sub>.
5. Oxalate : Nearly neutralize 10 mL of a 1 in 10 solution of the sample with ammonia TS, and add 10 mL of calcium sulfate TS. No turbidity is produced.
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Calcium : Dissolve 1 g of the sample in 10 mL of water, neutralize with ammonia TS. Then, add 1 mL of ammonium oxalate TS. The solution should not be turbid.
8. Loss on drying : Not more than 0.5% (over sulfuric acid, 3 hr).
9. Residue on ignition : Not more than 0.1%.
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.

Sodium *dl*-TartrateChemical formula:  $C_4H_4O_6Na_2$ 

Molecular weight: 194.06

1. Assay : Not less than 98.5% on the dried basis (105°C, 4 h)
2. Appearance : Colorless crystal or white crystalline powder.
3. Solution : Dissolve 1 g of the sample in 20 mL of water, the solution should be less than "almost clear".
4. Free Acid and free alkali : Test method of "5.Free Acid and free alkali" for "d-sodium tartrate" is applicable.
5. Sulfate : Not more than 0.02% of  $SO_4$ .
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Readily oxidizable matter : Dissolve 2 g of the sample in 20 mL of water 30 mL of dilute sulphuric acid.  
When 4 mL of 0.1 N potassium permanganate solution is added at 20°C, the solution color should not disappear within 3 minutes.
9. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 0.5% of its weight..
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.

Sodium *d*-TartrateChemical formula:  $C_4H_4O_6Na_2 \cdot 2H_2O$ 

Molecular weight: 230.09

1. Assay : Not less than 98.5% on the dried basis (105°C, 4 h).
2. Appearance : Colorless crystal or white crystalline powder.
3. Solution : Dissolve 1 g of the sample in 20 mL of water, the solution should be less than "almost clear".
4. Specific rotation :  $[\alpha]_D^{20} = +25.0 \sim +27.5^\circ$  (Dissolve 5 g of the sample in water to form a 50 mL solution)
5. Free Acid and free alkali : Dissolve 2 g of the sample in 20 mL of freshly boiled and cooled water. Add 2 drops of phenolphthalein TS. If a colorless solution is produced, not more than 0.1 mL of 0.1 N sodium hydroxide should be required to give a red color. If a red color is produced, not more than 0.1 mL of 0.1 N hydrochloric acid should be required to discharge it.
6. Sulfate : Not more than 0.02% of  $SO_4$ .
7. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : 14~16% (150°C, 4 hr).
10. Category : Food Additives Category 11
11. Uses : Seasoning Agents.

## Lactic Acid

**Synonyms**

INS No. 270

**Definition**

Obtained by the lactic fermentation of sugars or is prepared synthetically; may contain condensation products such as lactic acid, lactate and dilative.

Common products of commerce are 50-90% solutions. Solid products containing about 100-125% of treatable lactic acid also exist.

(Note: Lactic acid is hygroscopic and when concentrated by boiling or by distillation it forms condensation products which hydrolyze to lactic acid on dilution and heating in water).

**Chemical names**

Lactic acid,  
2-hydroxypropanoic acid,  
2-hydroxypropionic acid

**CAS NUMBER**

50-21-5  
(L-: 79-33-4;  
D-: 10326-41-7;  
DL-: 598-82-3)

**Chemical formula** $C_3H_6O_3$ **Molecular weight**

90.08

**Assay**

Not less than 95.0% and not more than 105.0% of the labelled concentration. (as  $C_3H_6O_3$ )

**Appearance**

Colorless, syrupy liquid or white to light yellow solid or powder.

**Characteristics****Identification****Solubility**

Liquid: Soluble in water and in ethanol.  
Solid: Sparingly soluble in water, soluble in acetone.

**Test for acid**

A 1 in 10 solution or dispersion of the sample is acid to litmus paper.

**Test for lactate**

Passes test.

**Purity****Sulfated ash**

Not more than 0.1%

**Chloride**

Not more than 0.2% of Cl.

**Sulfate**Not more than 0.25% of  $SO_4$ .

Iron	Not more than 10 mg/kg.
Cyanide	Passes test (limit approx. 1 mg/kg)
Citric, oxalic, phosphoric or tartaric acid	Dilute 1 g of the sample to 10 mL with water, add 40 mL of calcium hydroxide TS, and boil for 2 min. No turbidity is produced.
Sugars	Add 5 drops of the 40% sample solution (Concentration of lactic acid is calculated from the indicated concentration. No dilution required if the indicated concentration is less than 40%) to 10 mL of hot alkaline cupric tartrate TS. No red precipitate is formed.
Readily carbonizable substance	Superimpose carefully 5 mL of the sample solution kept at 15°C on 5 mL of sulfuric acid TS kept at 15°C. No deep grey color is produced within 15 min at the contact zone of the two liquids.
Lead	Not more than 2 mg/kg.
<b>Category</b>	Food Additives Category 11
<b>Uses</b>	Seasoning Agents.

## Sodium Lactate (solution)

**Synonyms**

INS No. 325

**Definition**

Chemical names

Sodium lactate, sodium 2-hydroxypropanoate

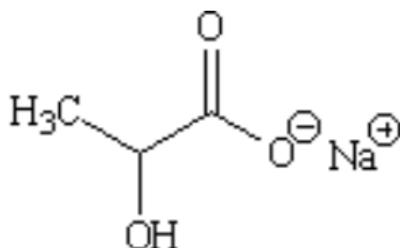
C.A.S. number

72-17-3

Chemical formula

 $C_3H_5NaO_3$ 

Structural formula



Formula weight

112.06 (anhydrous)

Assay

Not less than 95% and not more than 110% of the labelled amount. This specification is based on a 60% w/w solution of  $C_3H_5NaO_3$  in water.

**Description**

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

**Characteristics**

Identification

Ignition

Ignite to an ash. The ash is alkaline, and an effervescence occurs when acid is added

Colour reaction

Overlay 2 ml of the sample on 5 ml of a 1 in 100 solution of catechol in sulfuric acid. A deep red colour is produced at the zone of contact

Test for lactate

Passes test

Test for sodium

Passes test

Purity

Acidity

Neutralization of 1 g of sample shall require not more than 0.5 ml of 0.1 N sodium hydroxide solution, using phenolphthalein TS

pH

6.5 - 7.5 (1 in 5 soln)

<b>Lead</b>	Not more than 2 mg/kg
<b>Category</b>	Food additives category (11)
<b>Functional uses</b>	Seasoning Agents

## Sodium Lactate Solution

Chemical formula :  $\text{C}_3\text{H}_5\text{O}_3\text{Na}$ 

Formula weight : 112.06

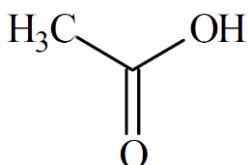
1. Assay : 50~60% (as  $\text{C}_6\text{H}_5\text{O}_3\text{Na}$ )
2. Appearance : Colorless, transparent, liquid. Odorless, or with a slight, characteristic odor.
3. Density : 1.26~1.32.
4. pH : 6.5~7.5 (1 in 5 soln)
5. Chloride : Not more than 70 ppm of Cl.
6. Sulfate : Not more than 0.012%  $\text{SO}_4$ .
7. Malate, tartrate and citrate : Add 1 mL of the sample to form a 50 mL solution.  
When adding 3 to 5 drops of lead acetate solution to  
5 mL of the solution, the turbidity should be below  
"slightly turbidity".
8. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Iron : Not more than 10 ppm.
11. Volatile fatty acids : When 5 mL of the sample is heated with 2 mL of dilute sulfuric acid on  
water bath, strong odor of fatty acid does not occur.
12. Methanol : Not more than 0.2%.
13. Category : Food Additives Category 11
14. Uses : Seasoning Agents.



## Acetic Acid

1. Assay : This product contains 29~31% of  $C_2H_4O_2$ .
2. Appearance : Colorless liquid, with a stimulating odor and sour taste.
3. Chloride : Not more than 1.46 ppm of Cl.
4. Sulfate : Not more than 6.5 ppm of  $SO_4$ .
5. Heavy metals : Not more than 10 ppm (as Pb).
6. Readily oxidizable matter : Add 0.3 mL of 0.1 N potassium permanganate solution to 20 mL of the sample, the color of the solution should not disappear within 30 minutes.
7. Non-volatile residue : Not more than 0.01%.
8. Formaldehyde : Add 0.1 g of chromo tropic acid and 5 mL of sulfuric acid to 1 mL of the sample. After heated in water bath for 30 minutes, cool it down. Add cold water to make a 250 mL solution, the liquid color should not be thicker than that of the 1 mL of formaldehyde standard solution that is treated with the same process. (1 mL=HCHO 0.01 mg)
9. Category : Food Additives Category 11
10. Uses : Seasoning Agents.

## Acetic Acid, Glacial

<b>Synonyms</b>	INS No. 260
<b>Definition</b>	Acetic acid is manufactured by aerial oxidation of C5-C6 fractions of aliphatic hydrocarbons, and separation of the various acids by distillation. Also by oxidation of acetaldehyde, methanol and of butane or as the reaction product of methanol and carbon dioxide.
Chemical names	Acetic acid, ethanoic acid
C.A.S. number	64-19-7
Chemical formula	CH <sub>3</sub> COOH
Structural formula	
Formula weight	60.05
Assay	Not less than 99.5%
<b>Description</b>	Colourless liquid, having a pungent characteristic odour
<b>Characteristics</b>	
Identification	
Solubility	Miscible with water, ethanol, glycerol and diethyl ether
Test for acid	1 in 3 aqueous solution is acidic
Test for acetate	Passes test
Purity	
Solidification point	Not lower than 15.6°C
Non-volatile residue	Not more than 0.01% after evaporation of 20 g of the sample and holding at 100°C for 2 h.
Readily oxidizable substances	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 color does not disappear within 30 min.
Lead	Not more than 0.5 mg/kg
<b>Category</b>	Food additives category 11
<b>Functional uses</b>	Seasoning Agents

§ 11022

DL-Malic Acid

**Synonyms**

2-Hydroxybutanedioic acid; INS No. 296

**Definition**

Chemical names

dl-Malic acid, 2-Hydroxybutanedioic acid, Hydroxysuccinic acid

CAS NUMBER

6915-15-7

Chemical formula

C<sub>4</sub>H<sub>6</sub>O<sub>5</sub>

Molecular weight

134.1

Assay

Not less than 99.0%

**Appearance**

White or off-white crystalline powder or particle.

**Characteristics**

**Identification**

Solubility

Very soluble in water, soluble in ethanol.

Melting range

127 - 132°C

Passes test.

Test for malate

Test 5 mL of a 1 in 20 solution of the sample, neutralized with ammonia TS.

**Purity**

Fumaric and maleic acid

Not more than 1.0% of fumaric acid and not more than 0.05% of maleic acid.

Lead

Not more than 2 mg/kg.

**Category**

Food Additives Category 11

**Uses**

Seasoning Agents.

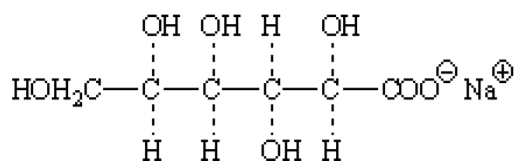
## Sodium DL-Malate

<b>Synonyms</b>	Malic acid sodium salt; INS No. 350(ii)
<b>Definition</b>	
Chemical names	Disodium DL-malate, hydroxybutanedioic acid disodium salt
CAS NUMBER	676-46-0
Chemical formula	Hemihydrate: $C_4H_4Na_2O_5 \cdot 1/2 H_2O$ Trihydrate: $C_4H_4Na_2O_5 \cdot 3 H_2O$
Molecular weight	Hemihydrate: 187.1 Trihydrate: 232.1
Assay	Not less than 98% and not more than 102% on the dried basis.
<b>Appearance</b>	Odorless white crystalline powder or lumps.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Soluble in water
Positive test for sodium	Passes test
Test for malate	Passes test (Test a 1 in 20 solution)
<b>Purity</b>	
Loss on drying	Hemihydrate: Not more than 7% (130°C, 4 hr) Trihydrate: 20.5% - 23.5% (130°C, 4 hr)
Alkalinity	Not more than 0.2% as $Na_2CO_3$ .  Dissolve 1 g of the sample in 20 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS. If a pink color is produced, add 0.4 mL of 0.1 N sulfuric acid. The color of the solution disappears.
Fumaric and maleic acid	Not more than 1.0% of fumaric acid and not more than 0.05% of maleic acid.
Lead	Not more than 2 mg/kg
<b>Category</b>	Food Additives Category 11
<b>Uses</b>	Seasoning Agents.

# Sodium Gluconate

Chemical formula:  $C_6H_{11}NaO_7$

Molecular weight: 218.14



1. Assay : Not less than 98%.
2. Appearance : White to tan, granular to fine, crystalline powder.
3. Solubility : Very soluble in water, slightly soluble in ethanol.
4. Reducing substances : Not more than 1.0% calculated as D-glucose.
5. Lead : Not more than 2 mg/kg.
6. Category : Food Additives Category 11
7. Uses : Seasoning Agents.

Glucono- $\delta$ -LactoneChemical formula:  $C_6H_{10}O_6$ 

Molecular weight: 178.15

1. Assay : Not less than 99.0% on the dried basis (105°C, 2 h)
2. Appearance : White, odorless or nearly odorless crystals or crystalline powder. The taste is sweet at first and then becomes sour.
3. Solution : Dissolve 1 g of the sample in 10 mL of water, the solution should be less than "almost clear" and colorless.
4. Chloride : Not more than 0.035% of Cl.
5. Sulfate : Not more than 0.024% of  $SO_4$ .
6. Arsenic : Not more than 1 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Calcium : Dissolve 1 g of the sample in 10 mL of water, neutralize with ammonia TS and add 1 mL of ammonium oxalate TS. No precipitate occurs.
9. Iron : Dissolve 0.5 g of the sample in 5 mL of water, mix with 1 drop of hydrochloric acid. Then add 3 drops of potassium ferrocyanide TS. The solution should not appear blue immediately.
10. Sucrose or reducing sugar : Boil 0.5 g of the sample, 10 mL of water and 2 mL of dilute hydrochloric acid for 2 minutes. Add 5 mL of sodium carbonate test solution after cooling. After standing for 5 minutes, add water to make the solution 20 mL. Add 2 mL of Fehling's reagent to 5 mL of the sample and boil for 1 minute. Orange-red precipitate does not form immediately.
11. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1% of its weight.
12. Residue on ignition : Not more than 0.1%.
13. Category : Food Additives Category 11
14. Uses : Seasoning Agents.

## Glycine

**Synonyms** Aminoacetic acid, Aminoethanoic acid, Glycocoll

**Definition**

Chemical names Glycine

CAS NUMBER 56-40-6

Molecular formula  $C_2H_5O_2N$

Molecular weight 75.07

Assay Not less than 98.5% on the dried basis.

**Appearance** White crystal or crystalline powder.

**Characteristics****Identification**

Infra-red absorption spectrum analysis The maximum absorption wavelength of the sample should be the same as the standard product.

**Purity**

Residue on ignition Not more than 0.1%.

Loss on drying Dry it at 105°C for 3 hours: it loses not more than 0.2% of its weight.

Arsenic Not more than 3 mg/kg.

Lead Not more than 5 mg/kg.

**Category** Food Additives Category 11

**Uses** Seasoning Agents.

## DL-Alanine

Chemical formula:  $C_3H_7O_2N$ 

Molecular weight: 89.10

1. Assay : Not less than 98.5% on the dried basis (105°C, 3 h)
2. Appearance : Colorless to white crystalline powder, with a sweet taste.
3. Solution and pH : When 1 g of the sample is dissolved in 10 mL of water, the solution should be clear and the pH is 5.5 – 7.0.
4. Chloride : Not more than 0.02% of Cl.
5. Ammonium salt : Not more than 0.03% of  $NH_4$ .
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Other amino acids : Test for other amino acid of “L-aspartate” is applicable.
9. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.3% of its weight..
10. Residue on ignition : Not more than 0.2%.
11. Category : Food Additives Category 11
12. Uses : Seasoning Agents.



## Sodium 5'- Inosinate

Chemical formula:  $C_{10}H_{11}O_8N_4PNa_2$ 

Molecular weight: 392.19

1. Assay : 97~102%.
2. Appearance : Colorless to white crystal or white crystalline powder, having a characteristic odor.
3. Solution : Dissolve 0.5 g of the sample in 10 mL of water, the solution should be less than "almost clear" and colorless.
4. pH : 7.0~8.5 (1 in 20 soln)
5. Ammonium salt : Not more than 0.02% of  $NH_4$ .
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Amino acid : Not detectable.
9. Absorbance ratio : The ratio  $A_{250}/A_{260}$  is between 1.55 and 1.65, and the ratio  $A_{280}/260$  is between 0.20 and 0.30 in a 1 in 50,000 solution of the sample in 0.01 N hydrochloric acid.
10. Other nucleotides : Dissolve 1 g of the sample in water to make a 100 mL solution. Take 0.01 mL of the solution to perform filter paper chromatography. When the developing solution drops about 30 cm from the origin, stop unfolding. Air-dry the filter paper, observe the back of the filter paper with ultraviolet light at a wavelength of about 250 nm in the dark. Only one spot should exist.
- Suspension : A 160:3:40 mixture of saturated ammonium sulfate solution, tert-butyl alcohol, and 0.025 N ammonium, respectively.
- Filter paper : Chromatography filter paper No.2
11. Water : Not more than 28.5% (Karl Fischer Method)
12. Category : Food Additives Category 11
13. Uses : Seasoning Agents.

Sodium 5'– Guanylate

Chemical formula:  $C_{10}H_{12}O_8N_5PNa_2$

Molecular weight: 407.20

1. Assay : Not less than 97.0% and not more than 102.0% calculated on the dried basis.  
(120°C, 4 h)
2. Appearance : Colorless to white crystal or white crystalline powder, having a  
characteristic odor.
3. Solution : Dissolve 0.1 g of the sample in 10 mL of water, the solution should be less  
than "almost clear" and colorless.
4. pH : 7.0~8.5 (1 in 20 soln)
5. Ammonium salt : Not more than 0.02% of  $NH_4$ .
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Amino acid : Not detectable.
9. Spectrophotometry : A 1 in 50,000 solution of the sample in 0.01 N hydrochloric acid exhibits an  
absorbance maximum at  $256\pm 2nm$ . The ratio  $A_{250}/A_{260}$  is between 0.95 and  
1.03, and the ratio  $A_{280}/260$  is between 0.36 and 0.71.
10. Other nucleic acid resolvent : Test method for other nucleic acid resolvent of "5'-hypoxanthine  
phosphate disodium" is applicable.
11. Loss on drying : Dry it at 120° for 4 hours: it loses not more than 25% of its weight.
12. Category : Food Additives Category 11
13. Uses : Seasoning Agents.

## Phosphoric Acid

Chemical formula:  $\text{H}_3\text{PO}_4$ 

Molecular weight: 98.00

1. Assay : Not less than 85%.
2. Appearance : Clear, colorless, odorless, viscous liquid.
3. Density : Not less than 1.69.
4. Solution : Dissolve 4 mL of the sample in 6 mL of ethanol. The solution should be less than "almost clear" and colorless.
5. Sulfate : Not more than 0.03% of  $\text{SO}_4$ .
6. Arsenic : Not more than 3 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Readily oxidizable matter : Dissolve 7 g of the sample in 5 mL of water, add 0.2 mL of 0.1 N potassium permanganate solution. The red color does not disappear within 10 minutes when heated on water bath.
9. Category : Food Additives Category 11
10. Uses : Seasoning Agents.

§ 11036

Potassium Chloride

The same as § 08063

## Calcium 5'-Ribonucleotide

1. Description : A mixture of calcium inosine-5'-monophosphate, calcium guanosine-5'-monophosphate, calcium cytidine-5'-monophosphate and calcium uridine-5'-monophosphate, or a mixture of calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate. Odorless, white or off-white crystals or powder, having a characteristic taste.
2. Assay : The anhydrous form of the sample contains not less than 97% and not more than 102% of calcium 5'-ribonucleotide. Calcium inosine-5'-monophosphate and calcium guanosine-5'-monophosphate accounts for more than 95%.
3. pH : Add 200 mL of water to 0.1 g of the sample and heat in a water bath until it dissolves. After cooling, the pH of the solution is 7.0-8.0 (1 in 2,000 soln).
4. Arsenic : Not more than 4 ppm (as  $\text{As}_2\text{O}_3$ ).
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Water soluble substances : Not more than 8%.
7. Water : Not more than 23%.
8. Category : Food Additives Category 11
9. Uses : Seasoning Agents.

## Caffeine

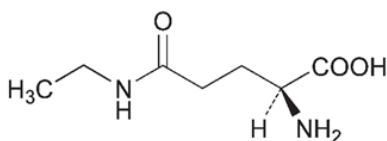
Chemical formula:  $C_8H_{10}N_4O_2$ 

Molecular weight: 194.19

1. Assay : Not less than 98.5% and not more than 101.0% on the dried basis
2. Appearance : The sample is anhydrous or monohydrated white powder or white flash needle, odorless and bitter. The solution is neutral on litmus paper. The hydrated form can be weathered in the air.
3. Description : 1 g of the hydrated sample is soluble in about 50 mL of water, 75 mL of alcohol, 60 mL of chloroform and 600 mL of ether.
4. Identification : (1) Take 5 mg of the sample in a magnetic dish and dissolve it in 1 mL of hydrochloric acid. Then add 50 mg of potassium chlorate and evaporate to dryness in a steam bath. Place the magnetic dish on a vessel containing a few drops of ammonia TS. The residue is purple. Add lye, and the purple color disappears.  
(2) Add tannic acid TS to the saturated solution of the sample, and the precipitate forms. However, the precipitate disappears after adding an excess of tannic acid TS.  
(3) Add 5 drops of iodine TS to 5 mL of the saturated solution of the sample. No precipitation should occur. However, a reddish brown precipitate can be produced by adding 3 drops of the diluted hydrochloric acid TS. If a little excess of sodium hydroxide TS is added, the precipitate dissolves.
5. Melting range : 235~237.5°C.
6. Other alkali : Add a few drops of 5 mL of potassium iodide TS that contains mercury to 5 mL of aqueous solution of the sample (1 g of the sample in 50 mL of water). No precipitation forms.
7. Arsenic : Not more than 3 ppm (as As).
8. Lead : Not more than 10 ppm.
9. Heavy metals : Not more than 20 ppm (as Pb).
10. Readily carbonizable substance : Dissolve 500 gm of the sample in 5 mL of sulfuric acid TS. The color produced should not be darker than the Matching Fluid D.
11. Water : Anhydrous: not more than 0.5%. Hydrated: not more than 8.5%.

12. Residue on : Not more than 0.1%.  
ignition
13. Category : Food Additives Category 11
14. Uses : Seasoning Agents.

## L-Theanine

Chemical formula:  $C_7H_{14}N_2O_3$ 

Molecular weight: 174.2

Chemical names: (2*S*)-2-Amino-4-(*N*-ethylcarbamoyl)butanoic acid

C.A.S. number: 3081-61-6

1. Assay : Not less than 98.0% and not more than 102.0% on the dried basis
2. Appearance : White crystalline powder, odorless, with a slightly characteristic and sweet taste.
3. Identification : (1) To 5 mL of a solution of L-Theanine (1 in 1000), add 1 mL of ninhydrin solution (1 in 1000), and heat for 3 minutes. A purple color develops.  
(2) Dissolve about 1 g of L-Theanine in 10 mL of diluted hydrochloric acid (1 in 2), put in a water bath that is equipped with a reflux cooler for 6 hours, and add water to 20 mL. Put 5 mL of the solution into a test tube and add 2 g of sodium hydroxide. Take another piece of red litmus paper to cover the mouth of the test tube after wetting it with water. After the tube is bathed for 5 minutes, the color of the litmus paper turns blue.
4. Specific rotation :  $[\alpha]_D^{20} = +7.7 \sim +8.5$  (Add 50 mL of water to 2.5 g of the sample)
5. Solution state : Dissolve 1 g of the sample in 20 mL of water. The solution should be colorless and almost clear.
6. pH : 5.0~6.0 (1 in 100 soln)
7. Chloride : Not more than 0.021% (as Cl).
8. Lead : Not more than 2 ppm.
9. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
10. Loss on drying : Dry it at 105°C for 3 hours: it loses not more than 0.5% of its weight.
11. Residue on ignition : Not more than 0.2%.
12. Category : Food Additives Category (11)
13. Uses : Seasoning Agents.



## Sodium Dihydrogen Citrate

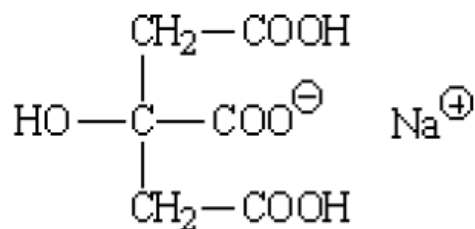
**Synonyms** : Monosodium citrate; sodium citrate monobasic; INS No. 331(i)

**Definition**

Chemical names : Monosodium citrate; monosodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid

Molecular formula :  $C_6H_7NaO_7$

Structural formula



Molecular weight : 214.11

Assay : Not less than 99.0% and not more than 101.0%.

**Appearance** : White, odorless crystals or crystalline powder.

**Characteristics****Identification**

Solubility : Freely soluble in water; practically insoluble in ethanol.

pH : 3.4-3.8 (1: 10 soln)

Test for citrate : Passes test

Positive test for

sodium

**Purity**

Loss on drying : Not more than 0.4% (105°C, 4 hr).

Oxalate : To 10 mL of a 1 in 10 solution of the sample add 5 drops of dilute acetic acid TS and 2 mL of calcium chloride TS. No turbidity develops within 1 h.

Lead : Not more than 2 mg/kg.

**Category** : Food Additives Category 11

**Uses** : Seasoning Agents.

## Category 11-1 Sweeteners

§ 11-1-001

§ 07087

### D-Sorbitol

#### Synonyms

INS No. 420(i); D-Glucitol, D-sorbitol, sorbit, sorbol

#### Definition

Chemical names

D-Sorbitol

CAS NUMBER

50-70-4

Molecular formula

$C_6H_{14}O_6$

Molecular weight

182.17

Assay

Not less than 97.0% of  $C_6H_{14}O_6$  of total glycitols and not less than 91.0% of D-sorbitol on the anhydrous basis. The term glycitols refers to compounds with the structural formula  $CH_2OH-(CHOH)_n-CH_2OH$ , where n is an integer less than or equal to 4.

#### Appearance

White hygroscopic powder, crystalline powder, flakes or granules.

#### Characteristics

##### Identification

Solubility

Very soluble in water, slightly soluble in ethanol.

Melting range

88~102°C

Thin layer

Passes test

chromatography

##### Purity

Water

Not more than 1% (Karl Fischer Method).

Sulfated ash

Not more than 0.1%.

Chloride

Not more than 50 mg/kg.

Sulfate

Not more than 100 mg/kg.

Nickel

Not more than 2 mg/kg.

Reducing sugar

Not more than 0.3%.

Total sugars

Not more than 1% (as glucose).

Lead

Not more than 1 mg/kg.

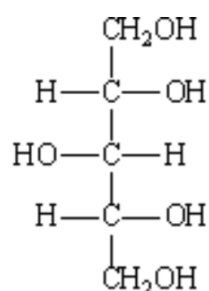
#### Category

Food Additives Category 11-1, 7.

**Uses**

Sweeteners, Food quality improvement, fermentation and food processing agents

## Xylitol

**Synonyms** INS No. 967**Definition**Chemical names XylitolC.A.S. number 87-99-0Chemical formula  $C_5H_{12}O_5$ **Structural formula**Formula weight 152.15Assay Not less than 98.5% and not more than 101.0% on the anhydrous basis**Description** White, crystalline powder, practically odourless**Characteristics**

Identification

Solubility Very soluble in water, sparingly soluble in ethanolMelting range 92 - 96°CInfrared absorption The infrared spectrum of a potassium bromide dispersion of the sample corresponds with the reference infrared spectrum belowPurityWater Not more than 0.5% (Karl Fischer Method)Sulfated ash Not more than 0.1%Nickel Not more than 2 mg/kg

Reducing sugars Not more than 0.2%

Other polyols Not more than 1.0%

<u>Lead</u>	<u>Not more than 1 mg/kg</u>
<b>Category</b>	Food additives category (7)(11-1)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Sweeteners.

Glycyrrhizin

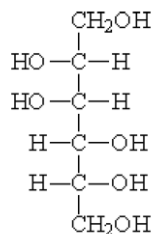
1. Assay : Not less than 95% on the dried basis (80°C, 4 h)
2. Appearance : Colorless to white crystals or powder with a strong sweet taste.
3. Solubility : Soluble in hot water, less soluble in cold water.
4. pH : 4.5~6.5 (1 in 100 soln)
5. Sulfate : Not more than 0.014% of SO<sub>4</sub>.
6. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Dry it at 80° for 4 hours: it loses not more than 5% of its weight.
9. Residue on : Not more than 8%.  
ignition
10. Category : Food Additives Category 11-1
11. Uses : Sweetening agent.

## D-Mannitol

Synonyms : Mannite; INS No. 421; CAS No. 69-65-8

Chemical formula:  $C_6H_{14}O_6$

Molecular weight: 182.17



1. Assay : Not less than 96.0% and not more than 102.0% on the dried basis.
2. Appearance : White, odorless, crystalline powder, with a sweet and cool taste.
3. Solubility : Soluble in water, very slightly soluble in ethanol; practically insoluble in ether
4. Melting range : 164 ~ 169°C.
5. Thin layer chromatography : Passes test
6. pH : 5~8 (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)
7. Specific rotation :  $[\alpha]_D^{20} = +23 \sim +25^\circ$  (Borate solution)
8. Chloride : Not more than 70 mg/kg of Cl.
9. Sulfate : Not more than 100 mg/kg ( $\text{SO}_4$ ).
10. Nickel : Not more than 2 mg/kg.
11. Lead : Not more than 1 mg/kg.
12. Reducing sugar : Not more than 0.3% (as glucose).
13. Total sugars : Not more than 1% (as glucose).
14. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 0.3% of its weight.
15. Residue on ignition : Not more than 0.1%.
16. Category : Food Additives Category 11-1, 7.
17. Uses : Sweeteners, Food quality improvement, fermentation and food processing agents

Saccharin

Chemical formula:  $C_7H_5NO_3S$

Molecular weight: 183.19

1. Assay : Not less than 98% on the dried basis (105°C, 2 h)
2. Appearance : Colorless or white crystals or a white, crystalline efflorescent powder, odorless or with a slight aroma. Has an intensely sweet taste that 10,000 times aqueous solution is still sweet.
3. Melting range : 226~230°C.
4. Solution : 1 g of the sample is dissolved in 30 mL hot water and 35 mL ethanol respectively. Both solution should be colorless and clear.
5. o-Toluenesulfonamide : Add 3 drops of ferric chloride TS to 15 mL of a hot water and 0.5 g of the sample. No precipitate or violet color appears.
6. o-Toluenesulfonamide : Not more than 100 ppm.
7. Heavy metals : Not more than 10 ppm (as Pb).
8. Readily carbonizable substance : Dissolve 0.2 g of the sample in 5 mL of sulfuric acid TS. Keep at 48°C to 50°C for 10 min. The color should not be darker than a very light brownish-yellow (Matching Fluid A).
9. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 1% of its weight.
10. Category : Food Additives Category 11-1
11. Uses : Sweetening agent.



Saccharin Sodium

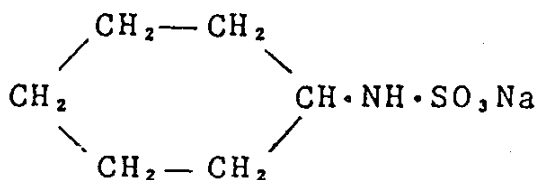
Chemical formula:  $C_7H_4O_3NNaS \cdot O \sim 2H_2O$

1. Assay : Not less than 98% of  $C_7H_4O_3NNaS$  (dried at 120°C for 4 hours)
2. Appearance : White crystals or a white, crystalline efflorescent powder, with an intensely sweet taste that 10,000 times aqueous solution is still sweet.
3. Solution : 1 g of this product (powder) is dissolved in 1.5 mL of water and 70 mL of ethanol respectively. The solution should be colorless and clear.
4. Free Acid and free alkali : Dissolve 1 g of the sample in 10 mL of freshly boiled and cooled water. Add a drop of phenolphthalein TS. No red color should appear. Add a drop of 0.1 N sodium hydroxide. A red color should appear.
5. Benzoic and salicylic acid : 0.5 g of this product is dissolved in 10 mL of water. Add 5 drops of acetic acid and 3 drops of ferric chloride test solution. No precipitate or violet color appears.
6. o-Toluenesulfonamide : Not more than 100 ppm.
7. Arsenic : Not more than 3 ppm (as  $As_2O_3$ ).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Readily carbonizable substance : Dissolve 0.2 g of the sample in 5 mL of sulfuric acid TS. Keep at 48°C to 50°C for 10 min. The color should not be darker than the Matching Fluid A.
10. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 15% of its weight.
11. Category : Food Additives Category 11-1
12. Uses : Sweetening agent.

Sodium Cyclamate

Chemical formula:  $C_6H_{12}NNaO_3S$

Molecular weight: 201.23

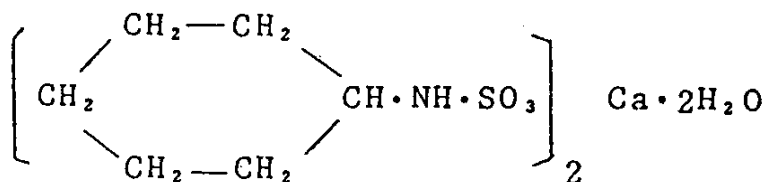


1. Description : White, odorless crystals or crystalline powder with a sweet taste. Soluble in water, practically insoluble in ethanol, ether, chloroform and benzene. The pH of its 10% solution is 5.5 to 7.5.
2. Assay :  $C_6H_{12}NNaO_3S$  Not less than 98.0%
3. Sulfate : Not more than 0.024% of  $SO_4$ .
4. Chloride : Not more than 0.014% of Cl.
5. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Loss on drying : Dry it at  $105^\circ\text{C}$  for 2 hours: it loses not more than 1.0% of its weight.
8. Category : Food Additives Category 11-1
9. Uses : Sweetening agent.

## Calcium Cyclamate

Chemical formula:  $C_{12}H_{24}O_6N_2S_2Ca \cdot 2H_2O$ 

Molecular weight: 432.58



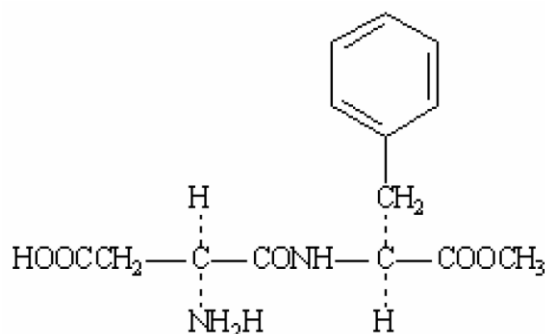
1. Description : White, odorless, sweet crystals or crystalline powder. Soluble in water, sparingly soluble in ethanol, insoluble in chloroform, ether and benzene. The pH of its 10% solution is 5.5-7.5.
2. Assay :  $C_{12}H_{24}O_6N_2S_2Ca$  Not less than 98.0%
3. Calcium : 9.9~10.3%.
4. Sulfate : Not more than 0.024% of  $SO_4$ .
5. Chloride : Not more than 0.035% of Cl
6. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Dry it at  $130^\circ$  for 4 hours: it loses not more than 9.5% of its weight.
9. Category : Food Additives Category 11-1
10. Uses : Sweetening agent.

## Aspartame

Chemical names : N-L- $\alpha$ -Aspartyl-L-Phenylalanine 1-Methyl Ester; APM

Chemical formula:  $C_{14}H_{18}N_2O_5$

Molecular weight: 294.31



1. Description : White, odorless, crystalline powder, having a strong sweet taste. Slightly soluble in water and in ethanol. The pH of its 0.8% solution is 4 - 6.5.
2. Identification
  - A. Dissolve 2 g of ninhydrin in 75 mL of dimethylsulfoxide, add 62 mg of hydrindantin, dilute to 100 mL with 4 M lithium acetate buffer solution (pH 9), and filter. Transfer about 10 mg of the sample to a test tube, add 2 mL of the reagent solution, and heat. A dark purple color is formed.
  - B. Dissolve about 20 mg in 1 mL of methanol, add 0.5 mL of methanol saturated with hydroxylamine hydrochloride, mix, and then add 0.3 mL of 5 N potassium hydroxide in methanol. Heat the mixture to boiling, then cool, adjust the pH to between 1 and 1.5 with hydrochloric acid TS, and add 0.1 mL of ferric chloride TS. A burgundy color is produced.
3. Assay :  $C_{14}H_{18}N_2O_5$  98.0% ~ 102.0% (on the dried basis; 105°C, 4 hr).
4. 5-Benzyl-3,6-dioxo-2-piperazineacetic Acid: Not more than 1.5%.
5. Specific rotation :  $[\alpha]_D^{20} = +12.5^\circ \sim +17.5^\circ$  (on the dried basis; 105°C, 4 hr).
6. Transmittance : Moderate.
7. Arsenic : Not more than 3 ppm (as As).
8. Heavy metals : Not more than 10 ppm (as Pb).
9. Loss on drying : Not more than 4.5%.
10. Residue on ignition : Not more than 0.2%.
11. Category : Food Additives Category 11-1

12. Uses : Sweetening agent.

## Steviol glycosides

### Synonyms

Steviol Glycosides from INS No. 960a

*Stevia Rebaudiana* Bertoni

Enzyme modified Steviol -

Glycosides

### Definition

Steviol glycosides consist of a mixture of compounds containing a steviol backbone conjugated to any number or combination of the principal sugar moieties (glucose, rhamnose, xylose, fructose, arabinose, galactose and deoxyglucose) in any of the orientations occurring in the leaves of *Stevia rebaudiana* Bertoni.

Steviol Glycosides from *Stevia Rebaudiana* Bertoni The product is obtained from the leaves of *Stevia rebaudiana* Bertoni. The leaves are extracted with hot water and the aqueous extract is passed through an adsorption resin to trap and concentrate the component steviol glycosides. The resin is washed with a solvent alcohol to release the glycosides and the product is recrystallized from methanol or aqueous ethanol. Ion exchange resins may be used in the purification process. The final product may be spray-dried.

Enzyme modified Steviol Glycosides The product is obtained from the enzymatic treatment of purified steviol glycosides extracted from the leaves of *Stevia rebaudiana* Bertoni. The purified leaf extract is treated with enzymes produced by non-toxicogenic non-pathogenic strains of *Pichia pastoris* and *Escherichia coli* that have been genetically modified with genes from multiple donor organisms (listed below) to produce glucosyltransferase and sucrose synthase. The resulting material is heated and filtered to denature and remove the enzymes. The raw product is concentrated using resin adsorption/desorption or solid/liquid filtration, followed by purification and preparation of the product of commerce using processes that may include decolourization, crystallization, and spray drying.

Enzyme production organism

Gene source

*Pichia pastoris*

*Horedum vulgare* L

*Stevia rebaudiana* Bertoni

*Vigna radiate*

*Escherichia coli*

*Acidithiobacillus caldus*

*Arapidopsis thaliana*

*Solanum tuberosum*

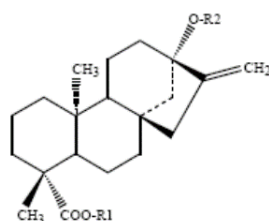
*Stevia rebaudiana* Bertoni

Chemical names See Appendix 1

C.A.S. number See Appendix 1

Chemical formula See Appendix 1

Structural formula



Steviol ( $R_1 = R_2 = H$ ) is the aglycone of the steviol glycosides.

Glc, Rha, Fru, deoxyGlc, Gal, Ara and Xyl represent, respectively, glucose, rhamnose, fructose, deoxyglucose xylose, galactose, arabinose and xylose sugar moieties.

Assay Not less than 95% on the dried basis.

**Description** White to light yellow powder, odourless or having a slight characteristic odour.

About 200 - 300 times sweeter than sucrose.

### Characteristics

#### Identification

Solubility Very slightly soluble to freely soluble in water; slightly soluble to freely soluble in a mixture of ethanol and water (50:50 v/v).

HPLC chromatographic profile Correspond to steviol glycoside standards

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, 2 h)
Residual solvents	Not more than 200 mg/kg methanol and not more than 5000 mg/kg ethanol
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Microbiological criteria	Total (aerobic) plate count: Not more than 1,000 CFU/g Yeasts and moulds: Not more than 200 CFU/g <i>E. coli</i> : Negative in 1 g <i>Salmonella</i> : Negative in 25 g
<b>Category</b>	Food additives category (11-1)
<b>Functional uses</b>	Sweeteners



## <Appendix 1>

Summary of Formula, Molecular weight, steviol equivalent and sugar moieties in Identified Steviol Glycosides from the Leaves of *Stevia rebaudiana* Bertoni.  
[Adapted from Purkayastha & Kwok (2020)]

#	Common Name	CAS Number	Trivial Formula	Mol. Wt	Steviol Equivalent	R1	R2	Reference
<b>1. Steviol + Glucose (SvGn)</b>								
1.01	Steviolmonoside		SvG1	481	0.66	H	Glcβ1-	Ohta et al. (2010)
1.02	Steviolmonoside A		SvG1	481	0.66	Glcβ1-	H	Gardana et al. (2010)
1.03	Rubusoside	64849-39-4	SvG2	643	0.49	Glcβ1-	Glcβ1-	Ohta et al. (2010)
1.04	Steviolbioside	41093-60-1	SvG2	643	0.49	H	Glcβ(1-2)Glcβ1-	Kohda et al. (1976)
1.05	Stevioside	57817-89-7	SvG3	805	0.40	Glcβ1-	Glcβ(1-2)Glcβ1-	Bridel and Lavielle (1931)
1.06	Stevioside A		SvG3	805	0.40	Glcβ(1-2)Glcβ1-	Glcβ1-	Wu et al. (2012)
1.07	Rebaudioside B	58543-17-2	SvG3	805	0.4	H	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Kohda et al. (1976)
1.08	Rebaudioside G		SvG3	805	0.4	Glcβ1-	Glcβ(1-3)Glcβ1-	Ohta et al. (2010)
1.09	Stevioside B		SvG3	805	0.4	Glcβ(1-3)Glcβ1-	Glcβ1-	Chaturvedula and Zamora (2014)
1.10	Rebaudioside E	63279-14-1	SvG4	967	0.33	Glcβ(1-2)Glcβ1-	Glcβ(1-2)Glcβ1-	Sakamoto et al. (1977a)
1.11	Rebaudioside A	58543-16-1	SvG4	967	0.33	Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Kohda et al. (1976)
1.12	Rebaudioside A2		SvG4	967	0.33	Glcβ1-	Glcβ(1-6)Glcβ(1-2)Glcβ1-	Chaturvedula and Prakash (2011a)
1.13	Rebaudioside D	63279-13-0	SvG5	1129	0.28	Glcβ(1-2)Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Sakamoto et al. (1977a)
1.14	Rebaudioside I		SvG5	1129	0.28	Glcβ(1-3)Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
1.15	Rebaudioside L		SvG5	1129	0.28	Glcβ1-	Glcβ(1-6)Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
1.16	Rebaudioside Q2		SvG5	1129	0.28	Glcα(1-2)Glcα(1-4)Glcβ1-	Glcβ(1-2)Glcβ1-	Chaturvedula and Prakash (2011b)
1.17	Rebaudioside Q		SvG5	1129	0.28	Glcβ1-	Glcα(1-4)Glcβ(1-2)[Glcβ(1-3)]	-

## <Appendix 1>

Summary of Formula, Molecular weight, steviol equivalent and sugar moieties in Identified Steviol Glycosides from the Leaves of *Stevia rebaudiana* Bertoni. [Adapted from Purkayastha & Kwok (2020)]

									Glcβ1-	
1.18	Rebaudioside I2		SvG5	1129	0.28			Glcβ1-	Glcα(1-3)Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Chaturvedula et al. (2011a)
1.19	Rebaudioside Q3		SvG5	1129	0.28			Glcβ1-	Glcα(1-4)Glcβ(1-3)[Glcβ(1-2)] Glcβ1-	Chaturvedula et al. (2011a)
1.20	Rebaudioside I3		SvG5	1129	0.28			Glcβ(1-2)[Glcβ(1-6)] Glcβ1-	Glcβ(1-2)Glcβ1-	Chaturvedula et al. (2011a)
1.21	Rebaudioside AM	2222580-26-7	SvG5	1129	0.28			Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-2)Glcβ1-	Prakash and Ma (2018)
1.22	Rebaudioside M	1220616-44-3	SvG6	1291	0.25			Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
1.23	Rebaudioside 1h		SvG7	1453	0.22			Glcβ(1-3)Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Prakash and Ma (2018)
1.24	Rebaudioside IX		SvG9	1778	0.18			Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-3)[Glcβ(1-3) [Glcβ(1-2)] Glcα(1-6)Glcβ(1-2)] Glcβ1-	Prakash and Ma (2018)
<b>2. Steviol + Rhamnose + Glucose (SvR1Gn)</b>										
2.01	Dulcoside A	64432-06-0	SvR1G2	789	0.40			Glcβ1-	Rhaα(1-2)Glcβ1-	Kobayashi et al. (1977)
2.02	Dulcoside B		SvR1G2	789	0.40			H	Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
2.03	Rebaudioside C	63550-99-2	SvR1G3	951	0.33			Glcβ1-	Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Sakamoto et al. (1977b)
2.04	Rebaudioside C2		SvR1G3	951	0.33			Rhaα(1-2)Glcβ1-	Glcβ(1-2)Glcβ1-	Purkayastha et al. (2019)
2.05	Rebaudioside S		SvR1G3	951	0.33			Rhaα(1-2)Glcβ1-	Glcα(1-2)Glcβ1-	Ibrahim et al. (2016)
2.06	Rebaudioside H		SvR1G4	1113	0.29			Glcβ1-	Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)] Glcβ1-	Ohta et al. (2010)
2.07	Rebaudioside K		SvR1G4	1113	0.29			Glcβ(1-2)Glcβ1-	Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
2.08	Rebaudioside K2		SvR1G4	1113	0.29			Glcβ(1-6)Glcβ1-	Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha et al. (2019)
2.09	Rebaudioside J		SvR1G4	1113	0.29			Rhaα(1-2)Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)
2.10	Rebaudioside N	1220616-	SvR1G5	1275	0.25			Rhaα(1-2)[Glcβ(1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)

## <Appendix 1>

Summary of Formula, Molecular weight, steviol equivalent and sugar moieties in Identified Steviol Glycosides from the Leaves of *Stevia rebaudiana* Bertoni.  
[Adapted from Purkayastha & Kwok (2020)]

		46-5					3]] Glcβ1-			
2.11	Rebaudioside N2		SVR1G5	1275	0.25		Glcβ(1-2)[Glcβ(1-3)]Glcβ1-3]] Glcβ1-	Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Prakash and Ma (2018)	
2.12	Rebaudioside N6		SVR1G5	1275	0.25		Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Glcβ(1-2)Glcβ1-	Prakash and Ma (2018)	
2.13	Rebaudioside O	1220616-48-7	SVR1G6	1437	0.22		Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Ohta et al. (2010)	
2.14	Rebaudioside O2		SVR1G6	1437	0.22		Glcβ(1-4)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha (2016)	
2.15	Rebaudioside O5		SVR1G6	1437	0.22		Glcβ(1-2)[Glcβ(1-3)]Glcβ1-3]] Glcβ1-	Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Prakash and Ma (2018)	
2.16	Rebaudioside O6		SVR1G7	1600	0.20		Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Glcβ(1-6)Glcβ(1-3)[Glcβ(1-2)]Glcβ1-	Prakash and Ma (2018)	
2.17	Rebaudioside O7		SVR2G6	1584	0.20		Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1-	Prakash and Ma (2018)	
<b>3. Steviol + Xylose + Glucose (SvX1Gn)</b>										
3.01	Stevioside F		SvX1G2	775	0.41		Glcβ1-	Xylβ(1-2)Glcβ1-	Chaturvedula and Prakash (2011c)	
3.02	Rebaudioside F	438045-89-7	SvX1G3	937	0.34		Glcβ1-	Xylβ(1-2)[Glcβ(1-3)]Glcβ1	Starratt et al. (2002)	
3.03	Rebaudioside F2		SvX1G3	937	0.34		Glcβ1-	Glcβ(1-2)[Xylβ(1-3)]Glcβ1-	Chaturvedula and Prakash (2011c)	
3.04	Rebaudioside F3		SvX1G3	937	0.34		Xylβ(1-6)Glcβ1-	Glcβ(1-2)Glcβ1-	Chaturvedula et al. (2011b)	
3.05	Rebaudioside R		SvX1G3	937	0.34		Glcβ1-	Glcβ(1-2)[Glcβ(1-3)] Xylβ1-	Ibrahim et al. (2016)	
3.06	Rebaudioside U		SvX1G4	1099	0.29		Xylβ(1-2)Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha et al. (2019)	
3.07	Rebaudioside U2		SvX1G4	1099	0.29		Xylβ(1-2)[Glcβ(1-3)]	Glcβ(1-2)Glcβ1-	Purkayastha (2016)	

## <Appendix 1>

Summary of Formula, Molecular weight, steviol equivalent and sugar moieties in Identified Steviol Glycosides from the Leaves of *Stevia rebaudiana* Bertoni. [Adapted from Purkayastha & Kwok (2020)]

3.08	Rebaudioside U3	SvX1G4	1099	0.29	Glcβ1- Xylβ(1-2)[Glcβ(1-4)] Glcβ1-	Glcβ(1-2)Glcβ1-	Purkayastha et al. (2019)
3.09	Rebaudioside V	SvX1G5	1261	0.25	Glcβ(1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-2)[Xylβ(1-3)]Glcβ1-	Purkayastha et al. (2019)
3.10	Rebaudioside V2	SvX1G5	1261	0.25	Xylβ (1-2)[Glcβ(1-3)] Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Prakash and Chaturvedula (2013)
<b>4. Steviol + Arabinose + Glucose (SvA1Gn)</b>							
4.01	Rebaudioside W	SvA1G4	1098	0.29	Glcβ(1-2)[Araβ(1-3*)] Glcβ1	Glcβ(1-2)Glcβ1-	Purkayastha (2016)
4.02	Rebaudioside W2	SvA1G4	1098	0.29	Araβ(1-2*)Glcβ1	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha (2016)
4.03	Rebaudioside W3	SvA1G4	1098	0.29	Araβ(1-6)Glcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha et al. (2019)
4.04	Rebaudioside Y	SvA1G5	1260	0.25	Glcβ(1-2)[Araβ(1-3*)] Glcβ1	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha et al. (2019)
<b>5. Steviol + Fructose + Glucose (SvF1Gn)</b>							
5.01	Rebaudioside A3	SvF1G3	967	0.33	Glcβ1-	Glcβ(1-2)[Fruβ(1-3)]Glcβ1-	Chaturvedula et al. (2011c)
<b>6. Steviol + Galactose + Glucose (SvGa1Gn)</b>							
6.01	Rebaudioside T	SvGa1G4	1129	0.28	Glcβ(1-2)Glcβ1-	Galβ(1-2)[Glcβ(1-3)]Glcβ1-	Purkayastha (2016)
<b>7. Steviol + Deoxyglucose + Glucose (SvdG1Gn)</b>							
7.01	Stevioside D	SvdG1G2	789	0.40	Glcβ1-	6-deoxyGlcβ(1-2)Glcβ1-	Chaturvedula and Prakash (2011d)
7.02	Stevioside E	SvdG1G3	951	0.33	Glcβ1-	6-deoxyGlcβ(1-2)[Glcβ(1-3)] Glcβ1-	Chaturvedula and Prakash (2011d)
7.03	Stevioside E2	SvdG1G3	951	0.33	6-deoxyGlcβ1-	Glcβ(1-2)[Glcβ(1-3)]Glcβ1-	Chaturvedula et al. (2011d)

# Licorice Extracts

1. Description : Extract of *Glycyrrhiza glabra* L. or other plants' roots and stems. The main ingredient of its sweet taste is glycyrrhizin. The sample is dark brown crystal, powder, granule, liquid, cream, scale or block, etc., with a unique sweet taste, odorless or with a characteristic odor.
2. Methanol : Not detectable.
3. Arsenic : Not more than 3 ppm (as As).
4. Lead : Not more than 10 ppm.
5. Heavy metals : Not more than 50 ppm (as Pb).
6. Category : Food Additives Category 11-1
7. Uses : Sweetening agent.



## Acesulfame Potassium

**Synonyms**

Acesulfame K; INS No. 950

**Definition**

## Chemical names

Potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide;  
potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide

## CAS NUMBER

55589-62-3

## Chemical formula

 $C_4H_4KNO_4S$ 

## Molecular weight

201.24

## Assay

99.0%-101.0% on the dried basis

**Appearance**

Odorless, white crystalline powder.

**Characteristics****Identification**

## Solubility

Freely soluble in water, very slightly soluble in ethanol

## Spectrophotometry

Dissolve 10 mg of the sample in 1,000 mL of water. The solution shows an  
absorbance maximum at  $227 \pm 2$  nm

## 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 cobaltinitrite to a solution of  
0.2 g of the sample in 2 mL of acetic acid TS and 2 mL of water. A yellow  
precipitate is produced.

**Purity**

## Loss on drying

Dry it at  $105^\circ\text{C}$  for 2 hours: it loses not more than 1.0% of its weight.

## pH

5.5 - 7.5 (1% soln)

## 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

**Category**

Food Additives Category 11-1

**Uses**

Sweetening agent.

Ammoniated Glycyrrhizinate

1. Ash : Not more than 2.5%.
2. Arsenic : Not more than 3 ppm (as As).
3. Heavy metals : Not more than 40 ppm (as Pb).
4. Category : Food Additives Category 11-1
5. Uses : Sweetening agent.

# Maltitol

Chemical formula:  $C_{12}H_{24}O_{11}$

Molecular weight: 344.31

1. Description : White crystalline masses. Very soluble in water, slightly soluble in ethanol.
2. Assay : D-maltitol: Not less than 98.0%.
3. Melting range : 148~151°C.
4. Specific rotation :  $[\alpha]_D^{20} = +105.5 \sim +108.5^\circ$  (Dissolve 5 g of this product in 100 mL of water)
5. Water : Not more than 1% (Karl Fischer Method)
6. Sulfated ash : Not more than 0.1%.
7. Reducing sugar : Not more than 0.1%.
8. Chloride : Not more than 50 ppm.
9. Sulfate : Not more than 100 ppm.
10. Nickel : Not more than 2 ppm.
11. Lead : Not more than 1 ppm.
12. Heavy metals : Not more than 10 ppm (as Pb).
13. Category : Food Additives Category 11-1, 7.
14. Uses : Sweeteners, Food quality improvement, fermentation and food processing agents



## Maltitol Syrup

<b><u>Synonyms</u></b>	<u>Hydrogenated high maltose-content glucose syrup, hydrogenated glucose syrup, dried maltitol syrup, maltitol syrup powder; INS No. 965(ii)</u>
<b><u>Definition</u></b>	<u>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. The article of commerce is typically supplied as a syrup. It may also be dried and supplied as a solid product</u>
Assay	<u>Not less than 99.0% of total hydrogenated saccharides on the anhydrous basis and not less than 50.0% of maltitol on the anhydrous basis</u>
<b><u>Description</u></b>	<u>Colourless and odourless, clear viscous liquids or white crystalline masses</u>
<b><u>Characteristics</u></b>	
<u>Identification</u>	
<u>Solubility</u>	<u>Very soluble in water, slightly soluble in ethanol</u>
<u>Thin layer chromatography</u>	<u>Passes test</u>
<u>Purity</u>	
<u>Water</u>	<u>Not more than 31% (Karl Fischer)</u>
Sulfated ash	Not more than 0.1%
Chloride	Not more than 50 mg/kg
Sulfate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Reducing sugars	Not more than 0.3%
Lead	Not more than 1 mg/kg
<b>Category</b>	Food additives category (07) (11-1)
<b>Functional uses</b>	Food quality improvement, fermentation and food processing agents; Sweeteners.

## Isomalt (Hydrogenated Palatinose)

Chemical names : A mixture of 6-O-alpha-D-glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-alpha-D-glucopyranosyl-D-mannitol dihydrate (1,1-GPM).

Synonyms : Hydrogenated isomaltulose; INS No. 953; CAS No. 64519-82-0

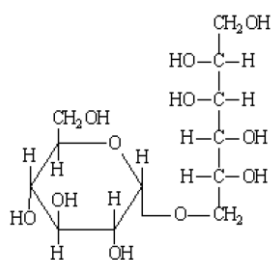
Chemical :  $C_{12}H_{24}O_{11}$  (1,6-GPS)

Molecular weight:

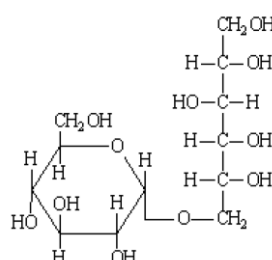
formula  $C_{12}H_{24}O_{11} \cdot 2H_2O$  (1,1-GPM)

344.32

380.32



6-O-alpha-D-glucopyranosyl-D-sorbitol



1-O-alpha-D-glucopyranosyl-D-mannitol

(without molecules of crystal water)

1. Assay : Not less than 98% of hydrogenated mono- and disaccharides and not less than 86% of the mixture of 1,6-GPS and 1,1-GPM.
2. Description : Odorless, white, crystalline slightly hygroscopic substance.
3. Solubility : Soluble in water, very slightly soluble in ethanol.
4. Identification : 0.5 g of the sample is soluble in 100 mL of water. Spot on a silicone plate with a thickness of 0.2 mm and a length of about 12 cm (Kieselgel 60 F254 or the same size).  
The sample can be expanded to get 1,6-GPS and 1,1-GPM
5. Water : Not more than 7.0% (Karl Fischer Method)
6. Sulfated ash : Not more than 0.05%.
7. D-Mannitol : Not more than 3%.
8. D-Sorbitol : Not more than 6% .
9. Reducing sugar : Not more than 13%.
10. Nickel : Not more than 2 mg/kg.
11. Lead : Not more than 1 mg/kg.
12. Heavy metals : Not more than 10 mg/kg.
13. Category : Food Additives Category 11-1, 7.
14. Uses : Sweeteners, Food quality improvement, fermentation and food processing agents

Lactitol

Chemical formula:  $C_{12}H_{24}O_{11}$

Molecular weight: 344.32

1. Assay : Not less than 95% and not more than 102% on the dried basis.
2. Description : Sweet tasting crystalline powders or colorless solutions. Very soluble in water.
3. Specific rotation :  $[\alpha]_D^{25} = 13 \sim 15^\circ$  (10% w/v aqueous solution)
4. Water content : Not more than 10.5% (Karl Fischer Method)
5. Other polyols : Not more than 2.5% (on the dried basis)
6. Reducing sugar : Not more than 0.2% (on the dried basis, as glucose)
7. Chloride : Not more than 100 ppm of Cl.
8. Sulfate : Not more than 200 ppm of  $SO_4$ .
9. Sulfated ash : Not more than 0.1%.
10. Nickel : Not more than 2 ppm of Ni.
11. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
12. Lead : Not more than 1 ppm (as Pb).
13. Heavy metals : Not more than 10 ppm (as Pb).
14. Category : Food Additives Category 11-1, 7.
15. Uses : Sweeteners, Food quality improvement, fermentation and food processing agents

Monoglucuronyl Glycyrrhetic Acid

1. Assay : glycyrrhizic acid 40~45%;  
monoglucuronyl glycyrrhetic acid 15~20%.
2. Description : The sample is obtained by hydrolyzing glycyrrhizin, extract of root or stem of  
Glycyrrhiza glabra L. or other plants of the same genus, by a glucuronic acid. Yellow  
powder, odorless, with a special sweet taste. Soluble in hot water.
3. Solution : When 1 g of the sample is dissolved in 10 mL of 50%(v/v) ethanol, the solution should  
be clear.
4. pH : 5.0~6.0 (1 in 100 soln)
5. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Not more than 6.0% (80°C, 3 h)
8. Residue on  
ignition : Not more than 16%
9. Category : Food Additives Category 11-1
10. Uses : Sweetening agent.

Thaumatococcus

1. Assay : Not less than 16.0% nitrogen
2. Description : Obtained by aqueous extraction of the arils of the fruit of *Thaumatococcus daniellii* (Benth); odorless, cream-colored powder with a sweet taste, odorless. Very soluble in water; insoluble in acetone.
3. Carbohydrates : Not more than 3.0% on the dried basis.
4. Specific absorbance : The specific absorption, A1% 1 cm at the wavelength of maximum absorption (about 279 nm) shall be not less than 12.0 and not more than 12.5 determined on the dried basis and using a 1 in 100 w/v solution of the sample in water at pH 2.7.
5. Aluminum : Not more than 100 ppm.
6. Lead : Not more than 10 ppm.
7. Arsenic : Not more than 3 ppm (as As).
8. Sulfated ash : Not more than 2.0% on the dried basis.
9. Loss on drying : Not more than 9.0% (105°C to constant weight).
10. Category : Food Additives Category 11-1
11. Uses : Sweetening agent.

# Erythritol

Chemical formula: C<sub>4</sub>H<sub>10</sub>O<sub>4</sub>

Molecular weight: 122.12

1. Assay : Not less than 99.5%
2. Description : Colorless to white, odorless crystals or crystalline powder, having a sweet taste. Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.
3. Reducing sugar : Not more than 13%.
4. Lead : Not more than 1 ppm.
5. Heavy metals : Not more than 5 ppm (as Pb).
6. Loss on drying : Not more than 0.2%.
7. Residue on ignition : Not more than 0.1% (Sulfated ash)
8. Category : Food Additives Category 11-1, 7.
9. Uses : Sweeteners, Food quality improvement, fermentation and food processing agents

## Sucralose

General name : Sucralose

Chemical names : 1,6-Dichloro-1,6-dideoxy- $\beta$ -D-fructofuranosyl-4-chloro-4-deoxy- $\alpha$ -D-galactopyranoside;  
4,1-Dichloro-1,6-dideoxy- $\beta$ -D-fr

Chemical formula:  $C_{12}H_{19}Cl_3O_8$

Molecular weight: 397.64

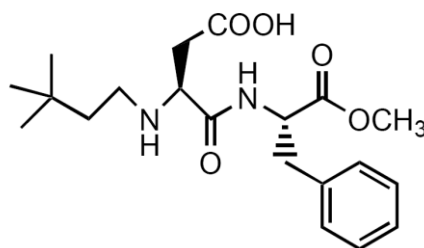
1. Description : White to off-white, practically odorless crystalline powder with a sweet taste. Freely soluble in water, methanol and ethanol; slightly soluble in ethyl acetate.
2. Identification : (1) The infrared absorption spectrum (absorption intensity may vary) obtained by the KBr disc method of the sample should be the same as the standard product.  
(2) The retention time of the major peak (except the solvent peak) in the chromatogram of the Assay Preparation is the same as that of the Standard Preparation.  
(3) The major spot in the test solution of the thin layer chromatography has the same R<sub>f</sub> value as that of the main spot of Standard Solution.
3. Assay : Not less than 98.0 and not more than 102.0% (as  $Cl_2H_{19}Cl_3O_8$  on the dried basis).
4. Heavy metals : Not more than 10 mg/kg (as Pb).
5. Arsenic : Not more than 3 mg/kg (as As).
6. Hydrolysis products : Passes test (Not more than 0.1%).
7. Methanol : Not more than 0.1%.
8. Related substances : Passes test (Not more than 0.5%).
9. Residue on ignition : Not more than 0.7%.
10. Specific rotation :  $[\alpha]_D^{20} = +84.0 \sim +87.5$  (10% w/v solution, on the dried basis).
11. Water : Not more than 2.0%.
12. Category : Food Additives Category 11-1
13. Uses : Sweetening agent.

# Neotame

Chemical names : N-[N-(3,3-Dimethylbutyl)-L- $\alpha$ -aspartyl]-L-phenylalanine 1-methyl ester

Chemical formula: C<sub>20</sub>H<sub>30</sub>N<sub>2</sub>O<sub>5</sub>

Molecular weight: 378.47



1. Definition : This product is manufactured from aspartame and 3,3-dimethylbutyraldehyde. Equimolar amounts (as As)partame and 3,3-dimethylbutyraldehyde are reacted with hydrogen gas in methanol. The product is obtained by isolation and purification.
2. Assay : Not less than 97.0 and not more than 102.0% on the dried basis.
3. Description : White to off-white powder.
4. Identification : (1) Solubility: Slightly soluble in water, soluble in ethanol.  
(2) Infrared spectrum: The product is identified by comparing the infrared absorption spectrum of a potassium bromide dispersion with that of a reference standard.
5. pH : 5.0–7.0 (0.5% soln).
6. Melting range : 81–84°C.
7. Water : Not more than 5.0% (Sampling 25±5 mg, Karl Fischer).
8. N-[N-(3,3-Dimethylbutyl)- $\alpha$ - aspartyl]-L-phenylalanine : Not more than 1.5%.
9. Other related substances : Not more than 2.0%.
10. Sulfated ash : Not more than 0.2%.
11. Specific rotation :  $[\alpha]_D^{20} = -40.0^\circ \sim -43.3^\circ$  (0.5% soln, on the dried basis)
12. Lead : Not more than 1 mg/kg.
13. Category : Food Additives Category 11-1
14. Uses : Sweetening agent.



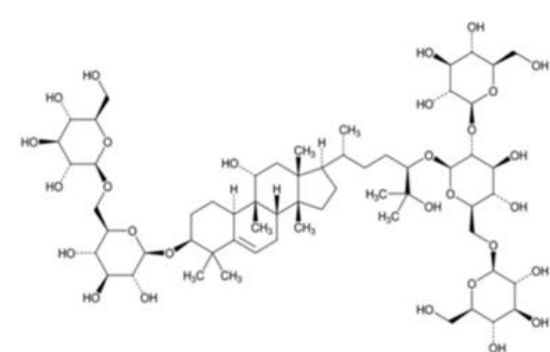
## Mogroside Extract

### DEFINITION

:Mogroside Extract is obtained from the fruits of the luohanguo plant *Siraitia grosvenorii* (Swingle) C. Jeffrey ex A. M. Lu & Zhi Y. Zhang (*Momordica grosvenori* Swingle) and consists mainly of mogrosides.

### Content

:Mogroside Extract, when dried, contains not less than 20% of mogroside V ( $C_{60}H_{102}O_{29} = 1287.43$ ).



### Mogroside V

### Description

: light yellow to light brown powder having a sweet taste.

### CHARACTERISTICS

#### IDENTIFICATION

Color reaction : To 5–10 mg of Mogroside Extract, previously dried, add 2 mL of acetic anhydride, warm for 2 minutes, and slowly add 0.5 mL of sulfuric acid. The boundary surface turns red-brown.

Chromatography : Major component corresponds with the Mogroside V.

### Purity

Lead	: Not more than 1.0 mg/kg.
Cadmium	: Not more than 1.0 mg/kg.
Arsenic	: Not more than 0.5 mg/kg.
Loss in Drying	: Not more than 6.0% (105°C , hours).
Residue on Ignition	: Not more than 2.0%.
<b>Category</b>	: Food additives category (11-1).
<b>Functional uses</b>	: Sweeteners.

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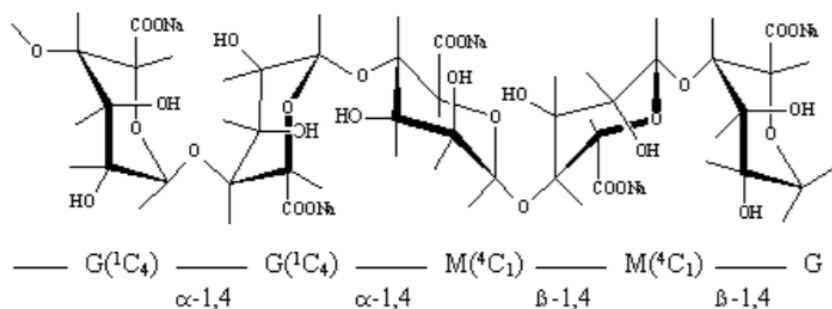
## Sodium Alginate

**Synonyms** INS No. 401**Definition** Sodium salt of alginic acid

C.A.S. number 9005-38-3

Chemical formula  $(C_6H_7NaO_6)_n$ 

Structural formula

The  
number  
and

sequence of the Mannuronate and Glucuronate residues shown above vary in the naturally occurring alginate. The water molecules associated with the alginate molecule are not shown in the above structural formula.

Formula weight Structural unit : 198.11 (theoretical), 222 (actual average) Macromolecule : 10,000 - 600,000 (typical average)

Assay Yields, on the dried basis, not less than 18.0% and not more than 21.0% of carbon dioxide ( $CO_2$ ), equivalent to not less than 90.8% and not more than 106.0% of sodium alginate  $(C_6H_7NaO_6)_n$ .

**Description** White to yellowish brown filamentous, grainy, granular or powdered forms**Characteristics**

Identification

Solubility Dissolves slowly in water, forming a viscous solution; insoluble in ethanol and ether

Precipitate formation with calcium chloride To a 0.5% solution of the sample in sodium hydroxide TS add one-fifth of its volume of a 2.5% solution of calcium chloride. A voluminous, gelatinous precipitate is formed.

Precipitate formation with ammonium sulphate To a 0.5% solution of the sample in sodium hydroxide TS add one-half of its volume of a saturated solution of ammonium sulfate. No precipitate is formed.

Test for alginate Passes test

Test for sodium	Passes test
Purity	
Loss on drying	Not more than 15% (105° , 4 h)
Water-insoluble matter	Not more than 2% on the dried basis
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Microbiological criteria	Total plate count: Not more than 5,000 colonies per gram. Yeasts and moulds: Not more than 500 colonies per gram Coliforms: Negative by test Salmonella: Negative by test
<b>Category</b>	Food additives category (12)
<b>Functional uses</b>	Pasting Agent

Propylene Glycol Alginate

1. Appearance : Occurs as white to yellowish brown filamentous, grainy, granular or powdered forms. It is almost odorless.
2. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
3. Heavy metals : Not more than 20 ppm (as Pb).
4. Degree of esterification : Not less than 75%.
5. Insoluble ash : Not more than 1.5%.
6. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 15% of its weight.
7. Category : Food Additives Category 12
8. Uses : Pasting Agent.

## Casein

1. Assay : Not less than 14.7% and not more than 16.0% of nitrogen on the dried basis (110°C, 3 h)
2. Appearance : White or pale yellow granules or powder; tasteless, odorless or having a specific aroma.
3. Solution : Dry the sample for 4 hours in reduced pressure sulfuric acid dryer, and ground the sample into a fine powder. Shake and mix 0.1 g of the sample and 30 mL of water. After standing for 10 minutes, add 2 mL of 0.1 N sodium hydroxide solution. While heating at 60 ° C for 1 hour, it was mixed by shaking to dissolve it. When cold water is added to make a 100 mL solution, the solution should be colorless and the turbidity should be below "slightly turbid".
4. pH : Add 1.5 g of the sample to 30 mL of water, shake and mix for 10 minutes, then filter. The pH of the filtrate should be 3.7 ~ 6.5.
5. Water soluble substances : Not more than 1%.
6. Fat : Not more than 1.5%.
7. Arsenic : Not more than 1 ppm (as As<sub>2</sub>O<sub>3</sub>).
8. Heavy metals : Not more than 20 ppm (as Pb).
9. Loss on drying : Dry it at 100° for 3 hours: it loses not more than 12% of its weight.
10. Residue on ignition : Dry it at 100° for 3 hours: it loses not more than 2.5% of its weight.
11. Category : Food Additives Category 12
12. Uses : Pasting Agent.

Sodium Caseinate

1. Assay : Not less than 14.5% and not more than 15.8% of nitrogen after drying 3 hours at 100°C.
2. Appearance : White or pale yellow granules or powder; practically odorless or having a specific aroma.
3. Solution : The test in “3. Solution” of Casein is applicable.
4. pH : 6.0~7.5. 6.5 - 7.5 (1 in 50 soln)
5. Fat : Not more than 1.5%.
6. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Loss on drying : Dry it at 100° for 3 hours: it loses not more than 15% of its weight.
9. Residue on ignition : Not more than 6% on the ignited basis (100°C, 3 h)
10. Category : Food Additives Category 12
11. Uses : Pasting Agent.

## Sodium Carboxymethyl Cellulose

Chemical names : Sodium salt of carboxymethyl ether of cellulose

Synonyms : Sodium cellulose glycolate, Na CMC, CMC, Cellulose Gum, INS No. 466, C.A.S. No. 9004-32-4

Chemical formula:  $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$

Molecular weight:

n is the degree of polymerization

Structural unit with a degree of substitution of

$x=1.50\sim2.80$

0.20: 178.14

$y=0.2\sim1.50$

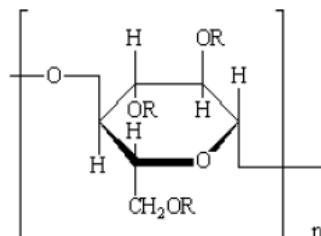
Structural unit with a degree of substitution of

$x+y=3.0$

1.50: 282.18

y=degree of substitution

Macromolecules: greater than about 17,000 (n about 100)



where R=H or  $CH_2COONa$

1. Assay : Not less than 99.5% of sodium carboxymethyl cellulose, calculated on the dried basis.
2. Appearance : White or slightly yellowish, almost odorless hygroscopic granules, powder or fine fibers.
3. Solubility : Yield viscous colloidal solution with water; insoluble in ethanol.
4. Identification : (1) Foam test: Vigorously shake a 0.1% solution of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose from other cellulose ethers and from alginates and natural gums.

(2) Precipitate formation: To 5 mL of an 0.5% solution of the sample add 5 mL of a 5% solution of copper sulfate or of aluminum sulfate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers, and from gelatine, carob bean gum and tragacanth gum).

(3) Color reaction: Add 0.5 g of powdered carboxymethylcellulose sodium to 50 mL of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced. To 1 mL of the solution, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol TS. Incline the test tube, and carefully



introduce down the side of the tube 2 mL of sulfuric acid so that it forms a lower layer. A red-purple color develops at the interface.

5. Loss on drying : Not more than 12.0% (105°C to constant weight).
6. pH : 6.0 - 8.5 (1 in 100 soln)
7. Sodium : Not more than 12.4% on the dried basis Determine total sodium content by Atomic Absorption Spectroscopy or Flame Photometry.
8. Sodium chloride : Not more than 0.5% on the dried basis.
9. Free glycolate : Not more than 0.4% calculated as sodium glycolate on the dried basis.
10. Degree of substitution : Not less than 0.20 and not more than 1.50 .
11. Lead : Not more than 2 mg/kg on the dried basis. Determine using an atomic absorption technique appropriate to the specified level.
12. Heavy metals : Not more than 20 mg/kg (as Pb).
13. Category : Food Additives Category 12
14. Uses : Pasting Agent.

# Calcium Carboxmethyl Cellulose

1. Appearance : White to off-white powder, odorless.
2. pH : Add 50 mL of freshly boiled and cooled water to 1 g of this product. After fully oscillating and mixing, the pH should be below 8.0.
3. Chloride : Not more than 0.6% of Cl.
4. Sulfate : Not more than 0.9% of SO<sub>4</sub>.
5. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
6. Heavy metals : Not more than 30 ppm (as Pb).
7. Starch : Add 10 mL of water to 0.1g of the sample, and dissolved it by heating. When adding 2 drops of iodine test solution after cooling, it should not be blue to violet.
8. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 10% of its weight.
9. Residue on ignition : 10~20% (ignited at 105°C for 4 hours)
10. Category : Food Additives Category 12
11. Uses : Pasting Agent.

## Food Starch, Modified

Synonyms	Acid treated starch: INS No. 1401 Alkaline treated starch: INS No. 1402 Bleached starch: INS No. 1403 Oxidized starch: INS No. 1404 Monostarch phosphate: INS No. 1410 Distarch phosphate: INS No. 1412 Phosphated distarch phosphate: INS No. 1413 Acetylated distarch phosphate: INS No. 1414 Starch acetate: INS No. 1420 Acetylated distarch adipate: INS No. 1422 Hydroxypropyl starch: INS No. 1440 Hydroxypropyl distarch phosphate: INS No. 1442 Starch sodium octenylsuccinate: INS No. 1450
Definition	: Food starches which have one or more of their original characteristics altered by treatment in accordance with good manufacturing practice by one of the procedures listed in Table 1. In the case of starches treated with heat in the presence of acid or with alkali, the alteration is a minor fragmentation. When the starch is bleached, the change is essentially in the color only. Oxidation involves the deliberate production of carboxyl groups. Acetylation results in substitution of hydroxyl groups with acetyl esters. Treatment with reagents such as orthophosphoric acid results in partial substitution in the 2, 3- or 6- position of the anhydroglucose unit unless the 6-position is occupied for branching. In cases of cross-linking, where a polyfunctional substituting agent, such as phosphorus oxychloride, connects two chains, the structure can be represented by: Starch-O-R-O-Starch, where R = cross-linking group and Starch refers to the linear and/or branched structure.
C.A.S. number	Starch acetate: 9045-28-7 Acetylated distarch adipate: 68130-14-3 Hydroxypropyl starch: 9049-76-7 Hydroxypropyl distarch phosphate: 53124-00-8 Starch sodium octenylsuccinate: 66829-29-6
Description	Most modified starches are white or off-white, odourless powders. According to the drying method these powders can consist of whole granules having the appearance of the original native starch, or aggregates consisting of a number of granules (pearl starch, starch-grits) or, if pre-gelatinized, of flakes, amorphous powder or coarse particles.

**Characteristics**

## Identification

Solubility	Insoluble in cold water (if not pre-gelatinized); forming typical colloidal solutions with viscous properties in hot water; insoluble in ethanol.
Microscopy	Modified starches which have not been pre-gelatinized retain their granular structure and can be identified as starches by microscopic observation. Shape, size and sometimes striations are characteristics of the botanical origin. In polarized light under cross nicol prisms the typical polarization cross will be observed
Iodine stain	Add a few drops of 0.1 N potassium tri-iodide to an aqueous suspension of the sample. These starches stain with iodine in the same way as native starches. The colour can range from dark blue to red.
Copper reduction	Place about 2.5 g of the sample previously washed with water, in a boiling flask, add 10 ml of dilute hydrochloric acid (3%) and 70 ml of water, mix, reflux for about three hours and cool. Add 0.5 ml of the resulting solution to 5 ml of hot alkaline cupric tartrate TS. A copious red precipitate is produced.
Differentiation test	Passes test for type of starch 1. Hypochlorite oxidized starch 2. Specific reaction for acetyl groups 3. Positive test for ester groups
<b>Purity</b>	
Sulfur dioxide	: Not more than 50 mg/kg for modified cereal starches Not more than 10 mg/kg for other modified starches unless otherwise specified in Table 1
Lead	: Not more than 2 mg/kg
Additional purity specifications for individual chemically modified starches	See Table 1
Category	: Food additives category (12)
Functional uses	: Pasting Agents

Table 1. Additional purity specifications for individual chemically modified starches (All percentages calculated on dry substance)

Modification	Process limitations	End-product specifications
Acid treated starch	Treatment with hydrochloric acid or ortho-phosphoric acid or sulfuric acid	Final pH 4.8 – 7.0

Gelatinized starch (Alkaline treated starch)	Treatment with sodium hydroxide or potassium hydroxide	Final pH 5.0 – 7.5
Bleached starch	Treatment with peracetic acid and/or hydrogen peroxide, or sodium hypochlorite or sodium chlorite, or sulfur dioxide or alternative permitted forms of sulfites, or potassium permanganate or ammonium persulfate	Added carbonyl group not more than 0.1% No residual reagent Residual sulfur dioxide not more than 50 mg/kg Residual manganese not more than 50 mg/kg
Oxidized starch	Treatment with sodium hypochlorite	Carboxyl groups not more than 1.1% Residual sulfur dioxide not more than 50 mg/kg
Monostarch phosphate	Esterification with orthophosphoric acid, or sodium or potassium orthophosphate, or sodium tripolyphosphate	Phosphate calculated as phosphorus not more than 0.5% for potato or wheat, and not more than 0.4% for other starches
Distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride	Phosphate calculated as phosphorus not more than 0.5% for potato and wheat, and not more than 0.4% for other starches
Phosphated distarch phosphate	Combination of treatments for Monostarch phosphate and Distarch phosphate	Phosphate calculated as phosphorus not more than 0.5% for potato and wheat, and not more than 0.4% for other starches
Acetylated distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride combined with esterification with acetic anhydride or vinyl acetate	Acetyl groups not more than 2.5%; phosphate calculated as phosphorus not more than 0.14% for potato and wheat, and 0.04% for other starches; and vinyl acetate not more than 0.1 mg/kg

Starch acetate	Esterification with acetic anhydride or vinyl acetate	Acetyl groups not more than 2.5%
Acetylated distarch adipate	Esterification with acetic anhydride and adipic anhydride	Acetyl groups not more than 2.5% and adipate groups not more than 0.135%
Hydroxypropyl starch	Etherification with propylene oxide	Hydroxypropyl groups not more than 7.0%; propylene chlorohydrin not more than 1 mg/kg
Hydroxypropyl distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride combined with etherification by propylene oxide	Hydroxypropyl groups not more than 7.0%; propylene chlorohydrin not more than 1 mg/kg; and residual phosphate calculated as phosphorus not more than 0.14% for potato and wheat, and not more than 0.04% for other starches
Starch sodium octenylsuccinate	Esterification with octenylsuccinic anhydride	Octenylsuccinyl groups not more than 3%; and residual octenylsuccinic acid not more than 0.3%
Oxidized Hydroxypropyl Starch	Chlorine, as sodium hypochlorite, not to exceed 5.5% of dry starch; active oxygen obtained from hydrogen peroxide, not to exceed 0.45%; and propylene oxide, not to exceed 25%	Propylene chlorohydrin not more than 5 mg/kg
Starch Aluminum Octenyl Succinate	Octenyl succinic anhydride, not to exceed 2%, and aluminium sulfate, not to exceed 2%	—

Starch Sodium Succinate	Succinic anhydride, not to exceed 4%	—
Distarchoxy Propanol	Acrolein not to exceed 0.6%	—
Modification	Process limitations	End-product specifications
Acid treated starch	Treatment with hydrochloric acid or ortho-phosphoric acid or sulfuric acid	Final pH 4.8 – 7.0
Gelatinized starch (Alkaline treated starch)	Treatment with sodium hydroxide or potassium hydroxide	Final pH 5.0 – 7.5
Bleached starch	Treatment with peracetic acid and/or hydrogen peroxide, or sodium hypochlorite or sodium chlorite, or sulfur dioxide or alternative permitted forms of sulfites, or potassium permanganate or ammonium persulfate	Added carbonyl group not more than 0.1% No residual reagent Residual sulfur dioxide not more than 50 mg/kg Residual manganese not more than 50 mg/kg
Oxidized starch	Treatment with sodium hypochlorite	Carboxyl groups not more than 1.1% Residual sulfur dioxide not more than 50 mg/kg
Monostarch phosphate	Esterification with orthophosphoric acid, or sodium or potassium ortho-phosphate, or sodium tripolyphosphate	Phosphate calculated as phosphorus not more than 0.5% for potato or wheat, and not more than 0.4% for other starches
Distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride	Phosphate calculated as phosphorus not more than 0.5% for potato and wheat, and not more than 0.4% for other starches

Phosphated distarch phosphate	Combination of treatments for Monostarch phosphate and Distarch phosphate	Phosphate calculated as phosphorus not more than 0.5% for potato and wheat, and not more than 0.4% for other starches
Acetylated distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride combined with esterification with acetic anhydride or vinyl acetate	Acetyl groups not more than 2.5%; phosphate calculated as phosphorus not more than 0.14% for potato and wheat, and 0.04% for other starches; and vinyl acetate not more than 0.1 mg/kg
Starch acetate	Esterification with acetic anhydride or vinyl acetate	Acetyl groups not more than 2.5%
Acetylated distarch adipate	Esterification with acetic anhydride and adipic anhydride	Acetyl groups not more than 2.5% and adipate groups not more than 0.135%
Hydroxypropyl starch	Etherification with propylene oxide	Hydroxypropyl groups not more than 7.0%; propylene chlorohydrin not more than 1 mg/kg
Hydroxypropyl distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride combined with etherification by propylene oxide	Hydroxypropyl groups not more than 7.0%; propylene chlorohydrin not more than 1 mg/kg; and residual phosphate calculated as phosphorus not more than 0.14% for potato and wheat, and not more than 0.04% for other starches



Starch sodium octenylsuccinate	Esterification with octenylsuccinic anhydride	Octenylsuccinyl groups not more than 3%; and residual octenylsuccinic acid not more than 0.3%
Oxidized Hydroxypropyl Starch	Chlorine, as sodium hypochlorite, not to exceed 5.5% of dry starch; active oxygen obtained from hydrogen peroxide, not to exceed 0.45%; and propylene oxide, not to exceed 25%	Propylene chlorohydrin not more than 5 mg/kg
Starch Aluminum Octenyl Succinate	Octenyl succinic anhydride, not to exceed 2%, and aluminium sulfate, not to exceed 2%	—
Starch Sodium Succinate	Succinic anhydride, not to exceed 4%	—
Distarchoxy Propanol	Acrolein not to exceed 0.6%	—

## Methyl Cellulose

Chemical formula:	$[C_6H_7O_2(OH)_x(OCH_3)_y]_n$	Molecular weight:	
		Unsubstituted	162.14
		Monosubstituted	176.17
		Disubstituted	190.20
		Trisubstituted	204.23
		Low Polymer(n about 200)	40,000
		High Polymer(n about 900)	180,000

1. Assay : Not less than 25% and not more than 33% of methoxyl groups.
2. Appearance : White or off-white, odorless fine granules, filaments or powder.
3. Transparency : Prepare two solutions. (1) Dissolve 1 g of the sample in 100 mL of water at about 70°C. After stirring, cool while shaking and mixing. Then place the solution in a cold place until a homogeneous paste is formed. (2) Add water to 4 mL of 0.01 N sulfuric acid solution, 1 mL of dilute hydrochloric acid, 5 mL of ethanol to make a solution 50 mL, then add 2 mL of cesium chloride TS and shake, place for 10 minutes. The transparency of the solution (1) should be higher.
4. Chloride : Not more than 0.14% of Cl.
5. Sulfate : Not more than 0.024% of SO<sub>4</sub>.
6. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
7. Heavy metals : Not more than 20 ppm (as Pb).
8. Sodium carboxymethyl cellulose : Add 1 g of the sample to 100 mL of water at 70°C. After stirring, cool while shaking and mixing, then place in a cold place to form a uniform paste. Take 40 mL of the paste and heat it while shaking and mixing. After boiling, filter with an insulated funnel. After cooling, add 1 mL of copper sulfate TS to 3 mL of filtrate. No precipitation forms.
9. Starch : Add 1 drop of iodine TS to the filtrate obtained in "8. Sodium carboxymethyl cellulose". The solution not turn blue.
10. Loss on drying : Not more than 8% (105°C, 4 hr).
11. Residue on ignition : Not more than 1% (105°C, 4 hr).

- 12. Category : Food Additives Category 12
- 13. Uses : Pasting Agent.

Sodium Polyacrylate

1. Appearance : powder, odorless, tasteless.
2. Transparency : Transparency test method for "methyl cellulose" is applicable.
3. Free alkali : Dissolve 0.2 g of the sample in 60 mL of water, stir. Add 3 mL of calcium chloride TS, heat on water bath for about 20 minutes, filter after cool. Wash the residue on the filter paper with water, combine the washing solution with the filtrate, and add water to make it 100 mL. Add 2 drops of phenolphthalein TS to 50 mL of the solution. The solution should not turn red.
4. Sulfate : Not more than 0.49% of SO<sub>4</sub>.
5. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Monomer : Not more than 1%.
8. Low complex : Not more than 5%.
9. Starch : Add 10 mL of water to 0.1 g of the sample to form a paste. When adding 2 drops of iodine TS, it should not be blue.
10. Loss on drying : Dry it at 105°C for 4 hours: it loses not more than 10% of its weight.
11. Residue on ignition : Not more than 76% (105°C, 4 h)
12. Category : Food Additives Category 12
13. Uses : Pasting Agent.

## Carrageenan

### Synonyms

Irish moss gelose (from *Chondrus* spp.); Eucheuman (from *Eucheuma* spp.); Iridophycan (from *Iridaea* spp.); Hypnean (from *Hypnea* spp.); Furcellaran or Danish agar (from *Furcellaria fastigiata*); INS No. 407.

### Definition

A substance with hydrocolloid properties obtained from certain members of the class *Rhodophyceae* (red seaweeds).

The principal commercial sources of carrageenans are the following families and genera of the class of *Rhodophyceae*:

*Furcellariaceae* such as *Furcellaria*

*Gigartinaceae* such as *Chondrus*, *Gigartina*, *Iridaea*

*Hypnaeaceae* such as *Hypnea*

*Phyllophoraceae* such as *Phyllophora*, *Gymnogongrus*, *Ahnfeltia*

*Solieriaceae* such as *Eucheuma*, *Anatheca*, *Meristotheca*.

Carrageenan is a hydrocolloid consisting mainly of the ammonium, calcium, magnesium, potassium and sodium sulfate esters of galactose and 3, 6-anhydrogalactose polysaccharides. These hexoses are alternately linked  $\alpha$ -1,3 and  $\beta$ -1,4 in the copolymer.

The relative proportions of cations existing in carrageenan may be changed during processing to the extent that one may become predominant.

The prevalent polysaccharides in carrageenan are designated as kappa-, iota-, and lambda-carrageenan. Kappa-carrageenan is mostly the alternating polymer of D-galactose-4-sulfate and 3, 6-anhydro-D-galactose; iota-carrageenan is similar, except that the 3,6-anhydrogalactose is sulfated at carbon 2. Between kappa-carrageenan and iota-carrageenan there is a continuum of intermediate compositions differing in degree of sulfation at carbon 2. In lambda-carrageenan, the alternating monomeric units are mostly D-galactose-2-sulfate (1,3-linked) and D-galactose-2,6- disulfate (1,4-linked).

Carrageenan is obtained by extraction from seaweed into water or aqueous dilute alkali.

Carrageenan may be recovered by alcohol precipitation, by drum drying, or by precipitation in aqueous potassium chloride and subsequent freezing. The alcohols used

during recovery and purification are restricted to methanol, ethanol, and isopropanol.

Articles of commerce may include sugars for standardization purposes, salts to obtain specific gelling or thickening characteristics, or emulsifiers carried over from drum drying processes.

C.A.S. number 9000-07-1

**Description** Yellowish or tan to white, coarse to fine powder that is practically odourless.

**Characteristics**

Identification

**Solubility** Insoluble in ethanol; soluble in water at a temperature of about 80°C, forming a viscous clear or slightly opalescent solution that flows readily; disperses in water more readily if first moistened with alcohol, glycerol, or a saturated solution of glucose or sucrose in water.

**Test for sulfate** Dissolve a 100-mg sample in 20 ml of water (with heating if necessary), and add 3 ml of barium chloride TS and 5 ml of hydrochloric acid, dilute TS; filter if a precipitate forms. Boil the solution or the filtrate for 5 min. A white, crystalline precipitate appears.

**Test for galactose and anhydrogalactose** Galactose and 3, 6-anhydrogalactose should be present.

**Identification of hydrocolloid and predominant type of copolymer** Add 4 g of sample to 200 ml of water, and heat the mixture in a water bath at 80°C, with constant stirring, until dissolved. Replace any water lost by evaporation, and allow the solution to cool to room temperature. It becomes viscous and may form a gel. To 50 ml of the solution or gel add 200 mg of potassium chloride, then reheat, mix well, and cool. A short textured ("brittle") gel indicates a carrageenan of a predominantly kappa type, and a compliant ("elastic") gel indicates a predominantly iota type. If the solution does not gel, the carrageenan is of a predominantly lambda type.

**Infrared absorption** Passes test

**Purity**

**Loss on drying** Not more than 12% (105°C to constant weight)

**pH** Between 8 and 11 (1 in 100 suspension)

**Viscosity** Not less than 5 cp at 75°C (1.5% solution)

Sulfate	Not less than 15% and not more than 40% (as $\text{SO}_4^{2-}$ ) on the dried basis
Total ash	Not less than 15% and not more than 40% on the dried basis
Acid-insoluble ash	Not more than 1%
Acid-insoluble matter	Not more than 2%
Residual solvents	Not more than 0.1% of ethanol, isopropanol, or methanol, singly or in combination
Microbiological criteria	Initially prepare a $10^{-1}$ dilution by adding a 50-g sample to 450 ml of Butterfield's phosphate-buffered dilution water and homogenising the mixture in a high-speed blender.  Total (aerobic) plate count: Not more than 5000 cfu/g  <i>Salmonella</i> spp.: Negative per test  <i>E. coli</i> : Negative in 1 g
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
<b>Category</b>	Food additives category (12)
<b>Functional uses</b>	Pasting Agent.

## Xanthan Gum

1. Description : A high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris*, purified by recovery with ethanol or isopropanol, dried and milled; 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.
2. Appearance : Cream-colored powder
3. Assay : Yields, on the dried basis, not less than 4.2% and not more than 5.4% of carbon dioxide (CO<sub>2</sub>), corresponding to between 91.0% and 117.0% respectively of xanthan gum.
4. Solubility : Soluble in water; insoluble in ethanol.
5. Identification : To 300 mL of water, previously heated to 80°C and stirred rapidly with a mechanical stirrer in a 400-mL beaker, add, at the point of maximum agitation, a dry blend of 1.5 g of the sample and 1.5 g of carob bean gum. Stir until the mixture goes into solution, and then continue stirring for 30 min longer. Do not allow the water temperature to drop below 60°C during stirring. Discontinue stirring, and allow the mixture to cool at room temperature for at least 2 h. A firm rubbery gel forms after the temperature drops below 40°C, but no such gel forms in a 1% control solution of the sample prepared in the same manner but omitting the carob bean gum.
6. Loss on drying : Dry it at 105°C for 2.5 hours: it loses not more than 15% of its weight.
7. Ash : Not more than 16%
8. Pyruvic acid : Not less than 1.5%
9. Nitrogen : Not more than 1.5%. Proceed according to the Kjeldahl method.
10. Ethanol and isopropanol : Not more than 500 mg/kg, singly or in combination.
11. Lead : Not more than 2 ppm.
12. Total plate count : Not more than 5000 cfu/g.
13. *E. coli* : Negative by test.
14. *Salmonella* : Negative by test.
15. Yeasts and moulds : Not more than 500 cfu/g.



16. Category : Food Additives Category 12
17. Uses : Pasting Agent.

## Alginic Acid

Chemical formula:  $(C_6H_8O_6)_n$ 

Formula weight: 176.13 (theoretical)

200.00 (actual average)

1. Description : Alginic acid is a naturally occurring hydrophilic colloidal polysaccharide obtained from the various species of brown seaweed (Phaeophyceae). It is a linear copolymer consisting mainly of residues of  $\beta$ -1,4-linked D-mannuronic acid and  $\alpha$ -1,4-linked L-glucuronic acid. These monomers are often arranged in homopolymeric blocks separated by regions approximating an alternating sequence of the two acid monomers. Occurs as white to yellowish brown filamentous, grainy, granular or powdered forms. Odorless and tasteless. Insoluble in water and organic solvents, but soluble in alkaline solution. pH of its (3 ess and tasteless.s of brown seaweed (P
2. Identification : A. To 5 mL of 1 in 150 solution of the sample add 0.1 N sodium hydroxide. A voluminous, gelatinous precipitate is formed.  
B. Add 1 mL of dilute sulfuric acid TS to 5 mL of the solution obtained in test A to form a viscous gelatinous precipitate.  
C. Put 5 mg of the sample in a test tube, add 5 mL of water, 1 mL of freshly dispensed naphtholresorcinol/ethanol solution and 5 mL of hydrochloric acid (1→100), mix and boil for 3 minutes, then cool to about 15°C. Transfer the contents of this tube to a 30 mL separatory funnel, and rinse the tube with 5 mL of water. Then extract with 15 mL of isopropyl ether. Compared with the blank test, the isopropyl ether extract layer of the experimental case has a deeper purple color.
3. Assay : Yields, on the dried basis not less than 20.0% and not more than 23.0% of carbon dioxide (CO<sub>2</sub>).
4. Ash : Not more than 4% on the dried basis
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 10 ppm.
7. Heavy metals : Not more than 0.004% (as Pb).
8. Loss on drying : Not more than 15%.
9. Category : Food Additives Category 12
10. Uses : Pasting Agent.

## Potassium Alginate (Algin)

Chemical formula:  $(C_6H_7O_6K)_n$ 

Formula weight: 241.22 (theoretical); 238.00

(actual average)

1. Description : The sample is a potassium salt of alginic acid (see the specification of alginic acid), which is white to yellowish fibrous or granular powder, nearly odorless and tasteless. The sample forms a viscous colloidal solution when dissolved in water. Insoluble in alcohol and solution having more than 30% of alcohol. The sample is also insoluble in chloroform, ether and acid with a pH below 3.
2. Identification : A. To 5 mL of 1 in 100 solution of the sample add 1 mL of calcium chloride TS. A voluminous, gelatinous precipitate is formed.  
B. To 10 mL of 1 in 100 solution of the sample add 1 mL of dilute sulphuric acid TS. A voluminous, gelatinous precipitate is formed.  
C. Same as the identification test C of alginic acid.  
D. Dip the "ash" of the sample with dilute hydrochloric acid TS, filter. The filtrate passes test for potassium.
3. Assay : Yields, on the dried basis not less than 16.5% and not more than 19.5% of carbon dioxide ( $CO_2$ ).
4. Ash : Not more than 22~33% on the dried basis.
5. Arsenic : Not more than 3 ppm (as As).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Loss on drying : Not more than 15%.
8. Category : Food Additives Category 12
9. Uses : Pasting Agent.

### Calcium Alginate (Algin)

Chemical formula:  $[(C_6H_7O_6)_2Ca]_n$

Formula weight: 195.16 (theoretical); 219.00

(actual average)

1. Description : The sample is a calcium salt of alginic acid (see the specification of alginic acid), which is white to slightly yellowish fibrous or granular powder, nearly odorless and tasteless. Insoluble in water and organic solvents, but soluble in alkaline solutions or solutions of compounds that bind to calcium.
2. Identification : A. Same as the identification test C of alginic acid.  
B. Dip the "ash" of the sample with dilute hydrochloric acid TS, filter. The filtrate passes test for potassium.
3. Assay : Not more than 18~21% on the dried basis.
4. Ash : Not more than 12~18% on the dried basis.
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 10 ppm.
7. Heavy metals : Not more than 0.004% (as Pb).
8. Loss on drying : Not more than 15%.
9. Category : Food Additives Category 12
10. Uses : Pasting Agent.

## Ammonium Alginate(Algin)

Chemical formula: (C<sub>6</sub>H<sub>7</sub>O<sub>6</sub>NH<sub>4</sub>)<sub>n</sub>

Formula weight: 193.16(theoretical); 217.00 (actual average)

1. Description : Ammonium alginate is the ammonium salt of alginic acid. Occurs as white to yellowish brown filamentous, grainy, granular or powdered forms. Dissolves slowly in water forming a viscous solution; insoluble in alcohol and aqueous solutions with an alcohol content of more than 30%, chloroform, ether and acid with pH below 3.
2. Identification : A. To 5 mL of 1 in 100 solution of the sample add 1 mL of calcium chloride TS. A voluminous, gelatinous precipitate is formed.  
B. To 10 mL of 1 in 100 solution of the sample add 1 mL of dilute sulphuric acid TS. A voluminous, gelatinous precipitate is formed.  
C. Same as the identification test C of alginic acid.  
D. Heat 1 g of the sample with 5 mL of sodium hydroxide TS in a tube. Swirl the mixture, and the odor of ammonia appears.
3. Assay : Not more than 18~21% on the dried basis.
4. Ash : Not more than 4% on the dried basis
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 10 ppm.
7. Heavy metals : Not more than 0.004% (as Pb).
8. Loss on drying : Not more than 15%.
9. Category : Food Additives Category 12
10. Uses : Pasting Agent.

§ 12022

Hydroxypropyl Cellulose

The same as § 07065

§ 12023

Hydroxypropyl Methylcellulose  
(Propylene Glycol Ether of Methylcellulose)

The same as § 07066

§ 12024

Polydextrose

The same as § 07067



## Curdlan

1. Description : Curdlan is produced by fermentation from *Alcaligemes faecalis* var. *myxogenes*.  
Odorless or almost odorless, white to nearly white powder.  
Adhesive strength should be in above of 500 g/cm.
2. Identification : (1) Heat a 2% aqueous suspension of the sample (produced by adding 10 mL water to 200 mg of the sample) in a boiling water bath for 10 min and cool. A firm gel forms.  
(2) Add 10 mL of water to 200 mg of the sample to form a suspension. Then add 10 mL of 10 N sulfuric acid, and heat in a boiling water bath for 20 minutes. After cooling, neutralize with cesium carbonate, centrifuge. Take 1 mL of the upper layer, and add 2 mL of Fehling's test solution to it. Reddish brown cuprous oxide precipitate forms after heating.
3. pH : 6.0~8.5. 6.0 - 8.5 (1% aqueous suspension for 30 min)
4. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Loss on drying : Not more than 10% (Not more than 10 mmHg, 60°C, 5 h).
7. Residue on : Not more than 7%.  
ignition
8. Category : Food Additives Category 12
9. Uses : Pasting Agent.

## Gellan Gum

<b>Synonyms</b>	INS No. 418
<b>Definition</b>	Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by <i>Pseudomonas elodea</i> , purified by recovery with isopropyl alcohol, 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 units, and is substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically-linked esters. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. It usually contains a small amount of nitrogen containing compounds resulting from the fermentation procedures.
CAS NUMBER	71010-52-1
Molecular weight	Approximately 500,000.
Assay	Yields, on the dried basis, not less than 3.3% and not more than 6.8% of carbon dioxide (CO <sub>2</sub> ).
<b>Appearance</b>	Off-white powder.
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Soluble in water, forming a viscous solution; insoluble in ethanol.
Gel test with calcium ion	Add 1.0 g of the sample to 99 mL of water, and stir for about 2 h, using a motorized stirrer having a propeller-type stirring blade. Draw a small amount of this solution into a wide bore pipet and transfer into a 10% solution of calcium chloride. A tough worm-like gel will be formed immediately.
Gel test with sodium ion	To the 1% solution of the sample prepared for the previous test, add 0.50 g of sodium chloride, heat to 80° with stirring, and hold at 80° for 1 min. Allow the solution to cool to room temperature. A firm gel is formed.
<b>Purity</b>	
Loss on drying	Dry it at 105°C for 2.5 hours: it loses not more than 15% of its weight.
Residual solvent	Not more than 50 mg/kg of ethanol; not more than 750 mg/kg of isopropyl alcohol.
Nitrogen	Not more than 3%.
Microbiological criteria	Total plate count: Not more than 10,000 colonies per gram. E. coli: Negative by test. Salmonella: Negative by test. Yeasts and moulds: Not more than 400 colonies per gram.

Lead	Not more than 2 mg/kg.
<b>Category</b>	Food Additives Category 12
<b>Uses</b>	Pasting Agent.

§ 12027

Gelatinized Starch ( Alkaline Treated Starch )

The same as §12008

§12028

Hydroxypropyl Distarch Phosphate

The same as §12008

§12029

Oxidized Hydroxypropyl Starch

The same as §12008

§12030

Bleached Starch

The same as §12008

§12031

Oxidized Starch

The same as§12008



§12032

Starch Acetate

The same as §12008

§12033

Acetylated Distarch Adipate

The same as §12008

§12034

Monostarch Phosphate

The same as §12008

§12035

Starch Sodium Octenyl Succinate

The same as §12008

§12036

Distarch Phosphate

The same as §12008

§12037

Phosphated Distarch Phosphate

The same as §12008

§12038

Acetylated Distarch Phosphate

The same as §12008

§12039

Hydroxypropyl Starch

The same as §12008



§ 12042

Starch Aluminum Octenyl Succinate

The same as § 12008

§ 12043

Starch Sodium Succinate

The same as §12008

§ 12044

Distarchoxy Propanol

The same as § 12008

**Pectins****SYNONYMS**

INS No. 440

**Definition**

Consists mainly of the partial methyl esters of polygalacturonic acid and their sodium, potassium, calcium and ammonium salts; obtained by extraction in an aqueous medium of appropriate edible plant material, usually citrus fruits or apples; no organic precipitants shall be used other than methanol, ethanol and isopropanol; in some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. Sulfur dioxide may be added as a preservative.

C.A.S. number

9000-69-5

**DESCRIPTION**

White, yellowish, light greyish or light brownish powder.

**Characteristics****IDENTIFICATION**

Test for pectins

Passes test.

Test for amide group

Passes test (amidated pectins only).

Loss on drying

Not more than 12% (105°C, 2 h).

Sulfur dioxide

Not more than 50 mg/kg.

Residual solvents

Not more than 1% methanol, ethanol and 2-propanol, singly or in combination.

Acid-insoluble ash

Not more than 1%.

Total insolubles

Not more than 3%.

Nitrogen content

Not more than 2.5% after washing with acid and ethanol.

Galacturonic acid

Not less than 65% calculated on the ash-free and dried basis.

Degree of amidation

Not more than 25% of total carboxyl groups of pectin.

Lead

Not more than 2 mg/kg.

**Category**

Food additives category (12) (16).

**Functional uses**

Pasting Agent; Emulsifiers.

## Guar Gum

### SYNONYMS

Gum cyamopsis, guar flour; INS No. 412

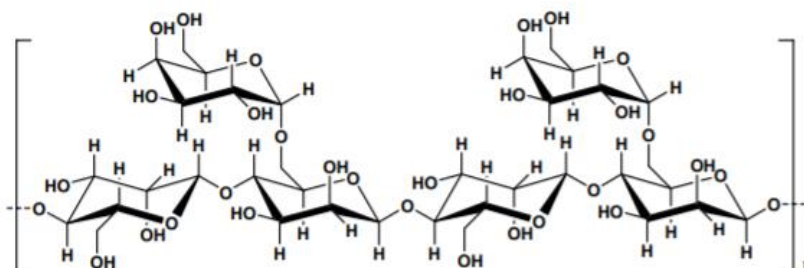
### Definition

Primarily the ground endosperm of the seeds from *Cyamopsis tetragonolobus* (L.) Taub. (Fam. *Leguminosae*) mainly consisting of high molecular weight (50,000-8,000,000) polysaccharides composed of galactomannans; the mannose:galactose ratio is about 2:1. The seeds are crushed to eliminate the germ, the endosperm is dehusked, milled and screened to obtain the ground endosperm (native guar gum). The gum may be washed with ethanol or isopropanol to control the microbiological load (washed guar gum).

C.A.S. number

9000-30-0

Structural formula



### DESCRIPTION

White to yellowish-white, nearly odourless, free-flowing powder.

### Characteristics

### IDENTIFICATION

Solubility

Insoluble in ethanol.

Gel formation

Add small amounts of sodium borate TS to an aqueous dispersion of the sample; a gel is formed.

Viscosity

Transfer 2 g of the sample into a 400-ml beaker and moisten thoroughly with about 4 ml of isopropanol. Add 200 ml of water with vigorous stirring until the gum is completely and uniformly dispersed. An opalescent, viscous solution is formed. Transfer 100 ml of this solution into another 400-ml beaker, heat the mixture in a boiling water bath for

about 10 min and cool to room temperature. There is no substantial increase in viscosity (differentiating guar gums from carob bean gums).

Gum constituents	Use galactose and mannose as reference standards. These constituents should be present.
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 a microscope. Guar gum shows close groups of round to pear formed cells, their contents being yellow to brown.

#### PURITY

Loss on drying	Not more than 15.0% (105°C, 5 h).
Borate	Disperse 1 g of the sample in 100 ml of water. The dispersion should remain fluid and not form a gel on standing. Mix 10 ml of dilute hydrochloric acid with the dispersion, and apply one drop of the resulting mixture to turmeric paper. No brownish red colour is formed.
Total ash	Not more than 1.5% (800°C, 3-4 h).
Acid-insoluble matter	Not more than 7.0%.
Protein	Not more than 10.0%.
Residual solvents	Not more than 1% of ethanol or isopropanol, singly or in combination.
Lead	Not more than 2 mg/kg.
<b>Category</b>	Food additives category (12) (16).
<b>Functional uses</b>	Pasting Agent; Emulsifiers.

### Carob Bean Gum

#### SYNONYMS

Locust bean gum, INS No. 410

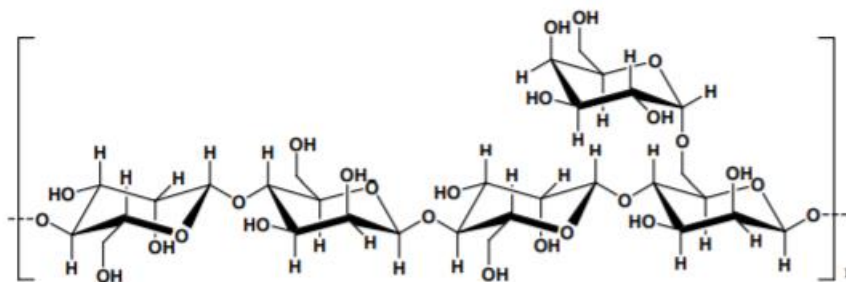
#### Definition

Carob bean gum, also known as locust bean gum, is a galactomannan polysaccharide obtained from the seeds of *Ceratonia siliqua* (L.) Taub. (Fam. Leguminosae). The ground endosperm of the seeds consists mainly of high molecular weight (approximately 50,000-3,000,000) polysaccharides composed of galactomannans with a mannose:galactose ratio of about 4:1. The seeds are dehusked by treating the seeds with dilute sulfuric acid or with thermal mechanical treatments, elimination of the germ followed by milling and screening of the endosperm to obtain native carob bean gum. The gum may be washed with ethanol or isopropanol to control the microbiological load (washed carob bean gum).

C.A.S. number

9000-40-2

Structural formula



#### DESCRIPTION

White to yellowish white, nearly odourless powder.

#### Characteristics

#### IDENTIFICATION

Solubility

Insoluble in ethanol.

Gel formation

Add small amounts of sodium borate TS to an aqueous dispersion of the sample; a gel is formed.

Viscosity

Transfer 2 g of the sample into a 400-mL beaker and moisten thoroughly with about 4 mL of isopropanol. Add 200 mL of water with vigorous stirring until the gum is completely and uniformly dispersed. An opalescent, slightly viscous solution is formed. Transfer 100 mL of this

solution into another 400-mL beaker. Heat the mixture in a boiling water bath for about 10 min and cool to room temperature. There is an appreciable increase in viscosity (differentiating carob bean gums from guar gums).

**Gum constituents** Use galactose and mannose as reference standards. These constituents should be present.

**Microscopic examination** Disperse a sample of the gum in an aqueous solution containing 0.5% iodine and 1% potassium iodide on a glass slide and examine under a microscope. Carob bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in Guar gum.

#### PURITY

**Loss on drying** Not more than 14% (105°C, 5 h).

**Total ash** Not more than 1.2% (800°C, 3-4 h).

**Acid-insoluble matter** Not more than 4.0%.

**Protein** Not more than 7.0%.

**Starch** To a 1 in 10 dispersion of the sample add a few drops of iodine TS; no blue colour is produced.

**Residual solvents** Not more than 1% of ethanol or isopropanol, singly or in combination.

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

**Category** Food additives category (12) (16).

**Functional uses** Pasting Agent; Emulsifiers.



Category 13 Coagulating Agents

§ 13002

Tetrasodium Pyrophosphate, Decahydrate

Sodium Pyrophosphate

Tetrasodium Diphosphate, Decahydrate

Chemical formula:  $\text{Na}_4\text{P}_2\text{O}_7 \cdot 10\text{H}_2\text{O}$

Molecular weight: 446.06

1. Assay : Not less than 95% of  $\text{Na}_4\text{P}_2\text{O}_7$  on the dried basis.
2. Description : Colorless or white crystals, or a white crystalline or granular powder. Soluble in water; insoluble in ethanol.
3. pH : 9.9 - 10.7 (1 in 100 soln)
4. Phosphate : Dissolve 1 g of the sample in 100 mL of water. Add a few drops of silver nitrate TS to 1 mL of the solution. No obvious yellow precipitate should be formed. If a white or yellowish precipitate is formed, the precipitate can be redissolved in dilute nitric acid.
5. Sodium : The 1 in 20 solution of the sample passes test for sodium.
6. Fluoride : Not more than 10 mg/kg.
7. Arsenic : Not more than 3 mg/kg (as As).
8. Lead : Not more than 5 mg/kg.
9. Heavy metals : Not more than 10 mg/kg (as Pb).
10. Loss on drying : Not more than 38~42% (dried at 105°C for 4 hours, and then dried at 800°C for 30 minutes)
11. Water-insoluble matter : Not more than 0.2%.
12. Category : Food Additives Category 13
13. Uses : Coagulating agent

Tetrasodium Pyrophosphate, Anhydrous

Sodium Pyrophosphate, Anhydrous

Tetrasodium Diphosphate, Anhydrous

Chemical formula:  $\text{Na}_4\text{P}_2\text{O}_7$

Molecular weight: 265.94

1. Assay : Not less than 95% of  $\text{Na}_4\text{P}_2\text{O}_7$  on the dried basis
2. Description : Colorless or white crystals, or a white crystalline or granular powder. Soluble in water; insoluble in ethanol.
3. pH : 9.9 - 10.7 (1 in 100 soln)
4. Phosphate : Dissolve 1 g of the sample in 100 mL of water. Add a few drops of silver nitrate TS to 1 mL of the solution. No obvious yellow precipitate should be formed. If a white or yellowish precipitate is formed, the precipitate can be redissolved in dilute nitric acid.
5. Sodium : The 1 in 20 solution of the sample passes test for sodium.
6. Fluoride : Not more than 10 mg/kg.
7. Arsenic : Not more than 3 mg/kg (as As).
8. Lead : Not more than 5 mg/kg.
9. Heavy metals : Not more than 10 mg/kg (as Pb).
10. Loss on drying : Not more than 0.5% (dried at 105°C for 4 hours, and then dried at 800°C for 30 minutes)
11. Water-insoluble matter : Not more than 0.2%.
12. Category : Food Additives Category 13
13. Uses : Coagulating agent

§ 13004

Potassium Polyphosphate

The same as § 07037

§ 13005

Sodium Polyphosphate

The same as § 07038

§ 13006

Potassium Metaphosphate

The same as § 07035

§ 13007

Sodium Metaphosphate

The same as § 07036

§ 13008

Potassium Dihydrogen Phosphate

The same as § 07026

§ 13009

Sodium Phosphate, Monobasic

The same as § 07029



§ 13010

Sodium Phosphate, Monobasic, Anhydrous

The same as § 07030

§ 13011

Potassium Phosphate, Dibasic

The same as § 07027

§ 13012

Sodium Phosphate, Dibasic

The same as § 07031

§ 13013

Sodium Phosphate, Dibasic, Anhydrous

The same as § 07032

§ 13014

Potassium Phosphate, Tribasic

The same as § 07028

§ 13015

Trisodium Phosphate

The same as § 07033

§ 13016

Sodium Phosphate, Tribasic, Anhydrous

The same as § 07034

§ 14001

Sodium Hydroxide

Chemical formula: NaOH

Molecular weight: 40.00

1. Assay : Not less than 95% .
2. Appearance : White or nearly white pellets, flakes, sticks, fused masses or other forms.
3. Solution : Dissolve 50 g of the sample in 250 mL of fresh boiled and cooled water. Mix 5 mL of the solution with 20 mL of water. The solution should be colorless and the turbidity should be below "almost clear".
4. Sulfate : Not more than 0.2% of SO<sub>4</sub>.
5. Sodium : Not more than 2%.  
carbonate
6. Arsenic : Not more than 3 ppm (as As<sub>2</sub>O<sub>3</sub>).
7. Heavy metals : Not more than 30 ppm (as Pb).
8. Mercury : Not more than 0.1 ppm.
9. Potassium : When the flame reaction is viewed from cobalt glass, it should not be continuous purple.
10. Category : Food Additives Category 14
11. Uses : Chemicals for food industry



## Potassium Hydroxide

Chemical formula: KOH

Molecular weight: 56.11

1. Assay : Not less than 85.0% of total alkali calculated as KOH.
2. Appearance : White or nearly white pellets, flakes, sticks, fused masses or other forms.
3. Solubility : Very soluble in water; freely soluble in ethanol
4. Test for alkali : A 1 in 100 solution of the sample is strongly alkaline.
5. Water-insoluble matter : A 1 in 20 solution of the sample is complete, clear, and colorless.
6. Carbonate : Not more than 3.5% of  $K_2CO_3$ .
7. Lead : Not more than 2 mg/kg.
8. Category : Food Additives Category 14
9. Uses : Chemicals for food industry

## Sodium Hydroxide Solution

1. Assay : The sample contains 95% to 120% of indicated NaOH content.
2. Appearance : Colorless or slightly colored liquid.
3. Solution : Add freshly boiled and cooled water to the sample to make 20 w/v% solution of NaOH according to the indicated amount. Mix 5 mL of the solution and 20 mL of water. The solution should be colorless and the turbidity should be below "almost clear".
4. Sulfate : Not more than 0.2% of  $\text{SO}_4$ .
5. Sodium : Not more than 2%.  
carbonate
6. Arsenic : Not more than 3 ppm (as  $\text{As}_2\text{O}_3$ ).
7. Heavy metals : Not more than 30 ppm (as Pb).
8. Potassium : When the flame reaction is viewed from cobalt glass, it should not be continuous purple.
9. Mercury : Not more than 0.1 ppm.
10. Category : Food Additives Category 14
11. Uses : Chemicals for food industry

## Hydrochloric Acid

Chemical formula: HCl

Molecular weight: 36.46

1. Assay : The sample contains 90% to 120% of indicated HCl content.
2. Appearance : Colorless to pale yellow liquid, with a stimulating odor.
3. Sulfate : Not more than 0.012 w/v% of SO<sub>4</sub>.
4. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 5 ppm (as Pb).
6. Mercury : Not more than 0.1 ppm.
7. Iron : Not more than 30 ppm.
8. Residue on ignition : Add 2 drops of sulfuric acid to 100 g of the sample. When it is evaporated to a constant amount on a sand bath, the amount of residue should be not more than 20 mg.
9. Category : Food Additives Category 14
10. Uses : Chemicals for food industry

## Sulfuric Acid

Chemical formula:  $\text{H}_2\text{SO}_4$ 

Molecular weight: 98.08

1. Assay : Not less than 94%
2. Appearance : Clear, colorless or slightly brown, very corrosive oily liquid.
3. Chloride : Not more than 50 ppm of Cl.
4. Nitric acid : Not more than 20 ppm.
5. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
6. Heavy metals : Not more than 10 ppm (as Pb).
7. Iron : Not more than 0.01%.
8. Selenium : Not more than 1 ppm.
9. Readily oxidizable matter : Dissolve 4 g of the sample in 10 mL of water. After cooling, add 3 drops of 0.1 N potassium permanganate solution. The color should not disappear within 5 minutes.
10. Residue on ignition : Not more than 0.02%.
11. Category : Food Additives Category 14
12. Uses : Chemicals for food industry

# Oxalic Acid

Chemical formula:  $C_2H_2O_4 \cdot 2H_2O$

Molecular weight: 126.07

1. Assay : 99.5~101.0%.
2. Appearance : Colorless crystal, odorless.
3. Solution : When 1 g of the sample is dissolved and boiled in 20 mL of water, the solution should be colorless and the turbidity should be below "almost clear".
4. Sulfate : Not more than 0.08% of  $SO_4$ .
5. Arsenic : Not more than 2 ppm (as  $As_2O_3$ ).
6. Heavy metals : Not more than 20 ppm (as Pb).
7. Residue on ignition : Not more than 13%.
8. Category : Food Additives Category 14
9. Uses : Chemicals for food industry

## Ion-Exchange Resin

- 1    **Appearance**    : Black, brown, pale auburn or white ball, block or powder, almost odorless.
- 2    **Solid matter**    : (1) Cation exchange resin: Take 25 mL of the sample into a chromatography tube with an inner diameter of about 3 cm. After eluting with 4% hydrochloric acid at a rate of 15 to 20 mL per minute, wash with the purified water at the same rate until the chlorine content in 10 mL of the solution is less than that of 0.3 mL of 0.1 N hydrochloric acid. Use it as a standard sample (H type).  
                               (2) Anion exchange resin: Take 25 mL of the sample into a chromatography tube with an inner diameter of about 3 cm. After eluting with 1,000 mL of 4% hydrochloric acid at a rate of 15 to 20 mL per minute, wash with the purified water at the same rate until the solution is not red to phenolphthalein TS. Use it as a standard sample (OH type).  
                               Fully impregnate the standard sample with purified water and absorb attached water by the filter paper. Weigh 10 g. If it is a cation exchange resin, dry at 100°C for 12 hours. If it is an anion exchange resin, dry in a vacuum dryer at 40°C and 30 mmHg for 12 hours. The amount should be not less than 25%.
- 3    **Water soluble substance**    : Fully impregnate the standard sample with purified water and absorb attached water by the filter paper. Weigh 10 g into a cylindrical filter paper with an inner diameter of 28 mm and a length of 100 mm, hang it in 1,000 mL of purified water, and shake it often for 5 hours.  
                               After extracting 50 mL of the extract, dry it at 110°C for 3 hours. The residue should be not more than 0.5%. The same method must be used as a control test.
- 4    **Arsenic**    : Fully impregnate the standard sample with purified water and absorb attached water by the filter paper. Put 2 g in the decomposition bottle, add 5 mL of sulfuric acid and 20 mL of nitric acid, slowly heat and add 2 to 3 mL of nitric acid until the liquid becomes colorless to pale yellow. After cooling, add 5 mL of saturated ammonium oxalate solution and heat to produce white smoke. After cooling, add water to make it 25 mL. Take 5 mL as the test liquid, and the arsenic content should not be more than 3 ppm.
- 5    **Total exchange capacity**    : (1) Cation exchange resin: Fully impregnate the standard sample with purified water and absorb attached water by the filter paper. Accurately weigh 5 g, immerse it in 500 mL of 0.2 N sodium hydroxide solution and shake it often for 12 hours. Take 10 mL of clear liquid and titrate with 0.1 N sulfuric acid (3 drops of methyl orange TS as indicator). Perform a

controlled test. When calculating the total exchange capacity according to the following formula, the value should be 1.0 meq/g or more.

Total exchange capacity=

$$\frac{0.1N \text{ sulfate titration required for control experiments (mL)} - 0.1N \text{ sulfate titration required for control experiments}}{\text{Standard sample volume (g)} \times \frac{\text{Solid matter(\%)}}{100}} \times 5 \left( \frac{\text{meq}}{\text{g}} \right)$$

(2) Anion exchange resin: The test method and calculation are the same as "cation exchange resin". However, 0.2 N hydrochloric acid solution is used instead of 0.2 N sodium hydroxide solution, and 0.1 N sodium hydroxide solution is used instead of 0.1 N sulfuric acid solution.

6 Category : Food Additives Category 14

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7 Uses : Chemicals for food industry

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§ 14009

Potassium Carbonate

The same as § 06011



§ 14010

Sodium Carbonate, Anhydrous

The same as § 07017

## Category 15 Carrier

§ 15001

### Propylene Glycol

Chemical formula:  $C_3H_8O_2$

Molecular weight: 76.10

1. Appearance : Clear, colorless, hygroscopic, viscous liquid
2. Density : 1.036~1.040.
3. Boiling Point : 183~195°C.
4. Free acid : Add 1 mL of phenol red TS to 50 mL water, then add 0.01N sodium hydroxide until solution remains red for 30 sec. To this solution add about 10 mL of the sample. Titrate with 0.2 m of 0.1 N sodium hydroxide until the original red color returns and remains for 30 sec.
5. Chloride : Not more than 70 ppm of Cl.
6. Heavy metals : Not more than 5 ppm (as Pb).
7. Glycerin and ethylene glycol : Accurately weigh 1 g of the sample and add water to make a 1000 mL solution. Add 0.2 g of potassium periodate, 1 mL of sulfuric acid and 50 mL of water to 13 mL of the solution, and distill at a rate of 3 to 5 mL per minute until the residue is about 1 mL (the receiver of the distillate should be placed in iced water). The distillate is added with water to make it 500 mL. Add 0.1 g of chromic acid and 5 mL of sulfuric acid to 1 mL of distillate solution, heat in a water bath for 30 minutes, then cool. When adding water to make it 250 mL, the liquid color should not be thicker than 1 mL of formaldehyde standard solution undergone the same process.
8. Residue on ignition : Not more than 0.05%.
9. Category : Food Additives Category 15
10. Uses : Carrier.

§ 15002

Glycerol

The same as § 07040

§ 16001

Glycerin Fatty Acid Ester

**Synonyms**

Mono- And Diglycerides: Glyceryl monostearate, glyceryl monopalmitate, glyceryl monooleate, etc; monostearin, monopalmitin, monoolein, etc.; GMS (for glyceryl monostearate); INS No. 471

Acetic and Fatty Acid Esters of Glycerol: Acetic acid esters of mono- and diglycerides, acetoglycerides, acetylated mono- and diglycerides, INS No.472a

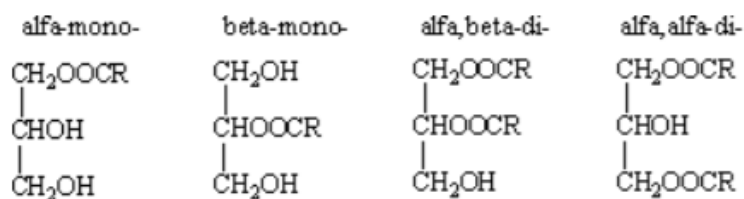
**Definition**

Mono- And Diglycerides: A mixture of mono- and diglyceryl esters of long chain, saturated and unsaturated fatty acids that occur in food fats; contain not less than 30% of alpha-monoglycerides and may also contain other isomeric monoglycerides, as well as di- and triglycerides, free glycerol, free fatty acids, soap and moisture; usually manufactured by the glycerolysis of edible fats and oils, but may also be prepared by esterification of fatty acids with glycerol, with or without molecular distillation of the product.

Acetic and Fatty Acid Esters of Glycerol: Mixed glycerol esters of acetic acid and fatty acids of food fats. Contains mono- and diesters of fatty acids with glycerol which is itself partially acetylated; may also contain free glycerol and free fatty acids.

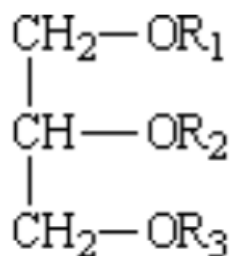
**Structural formula**

Mono- And Diglycerides:



where -OCR represents the fatty acid moiety

Acetic and Fatty Acid Esters of Glycerol:



where R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> each may be a fatty acid moiety, - COCH<sub>3</sub> or H

Formula weight

Mono- And Diglycerides:

Glyceryl monostearate: 358.6

Glyceryl distearate: 625.0

These are two major components of commercial products

Acetic and Fatty Acid Esters of Glycerol: -

## Description

Mono- And Diglycerides: White or cream coloured hard fats of waxy appearance, plastic products or viscous liquids.

Acetic and Fatty Acid Esters of Glycerol: From liquid to solid in consistency; white to pale yellow, may have the odour of acetic acid

The article of commerce may be further specified as the saponification value, acid value, free fatty acid content, solidification point of the free fatty acids, Reichert-Meissl value, iodine value and free glycerol content.

## Characteristics

Identification

Solubility

Mono- And Diglycerides: Insoluble in water; soluble in ethanol, chloroform and benzene  
Acetic and Fatty Acid Esters of Glycerol: Insoluble in water; soluble in ethanol

Infrared absorption

Mono- And Diglycerides: The infrared spectrum of the sample is characteristic of a partial fatty acid ester of a polyol

Acetic and Fatty Acid Esters of Glycerol: -

Tests for fatty acids

Passes tests

Test for glycerol

Passes tests

Purity

Water

Mono- And Diglycerides: Not more than 2.0% (Karl Fischer Method)

Acetic and Fatty Acid Esters of Glycerol: -

Acid value	<p>Mono- And Diglycerides: Not more than 6</p> <p>Acetic and Fatty Acid Esters of Glycerol: -</p>
Free glycerol	<p>Mono- And Diglycerides: Not more than 7%</p> <p>Acetic and Fatty Acid Esters of Glycerol: -</p>
Soap	<p>Mono- And Diglycerides: Not more than 6%, calculated as a sodium oleate</p> <p>Add 10.00 g of the sample to a mixture of 60 ml of acetone and 0.15 ml of bromophenol blue solution (0.5%), previously neutralized with 0.1 N hydrochloric acid or 0.1 N sodium hydroxide. Warm gently on a water bath until solution is complete, and titrate with 0.1 N hydrochloric acid until the blue colour is discharged. Allow to stand for 20 min, warm until any solidified matter has re-dissolved and, if the blue colour reappears, continue the titration. Each ml of 0.1 N hydrochloric acid is equivalent to 0.0304 g of <math>C_{18}H_{33}O_2Na</math>.</p> <p>Acetic and Fatty Acid Esters of Glycerol: -</p>
Lead	Not more than 2 mg/kg
<b>Category</b>	Food additives category (16)
<b>Functional uses</b>	Emulsifiers

Sucrose Fatty Acid Ester

1. Appearance : Stiff gels, soft solids or white to slightly greyish white powders.
2. Acid value : Not more than 5.
3. Nitrogen : Not more than 0.02%.
4. Arsenic : Not more than 1 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 20 ppm (as Pb).
6. Free sucrose : Not more than 10%.
7. Loss on drying : Not more than 4% (vacuum desiccator over sulfuric acid, 4 hr).
8. Residue on : Not more than 1.5%.  
ignition
9. Category : Food Additives Category 16
10. Uses : Emulsifier

Sorbitan Fatty Acid Ester

1. Appearance : White to tan liquid or wax.
2. Acid value : Not more than 14.
3. Arsenic : Not more than 2 ppm (as  $\text{As}_2\text{O}_3$ ).
4. Heavy metals : Not more than 20 ppm (as Pb).
5. Polyoxyethylene : Heat and oscillate 1 g of the sample and 20 mL of water. After cooling, add ammonium thiocyanate, 10 mL of cobalt nitrate TS, and mix thoroughly by shaking. Add 10 mL of chloroform, shake and mix. The chloroform layer should not be blue when placed.
6. Residue on ignition : Not more than 1.5%.
7. Category : Food Additives Category 16
8. Uses : Emulsifier



Propylene Glycol Fatty Acid Ester

1. Appearance : White or cream colored solids of waxy appearance, plastic products or viscous liquids.  
Odorless and tasteless.
2. Acid value : Not more than 8.
3. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
4. Heavy metals : Not more than 20 ppm (as Pb).
5. Polyoxyethylene : The test method for "5.Polyoxyethylene" of "fatty acid sorbitan ester" is applicable.
6. Residue on : Not more than 1.5%.  
ignition
7. Category : Food Additives Category 16
8. Uses : Emulsifier

## Diacetyl Tartaric Acid Esters of Mono- and Diglycerides

Synonyms	Diacetyltartaric acid esters of mono- and diglycerides; DATEM; Tartaric, acetic and fatty acid esters of glycerol, mixed; Mixed acetic and tartaric acid esters of mono and diglycerides of fatty acids; INS No. 472e.
Definition	<p>The product consists of mixed glycerol esters of mono- and diacetyltartaric acid and fatty acids from edible fats and oils. It is made by the interaction of diacetyltartaric anhydride and monoand diglycerides of fatty acids in the presence of acetic acid, or by interaction of acetic anhydride and mono- and diglycerides of fatty acids in the presence of tartaric acid.</p> <p>Because of inter- and intramolecular acyl-group exchange, both methods of production lead to the same essential components, the distribution of which depends on the relative proportions of the basic raw materials, on temperature, and on reaction time. The product may contain small amounts of free glycerol, free fatty acids, and free tartaric and acetic acids.</p>
C.A.S. numbers	308068-42-0 100085-39-0
Structural formula	$  \begin{array}{c}  \text{CH}_2-\text{OR}_1 \\    \\  \text{CH}-\text{OR}_2 \\    \\  \text{CH}_2-\text{OR}_3  \end{array}  $ <p>in which one or two of the R groups is a fatty acid moiety and the other R groups are either:</p> <ul style="list-style-type: none"> <li>- diacetylated tartaric acid moiety</li> <li>- monoacetylated tartaric acid moiety</li> <li>- tartaric acid moiety</li> <li>- acetic acid moiety</li> <li>- hydrogen</li> </ul>
Description	Liquid, paste, or wax-like solid
Characteristics	
Identification	

Solubility	Dispersible in cold and hot water; soluble in methanol, ethanol, acetone, and ethyl acetate.
1,2-diols	To a solution of 500 mg in 10 ml methanol, add dropwise, lead acetate TS. A white, flocculent, insoluble precipitate is formed.
Fatty acids	Passes test
Acetic acid	Passes test
Tartaric acid	Passes test
Glycerol	Passes test
Purity	
Acids	Acids other than acetic, tartaric and fatty acids, shall not be detectable.
Sulfated ash	Not more than 0.5% (determined at $800\pm 25^{\circ}\text{C}$ )
Acid value	40-130
Total acetic acid	8%-32% after hydrolysis
Total tartaric acid	10%-40% after saponification
Total glycerol	11%-28% after saponification
Free glycerol	Not more than 2.0%
Lead	Not more than 2 mg/kg
Category	Food Additives Category 8
Uses	Nutritional additives

## Sodium Aluminum Phosphate, Basic

1. Description : An autogenous mixture of an alkaline sodium aluminum phosphate (approximately  $\text{Na}_8\text{Al}_2(\text{OH})_2(\text{PO}_4)_4$ ) with about 30% dibasic sodium phosphate. White, odorless powder. Soluble in hydrochloric acid; the sodium phosphate moiety is soluble in water, whereas the sodium aluminum phosphate moiety is only sparingly soluble in water.
2. Identification : Test a 1 in 10 solution in dilute hydrochloric acid (1 in 2). Passes test for sodium, aluminum and phosphate.
3. Assay : Not less than 9.5% and not more than 12.5% of  $\text{Al}_2\text{O}_3$ , on the ignited basis.
4. Fluoride : Not more than 0.0025%.
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 10 ppm.
7. Heavy metals : Not more than 0.004% (as Pb).
8. Loss on ignition : Not more than 9%.
9. Category : Food Additives Category 16
10. Uses : Emulsifier

Polysorbate 20  
(Polyoxyethylene (20) Sorbitan Monolaurate)

1. Assay : Not less than 70.0 and not more than 74.0% of oxyethylene groups ( $-C_2H_4O-$ ), equivalent to not less than 97.3 and not more than 103.0% of polyoxyethylene (20) sorbitan monolaurate calculated on the anhydrous basis.
2. Description : Consists of a mixture of the partial esters of sorbitol and sorbitol anhydride with lauric acid and condensed with approximately 20 moles of ethylene oxide ( $C_2H_4O$ ) per mole of sorbitol and its anhydrides.  
  
Lemon to amber colored oily liquid, with a faint characteristic odor and bitter taste. Soluble in water, methanol, ethanol, ethyl acetate and dioxane; insoluble in mineral oil, mineral essential oil and petroleum ether.
3. Identification : To 5 mL of a 5% (w/v) aqueous solution of the sample add 5 mL sodium hydroxide TS. Boil for a few min, cool, and acidify with dilute hydrochloric acid. The solution is strongly opalescent.
4. Acid value : Not less than 2
5. Hydroxy value : 96~108.
6. Saponification value : 40~50.
7. Lauric acid : 15~17%.
8. Water : Not more than 3%.
9. 1, 4-dioxane : Not more than 10 mg/kg.
10. Arsenic : Not more than 3 ppm (as As).
11. Heavy metals : Not more than 10 ppm (as Pb).
12. Residue on ignition : Not more than 0.25%.
13. Category : Food Additives Category 16
14. Uses : Emulsifier

Polysorbate 60  
(Polyoxyethylene (20) Sorbitan Monostearate)

1. Assay : Not less than 65.0 and not more than 69.5% of oxyethylene groups, equivalent to not less than 97.0 and not more than 103.0% of polyoxyethylene (20) sorbitan monostearate, on the anhydrous basis.
2. Description : Consists of a mixture of the partial esters of sorbitol and its mono- and dianhydrides (which have an acid value below 10 and a water content below 0.2%) with the stearic acid and condensed with approximately 20 moles of ethylene oxide (C<sub>2</sub>H<sub>4</sub>O) per mole of sorbitol and its anhydrides. Yellow to orange colored oily liquid or semi-gel, with a faint characteristic odor and slightly bitter taste. Soluble in water, ethyl acetate, aniline and toluene; insoluble in mineral oil and vegetable oils.
3. Identification : (1) To 5 mL of a 5% (w/v) aqueous solution of the sample add 5 mL sodium hydroxide TS. Boil for a few min, cool, and acidify with dilute hydrochloric acid. The solution is strongly opalescent.  
(2) A mixture of 60 parts by volume of the sample and 40 parts of water yields a gelatinous mass at or below 25°C.
4. Acid value : Not less than 2
5. Hydroxy value : 81~96.
6. Saponification value : 45~55.
7. Stearic acid : 24~26%.  
and palmitic acid
8. Water : Not more than 3%.
9. 1, 4-dioxane : Not more than 10 mg/kg.
10. Arsenic : Not more than 3 ppm (as As).
11. Heavy metals : Not more than 10 ppm (as Pb).
12. Residue on ignition : Not more than 0.25%.
13. Category : Food Additives Category 16
14. Uses : Emulsifier

Polysorbate 65  
(Polyoxyethylene (20) Sorbitan Tristearate)

1. Assay : Not less than 46.0 and not more than 50.0% of oxyethylene groups, equivalent to not less than 96.0 and not more than 104.0% of polyoxyethylene (20) sorbitan tristearate on the anhydrous basis.
2. Description : Consists of a mixture of the partial esters of sorbitol and sorbitol dianhydrides with stearic acid and condensed with approximately 20 moles of ethylene oxide (C<sub>2</sub>H<sub>4</sub>O) per mole of sorbitol and its anhydrides. Tan colored, waxy solid, with a faint characteristic odor and bitter taste. Dispersible in water and in carbon tetrachloride; soluble in mineral oil, vegetable oils, petroleum ether, acetone, ether, dioxane, ethanol and methanol.
3. Identification : To 5 mL of a 5% (w/v) aqueous solution of the sample add 5 mL sodium hydroxide TS. Boil for a few min, cool, and acidify with dilute hydrochloric acid. The solution is strongly opalescent.
4. Acid value : Not less than 2
5. Hydroxy value : 40~60.
6. Saponification value : 88~98.
7. Stearic acid and palmitic acid : 42~44%.
8. Water : Not more than 3%.
9. 1, 4-dioxane : Not more than 10 mg/kg.
10. Arsenic : Not more than 3 ppm (as As).
11. Heavy metals : Not more than 10 ppm (as Pb).
12. Residue on ignition : Not more than 0.25%.
13. Category : Food Additives Category 16
14. Uses : Emulsifier

Polysorbate 80  
(Polyoxyethylene (20) Sorbitan Monooleate)

1. 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 polyoxyethylene (20) sorbitan monooleate, calculated on the anhydrous basis.
2. Description : Consists of a mixture of the partial esters of sorbitol and sorbitol anhydride with oleic acid and condensed with approximately 20 moles of ethylene oxide (C<sub>2</sub>H<sub>4</sub>O) per mole of sorbitol and its anhydrides. Lemon to amber colored oily liquid, with a faint characteristic odor and a little bitter taste. Soluble in water, forming an odorless and almost colorless solution. Soluble in ethanol, methanol, ethyl acetate and toluene; insoluble in mineral oil and petroleum ether.
3. Identification : (1) To 5 mL of a 5% (w/v) aqueous solution of the sample add 5 mL sodium hydroxide TS. Boil for a few min, cool, and acidify with dilute hydrochloric acid. The solution is strongly opalescent.  
(2) To a solution of the sample (1 in 20) add bromine TS dropwise. The bromine is decolorized.  
(3) A mixture of 60 parts by volume of the sample and 40 parts of water yields a gelatinous mass at or below 25°C.
4. Acid value : Not less than 2
5. Hydroxy value : 65~80.
6. Saponification value : 45~55.
7. Oleate : 22~24%.
8. Water : Not more than 3%.
9. 1, 4-dioxane : Not more than 10 mg/kg.
10. Arsenic : Not more than 3 ppm (as As).
11. Heavy metals : Not more than 10 ppm (as Pb).
12. Residue on ignition : Not more than 0.25%.
13. Category : Food Additives Category 16
14. Uses : Emulsifier



§ 16012

Hydroxypropyl Cellulose

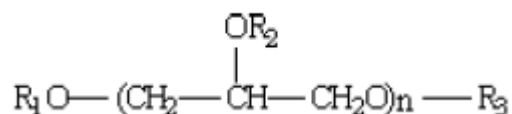
The same as § 07065

§ 16013

Hydroxypropyl Methylcellulose  
(Propylene Glycol Ether of Methylcellulose)

The same as § 07066

## Polyglycerol Esters of Fatty Acids

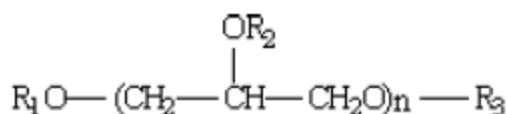


where the average value of n is about 3 and R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> each may be a fatty acid moiety or hydrogen.

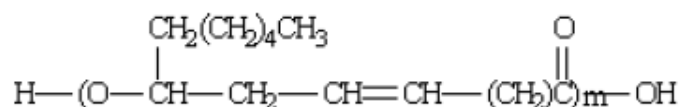
1. **Definition** : Mixed partial esters formed by reacting polymerized glycerols with edible fats, oils, or fatty acids; minor amounts of mono-, di-, and triglycerides, free glycerol and polyglycerols, free fatty acids, and sodium salts of fatty acids may be present; degree of polymerization varies, and is specified by a number (such as tri-) that is related to the average number of glycerol residues per polyglycerol molecule. A specified polyglycerol consists of a distribution of molecular species characteristic of its nominal degree of polymerization. By varying the proportions as well as the nature of the fats or fatty acids to be reacted with the polyglycerols, a large and diverse class of products may be obtained. The article of commerce may be further specified as to saponification value, solidification point of the free fatty acids, iodine value, hydroxyl value and ash content.
2. **Appearance** : 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.
3. **Identification** : (1)Tests for fatty acids: Passes test.  
(2)Test for glycerol and polyglycerols: Spot 5 to 20 µl of the aqueous layer obtained in the test for fatty acids Identification tests for functional groups alongside control spots of glycerol on paper such as Whatman No. 3 and develop using descending chromatography for 36 h with isopropanol: water (90:10). The glycerol spot moves 40 cm and the polyglycerols are revealed in succession below that for glycerol when the paper is sprayed with either permanganate in acetone or ammoniacal silver nitrate.
4. **Solubility** : From very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils.
5. **Acids** : Acids other than fatty acids shall not be detectable.
6. **Polyglycerols** : The polyglycerol moiety shall be composed of not less than 75% of di-, triand tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
7. **Lead** : Not more than 2 mg/kg.
8. **Category** : Food Additives Category 16
9. **Uses** : Emulsifier

## Polyglycerol Esters of Interesterified Ricinoleic Acid

The major components have the general structure:



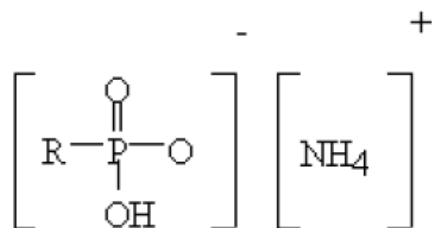
where the average value of n is about 3 and R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> each may be hydrogen or a linear condensation polymer of ricinoleic acid with itself thus:



where the average value of m is between 5 and 8.

1. Definition : Prepared by the esterification of polyglycerol with condensed castor oil fatty acids.
2. Appearance : Highly viscous liquids
3. Identification : (1) Tests for fatty acids: Passes test.  
 (2) Test for ricinoleic acid: The fatty acids liberated in test for fatty acids Identification tests for functional groups should have a Hydroxyl value corresponding to that for castor oil fatty acids (about 150 to 170).  
 (3) Test for glycerol and polyglycerols: Spot 5 to 20 µl of the aqueous layer obtained in the test for fatty acids under Identification test for functional groups alongside control spots of glycerol on paper such as Whatman No. 3 and develop using descending chromatography for 36 h with isopropanol : water, 90:10. The glycerol spot moves 40 cm and the polyglycerols are revealed in succession below that for glycerol when the paper is sprayed with either permanganate in acetone or ammoniacal silver nitrate.
4. Solubility : Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons.
5. Polyglycerols : The polyglycerol moiety shall be composed of not less than 75% of di-, triand tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol.
6. Lead : Not more than 2 mg/kg.
7. Category : Food Additives Category 16
8. Uses : Emulsifier

## Ammonium Phosphatide



where R may be a mono- or di-glyceride moiety

- Synonyms : Ammonium salts of phosphatidic acid;  
Mixed ammonium salts of phosphorylated glycerides  
INS No. 442
1. Definition : The product consists essentially of a mixture of the ammonium compounds of phosphatidic acids derived from the edible fat (usually partially hardened rapeseed oil). A mono- or diglyceride moiety may be attached to phosphorus. Moreover, two phosphorus esters may be linked together as phosphatidyl phosphatides.
  2. Assay : The phosphorus content is not less than 3.0% and not more than 3.4% by weight; the ammonium N content is not less than 1.2% and not more than 1.5%.
  3. Appearance : Unctuous semisolid
  4. Solubility : Insoluble in water, partially soluble in ethanol and in acetone, soluble in fats.
  5. Lead : Not more than 2 mg/kg.
  6. Category : Food Additives Category 16
  7. Uses : Emulsifier

§ 16031

**Pectins**

The same as § 12049

§ 16032

**Guar Gum**

The same as § 12050

§ 16033

**Carob Bean Gum**

The same as § 12051



Category 17 Others

§ 17001

Piperonyl Butoxide

Chemical formula:  $C_{19}H_{30}O_5$

Molecular weight: 338.45

1. Appearance : An oily colorless to slightly yellow liquid. Odorless or with a faint characteristic odor.
2. Color : The color should not be thicker than that of 1.4 mL of the cobalt chloride colorimetric standard stock solution, 4.3 mL of the ferric chloride colorimetric standard stock solution and 0.3 mL of the copper sulfate colorimetric standard stock solution.
3. Density : 1.05~1.07.
4. Index of refraction :  $n_D^{20} = 1.497 \sim 1.512$ .
5. Chloride compound : Not more than 0.2% (as 6-Propyl Piperonyl Chloride)
6. Heavy metals : Not more than 20 ppm of Ni.
7. Distillation range : Put 25 g of the sample in a 100 mL flask. Under the decompression of 4 mm mercury column, when distilling to 194°C, the residue in the bottle should be more than 85% of the sample amount. When distilled to 203°C, the residue in the bottle should be less than 5% of the sample amount.
8. Category : Food Additives Category 17
9. Uses : Others.

## Polyvinyl Acetate

1 Appearance : Colorless to light yellow particles or glassy blocks.

. ce

2 Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).

.

3 Heavy : Not more than 4 ppm (as Pb).

. metals

4 Free acid : Not more than 0.2% (as CH<sub>3</sub>COOH)

.

5 Residual : Accurately weigh 1 g of the sample, add 100 mL of 75% acetic acid solution to it. After placed for  
 . monovinyl 24 hours to dissolve, add 4 mL of bromine glacial acetic acid TS and 2 mL of potassium iodide TS.  
 Titrate free iodine with 0.1 N sodium thiosulfate (indicator: starch test solution). In another  
 controlled test, when the amount of residual vinyl monomer is calculated as follows, the amount  
 should be less than 1%.

Residual monovinyl =

$$\frac{0.0043 \times (0.1N \text{ sodium thiosulfate solution required for control test} - 0.1N \text{ sodium thiosulfate solution required for})}{\text{Sample volume (g)}}$$

100%

6 Residue : Not more than 0.05%.

. on

ignition

7 Category : Food Additives Category 17

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8 Uses : Others.

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Silicon Resin  
(polydimethyl siloxane)

1.     Appearance             : Clear, light grey and almost transparent, viscous liquid. Almost odorless.
2.     Density                : 0.98~1.02.
3.     Viscosity and index of   : 15 g of the sample is placed in a Soxhelt extractor and extracted with 150 mL of  
refraction                       carbon tetrachloride for 3 hours. Evaporated the extract on a water bath to form a  
viscous liquid. Its viscosity should be 100~1,100 Centistokes at 25°C and the  
refrindex be  $n_D^{25} = 1.400 \sim 1.410$ .
4.     Silica                 : The extract residue of "3. Viscosity and index of refraction" should range from 0.45 g to  
2.25 g after drying at 100°C for 1 hour.
5.     Category               : Food Additives Category 17
6.     Uses                  : Others.

§ 17005

Diatomaceous Earth

The same as § 07044

## Sodium Oleate

1. Appearance : White crystals or yellow amorphous granules, having a characteristic odor.
2. Solution : Mix and dissolve 0.5 mg of the sample in 20 mL of water. The liquid should be "almost clear".
3. Free alkali : Accurately weigh 5.0 gm of the sample powder, add 100 mL of neutral ethanol, heat to dissolve, and filter. Wash with warm neutral ethanol until the wash is colorless. Combine the wash with the filtrate. After cooling, titrate with 0.1 N sulfuric acid. Its consumption is expressed as a mL. Wash the residue with 10 mL of hot water for five times and combine the washings. After cooling, add 3 drops of bromophenol blue indicator dropwise and titrate with 0.1 N sulfuric acid. The consumption is expressed in b mL. When the amount of free alkali is determined according to the following formula, the amount should be less than 0.5%.  
Free alkali = 
$$\frac{0.004 \times a + 0.0053 \times b}{\text{Sample (gm)}} \times 100(\%)$$
4. Arsenic : Not more than 2 ppm (as As<sub>2</sub>O<sub>3</sub>).
5. Heavy metals : Not more than 40 ppm (as Pb).
6. Residue on ignition : 22~25%.
7. Category : Food Additives Category 17
8. Uses : Others.

## Oxyethylene Higher Aliphatic Alcohol

1. Appearance : White to pale yellow powder, flakes, or waxy lumps, odorless, tasteless or with a slight odor.
2. Solution : When 0.5 g of the sample is dissolved in 10 mL of Dioxan, the solution should be “almost clear”.
3. Hydroxy value : Accurately weigh 1.5 g of the sample into a long neck round bottom flask, add anhydrous acetic acid, 5 mL of pyridine TS. Place a funnel on the mouth of the flask and heat in a 95-100°C oil pan for 1 hour. After cooling, dissolve the attached matter on the funnel with 1 mL of water, thoroughly shake and mix in the flask. Then heat in an oil pan for 10 minutes. After cooling, wash the funnel with 5 mL of neutral ethanol and burn the bottleneck, which is titrated with 0.5 N potassium hydroxide ethanol solution (indicator: 1 mL of phenolphthalein test solution) Perform a blank test with same process. When calculating the hydroxyl value according to the following formula, the value should be 155 to 187. (Acid value is regarded as 0).

Hydroxy value =

$$\frac{0.5N \text{ potassium hydroxide ethanol solution consumption (ml)} \times 28.05}{\text{Sample (g)}}$$

4. Heavy metals : Not more than 40 ppm (as Pb).
5. Polyoxyethylene : Heat and oscillate 0.5 g of the sample and 20 mL of water. Filter after cooling, add 10 mL of Ammonium thiocyanate nitrate TS, and mix thoroughly by shaking. Add 10 mL of chloroform, shake and mix. The chloroform layer should not be blue when placed.
6. Residue on ignition : Not more than 0.5%.
7. Category : Food Additives Category 17
8. Uses : Others.

## Shellac

Synonyms : INS No. 904

1. Description : Shellac is a polyester resin obtained from lac, the resinous secretion of the insect *Laccifer (Tachardia) lacca* Kerr (Fam. Coccidae). Bleached shellac is obtained by dissolving the lac in aqueous sodium carbonate, followed by bleaching with sodium hypochlorite, precipitation of the bleached lac with dilute sulfuric acid solution, and drying; wax-free bleached shellac is prepared by further treatment whereby the wax is removed by filtration.
2. Appearance : Bleached shellac: off-white to tan, amorphous granular resin; wax-free bleached shellac: light yellow, amorphous, granular resin.
3. Color reaction : To 50 mg of the sample add a few drops of a solution of 1 g ammonium molybdate in 3 mL of sulfuric acid. A green color is produced, changing to lilac when the solution is neutralized with 6 N ammonium hydroxide.
4. Solubility : Insoluble in water; freely (though very slowly) soluble in ethanol; slightly soluble in acetone and ether.
5. Acid value : 60~89.
6. Loss on drying : Not more than 6.0% (40°C, 4 h, then room temperature over silica gel, 15 h)
7. Rosin : Dissolve 2 g of the sample in 10 mL of dehydrated ethanol, and add slowly, with shaking, 50 mL of solvent hexane. Transfer to a separator, wash with two 50-mL portions of water, and discard the washings. Filter the solvent layer, evaporate it to dryness, and to the residue add 2 mL of a mixture of 1 volume of liquefied phenol and 2 volumes of methylene chloride. Stir and transfer a portion of the mixture to a cavity of a color-reaction plate. Fill an adjacent cavity with a mixture of 1 volume of bromine and four volumes of methylene chloride, and cover both cavities with an inverted watch glass. No purple or deep indigo blue color is produced in or above the liquid containing the sample residue.
8. Wax : Bleached shellac: not more than 5.5%; wax-free bleached shellac, not more than 0.2%.
9. Lead : Not more than 2 mg/kg
10. Category : Food Additives Category 17
11. Uses : Others

§ 17010

Petroleum Wax (Refined Paraffin Wax, Microcrystalline Wax)

The same as § 07057



Petroleum Wax, Synthetic  
(Synthetic Wax, Ethylene Polymer)

1. Description : The sample is obtained by catalytic polymerization of ethylene. It is a paraffinic, refined solid hydrocarbon mixture. Amber to off-white. The melting point is between 85°C and 116°C (185 ~ 240°F). Soluble in aromatic hydrocarbons, but not soluble in ketones, esters and alcohols.
2. Identification : The infrared absorbance spectrum of the sample melted and prepared on a caesium or potassium bromide plate corresponds to the infrared absorption spectrum and the standard map.
3. Average molecular weight : 500~1,200.
4. Ultraviolet absorbance limits : 280~289 nm, not more than 0.15.  
290~299 nm, not more than 0.12.  
300~359 nm, not more than 0.08.  
360~400 nm, not more than 0.02.
5. Arsenic : Not more than 3 ppm (as As).
6. Lead : Not more than 3 ppm.
7. Heavy metals : Not more than 0.002% (as Pb).
8. Color, melting point and odor : Should meet the seller's own specifications.
9. Category : Food Additives Category 17
10. Uses : Others.

## Polyethylene Glycols

Chemical formula:  $\text{HOCH}_2-(\text{CH}_2\text{OCH}_2)_n\text{CH}_2\text{OH}$ 

Molecular weight: 200~9500

1. Solution : Dissolve 5 g of the sample in 50 mL of water. Those with a molecular weight of 700 or less shall be colorless and clear or colorless and slightly ambiguous liquid; those with a molecular weight of 700 to 900 should be semi-solid; those with a molecular weight greater than 1000 should be milky white, waxy solid or powder with no fluidity.
2. Arsenic : Not more than 3 ppm (as As).
3. 1, 4-Dioxane : Not more than 10 ppm.
4. Ethylene Glycol and Diethylene Glycol : Not more than 0.25% separately or in total.
5. Ethylene Oxide : Not more than 0.02%.
6. Heavy metals : Not more than 10 ppm (as Pb).
7. pH : Dissolve 5 g of the sample in 100 mL of water without  $\text{CO}_2$  that contains 0.3 mL of saturated potassium chloride solution. The pH of the solution should be 4.5-7.5.
8. Residue on ignition : Not more than 0.1%.
9. Viscosity : Should meet the criteria specified in the appendix.
10. Acidity : Not more than 0.05% w/w (as acetic acid).
11. Category : Food Additives Category 17
12. Uses : Others.

## Tannic Acid

Synonyms : Tannins (food grade), Gallotannic acid .INS No. 181

1. Definition : Consists of gallotannins obtained by solvent extraction from certain natural sources; the substance is not an acid in the chemical sense. The common name "Tannic acid" has been adopted to distinguish the commercial substance from other tannins, such as condensed tannins. These specifications relate only to hydrolysable gallotannins, i.e., those which yield gallic acid on hydrolysis. These specifications do not apply to many other kinds of tannins which occur in nature, including condensed (nonhydrolysable) tannins and hydrolysable ellagitannins. Hydrolysable gallotannins may be obtained from nutgalls, the excrescences which form on young twigs of various *Quercus* species, e.g., *Q. infectoria*; these include Chinese and Aleppo tannins. They may also be obtained from various Sumac species, e.g. *Rhus coriaria*, *R. galabra*, *R. thypia*; these include Sicilian and American sumacs. All of these consist essentially of polydigalloyl esters of glucose. A further source of hydrolysable gallotannins is the seed pods of Tara (*Caesalpinia spinosa*); these tannins consist essentially of the polydigalloyl esters of quinic acid.
2. Assay : Not less than 96% (on the dried basis)
3. Appearance : Amorphous powder, glistening scales or spongy mass, varying in color from yellowish white to light brown; odorless or with a characteristic odor.
4. Solubility : Soluble in water, acetone and ethyl alcohol; insoluble in benzene, chloroform and ether; 1 g dissolves in about 1 mL of warm glycerin.
5. Color reaction : To a 1 in 10 solution add a small quantity of ferric chloride TS. A bluish black color or precipitate forms.
6. Precipitate formation : A solution of the sample when added to a solution of either albumin or gelatin produces a precipitate.
7. Loss on drying : Not more than 7% (105°C, 2 h).
8. Sulfated ash : Not more than 1%.
9. Gums or dextrin : Dissolve 1 g in 5 mL of water, filter, and to the filtrate add 10 mL of alcohol; no turbidity is produced within 15 minutes.
10. Resinous substances : Dissolve 1 g in 5 mL of water, filter and dilute the filtrate to 15 mL; no turbidity is produced.

11. Condensed tannins : Not more than 0.5%.
12. Residual solvent : Not more than 25 mg/kg acetone or ethyl acetate, singly or in combination.
13. Lead : Not more than 2 mg/kg.
14. Category : Food Additives Category 17
15. Uses : Clarifying agent

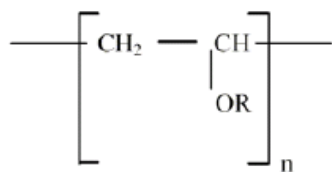
## Quillaia Extracts

<b>Synonyms</b>	Quillaja extract, Soapbark extract, Quillay bark extract, Bois de Panama, Panama bark extract, Quillai extract; INS No. 999
<b>Definition</b>	<p>Quillaia extract is obtained by aqueous extraction (Type 1) or either by chromatographic separation or ultrafiltration of the aqueous extraction (Type 2) of the milled inner bark or of the wood of pruned stems and branches of <i>Quillaja saponaria</i> Molina (family <i>Rosaceae</i>). It contains triterpenoid saponins (quillaia saponins, QS) consisting predominantly of glycosides of quillaic acid. Polyphenols and tannins are major components and some sugars and calcium oxalate will be present.</p> <p>Quillaia extract is available commercially as liquid product or as spray-dried powder that may contain carriers such as lactose, maltitol or maltodextrin. The liquid product is usually preserved with sodium benzoate or ethanol.</p>
C.A.S. number	68990-67-0
Formula weight	Monomeric saponins range from ca. 1800 to ca. 2300, consistent with a triterpene with 8-10 monosaccharide residues
Assay	<p>Saponin content:</p> <p>Type 1: not less than 20% and not more than 26% on the dried basis</p> <p>Type 2: not less than 65% and not more than 90% on the dried basis</p>
<b>Description</b>	<p>Type 1: Red-brownish liquid or light brown powder with a pink tinge</p> <p>Type 2: Light red-brownish liquid or powder</p>
<b>Characteristics</b>	
<b>Identification</b>	
Solubility	Very soluble in water, insoluble in ethanol, acetone, methanol and butanol
Foam	<p>Dissolve 0.5 g of powder extract in 9.5 g of water or 1 ml of liquid extract in 9 ml of water. Add 1 ml of this mixture to 350 ml of water in a 1000-ml graduated cylinder. Cover the cylinder, vigorously shake it 30 times, and allow settling. Record the foam level (ml) after 30 min. Typical values:</p> <p>Type 1: 150 ml.</p>

	Type 2: 260 ml.
Chromatography	The retention time of major peak of the sample corresponds to the major saponin peak (QS-18) of the standard.
Colour and turbidity	<p>Powder form only: Dissolve 0.5 g in 9.5 g of water. The solution is not turbid. Determine the absorbance of the solution against water at 520 nm.</p> <p>Type 1: The absorbance is less than 1.2.</p> <p>Type 1: The absorbance is less than 0.7.</p>
Purity	
Water	Powder form: not more than 6% (Karl Fischer Method)
Loss on drying	<p>Liquid form: (2 g, 105°C, 5 h)</p> <p>Type 1: 50 to 80%</p> <p>Type 2: 50 to 90%</p>
pH	3.7 -5.5 (4 % solution)
Ash	<p>Type 1: Not more than 14% on a dried basis</p> <p>Type 2: Not more than 5% on a dried basis</p> <p>Use 1.0 g for powder samples; for liquid samples, use the residue from loss on drying.</p>
Tannins	Not more than 8% on a dried basis
Lead	Not more than 2 mg/kg.
Category	Food additives category (17)
Functional uses	Others.

## Polyvinyl Alcohol

Chemical formula:  $(C_2H_3OR)$  where  $R=H$  or  $COCH_3$  (randomly distributed)



Where  $R=H$  or  $COCH_3$  (randomly distributed)

1. Definition : Polyvinyl alcohol is a synthetic resin prepared by the polymerization of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerization and the degree of hydrolysis.
2. Description : Odorless, translucent, white or cream-colored granular powder.
3. Identification : (1) Solubility: Soluble in water, insoluble in ethanol.  
(2)pH: 5.0—6.5 (1 in 5).  
(3) Infrared spectrum: The infrared absorption spectrum of a potassium bromide dispersion of the sample corresponds to that of a polyvinyl alcohol standard.  
(4) Color reaction A: Dissolve 0.01 g of the sample in 100 mL of water with warming and let the solution cool to room temperature. To 5 mL of the solution, add one drop of iodine TS and a few drops of boric acid solution (1 in 25). A blue color is produced.  
(5) Color reaction B: Dissolve 0.5 g of the sample in 10 mL of water with warming and let the solution cool to room temperature. Add 1 drop of iodine TS to 5 mL of solution and allow to stand. A dark red to blue color is produced.  
(6) Precipitation reaction: Add 10 mL of ethanol to the remaining 5 mL of solution prepared for Color Reaction B. A white, turbid or flocculent precipitate is formed.
4. Loss on drying : Not more than 5.0% (105°, 3 h)
5. Residue on ignition : Not more than 1.0%.
6. Water-insoluble matter : Not more than 0.1%.
7. Category : Food Additives Category 17
8. Uses : Others.

## Magnesium silicate(synthetic)

Synonyms : INS No. 553(i)

1. Definition : Magnesium silicate (synthetic) is manufactured by the precipitation reaction between sodium silicate and a soluble magnesium salt. The aqueous suspension of the precipitate is filtered and the collected solid washed, dried, classified for particle size and packaged. The molar ratio of MgO to SiO<sub>2</sub> is approximately 2:5.
2. Appearance : Very fine, white, odorless powder, free from grittiness.
3. Assay : Not less than 15% of MgO and not less than 67% of SiO<sub>2</sub>, calculated on the ignited basis.
4. Identification : (1) Solubility: Insoluble in water and in ethanol but soluble in mineral acids.  
(2) pH: 7.0-10.8 (1 in 10 soln).  
(3) Magnesium test: Mix about 0.5 g of the sample with 10 mL of 2.7 N dilute hydrochloric acid TS, filter, and neutralize the filtrate to litmus paper with 6 N ammonia TS. The neutralized filtrate gives a positive test for magnesium.  
(4) Silicate test: Prepare a bead by fusing a few crystals of sodium ammonium phosphate on a platinum loop in the flame of a Bunsen burner. Place the hot, transparent bead in contact with the sample, and again fuse. Silica floats about in the bead, producing, upon cooling, an opaque bead with a web-like structure.
5. Loss on drying : Dry it at 105°C for 2 hours: it loses not more than 15% of its weight.
6. Loss on ignition : Not more than 15% on the dried basis. Weigh to the nearest 0.1 mg, 1 g of the dried sample in a tared platinum crucible provided with a cover. Gradually apply heat to the crucible at first, then strongly ignite at 900/1000° for 20 min. Cool, weigh and calculate as percentage.
7. Soluble salts : Not more than 3%. Boil 10 g of the sample with 150 mL of water for 15 min. Cool to room temperature, and add water to restore the original volume. Allow the mixture to stand for 15 min, and filter until clear. Retain 20 mL of the filtrate for the test Free alkali. Evaporate 75 mL of the filtrate, representing 5 g of the sample in a tared platinum dish on a steam bath to dryness, and ignite gently to constant weight. Cool, weigh and calculate as percentage (the weight of the residue should not exceed 150 mg).
8. Free alkali : Not more than 1% (as NaOH) Add 2 drops of phenolphthalein TS to 20 mL of dilute filtrate prepared in the test for Soluble salts, representing 1 g of the sample. Not more



than 2.5 mL of 0.1 N hydrochloric acid should be required to discharge the pink color produced.

- 9. Arsenic : Not more than 0.1 ppm (as As).
- 10. Fluoride : Not more than 10 mg/kg. Determine using Fluoride Limit Test.
- 11. Lead : Not more than 5 mg/kg. Determine using an AAS/ICP-AES.
- 12. Category : Food Additives Category 17
- 13. Uses : Anticaking agent, filtering aid