The Draft Amendment of Standards for Specification, Scope, Application and Limitation of Food Additives
MOHW Food No.1051304331, 6 February, 2017

Appendix 2: Standards for Specification of Food Additives

01. Preservative

§ 01001

Sorbic Acid

Synonyms
INS No. 200

Definition

Chemical names Sorbic acid, 2,4-hexadienoic acid, 2-propenylacrylic acid
C.A.S. number 110-44-1
Chemical formula C₆H₈O₂
Formula weight 112.12
Assay Not less than 99.0% (calculated on the anhydrous basis)

Description
Colorless needles or white free flowing powder, having a slight characteristic odour

Characteristics

Identification

Solubility Slightly soluble in water; soluble in ethanol
Melting range 132-135°C
Spectrophotometry A 1 in 400,000 solution in isopropanol solution shows absorbance maximum at 254±2 nm

Test for double bond Shake about 0.02 g of the sample with 1 ml bromine TS; the colour disappears

Purity

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

Category Food additives category (1)

Functional uses Preservative

§ 01002

Potassium Sorbate

Synonyms INS No. 202

Definition

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

C.A.S. number 24634-61-5

Chemical formula \( \text{C}_6\text{H}_7\text{KO}_2 \)

Formula weight 150.22

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

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

Characteristics

Identification

Solubility Freely soluble in water; soluble in ethanol

Test for potassium Passes test

Melting range 132-135°C

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

Purity

Water Not more than 1% (105°, 3 h)

Acidity or alkalinity Not more than about 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)  

Functional uses  Preservative  

§ 01004  

Calcium Propionate  

Synonyms  Calcium propanoate, INS No. 282  

Definition  

Chemical names  Calcium propionate  

C.A.S. number  4075-81-4  

Chemical formula  \( \text{CaC}_6\text{H}_{10}\text{O}_4 \)  

Formula weight  186.22  

Assay  Not less than 98.0% on the dried basis  

Description  White crystals, powder or granules with not more than a faint odour of propionic acid  

Characteristics  

Identification  

Solubility  Freely soluble in water; soluble in ethanol  

Test for calcium  Passes test  

Test for propionate  Warm the sample with sulfuric acid. The propionic acid evolved may be recognized by its odour  

Test for alkali salt of organic acid  Ignite the sample at a relatively low temperature. The alkaline organic acid residue effervescences with acid  

Purity  

Water  Not more than 4% \((105^\circ \text{C}, 2 \text{ h})\)  

pH  7.5 - 10.5 \((1 \text{ in } 10 \text{ soln})\)  

Water insoluble matter  Not more than 0.3%  

Fluoride  Not more than 30 mg/kg
Iron Not more than 50 mg/kg
Lead Not more than 2 mg/kg
Category Food additives category (1)
**Functional uses** Preservative

§ 01005

**Sodium Propionate**

**Synonyms** Sodium propanoate, INS No. 281

**Definition**
Chemical names Sodium propionate
C.A.S. number 137-40-6
Chemical formula C₃H₅NaO₂
Formula weight 96.06
Assay Not less than 99.0% on the dried basis

**Description** White or colourless, hygroscopic crystals with not more than a faint characteristic odour

**Characteristics**
Identification
**Solubility** Freely soluble in water; soluble in ethanol
**Test for sodium** Passes test
**Test for propionate** Warm the sample with sulfuric acid. The propionic acid evolved may be recognized by its odour
**Test for alkali salt of organic acid** Ignite the sample at a relatively low temperature. The alkaline residue effervescences with acid
Purity
**Water** Not more than 4% (105°C, 2 h)
**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 2 mg/kg

Category
Food additives category (1)

Functional uses
Preservative

§ 01021

Propionic Acid

Synonyms
INS No. 280: Propanoic acid, ethylformic acid, methylacetic acid

Definition
Chemical names
Propionic acid
C.A.S. number
79-09-4
Chemical formula
C₃H₆O₂
Formula weight
74.08
Assay
Not less than 99.5% on the dried basis

Description
An oily liquid with a slightly pungent odour

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
Not more than 0.01% when dried at 140°C to constant
residue
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)
Functional uses
Preservative
01. Preservative

§ 01008

Benzoic Acid

**Synonyms**
INS No. 210

**Definition**

Chemical names: Benzoic acid, benzenecarboxylic acid, phenylcarboxylic acid

C.A.S. number: 65-85-0

Chemical formula: C₇H₆O₂

Formula weight: 122.12

Assay: Not less than 99.5% on the dried basis

**Description**
White crystalline solid, usually in the form of scales or needles, having not more than a faint characteristic odour

**Characteristics**

Identification

**Solubility**
Slightly soluble in water, freely soluble in ethanol

**Melting range**
121 - 123°C

**Test for benzoate**
Passes test

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

**Readily oxidizable**  
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 colour 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 colour that persists for 15 sec. Not more than 0.5 ml should be required.

**Chlorinated organic compounds**  Not more than 0.07% (as Cl₂)

**Category**  Food additives category (1)

**Functional uses**  Preservative
01.Preservative

§ 01009

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_5NaO_2
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
Melting range 121 - 123°C
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 Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 ml of sulfuric acid TS. The colour produced should not be
substances 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 colour 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 colour that persists for 15 sec. Not more than 0.5 ml should be required.

Chlorinated organic compounds Not more than 0.07% (as chlorine)

Category Food additives category (1)

Functional uses Preservative
03. Antioxidants

§ 03008

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-gulofuranolactone sodium enolate monohydrate

C.A.S. number 6381-77-7

Chemical formula C₆H₇O₆Na · H₂O

Formula weight 216.13

Assay Not less than 98% after drying

Description White, almost odourless crystalline powder

Characteristics

Identification

Solubility Freely soluble in water, very slightly soluble in ethanol

Reducing activity A solution of the sample will decolourize 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: Between +95.5° and +98.0° (10% (w/v) solution)

pH 5.5 - 8.0 (1 in 10 soln)

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)
Functional uses  Antioxidant
D-Sorbitol

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

**Definition**

**Chemical names** D-Sorbitol

**C.A.S. number** 50-70-4

**Chemical formula** \( C_6H_{14}O_6 \)

**Formula 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.

**Description**
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

Proceed as directed under Thin Layer Chromatography of Polyols Use the following: Standard solution: Dissolve 50 mg of reference standard sorbitol (available from US Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD 20852, USA) in 20 ml water Test solution: Dissolve 50 mg of the sample in 20 ml of water

**Purity**

**Water** Not more than 1% (Karl Fischer Method)

**Sulfated ash** Not more than 0.1%

**Chlorides** Not more than 50 mg/kg
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<td><strong>Nickel</strong></td>
<td>Not more than 2 mg/kg</td>
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<tr>
<td><strong>Reducing sugars</strong></td>
<td>Not more than 0.3%</td>
</tr>
<tr>
<td><strong>Total sugars</strong></td>
<td>Not more than 1% (as glucose)</td>
</tr>
<tr>
<td><strong>Lead</strong></td>
<td>Not more than 1 mg/kg</td>
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11. Seasoning Agents

§ 11028

Glycine

Synonyms  Aminoacetic acid, Aminoethanoic acid, Glycocoll

Definition

Chemical names  Glycine
C.A.S. number  56-40-6
Chemical formula  C₂H₅O₂N
Formula weight  75.07
Assay  Not less than 98.5% on the dried basis

Description  White crystalline powder

Characteristics

Identification

Residue on ignition  Not more than 0.1%

Purity

Loss on drying  Not more than 0.2% (105°C, 3h)
Arsenic  Not more than 3 mg/kg
Lead  Not more than 5 mg/kg

Category  Food additives category (11)-1; Food additives category (7)

Functional uses  Food quality improvement, fermentation and food processing agents
Sweeteners
12. Pasting Agents

§ 12026

Gellan Gum

**Synonyms**

INS No. 418

**Definition**

Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by Pseudomonas elodea, purified by recovery with ethanol or 2-propanol, 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.

**C.A.S. number**

71010-52-1

**Formula weight**

Approximately 500,000

**Assay**

Yields, on the dried basis, not less than 3.3% and not more than 6.8% of carbon dioxide (CO₂).

**Description**

Off-white powder

**Characteristics**

Identification

**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**
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. 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.

**Purity**

**Loss on drying**
Not more than 15% (105°C, 2½ h)

**Nitrogen**
Not more than 3%

**Residual solvents**
not more than 750 mg/kg of 2-propanol

**Microbiological criteria**
Total plate count: Not more than 10,000 cfu/g
E. coli: Negative by test
Salmonella: Negative by test
Yeasts and moulds: Not more than 400 cfu/g

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

**Category**
Food additives category (12)

**Functional uses**
Pasting Agents