

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

MOHW Food No.1051301058, 8 April, 2016

Appendix 2: Standards for Specification of Food Additives

07. Food quality improvement, fermentation and food processing agents

§ 07001

Calcium chloride

Synonyms INS No. 509

Definition

Chemical names Calcium chloride

C.A.S. number 10043-52-4

Chemical formula Anhydrous: CaCl_2
Dihydrate: $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$
Hexahydrate: $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$

Formula weight Anhydrous: 110.99
Dihydrate: 147.02
Hexahydrate: 219.08

Assay Anhydrous: Not less than 93%
Dihydrate: 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
Dihydrate: White, hard, deliquescent fragments or granules
Hexahydrate: Colourless, very deliquescent crystals

Characteristics

Identification

Solubility Anhydrous: Freely soluble in water and ethanol
Dihydrate: Freely soluble in water; soluble in ethanol

	Hexahydrate: Very soluble in water and ethanol
<u>Test for chloride</u>	Passes test
<u>Test for calcium</u>	Passes test
Purity	
<u>Free alkali</u>	Not more than 0.15% as Ca(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.
<u>Magnesium and alkali salts</u>	Not more than 5%
<u>Fluoride</u>	Not more than 40 mg/kg
<u>Lead</u>	Not more than 2 mg/kg
Category	Food additives category (7)
Functional uses	Food quality improvement, fermentation and food processing agents

11. Seasoning Agents

§ 11017

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 dilactide. Common products of commerce are 50-90% solutions. Solid products containing about 100-125% of titratable 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

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

Chemical formula $C_3H_6O_3$

Formula weight 90.08

Assay Not less than 95.0% and not more than 105.0% of the labelled concentration.

Description Colourless, 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%

Sulfate Not more than 0.25%

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 sample solution to 10 ml of hot alkaline cupric tartrate TS. No red precipitate is formed.

<u>Readily carbonizable substances</u>	Superimpose carefully 5 ml of the sample solution kept at 15o on 5 ml of sulfuric acid TS kept at 15o. No deep grey color is produced within 15 min at the contact zone of the two liquids.
<u>Lead</u>	Not more than 2 mg/kg
Category	Food additives category (11)
Functional uses	Seasoning Agents

§ 11022

DL-Malic Acid

Synonyms	INS No. 296; 2-Hydroxybutanedioic acid
Definition	
Chemical names	dl-Malic acid, 2-Hydroxybutanedioic acid, Hydroxysuccinic acid
C.A.S. number	6915-15-7
Chemical formula	C ₄ H ₆ O ₅
Formula weight	134.1
Assay	Not less than 99.0%
Description	White or nearly white crystalline powder or granules
Characteristics	
Identification	
<u>Solubility</u>	Very soluble in water; freely soluble in ethanol
<u>Melting range</u>	127 - 132°C
<u>Test for malate</u>	Passes test Test 5 ml of a 1 in 20 solution of the sample, neutralized with ammonia TS
Purity	
<u>Sulfated ash</u>	Not more than 0.1%
<u>Fumaric and maleic</u>	Not more than 1.0% of fumaric acid and not more than

<u>acid</u>	0.05% of maleic acid
<u>Lead</u>	Not more than 2 mg/kg
Category	Food additives category (11)
Functional uses	Seasoning Agents

§ 11023

Sodium DL–Malate

Synonyms Malic acid sodium salt; INS No. 350(ii)

Definition

Chemical names Disodium DL-malate, hydroxybutanedioic acid disodium salt

C.A.S. number 676-46-0

Chemical formula Hemihydrate: $C_4H_4Na_2O_5 \cdot 1/2 H_2O$
Trihydrate: $C_4H_4Na_2O_5 \cdot 3 H_2O$

Formula weight Hemihydrate: 187.1
Trihydrate: 232.1

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

Description Odourless white crystalline powder or lumps

Characteristics

Identification

Solubility Freely soluble in water

Test for sodium Passes test

Test for malate Passes test
Test 5 ml of a 1 in 20 solution of the sample

Purity

Loss on drying Hemihydrate: Not more than 7% (130°C, 4 h)
Trihydrate: 20.5% - 23.5% (130°C, 4 h)

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.

<u>Fumaric and maleic acid</u>	Not more than 1.0% of fumaric acid and not more than 0.05% of maleic acid
<u>Lead</u>	Not more than 2 mg/kg
Category	Food additives category (11)
Functional uses	Seasoning Agents

11-1. Sweeteners

§ 11-1-014

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
C.A.S. number	55589-62-3
Chemical formula	C ₄ H ₄ KNO ₄ S
Formula weight	201.24
Assay	Not less than 99.0% and not more than 101.0% on the dried basis
Description	Odourless, white crystalline powder
Characteristics	
Identification	
<u>Solubility</u>	Freely soluble in water, very slightly soluble in ethanol
<u>Spectrophotometry</u>	Dissolve 10 mg of the sample in 1,000 ml of water. The

	solution shows an absorbance maximum at 227 ± 2 nm
<u>Test for potassium</u>	Passes test
	Test the residue obtained by igniting 2 g of the sample
<u>Precipitation test</u>	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
<u>Purity</u>	
<u>Loss on drying</u>	Not more than 1.0% (105°C, 2 h)
<u>pH</u>	5.5 - 7.5 (1% soln)
<u>Organic impurities</u>	Passes test for 20 mg/kg of UV active components
<u>Fluoride</u>	Not more than 3 mg/kg
<u>Lead</u>	Not more than 1 mg/kg
Category	Food additives category (11-1)
Functional uses	Sweeteners