



15 April 2020

(20-2911)

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Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

### *Addendum*

The following communication, received on 14 April 2020, is being circulated at the request of the Delegation of The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu.

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

The Amendment of Standards for Specification, Scope, Application and Limitation of Food Additives (G/SPS/N/TPKM/514). The final amendment has entered into force on 14 April 2020.

#### **This addendum concerns a:**

- Modification of final date for comments
- Notification of adoption, publication or entry into force of regulation
- Modification of content and/or scope of previously notified draft regulation
- Withdrawal of proposed regulation
- Change in proposed date of adoption, publication or date of entry into force
- Other:

**Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)**

- Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Not applicable.

**Agency or authority designated to handle comments: [X] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

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Ministry of Health and Welfare  
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**The Amendment of Standards for Specification, Scope, Application  
and Limitation of Food Additives**

MOHW Food No.1081303084, 7 November, 2019

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

11-1. Sweeteners

<b>Code</b>	<b>Food Additive Items</b>	<b>Scope and Application Standards</b>	<b>Limitations</b>
11-1-026	Mogroside Extract	All foods: as <u>practically needed.</u>	For <u>manufacturing or processing purpose.</u>

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

MOHW Food No. 1081303084, 7 November, 2019

**Appendix 2: Standards for Specification of Food Additives**

**11-1. Sweeteners**

§ 11-1-026

**Mogroside Extract**

**SYNONYMS**

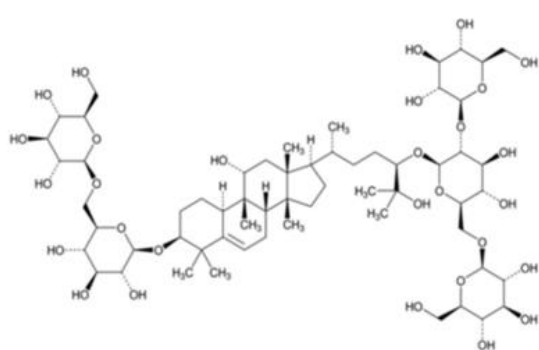
Luohanguo Extract, Monk Fruit Extract

**DEFINITION**

Luohanguo 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**

: Luohanguo 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 Luohanguo 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 %.

**Category** : Food additives category (11-1).

**Functional uses** : Sweeteners.

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

§ 07021

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.

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

§ 07018

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



Magnesium Hydroxide Carbonate: Not more than 1.0%

Calcium

Magnesium Carbonates: Not more than 0.4%

Magnesium Hydroxide Carbonate : 1.0% 以下

Lead

Not more than 2 mg/kg

Arsenic

Not more than 4 mg/kg (As As<sub>2</sub>O<sub>3</sub>)

**Category**

: Food additives category (7).

**Functional uses**

: Food quality improvement, fermentation and food processing agents.

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

## 8. 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

<u>Arsenic</u>	: <u>Not more than 3 mg/kg</u>
<u>Lead</u>	: <u>Not more than 4 mg/kg</u>
<b><u>Category</u></b>	: Food additives category (7); (8).
<b><u>Functional uses</u></b>	: Food quality improvement, fermentation and food processing agents; Nutritional additives.

## 8. Nutritional additives

### 9. Colors

§ 08133

§ 09033

#### Lutein

#### SYNONYMS

: Vegetable lutein; vegetable luteol

#### Definition

: Crystalline lutein is obtained by extracting with solvent, saponifying, centrifuging marigold flower or other plant edible part. The crystal contains a small amount of zeaxanthin.

#### Chemical names

: 3R,3'R,6'R- $\beta,\epsilon$ -carotene-3,3'-diol; all-*trans*-lutein; 4',5'-didehydro-5',6'-dihydro-beta,beta-carotene-3,3'-diol

#### C.A.S. number

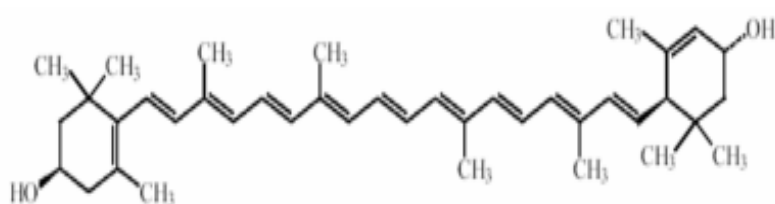
: 127-40-2

#### Chemical formula

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

#### Structural formula

:  

#### Formula weight

: 568.88

#### Assay

: Not less than 80% total carotenoids, not less than 70% lutein

#### DESCRIPTION

A free-flowing, orange-red powder

#### CHARACTERISTICS

##### IDENTIFICATION

##### Solubility

: Insoluble in water, soluble in hexane

##### Spectrophotometry

: A 2 mg/l solution in acetone shows maximum absorbance at approximately 446 nm.

Test for  
carotenoids

The colour of 2 ml of a 2 – 4 mg/l solution of the  
sample in acetone immediately disappears after  
successive addition of about 0.5 ml of 5% sodium  
nitrite and about 0.5 ml of 0.5 M sulfuric acid.

**PURITY**

Moisture

Not more than 1.0%

Ash

Not more than 1.0%

Zeaxanthin

Not more than 9.0%

Lead

Not more than 3 mg/kg

Hexane

Not more than 50 mg/kg

Acetone

Not more than 30 mg/kg

Methanol

Not more than 10 mg/kg

Propylene glycol

Not more than 1,000 mg/kg

Waxes

Not more than 14.0%

**Category**

: Food additives category (8); (9).

**Functional uses**

: Nutritional additives; Colors.

## 1. Preservatives

§ 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<sub>7</sub>H<sub>5</sub>O<sub>2</sub>Na

##### 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. 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** Preservatives.

## 8. Nutritional additives

§ 08040

### Ferrous Lactate

Synonyms : INS No. 585.

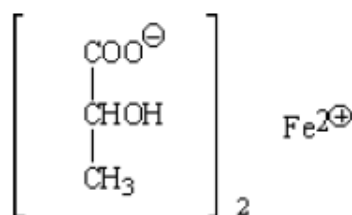
Chemical formula:

$C_6H_{10}FeO_6 \cdot xH_2O$ , (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, 14approx.. 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



## 8. Nutritional additives

§ 08043

### 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