## Chapter 3:
## SUBSTANCES ADDED TO FOOD

**[18][3.1: Food Additives**
**3.1.1:**

**(1) Food Additives included in these Regulations**

The food additives listed herein are recognised as suitable for use in foods in conformance with the provisions of these regulations and have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe and use of additives in conformance with these regulations is considered to be technologically justified.

**(2) Food in which Additives may be used**

The conditions under which food additives may be used in foods, whether or not they have previously been permitted by the Food Safety and Standards (Food Standards and Food Additives) regulations, 2011.

**(3) Foods in which Additives may not be used**

Food categories or individual food items in which the use of food additives is not allowed, or where use should be restricted, are defined by these Regulations.

**(4) Food Additive** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods but does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

**(5) Acceptable Daily Intake (ADI)** means the amount of a food expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk andan dditive, meeting this criterion shall be used within the bounds of Good Manufacturing Practice (GMP) as specified in clause (8) of this sub-regulation.

**(6) Maximum Use Level** of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe and it is generally expressed as mg/kg of food and he maximum use level shall not usually correspond to the optimum, recommended, or typical level of use and under Good Manufacturing Practice (GMP), the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers. [52][Unless otherwise specified, maximum use levels for additives in Tables are set on the final product as consumed.]

**(7) Justification for the use of Food Additives**

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions as specified in these regulations and the needs set out in sub-clause (a) to (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food shall be justified in the circumstances dealt within sub-clause (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that it does not change the nature, substance or quality of the food so as to deceive the consumer;

(d) to aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable

(including unhygienic) practices or techniques during the course of any of these activities.

**(8) Good Manufacturing Practice (GMP)**

All food additives subject to the provisions of these regulations shall be used under conditions of Good Manufacturing Practice, which includes the following, namely:-

(a) the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;

(b) the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,

(c) The additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

**(9) Specifications for the Identity and Purity of Food Additives**

Food additives used in accordance with these regulations shall be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended under these regulations and in terms of safety, food grade quality is achieved by conformance of additives to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with Good Manufacturing Practice (GMP).

**(10) Carry-Over of Food Additives into Foods**

**(a) Conditions applying to carry-over of Food Additives from ingredients and raw materials into foods**

Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that,-

(i) the additive is acceptable for use in the raw materials or other ingredients (including food additives) in accordance with the provisions of these Regulations;

(ii) the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in these regulations;

(iii) the food into which the additive is carried over does not contain the additive in a quantity greater than that shall be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of these regulations.

**(b) Special conditions applying to the use of Food Additives not directly authorised in food ingredients and raw materials**

An additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of these regulations, including that any maximum level applying to the food is not exceeded.

**(d) Foods for which the carry-over of Food Additives is unacceptable**

Carry-over of a food additive from a raw material or ingredient shall not be permissible for foods belonging to the following food categories; unless a food additive provision in the specified category is mentioned in these regulations:

(i) infant formulae, follow-up formulae, and formulae for special medical purposes for infants.

(ii) complementary foods for infants and young children.]

**3.2: Standards of Additives**

3.2.1 Food Colours: Standards of various Food Colours with characteristics are specified in the table below:

**1. Tartrazine**

| | |
|---|---|
| Common Name | Tartrazine |
| Synonyms | FD and C Yellow No.5, E.E.C. Serial No.E 102, L-Gebb 2, C.I. Food Yellow 4. |
| Colour of the 0.1 Per cent (M/V) solution in distilled water. | Yellow |
| Colour Index Number (1975) | No 19140 |
| Class | Monoazo. |
| Chemical Name | Trisodium salt of 5-hydroxy-1-p-sulphopheny1-4-(p- sulphophenylazo) pyrazol-3-carboxylic acid. |
| Empirical formula | $C_{16}\ H_9\ N_4\ O_9\ S_2\ Na_3$ |
| Molecular Weight | 534.37 |
| Solubility | Soluble in water. Sparingly soluble in Ethanol. |

General Requirements

The material shall conform to the requirements prescribed in Table below:—

TABLE

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|
| 1. | Total dye content, corrected for Sample dried at 105±1°C for 2 hours, per cent by mass, Min. | 87 |
| 2. | Loss on drying at 135°C and Chlorides and Sulphates expressed as sodium salt, percent by mass, Max. | 13 |
| 3. | Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. | Combined ether extracts, percent by mass,max | 0.2 |
| 5. | Subsidiary dyes, percent by mass, Max. | 1.0 |
| 6. | Dye intermediates, percent by mass, Max. | 0.5 |
| 7. | Lead, mg/kg, Max. | 10 |
| 8. | Arsenic, mg/kg, Max. | 3 |
| 9. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, copper and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, and

cyanides.

## 2. SUNSET YELLOW

| | |
|---|---|
| Common Name | Sunset Yellow |
| Synonyms | FD and C Yellow No.6, Janus Orange S, C.l. Food Yelow 3, -Orange 2, Janune soil, EEC Serial No.E.10 |
| Colour of the 0.1 Percent (M/V) solution in distilled water | Orange |
| Colour Index Number (1975) | No 15985 |
| Class | Monoazo |
| Empirical formula | Disodium salt of 1.(4-sulphophenylazo) 2-napthol-6-sulphonic acid |
| Chemical Name | $C_{10}H_{10}N_2O_7S_2Na_2$ |
| Molecular Weight | 452.37 |
| Solubility | Soluble in water. Sparingly soluble in Ethanol |

General Requirements

The material shall conform to the requirements prescribed in Table below:-

TABLE

Requirements for Sunset Yellow, FCF

| *Sl. No. Requirements for Sunset Yellow, FCF Characteristic* | *Requirement* |
|---|---|
| 1. Total dye content, corrected for Sample dried at 105±1°C for 2 hours, per cent by mass, Min. | 87 |
| 2 Loss on drying at 135°C, percent by mass and Chlorides and Sulphates expressed as sodium salt, percent by mass, Max | 13 |
| 3. Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. Combined ether extracts, percent by mass. Max. | 0.2 |
| 5. Subsidiary dyes, (lower sulphonated dyes including traces of orange II) percent by mass, Max. | 3.0 |
| 6. Dye intermediates, percent by mass, Max. | 0.5 |

| | | |
|---|---|---|
| 7. | Lead, mg/kg, Max. | 10 |
| 8. | Arsenic, mg/kg, Max. | 3 |
| 9. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, copper and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, and cyanides;

**3. ERYTHROSINE**

| | |
|---|---|
| Common Name | Erythrosine |
| Synonyms | FD and C red No.3, C.l. Food Red 14, LB-Rot-I |
| Colour of the 0.1 Percent (M/V) solution in distilled water | Red |
| Colour Index Number (1975) | No 45430 |
| Class | Xanthene |
| Chemical Name | Disodium or dipotassium salt of 2',4', 5', 7', tetraiodo- fluerescein |
| Empirical formula | $C_{20}H_6O_5I_4Na_2$ |
| Molecular Weight | 879.87 (Disodium Salt) |
| Solubility | Soluble in water. Sparingly soluble in Ethanol |

General Requirements

The material shall conform to the requirements prescribed in Table below:—

TABLE

| *Sl. No.* | *Requirements for Sunset Yellow, FCF Characteristic* | *Requirement* |
|---|---|---|
| 1. | Total dye content, corrected for Sample dried at 105°±1°C for 2 hours, per cent by mass, Min. | 87 |
| 2. | Loss on drying at 135°C percent by mass and Chlorides and Sulphates expressed as sodium salt percent by mass, Max. | 13 |
| 3. | Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. | Ether extractable matter, (alkaline), percent by mass. Max. | 0.2 |
| 5. | Inorganic Iodide, percent by mass as sodium iodide, Max. | 0.1 |
| 6. | Subsidiary colouring matters except flourescein, percent by mass, Max. | 4 |

| | | |
|---|---|---|
| 7. | Fluorescein, mg/kg, Max. | 20 |
| 8. | Organic compounds other than colouring matter<br>(a) Tri-iodoresorcinol, percent by mass, Max.<br>(b) 2.(2,4-dihydroxy-3,5-di-iodobenzoyl) benzoic acid, percent by mass, Max. | 0.2<br>0.2<br>0.2 |
| 9. | Lead, mg/kg, Max. | 10 |
| 10. | Arsenic, mg/kg, Max. | 3 |
| 11. | Zinc, mg/kg, Max. | 50 |
| 12. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, copper and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, and cyanides.

## 4. INDIGO CARMINE

| | |
|---|---|
| Common Name | Indigo carmine |
| Synonyms | Indigotine, FD and C Blue No.2, Cl Food Blue 1, EEC Serial No. E132 L-Blue 2 |
| Colour of the 0.1 Percent (M/V) solution in distilled water | Blue |
| Colour Index Number (1975) | No 73015 |
| Class | Indigoid |
| Chemical Name | Disodium Salt of indigotine-5, 5'-Disulphonic acid |
| Empirical formula | $C_{16}H_8N_2O_8S_2Na_2$ |
| Molecular Weight | 466.36 |
| Solubility | Soluble in water. Sparingly soluble in Ethanol |

General Requirements

The material shall conform to the requirements prescribed in Table below:-

TABLE

Requirement for Indigo Carmine

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|
| 1. | Total dye content, corrected for Sample dried at 105±1oC for 2 hours, per cent by mass, Min. | 85 |

| | | |
|---|---|---|
| 2. | Loss on drying at 135oC, percent by mass and Chlorides and Sulphates expressed as sodium salt, 15 percent by mass, Max. | 15 |
| 3. | Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. | Combined ether extracts, percent by mass. Max. | 0.2 |
| 5. | Subsidiary dyes, percent by mass, Max. | 1.0 |
| 6. | Isatin Sulphonic acid, percent by mass, Max. | 0.5 |
| 7. | Lead, mg/kg, Max. | 10 |
| 8. | Arsenic, mg/kg, Max. | 3 |
| 9. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, copper and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, and cyanides.

**5. β-CAROTENE.**

β-Carotene is obtained as dark violet hexagonal prisms when crystallised from benzene methanol solution; or as red rhombic, almost quardratic plates, from petroleum ether.

| | |
|---|---|
| Synonyms | C.I. natural yellow 26 |
| Colour Index Number (1956) | No.75130 |
| Class | Carotenoids |
| Chemical Name | all trans β-Carotene |
| Empirical formula | $C_{40}$ $H_{56}$ |
| Molecular Weight | 536.89 |
| Melting Point | 183°C ± 1°C |

Solubility.- Soluble in carbon disulphide, benzene and chloroform, moderately soluble in normal hexane, cyclohexane, ether, petroleum ether and oils; practically insoluble in methanol; insoluble in water.

Spectrophotometric Requirement.-The wavelengths of absorption maxima of all trans β-Carotene in cyclohexane (0.2 mg per 100 ml. approximately) and in-1cm cell shall be 456 mμ to 484 mμ region. There shall be no cis-peak in the 330 mμ to 355 mμ region.

A solution of β-carotene in chloroform on addition of antimony trichloride solution shall give a dark blue colour having maximum absorption at a wavelength of 590 mμ.

Colour Reaction- When 2ml. of concentrated sulphuric acid is added to 2ml. of 0.2 per cent solution of β-Carotene in chloroform, the acid layer shall turn blue.

The material shall have a minimum purity of 96.0 per cent.

Maximum limit of metallic impurities shall be:—

| | |
|---|---|
| Arsenic (as As) | 3 ppm |
| Lead (as Pb) | 10 ppm. |
| Heavy metal | 40 ppm. |

And shall also meet the following requirements:—

| | | |
|---|---|---|
| (i) | Subsidiary colouring matter, percent by weight, Max | 3 |
| (ii) | Sulphated ash, percent of total colouring matters, Max | 0.1 |

**6-CHLOROPHYLL:**

Chlorophyll, the green pigment of plants, is extracted and widely used as a colouring matter for various food items.

| | |
|---|---|
| Synonyms | C.I. Natural Green 3; Lebensmittel Green No.1 |
| Colour Index Number (1956) | No.75810 |
| Colour Index Number (1924) | No. 12499 |
| Color | Green |
| Class | Phorbin (dihydrophorphin) |
| Chemical Name | Chlorophyll a - magnesium complex of 1,3,5,8-tetramethyl 4-ethyl-2-vinyl-9-keto-10 carbomethoxy phorbinphytyl-7-propionate.<br>Chlorophyll b magnesium complex 1,5,8 trimethyl-3-formyl-4-ethyl-2-vinyl-9-keto-10 carbomethoxyphorbinphytyl-7-propionate |
| Empirical formula | Chlorophyll a - $C_{55}H_{72}O_5N_4Mg$<br>Chlorophyll b- $C_{55}H_{70}O_6N_4Mg$ |
| Molecular Weight | Chlorophyll a- 893.54<br>Chlorophyll b - 907.52 |

General- The material shall be an intensely dark green, aqueous, ethanolic,

or oily solution of chlorophyll degradation products. It shall be soluble in ethanol, ether, chloroform and benzene. It shall be insoluble in water.

Identification test- A solution of chlorophyll in ethanol shall be blue with deep red flourescence.

Brown-phase Reaction-When green ether or petroleum ether solution of chlorophyll is treated with a small quantity of a 10 percent solution of potassium hydroxide in methanol, the colour shall become brown quickly returning to green.

Note.- This test is applicable only when chlorophyll has not been treated with alkalies.

Maximum limits for metallic impurities shall be:—

| | |
|---|---|
| Arsenic (as As) | 3 ppm |
| Lead (as Pb) | 10 ppm |
| Copper (as Cu) | 30 ppm |
| Zinc (as Zn) | 50 ppm |

The material shall also conform to the following requirements:—

CHLOROPHYLL - MAGNESIUM COMPLEX

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|
| 1 | Total combined phaeophytines and their magnesium complexes, percent by weight, max. | 10 |
| 2 | Residual solvents, mg/kg, Max. Acetone, methanol, ethanol, propan-2-ol, hexane | 50 |
| | Dichloromethane | 10 |

**7 - CARAMEL**

Caramel shall be prepared from the food grade carbohydrates or their combinations in the presence of food grade acids, alkalis or salts. It shall be of four types, namely:—

Type-I- Plain Caramel-It shall be prepared by heating carbohydrates with or without acids or alkalis, or their salts. No. ammonium or sulphite compounds are used.

Type-II- Caustic sulphite caramel- It shall be prepared by heating carbohydrates with or without acids or alkalis or their salt in the presence of sulphite compounds; no ammonium compounds are used.

Type - III- Ammonia Process Caramel- It shall be prepared by heating carbohydrates with or without acids or alkalis or their salts in the presence of ammonium compounds; no sulphites are used.

Type-IV- Ammonia Sulphite Caramel- It shall be prepared by heating carbohydrates with or without acids or alkalis or their salts in the presence of both sulphite and ammonium compounds.

RAW MATERIALS

1. Carbohydrates - Caramel shall be prepared from the following carbohydrates or their mixtures:—

Sucrose, glucose, fructose, invert sugar, lactose, malt syrup, molasses, starch hydrolysates and fractions there of and/or polymer thereof.

2. Acids and alkalis- The acids used are sulphuric acid, phosphoric acid, acetic acid, or citric acid and the alkalis used are sodium, potassium or calcium hydroxide or mixture thereof.

Where the ammonium compounds are used, they are one or more of the following:—

Ammonium hydroxide
Ammonium Carbonate and Bicarbonate
Ammonium phosphate
Ammonium sulphate

Ammonium sulphite, Bisulphite, Metasulphite

Where the sulphite compounds are used, they are one or more of the following:— Sulphurous acid, Potassium, Sodium or ammonium Sulphite or Bisulphite.

It shall be a dark brown to black liquid or solid materials having the characteristic odour of burnt sugar and a pleasant, bitter taste. Its solution, when spread in a thin layer on a glass plate should appear homogeneous, transparent and have reddish-brown colour. It shall be miscible with water. It shall be free from any other extraneous colouring matter. It may contain permitted emulsifying and stabilising agents.

It shall conform to the requirements prescribed in Table 1 below. All requirements shall be on solids basis, except metallic impurities.

TABLE 1 - ROUTINE TEST REQUIREMENTS FOR CARAMEL

| *Sl. No.* | *Characteristic* | *Type I Plain* | *Type II CausticSulphite* | *Type III AmmoniaProcess* | *Type IV Sulphite Ammonia* |
|---|---|---|---|---|---|
| 1. | Solid content, per cent by mass | 62-77 | 65-72 | 53-83 | 40-75 |
| 2. | Colour intensity, | 0.01-0.12 | 0.06-0.10 | 0.08-0.36 | 0.10-0.60 |
| 3. | Ammonical nitrogen per cent by mass, max. | 0.01 | 0.01 | 0.4 | 0.5 |
| 4. | 4-Methylimidazole | - | - | Max.300 mg/kg & Max.200 mg/kg on equivalent colour basis | Max.1000 mg/kg & Max.250 mg/kg on equivalent colour basis |
| 5. | Lead (as Pb), mg/kg, Max. | 5 | 5 | 5 | 5 |
| 6. | Arsenic(as AS) mg/kg. | 3 | 3 | 3 | 3 |

Note: Requirement of ammoniacal nitrogen is based on a product colour having a minimum colour intensity prescribed at Sl. No. (2) proportionately higher values of ammoniacal nitrogen apply for products of higher colour intensity.

Type Test

The material shall also conform to the requirements prescribed in Table 2 below.

All requirements shall be on solid basis except metallic impurities.

**TABLE 2 - TYPE TEST REQUIREMENTS FOR CARAMEL**

| Sl. No. | Characteristic | Type I Plain | Type II Caustic Sulphite | Type III Ammonia Process | Type IV Sulphite Ammonia |
|---|---|---|---|---|---|
| 1. | Total sulphur Percent by mass. | Max 0.3 | 1.3-2.5 | Max.0.3 | 1.4-10.0 |
| 2. | Sulphur dioxide (as SO2) | -- | Max. 0.2% | -- | Max.0.5% |
| 3. | Total nitrogen, Percent by mass | Max.0.1 | Max.0.2 | 1.3-6.8 | 0.5-7.5 |
| 4. | Heavy metals mg/kg (Max.) | 25 | 25 | 25 | 25 |
| 5. | 2-Acetyl-4- tetra hydroxy butylimidazole (THI) | -- | -- | Max.40 mg/kg & Max. 25 mg/kg on an equivalent colour basis | -- |
| 6. | Mercury (as Hg) mg/kg, Max. | 0.1 | 0.1 | 0.1 | 0.1 |
| 7. | Copper (as Cu) mg/kg, Max. | 20 | 20 | 20 | 20 |

The material shall be filled in amber coloured glass or high density polythylene containers or any other well closed suitable containers with as little air space as possible. The containers shall be such as to preclude contamination of the contents with metals or other impurities.

**8. ANNATTO**

| | |
|---|---|
| Class | Carotenoids |
| Code Number | Cl (1975) No. 75120',<br>Cl (1975) Natural Orange 4 EEC No.E-160 b |
| Chemical Name | Annatto extract in oil contains several coloured components, the major single one being bixin which may be present in both Cis and Trans forms. Thermal degradation products of bixin may also be present. |
| Solubility | Water soluble annatto contains norbixin, the hydrolysis product of bixin, in the form of sodium or potassium salt, as the major colouring principle. Both cis and trans forms |

| | |
|---|---|
| | may be present |
| Chemical Formula | Bixin $C_{25}$ $H_{30}$ $O_4$ |
| | Norbixin $C_{24}$ $H_{28}$ $O_4$ |
| Molecular Weight | Bixin 394.50 |
| | Norbixin 380.48 |

The material shall be of the following two types:

(a) Solution in oil for use in butter and other food products, and

(b) Solution in water for use in cheese and other food products.

General

The material shall be derived only from the plant Bixa orellana L. and shall not contain any extraneous colouring matter. It shall be processed, packed, stored and distributed under hygienic conditions in licensed premises.

(1) Solution of Annatto Colour in Oil for Use in Butter and Other Food Products:—

Annatto extract in oil, as solution or suspension, is prepared by extraction of the outer coating of seeds with vegetable oils. In the preparation of the solution of annatto colour in oil, only the edible vegetable oils shall be used, either singly or in a mixture.

The solution of annatto colour in oils shall be clear and shall remain so on storage in suitable containers at 15°C except for a slight deposit of stearine or shall be in the form of a suspension. The suspension on dilution with hot oil to bring the bixin content to 0.24 per cent shall be a clear solution.

Colour

The colour of solution in amyl acetate at a dilution of 1:1000 (m/v) when measured in a Lovibond Tintometer with a 1 cm Cell Spectrophotometrically/Calorimeterically shall be not less than the following:

| | |
|---|---|
| Yellow units | 5.0 |
| Red units | 0.4 |

or be not less than the colour of the following inorganic solution at a liquid depth of one centimeter which may be employed for matching the stated dilution in a plunger type colorimeter using incident light closely approximating the normal day light:

| | |
|---|---|
| Potassium Bichromate | 0.320 g |
| Cobalt ammonium sulphate ($CoSO_4$ $(NH_4)_2$ $SO_4$ $6H_2O$) | 2.02 g |
| Sulphuric acid, Sp-gr 1.84 | 2ml |
| Distilled water | to make solution to one litre |

These reagents shall be of the analytical reagent grade. Although the solution retains its tinctorial value for a considerable time, after prolonged storage, its optical clarity shall be examined before use, to ensure that no alteration has taken place.

Note 1 - Diluted solution of annatto colour in amyl acetate is not stable in colour quality, particularly if exposed to light, and measurement shall be carried out on the diluted solution without undue delay.

(ii) Solution of Annatto Colour in Water for use in Cheese and Other Food Products:

Water soluble annatto colour is prepared by extraction of the outer coating of the seeds with aqueous alkali (sodium or potassium hydroxide). In the preparation of the solution, potable water shall be used. A little quantity (0.5 to 3 per cent) of alkali may be added.

The solution shall be clear and shall remain so on storage in suitable containers at a temperature of 15°C. Colour

The colour of the solution in 0.1 N sodium hydroxide or potassium hydroxide at a dilution of 1:1000 (m/v) measured in a 1-cm shall be the same as that specified in (i) above.

The material shall conform to the requirements prescribed in Table below:

TABLE
Requirement for Annatto

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|

| | | |
|---|---|---|
| 1. | Carotenoid | |
| | (a) Annatto extract in oil, expressed as bixin, percent by mass, Min. | 0.24 |
| | (b) Water-soluble annatto, expressed as norbixin, percent by mass, Min. | 0.24 |
| 2. | Arsenic, mg/kg, Max. | 3 |
| 3. | Lead, mg/kg, Max. | 10 |
| 4. | Copper, mg/kg, Max. | 30 |
| 5. | Heavy metal, mg/kg, Max. | 40 |

**9-RIBOFLAVIN**

Riboflavin is a yellow to orange-yellow crystalline powder. Melting point about 280$^{o}$C with decomposition.

Solubility-slightly soluble in water, more soluble in saline solution and in a 10 per cent (w/v) solution of urea, sparingly soluble in alcohol, practically insoluble in chloroform and in solvent ether and soluble in dilute solution of alkali hydroxides.

| | |
|---|---|
| Synonyms | Vitamin B2, Lactoflavin and Lactroflavine |
| Color | Yellow to orange-yellow |
| Class | Isoalloxazine |
| Chemical Name | 6.7-dimethyl-9-(d-1-ribityl)- isoalloxazine |
| Empirical formula | $C_{17}H_{20}N_4O_6$ |
| Molecular Weight | 376.38 |

Identification.-A solution of 1 mg of Riboflavin in 100 ml water is pale greenish yellow in transmitted light, and has an intense yellowish green flourescence which disappears on the addition of sodium dithionite and mineral acids or alkalies.

Spectrophotometry-Absorption maxima of aqueous solution shall be at 220 to 225, 266, 371 and 444 mu.

Specific Rotation-It shall be determined in a 0.5 per cent w/v solution in a mixture of 1.5 ml of 0.1 N alcoholic solution of potassium hydroxide (free from carbonate) and sufficient freshly boiled and cooled water to produce 10 ml. The specific rotation, when calculated with reference to the substance dried to constant weight in the dark at 105oC, shall be,- 122oC.

The material shall have minimum purity of 97.0 per cent.

Maximum limit of metallic impurities shall be:—

| | |
|---|---|
| Arsenic (as As) | 5 ppm |
| Lead (as Pb) | 20 ppm. |

**10 - PONCEAU 4R**

| | |
|---|---|
| Common Name | Ponceau 4R |
| Synonyms | Cl Food Red 7, L-Rot No.4, Coccine Nouvelle, Cochineal Red A; EEC Serial No.E 124 |
| Colour of the 0.1 Percent (m/v) solution in distilled water | Red |
| Colour Index Number (1975) | No. 16255 |
| Class | Monoazo |
| Chemical Name | Trisodium salt of 1-(4-sulpho-1-naphtylazo) naphthol-6, 8- disulphonic acid |
| Empirical formula | $C_{20}$ $H_{11}$ $N_2$ $O_{10}$ $S_3$ $Na_2$ |
| Molecular Weight | 604.5 |
| Solubility | Soluble in water. Sparingly soluble in Ethanol |

The material shall conform to the requirements prescribed in Table below:—

TABLE

Requirements for Ponceau 4R

| Sl. No. | Characteristic | Requirement |
|---|---|---|
| 1. | Total dye content, corrected for Sample dried at 105±1°C for 2 hours, per cent by mass, Min. | 85 |
| 2 | Loss on drying at 135°C, percent by mass, Max. and Chlorides and Sulphates | 18 |

| | | |
|---|---|---|
| | expressed as sodium salt, per cent by mass, Max | |
| 3. | Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. | Combined ether extracts, percent by mass. Max. | 0.2 |
| 5. | Subsidiary dyes, percent by mass, Max. | 1.0 |
| 6. | Dye intermediates, per cent by mass, Max. | 0.5 |
| 7. | Lead, mg/kg, Max. | 10 |
| 8. | Arsenic, mg/kg, Max. | 3 |
| 9. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, selenium and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, and cyanides.;

**11-CARMOISINE**

| | |
|---|---|
| Common Name | Carmoisine |
| Synonyms | Azorubine, C.I. Food Red 3, EEC. Serial No.E 122 |
| Colour of the 0.1 Percent (m/v) solution in distilled water | Red |
| Colour Index Number (1956) | No.14720 |
| Class | Monoazo |
| Chemical Name | Disodium salt of 2-(4-sulpho-1-naphthylazo)-1-hydroxy- naphthalene-4-sulphonic acid |
| Empirical formula | $C_{20}H_{12}N_2O_7S_2Na_2$ |
| Molecular Weight | 502. 44 |

General Requirements: The material shall be free from mercury, selenium and chromium in any form, aromatic amines, aromatic nitro compounds, aromatic hydrocarbons and cyanides.

Carmoisine shall also comply with requirements prescribed in Table below:—

TABLE

Requirements for Carmoisine

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|
| 1. | Total dye content, corrected for Sample dried at 105±1°C | 87 |

| | | |
|---|---|---|
| | for 2 hours, per cent by mass, Min. | |
| 2. | Loss on drying at 135ºC, percent by mass, Max. and Chlorides and Sulphates expressed as sodium salt, per cent by mass, Max. | 13 |
| 3. | Water insoluble matter, percent by mass, Max. | 0.2 |
| 4. | Combined ether extracts, percent by mass. Max. | 0.2 |
| 5. | Subsidiary dyes, percent by mass, Max. | 1.0 |
| 6. | Dye intermediates, per cent by mass, Max. | 0.5 |
| 7. | Lead, mg/kg, Max. | 10 |
| 8. | Arsenic, mg/kg, Max. | 3 |
| 9. | Heavy metals, mg/kg, Max. | 40 |

**12-SYNTHETIC FOOD COLOUR - PREPARATION AND MIXTURES**.

Colour Preparation

A Preparation containing one or more of the permitted synthetic food colours conforming to the prescribed standard alongwith diluents and/or filler materials and meant to be used for imparting colour to food. It may contain permitted preservatives and stabilizers.

The colour preparation would be either in the form of a liquid or powder. Powder preparations shall be reasonably free from lumps and any visible extraneous/foreign matter. Liquid preparations shall be free from sediments.

Only the following diluents or filler materials shall be permitted to be used in colour preparations conforming to the prescribed standards:—

1. Potable water
2. Edible common salt
3. Sugar
4. Dextrose Monohydrate
5. Liquid glucose
6. Sodium sulphate
7. Tartaric acid
8. Glycerine
9. Propylene glycol
10. Acetic acid, dilute
11. Sorbitol
12. Citric acid

13. Sodium carbonate and sodium hydrogen carbonate
14. Lactose
15. Ammonium, sodium and potassium alginates
16. Dextrins
17. Ethyl acetate
18. Starches
19. Diethyl ether
20. Ethanol
21. Glycerol mono, di and tri acetate
22. Edible oils and fats
23. Isopropyl alcohol
24. Bees wax
25. Sodium and ammonium hydroxide
26. Lactic acid
27. Carragenan and gum arabic
28. Gelatin
29. Pectin

Colour Mixtures

A mixture of two or more permitted synthetic food colour conforming to prescribed standards without diluents and filler material and meant to be used for imparting colour to food.

It may contain permitted preservatives and stabilizers.

General Requirements- For Colour Preparation & Colour Mixture. The total Synthetic dye content, per cent by mass (m/v) in the colour preparation or in the mixture shall be declared on the label of the container. In powder preparations the declared value shall be on moisture free basis and in case of liquid preparations on as in basis. The total dye content shall be within the tolerance limits given below on the declared value:

| | | |
|---|---|---|
| (a) | Liquid preparation | +15 per cent |
| | | -5 per cent |
| (b) | Solid preparations | ±7.5 per cent |

The limits of impurities shall be as prescribed in Table below:—

TABLE

Limits for Impurities

| | | |
|---|---|---|
| 1. | Water insoluble matter, per cent by mass, Max. (on dry basis), Max. | 1.0 |
| 2. | Lead, (as Pb), mg/kg, Max. | 10 |
| 3. | Arsenic, (as As) mg/kg, Max. | 3.0 |
| 4. | Heavy metals, mg/kg, Max. | 40 |

It shall be free from mercury, copper and chromium in any form; aromatic amines, aromatic nitro compounds, aromatic hydrocarbons, polycyclic aromatic hydrocarbon, 2-naphthyl aminobenzidine, amino-4-diphenyl (xenylamine) or their derivatives and cyanides.

The total coal tar dye content percent by mass (m/v) in colour preparation or in mixture shall be declared on the lable of the container. In powder preparation, the declared value shall be on moisture free basis and in case of liquid preparation on ' as is basis' and the total dye content shall within ± 15 percent of the declared value. Colour preparation and colour mixture shall also comply with the following requirements namely: -

| *Sl. No.* | *Characteristics* | *Requirements* |
|---|---|---|
| 1 | Water insoluble matter, percent by mass | Not more than 1.0 |
| 2 | Arsenic as (As), parts per million | Not more than 3 |
| 3 | Lead as (Pb) parts per million | Not more than 10 |

**13 BRILLIANT BLUE FCF**

Brilliant Blue FCF is hydroscopic in nature and its shade changes with different pH. Suitable precautions should, therefore, be taken in packing the colour.

Colour Brilliant Blue FCF is described below, namely:—

| | |
|---|---|
| Common Name | Brilliant Blue FCF |
| Synonyms | C.l. Food Blue FD and C Blue No.1 Blue brilliant FCF |
| Colour | Blue |
| Colour Index Number (1975) | No.42900 |

| | |
|---|---|
| Class | Triarymethane |
| Chemical Name | Disodium salt of alpha 4-(N- ethylbeta ulfobenzylamino)-<br>phenyl] alpha [4-(N-ethyl-3 Sulfonatobenzylimino]<br>cyclohexa-2, 5-dienylidene] toluene-2-sulfonate |
| Empirical formula | $C_{37}H_{34}N_2Na_2O_9S_3$ |
| Molecular Weight | 792.86 |

General requirements: The material shall conform to the requirement prescribed in Table below, namely:—

TABLE FOR BRILLIANT BLUE FCF

| *Sl. No.* | *Characteristics* | *Requirements* |
|---|---|---|
| (i) | Total dye content, corrected for Sample dried at 105±1oC for 2 hours, percent by Mass, Minimum | 85 |
| (ii) | Loss on drying at 135°C, and Chlorides and Sulphates expressed as sodium salt, per cent by Mass, Maximum | 15 |
| (iii) | Water insoluble matter, percent by Mass, Maximum | 0.2 |
| (iv) | Combined ether extracts, percent by Mass. Maximum | 0.2 |
| (v) | Subsidiary dyes, percent by Mass, Maximum | 3 |
| (vi) | Dye intermediates, percent by Mass, Max. | |
| | (a) O, sulpho-benzaldehyde, Maximum | 1.5 |
| | (b) N-N' ethyl-benzyl-aniline-3-sulphonic acid, Maximum | 0.3 |
| | (c) Leuco base, percent by Mass, Maximum | 5 |
| (vii) | Heavy metals, (as Pb), mg/kg, Maximum | 40 |
| | Lead, mg/kg, Maximum | 10 |
| | Arsenic, mg/kg, Maximum | 3 |
| | Chromium, mg/kg, Maximum | 50 |

Note:- The material shall be free from aromatic amines, aromatic nitro compounds, aromatic hydrocarbons and cyanides.

**14. Fast Green FCF:**

Fast Green FCF is hydroscopic in nature and its shade changes with different pH. Suitable precautions should, therefore, be taken in packing the colour.

14. Fast Green FCF is described below, namely:—

| | |
|---|---|
| Common Name | Fast Green FCF |
| Synonyms | C.l. Food Green 3, FD and C Green No.3, Vert Solide FCF |
| Class | Triary methane |
| Colour | Green |
| Colour Index | (1975) No.42053 |
| Chemical Name | Disodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-phenyl-(4-hydroxy-2-sulphonumphenyl)-methylene]-(N-ethyl-N-p-sulphobenzyl 2, 5-cyclohexadienimine). |
| Empirical Formula | $C_{37}$ $H_{34}$ $O_{10}$ $N_2$ $S_2$ $Na_2$ |
| Molecular Weight | 808.86 |

Requirements: The material shall conform to the requirement prescribed in Table below, namely:—

TABLE FOR FAST GREEN FCF

| *Sl. No.* | *Characteristic* | *Requirement* |
|---|---|---|
| (i) | Total dye content, corrected for Sample dried at 105±1°C for 2 hours, percent by mass, Minimum | 85 |
| (ii) | Loss on drying at 135°C, and, percent by Mass, Maximum and chlorides and Sulphates expressed | 13 |
| | as sodium salt, percent by mass, Maximum | |
| (iii) | Water insoluble matter, percent by Mass, Maximum | 0.2 |
| (iv) | Combined ether extracts, percent by Mass. Max | 0.2 |
| (v) | Subsidiary dyes, percent by mass, Maximum | 1.0 |
| (vi) | Organic compound other than colouring matter uncombined intermediates and products of side reactions | |
| | (a) Sum of 2-, 3-, 4-formyl benzene sulphonic acid, sodium salts, percent by Mass, Maximum | 0.5 |
| | (b) Sum of 3- and 4-[ethyl (4-sulfophenyl) amino methyl benzene sulphonic acid, disodium salts, Percent by Mass, Maximum | 0.3 |
| | (c) 2-formyl-5-hydroxybenzene sulphonic acid sodium salt, percent by Mass, Maximum | 0.5 |
| | (d) Leuco base, percent by Mass, Maximum | 5.0 |

| | | |
|---|---|---|
| | (e) Unsulphonated primary aromatic amines (calculated as aniline), percent by Mass, Maximum | 0.01 |
| (vii) | Lead, mg/kg, Maximum | 10 |
| (viii) | Arsenic, mg/kg, Maximum | 3 |
| (ix) | Chromium, mg/kg, Maximum | 50 |
| (x) | Mercury, mg/kg, Maximum | Absent |
| (xi) | Heavy metals, mg/kg, Maximum | 40 |

Note:- The material shall be free from aromatic nitro compounds, aromatic hydrocarbons and cyanides

**15. Aluminium Lake of Sunset Yellow FCF-** Food Yellow No.5 Aluminium Lake is a fine orange yellow water soluble, odourless powder. It is prepared by percipating Sunset Yellow FCF (conforming to specification under 10.02 of Appendix C of these Regulations on to a substratum of Alumina.

Chemical Name - Sunset Yellow FCF Aluminium Lake -6, hydroxy-5 (4-sulfophenlyazo)-2 Naphthalenesulphonic acid, Aluminium Lake.

Synonym - CI Pigment Yellow, 104, FD and C Yellow No. 6, Aluminium Lake (USA), Food Yellow No. 5 Aluminium Lake (Japan).

(1) Sunset yellow dye used in preparation of lake colour shall conform to specifications laid down under table 2 of these Regulations.

| | | |
|---|---|---|
| (2) | Pure dye content of Aluminium Lake weight by weight | not less than 17 percent |
| (3) | Substratum of Aluminium oxide | not more than 83 percent. |
| (4) | Aluminium content in the lake weight by weight | not more than 44 percent |
| (5) | Sodium chlorides and sulphates (as sodium salts) | not more than 2.0 percent |
| (6) | Inorganic matter (HCl insoluble) | not more than 0.5 percent |
| (7) | Lead (as Pb) | not more than 10 ppm |
| (8) | Arsenic (as As) | not more than 3 ppm |

Alumina used in colour shall conform to following, namely:—

(a) Identity: Alumina (dried as aluminium hydroxide) is a white, odourless, tasteless, amorphous powder consisting essentially of Aluminium hydroxide ($Al_2O_3 \times H_2O$).

(b) Specifications: Alumina (dried aluminium hydroxide) shall conform

to the following specifications, namely:-

| | | |
|---|---|---|
| (i) | Acidity or alkalinity | Agitate 1 gm with 25ml of water and filter.<br>The filtrate shall be neutral to litmus paper |
| (ii) | Lead (as Pb) | not more than 10 parts per million |
| (iii) | Arsenic (as As) | not more than 1 parts per million |
| (iv) | Mercury (as Hg) | not more than 1 parts per million |
| (v) | Aluminium oxide ($Al_2O_3$) | not less than 50 percent |

Solubility: Lakes are insoluble in most solvents. They are also insoluble in water in pH range from 3.5-9.0 but outside this range and lake substrate tends to dissolve releasing the captive dye.

**[42][16. Beta-apo-8'-carotenal:**

(1) Beta-apo-8'-carotenal in crystal form shall be deep violet with metallic luster, and in case of solution in oil, fat or organic solvents or water-dispersible forms including powder, granules or capsules, it shall be orange to red in colour and as described below, namely:-

| | |
|---|---|
| Common Name | Beta-apo-8'-carotenal |
| Colour Index (DFG Lebensmittel) | Orange 8 |
| INS No. | 160e |
| C.A.S No. | 1107-26-2 |
| Chemical Name | Trans-beta-apo-8'-carotenal. |
| Empirical Formula | $C_{30}H_{40}O$ |
| Molecular Weight | 416.65 |

(2) Beta-apo-8'-carotenal shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |

| | | |
|---|---|---|
| 1. | Purity as $C_{30}H_{40}O$ per cent. by weight, Min | 96 |
| 2. | Sulphated ash, per cent. by weight, Max | 0.1 |
| 3. | Melting range, $0^0C$ | 136 - 140 |
| 4. | Arsenic , mg/kg, Max | 3.0 |
| 5. | Lead, mg/kg, Max | 2.0 |

**17. Ethylester of Beta-apo-8'-carotenoic acid:**

(1) Ethyl ester of Beta-apo-8'-carotenoic acid in crystal form shall be red and in case of solution in oil, fat or organic solvent or water-dispersible forms including, powder, granules or capsules, it shall be yellow to orange in colour and as described below, namely:-

| | |
|---|---|
| Common Name | Ethyl ester of beta-apo-8'-carotenoic acid |
| Colour Index (DFG Lebensmittel) | Orange 9 |
| INS No. | 160f |
| C.A.S No. | 1109-11-1 |
| Chemical Name | Trans-beta-apo-8'-carotenoic acid, ethyl ester. |
| Empirical Formula | $C_{22}H_{44}O_8$ |
| Molecular Weight | 460.70 |

(2) Ethylester of Beta-apo-8'-carotenoic acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_{22}H_{44}O_8$, per cent. by mass, *Min* | 96 |
| 2. | Sulphated ash, per cent. by mass, *Max* | 0.1 |
| 3. | Melting range, $^0C$ | 134 - 138 |
| 4. | Arsenic , mg/kg, *Max* | 3.0 |
| 5. | Lead, mg/kg, *Max* | 2.0 |

**18. Titanium dioxide:**

(1) Titanium Dioxide shall be a white, tasteless, odourless, infusible powder and as described below, namely:-

| | |
|---|---|
| Common Name | Titanium dioxide |
| INS No. | 171 |
| C.A.S No. | 13463-67-7 |
| Chemical Name | Titanium Dioxide |
| Empirical Formula | $TiO_2$ |
| Molecular Weight | 79.88 |

(2) Titanium dioxide shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $TiO_2$, per cent. by mass, Min | 99 |
| 2. | Loss on drying at 105 $^0$C for 3 hours, per cent. by mass, Max | 0.5 |
| 3. | Loss on ignition (at 800 $^0$C), per cent. by mass. Max | 0.5 |
| 4. | Acid soluble substances, per cent. by mass, Max | 0.35 |
| 5. | Water soluble substances, per cent. by mass, Max | 0.25 |
| 6. | Aluminium oxide and/or silicon dioxide (either singly or combined), per cent. by mass, Max | 2.0 |
| 7. | Mercury, mg/kg, *Max* | 1.0 |
| 8. | Antimony, mg/kg, *Max* | 2.0 |
| 9. | Zinc, mg/kg, *Max* | 50.0 |

| | | |
|---|---|---|
| 10. | Arsenic, mg/kg, *Max* | 1.0 |
| 11. | Lead, mg/kg, *Max* | 2.0 |
| 12. | Barium compounds, mg/kg, *Max* | 3.0 |
| 13. | Aluminium, mg/kg, *Max* | 1.0] |

[10][**3.2.2 Sweetener**:-

[75][The sweeteners (as food additives) shall be classified as "Caloric sweeteners" and "Non–caloric sweeteners", defined as follows:

(a) Caloric sweeteners: Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity. These include Sorbitol, Sorbitol syrup, Mannitol, Isomalt, Polyglycitol syrup, Maltitol, Maltitol syrup, Lactitol and Xylitol.

(b) Non-caloric sweeteners: Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity. These include Erythritol, Steviol glycoside, Thaumatin, Aspartame, Sucralose, Neotame, Acesulfame potassium, Aspartame-Acesulfame potassium salt and Saccharins.]

The standards for various sweeteners with characteristics are –

**(1) Steviol Glycoside**- White to light yellow powder, odorless or having a slight characteristic odor. About 200 - 300 times sweeter than sucrose. 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 re-crystallized from methanol or aqueous ethanol. Ion exchange resins may be used in the purification process. The final product may be spray-dried. Stevioside and rebaudioside A are the component glycosides of principal interest for their sweetening property. Associated glycosides include rebaudioside B, rebaudioside C, rebaudioside D, rebaudioside F, dulcoside A, rubusoside and

steviolbioside which are generally present in preparations of steviol glycosides at levels lower than stevioside or rebaudioside A.

| | |
|---|---|
| Synonyms | INS no. 960. |
| Chemical name | Stevioside:13-[(2-O-β-D-glucopyranosyl-β glucopyranosyl)oxy] kaur-16-en-18-oic acid, β-D-glucopyranosyl ester. |
| | Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester. |
| Empirical formula | Stevioside: $C_{38}H_{60}O_{18}$ |
| | Rebaudioside A: $C_{44}H_{70}O_{23}$ |
| Formula weight | Stevioside: 804.88 |
| | Rebaudioside A: 967.03. |
| Solubility | Freely soluble in water |
| | Stevioside and |
| | rebaudioside A |
| | The main peak in the chromatogram obtained by following the procedure in Method of Assay corresponds to either stevioside or rebaudioside A. |
| pH | Between 4.5 and 7.0 (1 in 100 solution). |
| [51][Assay/purity | Not less than 95 per cent. of the total of steviol glycosides on the dry weight basis] |
| [51][Total ash | Not more than 1 percent.] |
| Loss on drying | Not more than 6 percent (105°, 2h). |

| | |
|---|---|
| Residual solvents | Not more than 200 mg/kg methanol and not more than 5000 mg/kg ethanol (Method I in Vol. 4, General Methods, Organic Components, Residual Solvents). |
| Arsenic | Not more than 1 mg/kg Determine by the atomic absorption hydride technique (Use Method II to prepare the test (sample) solution). |
| Lead | Not more than 1 mg/kg Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Vol. 4 (under "General Methods, Metallic Impurities")] |

**Amendment for substitution of highlighted provision**

**"(1) STEVIOL GLYCOSIDES FROM STEVIA REBAUDIANA BERTONI**

| | |
|---|---|
| INS number | 960 |
| 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. 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. |
| Chemical name | See Appendix 1 |
| Chemical formula | See Appendix 1 |
| Formula weight | See Appendix 1 |
| Assay/purity | Not less than 95% of total of steviol glycosides, on the dried basis, determined as the sum of all compounds containing a steviol backbone conjugated to any number, combination or orientation of saccharides (glucose, rhamnose, fructose, deoxyglucose, xylose, galactose, arabinose and xylose) occurring in the leaves of Stevia rebaudiana Bertoni. |
| Description | White to light yellow powder, odourless or having a slight characteristic odour. About 200 - 300 times sweeter than sucrose. |
| Characteristics | |
| (a) Identification | |

| | |
|---|---|
| Solubility | Freely soluble in a mixture of ethanol and water (50:50) |
| HPLC Chromatographic assay | The main peaks in a chromatogram correspond to steviol glycosides (method of assay as per JECFA monograph) |
| pH | Between 4.5 and 7.0 (1 in 100 solution) |
| (b) 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<br>Yeasts and moulds: Not more than 200 CFU/g<br>*E. coli*: Negative per g<br>*Salmonella*: Negative per 25g |

Analytical methods or method of assay:

As per Joint FAO/WHO Expert Committee on Food Additives (JECFA) monograph (2017) on STEVIOL GLYCOSIDES FROM STEVIA REBAUDIANA BERTONI

# Appendix 1: Chemical Information of Some Steviol Glycoside

| Common Name | Trivial Name | $R_1$ | $R_2$ | Chemical Name | CAS Number | Chemical Formula | Formula Weight |
|---|---|---|---|---|---|---|---|
| **Group 1: Steviol + Glucose (SvGn)** | | | | | | | |
| Steviolmonoside | SvG1 | H | Glcβ1- | 13-[(β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid | 60129-60-4 | $C_{26}H_{40}O_8$ | 481 |
| Steviolmonoside A | SvG1 | Glcβ1- | H | 13-[(hydroxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 64977-89-5 | $C_{26}H_{40}O_8$ | 481 |
| Rubusoside | SvG2 | Glcβ1- | Glcβ1- | 13-[(β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 64849-39-4 | $C_{32}H_{50}O_{13}$ | 643 |
| Steviolbioside | SvG2 | H | Glcβ(1-2)Glcβ1- | 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid | 41093-60-1 | $C_{32}H_{50}O_{13}$ | 643 |
| Stevioside | SvG3 | Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 57817-89-7 | $C_{38}H_{60}O_{18}$ | 805 |
| Stevioside A Or Rebaudioside KA | SvG3 | Glcβ(1-2)Glcβ1- | Glcβ1- | 13-[(2-O-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid 4')-*O*-β-D-glucopyranosyl-deoxy-(1,2)-O-[β-(-d-glucopyranosyl ester | 127345-20-4 | $C_{38}H_{60}O_{18}$ | 805 |
| Stevioside B | SvG3 | Glcβ(1-3)Glcβ1- | Glcβ1- | 13-[(2-O-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, *O*-β-D-glucopyranosyl-deoxy-(1,3)-O-[β-D-glucopyranosyl ester | - | $C_{38}H_{60}O_{18}$ | 805 |
| Rebaudioside *B* | SvG3 | H | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid | 58543-17-2 | $C_{38}H_{60}O_{18}$ | 805 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Rebaudioside G | SvG3 | Glcβ1- | Glcβ(1-3)Glcβ1 | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid(4')-*O*-β-D-glucopyranosyl ester | 127345-21-5 | $C_{38}H_{60}O_{18}$ | 805 |
| Rebaudioside *E* | SvG4 | Glcβ(1-2)Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(*O*-β- D-glucoopyranosyl-(1,2)-*O*-[ β- D-glucopyranosyl)-oxy]-kaur-16-en-18-oic acid (4')-*O*-β-D-glucopyranosyl-deoxy-(1,2)-*O*-[ β-D-glucopyranosyl ester | 63279-14-1 | $C_{44}H_{70}O_{23}$ | 967 |
| Rebaudioside *A* | SvG4 | Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 58543-16-1 | $C_{44}H_{70}O_{23}$ | 967 |
| Rebaudioside A2 | SvG4 | Glcβ1- | Glcβ(1-6)[Glcβ(1-2)]Glcβ1- | 13-[(6-O-β-D-glucopyranosyl-2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl ester | 1326217-29-1 | $C_{44}H_{70}O_{23}$ | 967 |
| Rebaudioside *D* | SvG5 | Glcβ(1-2)Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester | 63279-13-0 | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside L | SvG5 | Glcβ1- | Glcβ(1-6)Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(6-O-β-D-glucopyranosyl-2-O-β-D-glucopyranosyl-3-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl ester | 1220616-38-5 | $C_{50}H_{80}O_{28}$ | 1129 |

| Common Name | Trivial Name | $R_1$ | $R_2$ | Chemical Name | CAS Number | Chemical Formula | Formula Weight |
|---|---|---|---|---|---|---|---|
| Rebaudioside I | SvG5 | Glcβ(1-3)Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside I2 | SvG5 | Glcβ1- | Glcα(1-3)Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(3-O-β-D-glucopyranosyl-2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside I3 | SvG5 | [Glcβ(1-2)Glcβ(1-6)]Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-O-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-6-O- β-D-glucopyranosyl-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside Q | SvG5 | Glcβ1- | Glcα(1-4)Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(4-O-β-D-glucopyranosyl-2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside Q2 | SvG5 | [Glcα(1-2)Glcα(1-4)]Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-4-O-β-D-glucopyranosyl- β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Rebaudioside Q3 | SvG5 | Glcβ1- | Glcα(1-4)Glcβ(1-3)[Glcβ(1-2)]Glcβ1- | 13-[(4-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-2-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{28}$ | 1129 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Rebaudioside *M* | SvG6 | Glcβ(1-2)[Glcβ (1-3)]Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(*O*-β- D-glucopyranosyl-(1,2)-*O*-[ β- D-glucopyranosyl-(1,3)]-β- D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid (4')-*O*-β- D-glucopyranosyl-(1,2)-*O*-[β- D-glucopyranosyl-(1,3)]-β- D-glucopyranosyl ester | 1220616-44-3 | $C_{56}H_{90}O_{33}$ | 1291 |
| Related SvGn#1 | | - | - | - | - | $C_{21}H_{30}O_{11}$ | 458 |
| Related SvGn#2 | | - | - | - | - | $C_{40}H_{70}O_{24}$ | 982 |
| Related SvGn#3 | | - | - | - | - | $C_{32}H_{52}O_{15}$ | 676 |
| Related SvGn#4 | | - | - | - | - | $C_{50}H_{80}O_{28}$ | 1129 |
| Related SvGn#5 | | - | - | - | - | $C_{40}H_{70}O_{24}$ | 982 |
| **Group 2: Steviol + Rhamnose + Glucose (SvR1Gn)** | | | | | | | |
| Dulcoside *A* | SvR1G2 | Glcβ1- | Rhaα(1-2)Glcβ1- | 13-[(2-O-α–L-rhamnopyranosyl-β–D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 64432-06-0 | $C_{38}H_{60}O_{17}$ | 789 |
| Dulcoside C | SvR1G2 | H | Rhaα(1-2)[Glcβ(1-3)] Glcβ1- | 13-[(2-O-β-D-rhamnopyranosyl-3-β-D-glucopyranosyl- β-D-glucopyranosyl -oxy]kaur-16-en-18-oic acid | | $C_{38}H_{60}O_{17}$ | 789 |
| Rebaudioside *C* | SvR1G3 | Glcβ1- | Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-α–L-rhamnopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 63550-99-2 | $C_{44}H_{70}O_{22}$ | 951 |

| Common Name | Trivial Name | $R_1$ | $R_2$ | Chemical Name | CAS Number | Chemical Formula | Formula Weight |
|---|---|---|---|---|---|---|---|
| Rebaudioside C2 | SvR1G3 | Rhaα(1-2)Glcβ1 | Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-rhamnopyranosyl- β-D-glucopyranosyl ester | - | $C_{44}H_{70}O_{22}$ | 951 |
| Rebaudioside *N* | SvR1G5 | Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-*O*-β- D-glucopyranosyl-(1,2)-*O*-[β- D-glucopyranosyl-(1,3)]-β- D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid (4')-*O*-2-deoxy-L-rhmanopyranosyl-3-*O*-β- D-glucopyranosyl-β- D-glucopyranosyl ester | 1220616-46-5 | $C_{56}H_{90}O_{32}$ | 1274 |
| Rebaudioside *O* | SvR1G6 | Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy] ent-kaur-16-en-19-oic acid-[(2-O-(3-O-β-D-glucopyranosyl-α-L-rhamnopyranosyl)-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl) ester] | 1220616-48-7 | $C_{62}H_{100}O_{37}$ | 1436 |
| Rebaudioside *O2* | SvR1G6 | Glcβ(1-4*)Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(*O*-β-D-glucopyranosyl-(1,2)-*O*-[β-D-glucopyranosyl-(1,3)]-β-D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid (4')-*O*-β-D-glucopyranosyl-(1,4)-*O*-6- deoxy-L-rhmnopyranosyl-(1,2)-*O*-[β-D-glucopyranosyl-(1,3)]-β-D-glucopyranosyl ester | - | $C_{62}H_{100}O_{37}$ | 1436 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Rebaudioside K | SvR1G4 | Glcβ(1-2)Glcβ1- | Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-rhamnopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | 1220616-40-9 | $C_{50}H_{80}O_{27}$ | 1112 |
| Rebaudioside S | SvR1G3 | Rhaα(1-2)Glcβ1- | Glcα (1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, O-2-deoxy-L-rhamnopyranosyl β-D-glucopyranosyl ester | 1931085-11-8 | $C_{44}H_{70}O_{22}$ | 951 |
| Rebaudioside K2 | SvR1G4 | Glcβ(1-6)Glcβ1- | Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-rhamnopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 6-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | - | $C_{50}H_{80}O_{27}$ | 1112 |
| Rebaudioside H | SvR1G4 | Glcβ1- | Glcβ(1-3)Rhaα(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(3-O-β-D-glucopyranosyl-2-O-β-D-rhamnopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 1220616-36-3 | $C_{50}H_{80}O_{27}$ | 1112 |
| Rebaudioside J | SvR1G4 | Rhaα(1-2)Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]-kaur-16-en-18-oic acid, 2-O-6- deoxy-L-rhmnopyranosyl-β-D-glucopyranosyl ester | 1313049-59-0 | $C_{50}H_{80}O_{27}$ | 1112 |
| **Group 3: Steviol + Xylose + Glucose (SvX1Gn)** | | | | | | | |
| Stevioside F | SvX1G2 | Glcβ1- | Xylβ(1-2)Glcβ1- | 13-[(2-O-β-D-xylopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | - | $C_{37}H_{59}O_{17}$ | 775 |

| Common Name | Trivial Name | $R_1$ | $R_2$ | Chemical Name | CAS Number | Chemical Formula | Formula Weight |
|---|---|---|---|---|---|---|---|
| Rebaudioside F | SvX1G3 | Glcβ1- | Xylβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-xylopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 438045-89-7 | $C_{43}H_{68}O_{22}$ | 937 |
| Rebaudioside F2 | SvX1G3 | Glcβ1- | Glcβ (1-2)[ Xylβ (1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-xylopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | - | $C_{43}H_{68}O_{22}$ | 937 |
| Rebaudioside F3 | SvX1G3 | Xylβ(1-6) Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 6-O-β-D-xylopyranosyl-β-D-glucopyranosyl ester | - | $C_{43}H_{68}O_{22}$ | 937 |
| Rebaudioside R | SvX1G3 | Glcβ1- | Glcβ(1-2)[Glcβ1-3] Xylβ1 | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-xylopyranosyl-3)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | 1931083-53-2 | $C_{43}H_{68}O_{22}$ | 937 |
| Rebaudioside U2 | SvX1G4 | Xylβ(1-2*)[Glcβ(1-3)]Glcβ1- | Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-xylopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | - | $C_{50}H_{82}O_{26}$ | 1099 |
| Rebaudioside T | SvX1G4 | Xylβ(1-2)Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-xylopyranosyl-β-D-glucopyranosyl ester | | $C_{50}H_{82}O_{26}$ | 1099 |
| Rebaudioside V2 | SvX1G5 | Xylβ (1-2)[Glcβ(1-3)]Glcβ1- | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-xylopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester | - | $C_{56}H_{92}O_{31}$ | 1261 |

| Common Name | Trivial Name | $R_1$ | $R_2$ | Chemical Name | CAS Number | Chemical Formula | Formula Weight |
|---|---|---|---|---|---|---|---|
| **Group 5: Steviol + Galactose + Glucose (SvGa1Gn)** | | | | | | | |
| Rebaudioside T1 | SvGa1G4 | Galβ(1-2*)Glcβ1 | Glcβ(1-2)[Glcβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-galactopyranosyl-β-D-glucopyranosyl ester | - | C50H80O28 | 1128 |
| **Group 6: Steviol + Fructose + Glucose (SvFruGn)** | | | | | | | |
| Rebaudioside *A3* | SbF1G3 | Glcβ1- | Glcβ(1-2)[Fruβ(1-3)]Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-fructofuranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | - | $C_{44}H_{70}O_{22}$ | 951 |
| **Group 7: Steviol + -de-oxy glucose + Glucose (SvdG1Gn)** | | | | | | | |
| Stevioside D | SvDg1G2 | Glcβ1- | 6-deoxy Glcβ(1-2)Glcβ1- | 13-[(2-O-β-D-6-deoxyglucopyranosyl-β-D-glucopyranosy)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | - | $C_{38}H_{60}O_{17}$ | 789 |
| Stevioside E | SvDg1G3 | Glcβ1- | 6-deoxy Glcβ(1-2)[Glcβ(1-3)] Glcβ1- | 13-[(2-O-β-D-6-deoxyglucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester | - | $C_{44}H_{70}O_{22}$ | 951 |
| Stevioside E2 | SvDg1G3 | 6-deoxy Glcβ1- | Glcβ(1-2)[Glcβ(1-3)] Glcβ1- | 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl- β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-6-deoxyglucopyranosyl-ester | - | $C_{44}H_{70}O_{22}$ | 951 |

Steviol (R1 = R2 = H) is the aglycone of the steviol glycosides.
Glc, Rha, Fru, deoxyGlc, Gal, Ara and Xyl represent, respectively, glucose, rhamnose, fructose, deoxyglucose, galctose, arabinose and xylose sugar moieties.

Note: This list is not exhaustive. More steviol glycosides may have been identified in stevia leaf extracts in the literature

[This amendment shall come into force on 1st September, 2023]

[27]**[3.2.3 Baker's Yeast**

1. The Baker's Yeast shall be of the following types:
   (i) Baker's Yeast, Compressed; and
   (ii) Baker's Yeast, Dried.

**(i) Baker's Yeast (Compressed)** shall be in the form of a block having creamy white colour, and odour characteristic of good baker's yeast (compressed) and a fine even texture. It shall not be slimy or mouldy and shall not show any sign of deterioration or decomposition. It shall be free from extraneous materials. Starch of an edible quality may, however, be added in a quantity not exceeding 7% by weight on dry basis. Permissible edible binders and fillers may be added. It shall break sharply on bending. The yeast blocks shall be stored at temperature between 1 to $5^0$C.

**(ii) Baker's Yeast (Dried)** shall be in the form of small powder granules, pellets or flakes. It shall have an odour characteristic of good baker's yeast

(dried). It shall not be mouldy and shall not show any sign of deterioration or decomposition. It shall be free from adulterants and other extraneous materials. Starch of an edible quality may, however, be added in a quantity not exceeding 10 % by weight of the material. The yeast shall be stored in a cool and dry place at a temperature not more than $25^0$C.

Baker's Yeast shall conform to the following standards namely:-

| *Characteristics* | *Requirements for* | |
|---|---|---|
| | *Baker's yeast Compressed* | *Baker's Yeast Dried* |
| Moisture, percent by weight, max | 73 | 8 |
| Dispersibility in water | To satisfy the test* | To satisfy the test* |
| Fermenting power*, Min | 1000 | 350 |
| Dough-raising capacity | To satisfy the test* | To satisfy the test* |

* As per method prescribed in IS: 1320.

**Note:** These parameters shall be tested within 24 hours of production of yeast.

**2. Food Additives**

Only those food additives permitted under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 shall be used.

**3. Hygiene**

The product shall be prepared and handled in accordance with the guidelines provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011 and such guidance as provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**4. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

The products covered in this standard shall conform to the Microbiological Requirements given in Appendix B of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

**5. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

**3.2.4 Lactic Acid (Food Grade) (INS 270)**

**1.** Lactic acid shall be yellowish to colourless syrupy liquid with an acidic taste and no odour. It shall be obtained by lactic fermentation of sugars or prepared synthetically. It shall be miscible in water and ethanol. It shall give positive test for lactate. It shall conform to the following specifications:

| *Characteristics* | *Requirement* |
|---|---|
| Purity ($C_3H_6O_3$), % by weight of the labelled concentration | Not less than 95.0% |
| Sulphated ash, % by weight, Max | 0.1 |
| Chlorides, % by weight, Max | 0.2 |
| Sulphates (as $SO_4$), % by weight, Max | 0.25 |
| Citric, oxalic, phosphoric and tartaric acids | Conform to test* |
| Sugars | Conform to test* |
| Readily carbonizable substances | Conform to test* |
| Cyanide | Conform to test* |
| Iron, mg/kg, Max | 10 |
| Lead mg/kg, Max | 2 |

*As per method prescribed in IS: 9971.

**2. Hygiene**

The product shall be prepared and handled in accordance with the guidelines provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidance as provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**3. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

**4. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

### 3.2.5 Ascorbic Acid (Food Grade) (INS 300)

**1.** Ascorbic acid shall be a white or almost white odourless crystalline solid. Its melting range is 190°C to 192°C with decomposition. The material is freely soluble in water and sparingly soluble in ethanol and insoluble in ether. It shall conform to the following standards:

| *Characteristic* | *Requirement* |
|---|---|
| Purity as $C_6H_8O_6$ % by weight , Min | 99 |
| Loss on drying over sulphuric acid for 24 hours, % by weight, Max | 0.4 |
| Sulphated ash, % by weight, Max | 0.1 |
| Specific rotation, when determined in a 2 % (m/v) solution in water at $20^0$C | $+20.5^0$ to $+21.5^0$ |
| pH of 2 % (m/v) solution | 2.4 - 2.8 |
| Lead mg/kg, Max | 2 |

**2. Hygiene**

The product shall be prepared and handled in accordance with the guidelines provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, and such guidance as

provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**3. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

**4. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

### 3.2.6 Calcium Propionate (Food Grade) (INS 282)

**1.** Calcium propionate shall be in the form of white crystals or crystalline solid possessing a faint odour of propionic acid. The material shall be freely soluble in water. It shall conform to the following standards:

| **Characteristic** | **Requirement** |
|---|---|
| Purity as $C_6H_{10}O_4Ca$, % by weight on dry basis, Min | 98 |
| Moisture, % by weight, Max | 5.0 |
| Matter insoluble in water, % by weight, Max | 0.3 |
| Iron (as Fe), mg/kg, Max | 50 |
| Fluoride, mg/kg, Max | 10 |
| Lead mg/kg, Max | 5 |
| Magnesium (as MgO) | To pass the test (about 0.4%) |
| pH of the 10 %(m/v) solution at 25 $\pm$ $2^0$C | 7-9 |

**2. Hygiene**

The product shall be prepared and handled in accordance with the guideline provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, and such guidance as provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**3. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

**4. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

### 3.2.7 Sodium Metabisulphite (Food Grade) (INS 223)

**1.** Sodium Metabisulphite shall be colourless crystals or white to yellowish crystalline powder having an odour of sulphur dioxide. The material is soluble in water but insoluble in ethanol. It shall conform to the following standards:

| *Characteristics* | *Requirement* |
|---|---|
| Purity | |
| (a) As $Na_2S_2O_5$, % by weight , Min | 95 |
| (b) As $SO_2$, % by weight, Min | 64 |
| Water insoluble matter, % by weight, Max | 0.05 |
| Thiosulphate, % by weight, Max | 0.01 |
| Iron mg/kg, Max | 5 |
| Selenium (as Se), mg/kg, Max | 5 |
| Lead mg/kg, Max | 2 |
| pH | Acidic to litmus |

**2.Hygiene**

The product shall be prepared and handled in accordance with the guideline provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011 and such guidance as provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**3. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

**4. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

### 3.2.8 Potassium Metabisulphite (Food Grade) (INS 224)

**1.** Potassium Metabisulphite shall be white or colourless, free flowing crystals, crystalline powder or granules usually having an odour of sulphur dioxide. It gradually oxidizes in air to sulphate. The material is soluble in water but insoluble in ethanol. It shall conform to the following standards:

| *Characteristic* | *Requirement* |
|---|---|
| Purity, as $K_2S_2O_5$, % by weight , Min | 90 |
| Water insoluble matter, %by weight, Max | 0.05 |
| Thiosulphate, % by weight, Max | 0.1 |
| Iron, mg/kg, Max | 5 |
| Selenium (as Se), mg/kg, Max | 5 |
| Lead mg/kg, Max | 2 |
| pH | Acidic to litmus |

**2. Hygiene**

The product shall be prepared and handled in accordance with the guidelines provided in Schedule 4, Part-II of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such guidance provided from time to time under the provisions of the Food Safety and Standards Act, 2006.

**3. Contaminants, Toxins and Residues**

The product covered in this standard shall comply with the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

**4. Packaging and Labelling**

The products shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.]

[42][**3.2.9. Preservatives:**

**1. Sodium benzoate:**

(1) Sodium benzoate shall be a white, almost odourless, crystalline powder or flakes and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium benzoate |
| INS No. | 211 |
| C.A.S No. | 532-32-1 |
| Chemical Name | Sodium salt of benzene carboxylic acid, and sodium salt of phenyl carboxylic acid |
| Empirical Formula | $C_7H_50_2Na$ |
| Molecular Weight | 144.11 |

(2) Sodium benzoate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |

| | | |
|---|---|---|
| 1. | Purity, expressed as $C_7H_50_2Na$, per cent. by mass, Min | 99.0 |
| 2. | Melting range of liberated benzoic acid | 121.5°C- 123.5°C |
| 3. | Moisture, per cent. by mass, Max | 1.5 |
| 4. | Acidity or alkalinity | shall conform to test as per BIS standard |
| 5. | Readily carbonizable substances | shall conform to test as per BIS standard |
| 6. | Readily oxidizable substances | shall conform to test as per BIS standard |
| 7. | Chlorinated organic compounds | shall conform to test as per BIS standard |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |
| 9. | Lead, mg/kg, Max | 2.0 |

**2. Benzoic acid:**

(1) Benzoic acid shall be in the form of white crystals, scales or needles and as described below, namely:-

| | |
|---|---|
| Common Name | Benzoic acid |
| INS No. | 210 |
| C.A.S No. | 65-85-0 |
| Chemical Name | benzene carboxylic acid,<br>and phenyl carboxylic acid |
| Empirical Formula | $C_7H_60_2$ |
| Molecular Weight | 122.12 |

(2) Benzoic acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|

| (1) | (2) | (3) |
|---|---|---|
| 1. | Purity, as $C_7H_60_2$, per cent. by mass, Min | 99.5 |
| 2. | Melting range | 121.5°C - 123.5°C |
| 3. | Sulphated ash, per cent. by mass, *Max* | 0.05 |
| 4. | Readily carbonizable substances | shall conform to test as per BIS standard |
| 5. | Readily oxidizable substances | shall conform to test as per BIS standard |
| 6. | Loss on drying (for 3 hours over sulphuric acid or silica gel at ambient temperature in a dessicator) per cent. by mass, *Max* | 0.5 |
| 7. | Chlorinated organic compounds | shall conform to test as per BIS standard |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |
| 9. | Lead, mg/kg, Max | 2.0 |

**3. Potassium nitrate:**

(1) Potassium nitrate shall be colourless, odourless and salty to taste and may be in the form of transparent prisms or white granules or crystalline powder and as described below, namely:-

| | |
|---|---|
| Common Name | Potassium nitrate |
| INS No. | 252 |
| C.A.S No. | 7757-79-1 |
| Chemical Name | Potassium nitrate |
| Empirical Formula | $KNO_3$ |
| Molecular Weight | 101.11 |

(2) Potassium nitrate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|

| (1) | (2) | (3) |
|---|---|---|
| 1. | Purity, as $KNO_3$, per cent. by mass, Mi*n* | 99 |
| 2. | Moisture per cent. by mass, *Max* | 1 |
| 3. | Matter insoluble in water | Shall pass the test as per BIS standard |
| 4. | Chlorates | Shall pass the test as per BIS standard |
| 5. | Sulphates (as $K_2SO_4$), per cent. by mass, Max | 0.10 |
| 6. | Arsenic, mg/kg, *Max* | 3.0 |
| 7. | Lead, mg/kg, Max | 2.0 |
| 8. | Nitrite, mg/kg, *Max* | 20.0 |

**4. Sorbic acid:**

(1) Sorbic acid shall be colourless needles or white free flowing powder, having a slight characteristic odour and as described below, namely:-

| | |
|---|---|
| Common Name | Sorbic acid |
| INS No. | 200 |
| C.A.S No. | 110-44-1 |
| Chemical Name | Sorbic acid; trans, all trans 2, 4-hexadienoic acid. |
| Empirical Formula | $C_6H_8O_2$ |
| Molecular Weight | 112.13 |

(2) Sorbic acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity, as $C_6H_8O_2$, per cent. by mass(on dry basis), *Min* | 99 |

| | | |
|---|---|---|
| 2 | Moisture, per cent. by mass, *Max* | 0.5 |
| 3 | Sulphated ash, per cent. by mass, Max | 0.2 |
| 4 | Aldehydes, per cent. by mass, Max | 0.1 |
| 5 | Melting range, $^0$C | 132 - 135 |
| 6 | Arsenic, mg/kg, *Max* | 3.0 |
| 7 | Lead, mg/kg, Max | 2.0 |

**5. Potassium nitrite:**

(1) Potassium nitrite shall be in the form of small white or yellowish deliquescent granules or cylindrical sticks and as described below, namely:-

| | |
|---|---|
| Common Name | Potassium nitrite |
| INS No. | 249 |
| C.A.S No. | 7758-09-0 |
| Chemical Name | Potassium nitrite |
| Empirical Formula | $KNO_2$ |
| Molecular Weight | 85.11 |

(2) Potassium nitrite shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity, as ($KNO_2$), on dry basis, per cent. by mass, *Min* | 97 |
| 2. | Loss on drying when dried over silica gel for four hours, per cent. by mass, Max | 1 |
| 3. | Arsenic, mg/kg, *Max* | 3.0 |
| 4. | Lead, mg/kg, Max | 2.0 |

**6. Sodium propionate:**

(1) Sodium propionate shall be colourless and in the form of transparent crystals or granular crystalline powder and shall be odourless or with a faint acetic butyric odour and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium propionate |
| INS No. | 281 |
| C.A.S No. | 137-40-6 |
| Chemical Name | Sodium Propionate |
| Empirical Formula | $C_3H5O_2Na$ |
| Molecular Weight | 96.06 |

(2) Sodium propionate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_3H_5O_2Na$, per cent. by mass, on dry basis, *Min* | 99 |
| 2. | Moisture, per cent. by mass, *Max* | 1 |
| 3. | Matter insoluble in water, per cent. by mass, Max | 0.1 |
| 4. | Iron, mg/kg, *Max* | 30 |
| 5. | Arsenic, mg/kg, *Max* | 3.0 |
| 6. | Lead, mg/kg, Max | 5.0 |

**7. Sulphur dioxide:**

(1) Sulphur dioxide shall be a colourless, non-flammable gas, with a strong, pungent suffocating odour and as described below, namely:-

| | |
|---|---|
| Common Name | Sulphur dioxide |
| INS No. | 220 |
| C.A.S No. | 7446-09-5 |

| | |
|---|---|
| Chemical Name | Sulphur dioxide, sulphurous acid anhydrate |
| Empirical Formula | $SO_2$ |
| Molecular weight | 64.007 |

(2) Sulphur dioxide shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity (as SO2), per cent. by mass, on dry basis, Min | 95 |
| 2. | Non-volatile residue | shall conform to test as per BIS Standard |
| 3. | Moisture, per cent. by mass, Max | 0.05 |
| 4. | Selenium, mg/kg, Max | 20.0 |
| 5. | Arsenic, mg/kg, Max | 3.0 |
| 6. | Lead, mg/kg, Max | 5.0 |

**3.2.10 Acidity regulator:**

**1. Ammonium hydrogen carbonate:**

(1) Ammonium hydrogen carbonate shall be in the form of white crystals or fine white crystalline powder and as described below, namely:-

| | |
|---|---|
| Common Name | Ammonium bicarbonate |
| INS No. | 503(ii) |
| C.A.S No. | 1066-33-7 |
| Chemical Name | Ammonium hydrogen carbonate |
| Empirical Formula | $CH_5NO_3$ |

| | |
|---|---|
| Molecular Weight | 79.06 |

(2) Ammonium hydrogen carbonate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Ammonium Hydrogen Carbonate, per cent. by mass, *Min* | 98.0 |
| 2. | Chlorides (as Cl), per cent. by mass, *Max* | 0.2 |
| 3. | Sulphates (as $SO_4$), per cent. by mass, *Max* | 0.1 |
| 4. | Non-volatile matter, per cent. by mass, *Max* | 0.1 |
| 5. | Iron (as Fe), per cent. by mass, Max | 0.004 |
| 6. | Non-volatile matter, per cent. by mass, *Max* | 0.1 |
| 7. | Arsenic, mg/kg, *Max* | 0.6 |
| 8. | Lead, mg/kg, Max | 2.0 |
| 9. | Copper, mg/kg, *Max* | 5.0 |

**2. Trisodium citrate:**

(1) Trisodium citrate shall be in the form of colourless crystals or white crystalline powder and as described below, namely:-

| | |
|---|---|
| Common Name | Trisodium citrate |
| INS No. | 331 (iii) |
| C.A.S No. | 68-04-2 |
| Chemical Name | Trisodium citrate |

| | |
|---|---|
| Empirical Formula | $C_6H_5Na_3O_7.2H_2O$ |
| Molecular Weight | 294.10 |

(2) Trisodium citrate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity, (as$C_6H_5Na_3O_7$), on dry basis, per cent. by mass, *Min* | 99 |
| 2. | Moisture, per cent. by mass, *Max*<br>a) Anhydrous<br>b) Dehydrate | <br>1<br>13 |
| 3. | Alkalinity | shall pass the test as per BIS standard |
| 4. | Arsenic, mg/kg, *Max* | 3.0 |
| 5. | Lead, mg/kg, Max | 2.0 |

**3. Fumaric acid:**

(1) Fumaric acid shall be in the form of white, odourless granules or crystalline powder with characteristic acid taste and as described below, namely:-

| | |
|---|---|
| Common Name | Fumaric acid |
| INS No. | 297 |
| C.A.S No. | 110-17-8 |
| Chemical Name | trans-butenedioic acid, and trans-1,2 ethylene dicarboxylic acid |
| Empirical Formula | $C_4H_4O_4$ |
| Molecular Weight | 116.07 |

(2) Fumaric acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_4H_4O_4$, per cent. by mass, (on anhydrous basis), Min | 99.5 |
| 2. | Moisture, per cent. by mass, Max | 0.5 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.1 |
| 4. | Maleic acid, per cent. by mass, Max | 0.1 |
| 5. | Arsenic, mg/kg, Max | 3.0 |
| 6. | Lead, mg/kg, Max | 2.0 |

**4. L (+) - Tartaric acid:**

(1) L (+) - Tartaric acid shall be either in the form of colorless or translucent crystals, or a white, fine to granular, crystalline powder and shall be odourless, acidic in taste and stable in air and as described below, namely:-

| | |
|---|---|
| Common Name | L (+) - Tartaric acid |
| INS No. | 334 |
| C.A.S No. | 87-69-4 |
| Chemical Name | Tartaric acid - 2,3-dihydroxy succinic acid |
| Empirical Formula | $C_4H_6O_6$ |
| Molecular Weight | 150.09 |

(2) L(+) – Tartaric acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as ($C_4H_6O_6$), per cent. by mass (on dry basis), Min | 99.5 |

| | | |
|---|---|---|
| 2. | Loss on drying, per cent. by mass, on drying at 105 $^0$C for 3 hours over $P_3O_4$,Max | 0.5 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.1 |
| 4. | Oxalate | shall pass the test as per BIS standard |
| 5. | Sulphate | 0.05 |
| 6. | Arsenic, mg/kg, *Max* | 3.0 |
| 7. | Lead, mg/kg, Max | 2.0 |

**5. Dicalcium phosphate:**

(1) Dicalcium phosphate shall be white crystals or granules or granular powder or powder and as described below, namely:-

| | |
|---|---|
| Common Name | Calcium hydrogen phosphate, dibasic calcium phosphate |
| INS No. | 341 (ii) |
| C.A.S No. | 7757-93-9 |
| Chemical Name | Secondary calcium phosphate, calcium hydrogen orthophosphate, calcium hydrogen phosphate. |
| Empirical Formula | $CaHP0_4$ (Anhydrous)<br>$CaHPO_4.2H_2O$ (Dihydrate) |
| Molecular Weight | 136.06 (Anhydrous)<br>172.09 (Dihydrate) |

(2) Dicalcium phosphate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as (CaHP04), after drying at 200 0C for 3 h, per cent. by mass | 98 to 102 |
| 2. | Loss on drying, per cent. by mass, after drying at 200 $^0$C for 3 h | |

| | | |
|---|---|---|
| | a) Anhydrous, Max | 2 |
| | b) Dihydrate | 18 to 22 |
| 3. | Fluoride, mg/kg, *Max* | 50.0 |
| 4. | Arsenic, mg/kg, *Max* | 3.0 |
| 5. | Lead, mg/kg, Max | 4.0 |

**6. Phosphoric Acid:**

(1) Phosphoric Acid shall be a clear, colourless, odourless viscous liquid and as described below, namely:-

| | |
|---|---|
| Common Name | Phosphoric Acid |
| INS No. | 338 |
| C.A.S No. | 7664-38-20 |
| Chemical Name | Phosphoric acid, orthophosphoric acid |
| Empirical Formula | $H_3PO_4$ |
| Molecular Weight | 98.0 |

(2) Phosphoric acid shall conform to the requirements specified in the table below:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $H_3PO_4$, per cent. by mass, Min | 85 |
| 2. | Nitrates, mg/kg, Max | 5 |
| 3. | Volatile acids, mg/kg, Max | 10 |
| 4. | Chlorides, mg/kg, Max | 200 |
| 5. | Sulphates per cent. by mass, Max | 0.15 |
| 6. | Chloride, mg/kg, Max | 200.0 |
| 7. | Fluoride, mg/kg, *Max* | 10.0 |
| 8. | Arsenic, mg/kg, *Max* | 2.0 |
| 9. | Lead, mg/kg, Max | 4.0 |

**7. Citric Acid:**

(1) Citric Acid shall be white or colourless, odourless, crystalline solid which in monohydrate form effloresces in dry air and as described below, namely:-

| | |
|---|---|
| Common Name | Citric Acid |
| INS No. | 330 |
| C.A.S No. | 77-92-9(anhydrous)<br>5949-29-1 (monohydrate) |
| Chemical Name | 2-hydroxyl-l,2,3-propanetricarboxylic acid; B-hydroxytricarboxylic acid. |
| Empirical Formula | $C_6H_80_7$ (anhydrous)<br>$C_6H_8O_7.H_2O$(monohydrate) |
| Molecular Weight | 192.13 (anhydrous)<br>210.15 (monohydrate) |

(2) Citric acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Water insoluble matter, ppm, Max | 30 |
| 2. | Chloride (as Cl), ppm, Max | 5 |
| 3. | Calcium, ppm, Max | 25 |
| 4. | Tridodecylamine, ppm, Max | 0.1 |
| 5. | Arsenic, mg/kg, Max | 3.0 |
| 6. | Lead, mg/kg, Max | 0.5 |

**8. Malic acid:**

(1) Malic acid shall be a white to nearly white crystalline powder or granules having a strong acid taste and as described below, namely:-

| | |
|---|---|
| Common Name | Malic Acid |
| INS No. | 296 |
| C.A.S No. | 6915-15-7 |
| Chemical Name | DL-malic acid and hydroxyl succinic acid |
| Empirical Formula | $C_4H_6O_5$ |
| Molecular Weight | 134.09 |

(2) Malic acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as $C_4H_6O_5$ (on dry basis), per cent. by mass, Min | 99.0 |
| 2 | Moisture, per cent. by mass, Max | 0.3 |
| 3 | Residue on ignition (on dry basis), per cent. by mass, Max | 0.1 |
| 4 | Water insolube matter, per cent. by mass, Max | 0.1 |
| 5 | Fumaric acid, per cent. by mass, Max | 1.0 |
| 6 | Maleic acid, per cent. by mass, Max | 0.05 |
| 7 | Lead, mg/kg, Max | 2.0 |
| 8 | Arsenic, mg/kg, *Max* | 3.0 |

**9. Sodium Hydroxide:**

(1) Sodium Hydroxide may be in the form of white or nearly white pellets, flakes, sticks, fused masses or in any other form and as described below, namely:-

| | |
|---|---|
| Common Name | Caustic soda, lye, sodium hydrate |
| INS No. | 524 |
| C.A.S No. | 1310-73-2 |
| Chemical Name | Sodium hydroxide |
| Empirical Formula | NaOH |
| Molecular Weight | 40.0 |

(2) Sodium Hydroxide shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as NaOH, per cent. by mass, Min | 95 |
| 2 | Carbonate, per cent. by mass as $Na_2CO_3$, Max | 3 |
| 3 | Lead, mg/kg, Max | 2.0 |
| 4 | Mercury, mg/kg, Max | 1.5 |

**3.2.11 Gelling agent or Thickener or stabilizer:**

**1. Sodium alginate:**

(1) Sodium Alginate shall be white, yellowish or pale brown fibrous or granular powder and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium alginate |
| INS No. | 401 |
| C.A.S No. | 9005-38-3 |
| Chemical Name | Sodium alginate |
| Empirical Formula | $(C_6H_7O_6Na)_n$ |
| Equivalent Weight (average) | 222.00 |

(2) Sodium alginate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI.No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as ($C_6H_7O_6Na$), per cent. by mass | 91 to 106 |
| 2 | Moisture, per cent. by mass, *Max* | 15 |
| 3 | Matter insoluble in water, per cent. by mass, *Max* | 1 |
| 4 | Viscosity of a one per cent. solution (m/m), in centipoise, Min | 30 |
| 5 | Ash (on dry basis), per cent. by mass, Max | 18 to 27 |
| 6 | Acid insoluble ash (on dry basis), per cent. by mass, Max | 0.5 |
| 7 | Lead, mg/kg, *Max* | 5.0 |
| 8 | Arsenic, mg/kg, *Max* | 3.0 |

**2. Sodium Carboxymethyl Cellulose:**

(1) Sodium Carboxymethyl Cellulose shall be a white or slightly yellowish powder consisting of very fine particles, fine granules or fine fibers with hygroscopic nature and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium Carboxymethyl Cellulose |
| INS No. | 466 |
| C.A.S No. | 9004-32-4 |
| Chemical Name | Sodium salt of carboxy methyl ether of cellulose. |
| Empirical Formula | $[C_6H_7O_2(OH)$ x $(OCH_2COONa)y]n$<br>x = 2.00 to 2.80<br>y = 0.20 to 1.00 = degree of substitution or 3.00 - x |

| | |
|---|---|
| | x + y = 3.00<br><br>Structural units with degree of substitution of 0.20 178.14<br><br>Mono substituted structural units: 242.16 |
| Molecular Weight | 178.14 |

(2) Sodium Carboxymethyl Cellulose shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity, as sodium carboxy methyl cellulose per cent. by mass, Min | 99.5<br>(Purity is determined by subtracting from 100, the per cent.age of combined sodium chloride and free glycolate) |
| 2 | Degree of substitution, Max | 0.20 to 1.00 |
| 3 | Loss on drying, per cent. by mass, Max | 10 |
| 4 | Sodium chloride, on dry basis, per cent. by mass, Max | 0.5 |
| 5 | Free glycolate, on dry basis, per cent. by mass, Max | 0.1 |
| 6 | pH of 1 per cent. colloidal solution | 6 to 8.5 |
| 7 | Combined sodium chloride and free glycolate (on dry basis), per cent. by mass, Max | 0.5<br>(Obtained by the simpl addition of value obtained at SI No. (4 & 5). |

| | | |
|---|---|---|
| 8 | Lead, mg/kg, Max | 2.0 |
| 9 | Arsenic, mg/kg, Max | 3.0 |

**3. Sodium Carboxymethyl Cellulose, enzyme hydrolysed:**

(1) Sodium Carboxymethyl Cellulose, Enzyme hydrolysed shall be a white or slightly yellowish or greyish, odourless, slightly hygroscopic granular or fibrous powder and as described below, namely:-

| | |
|---|---|
| Common Name | Enzymatically hydrolyzed sodium carboxy methyl cellulose |
| INS No. | 469 |
| Chemical Name | Carboxymethyl cellulose, sodium, partially enzymatically hydrolyzed |
| Empirical Formula | $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$<br>x = 1.50 to 2.80<br>y = 0.20 to 1.50 = degree of substitution or 3.00 - x<br>x + y = 3.00<br>Structural units with degree of substitution of 0.20 178.14<br>Mono substituted structural units: 242.16 |
| Molecular Weight | 178.14 |

(2) Sodium Carboxymethyl Cellulose, enzyme hydrolysed shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Loss on drying, per cent., Max | 12 |
| 2 | pH | 6 - 8.5 |
| 3 | Sodium chloride and sodium glycolate, per | 0.5 |

| | | |
|---|---|---|
| | cent., Max | |
| 4 | Degree of substitution | 0.2 - 1.5 |
| 5 | Residual enzyme activity | shall pass test as per BIS standard |
| 6 | Lead, mg/kg, Max | 3.0 |

**4. Agar**

(1) Agar shall be a dried hydrophylic, colloidal polygalactoside extracted from *Gelidiella* species and *Gracilaria* species or any other red algae species of the class *Rhodophyceae* and may be in bundles consisting of thin, membranous strips or in cut, flaked, granulated, or powdered form and shall be white to pale yellow in colour and as described below, namely:-

| | |
|---|---|
| Common Name | Agar-agar, gelose, Japanese isinglass |
| INS No. | 406 |
| C.A.S No. | 9002-18-0 |

(2) Agar shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Water absorption | shall pass the test as per BIS standards |
| 2 | Moisture, per cent. by mass, Max | 20 |
| 3 | Total ash, per cent. by mass, Max | 6.5 |
| 4 | Acid insoluble ash, per cent. by mass, Max | 0.5 |
| 5 | Gelatin | shall pass the test as per BIS standards |
| 6 | Insoluble matter, per cent. by mass, Max | 1 |

| | | |
|---|---|---|
| 7 | Starch and dextrins | shall pass the test as per BIS standards |
| 8 | Arsenic, mg/kg, Max | 3.0 |
| 9 | Lead, mg/kg, Max | 5.0 |

**5. Gum Arabic or Acacia Gum:**

(1) Acacia gum,-

(a) shall be a dried gummy exudation obtained from the stems and branches of *Acacia senegal* (L) wild or *Acacia seyal* (L) wild, or other related species of Acacia (Family Leguminosae);

(b) may contain extraneous matter like pieces of bark, but which shall be removed before use in foods;

(c) Acacia gum (*A. senegal*) shall be pale white to orange brown solid, which breaks with a glassy fracture;

(d) the best grades shall be in the form of whole, spheroidal tears of varying sizes with a matt surface texture and when ground, the pieces are paler and have a glassy appearance;

(e) shall also be available in the form of white to yellowish-white flakes, granules, powder, roller dried or spray dried material; and

(f) as described below, namely:-

| | |
|---|---|
| Common Name | Acacia gum |
| INS No. | 414 |
| C.A.S No. | 9000-01-5 |

(2) Gum Arabic shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|

| (1) | (2) | (3) |
|---|---|---|
| 1 | Loss on drying, per cent. by mass, Max<br>a) Granular material<br>b) Spray dried material | <br>15<br>10 |
| 2 | Total ash, per cent. by mass, Max | 4 |
| 3 | Acid insoluble ash, per cent. by mass, Max | 0.5 |
| 4 | Insoluble matter, per cent. by mass, Max | 1 |
| 5 | Starch and dextrins | shall pass the test as per BIS standard |
| 6 | Tannin-bearing gums | shall pass the test as per BIS standard |
| 7 | Salmonella per g, Max | Negative |
| 8 | Escherichia coli per g, Max | Negative |
| 9 | Arsenic, mg/kg, *Max* | 2.0 |
| 10 | Lead, mg/kg, Max | 3.0 |

**6. Tragacanth gum:**

(1) Tragacanth gum,-

(a) in raw form, is dried gummy exudation obtained from *Astragalus strobiliferus* or other species of *Astragalus* (Fam, Leguminosae) which is a white to yellowish-white and nearly odourless powder;

(b) in powdered form shall be in white to yellowish-white colour;

(c) in un-ground form, is flattened or lamellated or frequently curved fragments or straight or spirally tested linear pieces from 0.5 to 2.5 mm in thickness and white to pale yellow in colour, translucent, horny in texture and breaks with short fracture, odourless, insipid mucilaginous in taste and as described below, namely:-

| | |
|---|---|
| Common Name | Tragacanth gum |
| INS No. | 413 |

| | |
|---|---|
| C.A.S No. | 9000-65-1 |

(2) Tragacanth gum shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Loss on drying, per cent. by mass, Max | 10 |
| 2 | Total ash, per cent. by mass, Max | 4 |
| 3 | Acid insoluble ash, per cent. by mass, Max | 0.5 |
| 4 | Starch and dextrins | shall pass the test as per BIS standard |
| 5 | Tannin-bearing gums | shall pass the test as per BIS standard |
| 6 | Viscosity of a 1 per cent. solution, Min | 250 |
| 7 | Karaya gum test, per cent. by mass, Min | shall pass the test as per BIS standard |
| 8 | *Salmonella* per g, Max | Negative |
| 9 | *Escherichia coli* per g, Max | Negative |
| 10 | Lead, mg/kg, *Max* | 2.0 |
| 11 | Arsenic, mg/kg, *Max* | 3.0 |

**7. Gum Ghatti:**

(1) Gum Ghatti is a dried gummy exudation obtained from *Anogeissus latifolia* Wall (family Combretaceae) consisting mainly of a calcium salt (which on occasions occur as a magnesium salt) of high molecular weight polysaccharide which on hydrolysis yields arabinose, galactose, mannose, xylose and glucuronic acid and shall be amorphous translucent rounded tears with a glassy texture, light brown to dark brown in colour with lighter colour giving better

grade of material and powdered material shall have grey to reddish grey colour, and as described below, namely:-

| | |
|---|---|
| Common Name | Indian gum, ghatti gum, gum ghati |
| INS No. | 419 |
| C.A.S No. | 9000-28-6 |

(2) Gum Ghatti shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Loss on drying, per cent. by mass, Max | 14 |
| 2 | Total ash, per cent. by mass, Max | 6 |
| 3 | Acid insoluble ash, per cent. by mass, Max | 0.5 |
| 4 | Insoluble matter, per cent. by mass, Max | 10 |
| 5 | Starch and dextrins | shall pass the test as per BIS standard |
| 6 | Tannin-bearing gums | shall pass the test as per BIS standard |
| 7 | Salmonella per g, Max | Negative |
| 8 | Escherichia coli per g, Max | Negative |
| 9 | Lead, mg/kg, *Max* | 5.0 |
| 10 | Arsenic, mg/kg, *Max* | 3.0 |

**8. Calcium Alginate:**

(1) The calcium salt of alginic acid shall be a white to yellowish fibrous or granular powder and as described below, namely:-

| | |
|---|---|
| Common Name | Calcium Alginate |
| INS No. | 404 |

| | |
|---|---|
| C.A.S No. | 9005-35-0 |
| Chemical Name | Calcium alginate |
| Empirical Formula | $[(C_6H_70_6)_2Ca]$ |
| Equivalent Weight (average) | 219.00 |

(2) Calcium Alginate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as $[(C_6H_70_6)_2Ca]$, per cent. by mass, on dry basis, Min | 90 |
| 2 | Moisture, per cent. by mass, (on drying at 105°C for 4 h), Max | 15 |
| 3 | Insoluble matter, per cent. by mass, Max | 0.2 |
| 4 | Ash, per cent. by mass, Max | 18-27 |
| 5 | Total plate count per g, Max | 5000 |
| 6 | Yeasts and moulds per g, Max | 500 |
| 7 | Arsenic, mg/kg, *Max* | 3.0 |
| 8 | Lead, mg/kg, *Max* | 5.0 |

**9. Alginic acid:**

(1) Alginic acid shall be the hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from various species of brown seaweed (Phaeophyceae),described chemically as a linear glycurono glycan consisting mainly of B (1-4) linked D-mannuronic and L-guluronic acid units in the pyranose ring forms and white to yellowish-white, fibrous powder and as described below, namely:-

| | |
|---|---|
| Common Name | Alginic Acid |
| INS No. | 400 |

| | |
|---|---|
| C.A.S No. | 9005-32-7 |
| Chemical Name | Alginic acid |
| Empirical Formula | $(C_6H_8O_6)_n$ |
| Equivalent Weight (average) | 200.00 |

(2) Alginic acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as $(C_6H_8O_6)_n$, per cent. by mass, Min | 91 |
| 2 | Moisture, per cent. by mass, on drying at 105°C for 4 h, Max | 15 |
| 3 | Insoluble matter, per cent. by mass, Max | 0.2 |
| 4 | Ash (on dry basis), per cent. by mass, Max | 4 |
| 5 | Acid insoluble ash (on dry basis), per cent. by mass, Max | 0.5 |
| 6 | *Escherichia coli* | Absent (in 1 g) |
| 7 | *Salmonella* | Absent (in 10 g) |
| 8 | Arsenic, mg/kg, *Max* | 3.0 |
| 9 | Lead, mg/kg, *Max* | 5.0 |

**10. Guar Gum:**

(1) Guar Gum shall be a white to yellowish white powder with a characteristic guar odour and as described below, namely:-

| | |
|---|---|
| Common Name | Guar Gum |
| INS No. | 412 |

| | |
|---|---|
| C.A.S No. | 9000-30-0 |
| Chemical Name | Galactomannan |

(2) Guar Gum shall conform to the requirements specified in the table below, namely:-

**Table**

**Requirements for Guar Gum**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Purity as galactomannans, per cent. by mass, Min | 77.5 |
| 2 | Acid insoluble matter, per cent. by mass, Max | 3.0 |
| 3 | Total ash, per cent. by mass, Max | 1.5 |
| 4 | Protein (N x 5.7), per cent. by mass, Max | 6.0 |
| 5 | Starch | shall pass the test as per BIS standard |
| 6 | Loss on drying at 105 $^0$C for 5 h, Max | 12.0 |
| 7 | Mould and yeast count per g, Max | 500 |
| 8 | *Escherichia coli*, per g, Max | Absent |
| 9 | *Salmonella* | Absent (in 10 g) |
| 10 | Total plate count per g, Max | 5000 |
| 11 | Arsenic, mg/kg, *Max* | 3.0 |
| 12 | Lead, mg/kg, *Max* | 2.0 |

**11. Gum Karaya:**

(1) Gum Karaya shall be a dried gummy exudation obtained from the stems and branches of *Sterculiaurens Roxb and S. Villosa* Roxb of family Sterculiaceae, white to amber colour in the form of tears of variable size or in broken irregular pieces and as described below, namely:-

| | |
|---|---|
| Common Name | Karaya, Gum Karaya, Sterculia, Gum Sterculia, Kadaya, Katilo, Kullo, Kuterra |
| INS No. | 416 |
| C.A.S No. | 9000-36-6 |

(2) Gum Karaya shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1 | Loss on drying, per cent. by mass, Max | 16 |
| 2 | Starch | Nil |
| 3 | Total ash, per cent. by mass (on dry basis), Max | 8 |
| 4 | Acid insoluble ash, per cent. by mass (on dry basis), Max | 1 |
| 5 | Acid insoluble matter, per cent. by mass (on dry basis), Max | 3 |
| 6 | Chlorides | Nil |
| 7 | Sulphates | Nil |
| 8 | Volatile acid (as acetic acid), per cent. by mass, Min | 10 |
| 9 | Swelling property, ml, Min | 200 |
| 10 | Water absorption, ml, Min | 75 |
| 11 | Freedom from animal filth | shall pass test as per BIS Standard |
| 12 | Salmonella | Negative (on 1 g) |
| 13 | E. coli | Negative (on 1 g) |
| 14 | Arsenic, mg/kg, *Max* | 3.0 |
| 15 | Lead, mg/kg, *Max* | 2.0 |

**12. Polyglycerol esters of fatty acids**

(1) Polyglycerol esters of fatty acids shall be yellowish to amber unctuous liquids, semi-solids or waxy solids and as described below, namely:-

| | |
|---|---|
| Common Name | Polyglycerol esters of fatty acids |
| INS No. | 475 |
| Chemical Name | polyglycerol fatty acid ester and glyceran fatty acid esters |

(2) Polyglycerol esters of fatty acids shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Total fatty acid ester content, per cent. by mass, Min | 90 |
| 2. | Free fatty acids (estimated as oleic acid), per cent. by mass ,Max | 6 |
| 3. | Total glycerol and polyglycerol, per cent. by mass | 18-60 |
| 4. | Free glycerol and polyglycerol, per cent. by mass, Max | 7 |
| 5. | Sulphated ash, per cent. by mass, Max | 0.5 |
| 6. | Lead, mg/kg, *Max* | 2.0 |
| 7. | Copper and zinc, mg/kg, *Max* | 50 |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |

**13. Polyglycerol Esters of Interesterified Ricinoleic Acid:**

(1) Polyglycerol Esters of Interesterified Ricinoleic Acid shall be a highly viscous liquids, yellowish to brown in colour, with a typical fat-related odour and as described below, namely:-

| | |
|---|---|
| Common Name | glyceran ester of condensed castor oil fatty acids and polyglycerol esters of polycondensed fatty acids from castor oil |
| INS No. | 476 |
| Chemical Name | Polyglycerol Esters of Interesterified Ricinoleic Acid |

(2) Polyglycerol Esters of Interesterified Ricinoleic Acid shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Hydroxyl value | 80-100 |
| 2. | Refractive index | 1.4630 to 1.4665 |
| 3. | Acid value, Max (mg KOH per g) | 6 |
| 4. | Iodine value, Wijs | 72-103 |
| 5. | Lead, mg/kg, *Max* | 2.0 |
| 6. | Copper and zinc, mg/kg, *Max* | 50 |
| 7. | Arsenic, mg/kg, *Max* | 3.0 |

**14. Glycerol Esters of Wood Rosin:**

(1) Glycerol Esters of Wood Rosin shall be a hard pale amber coloured resin produced by the esterification of pale wood rosin with food grade glycerin and as described below, namely:-

| | |
|---|---|
| Common Name | Ester Gums |
| INS No. | 445(iii) |

| | |
|---|---|
| C.A.S No. | 8050-30-4 |
| Chemical Name | Glycerol Esters of Wood Rosin |

(2) Glycerol Esters of Wood Rosin shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Acid value (mg KOH/g) | 3- 9 |
| 2. | Drop softening point, $^0$C | 88- 96 |
| 3. | Hydroxyl number | 15- 45 |
| 4. | Lead, mg/kg, *Max* | 1.0 |
| 5. | Arsenic, mg/kg, *Max* | 3.0 |

**15. Pectin:**

(1) Pectin shall be white, yellowish, light greyish or light brownish powder and as described below, namely:-

| | |
|---|---|
| Common Name | Pectin |
| INS No. | 440 |
| C.A.S No. | 9000-69-5 |
| Chemical Name | Pectin |

(2) Pectin shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Loss on drying, per cent. by mass, Max | 12 |
| 2. | Sulphur dioxide, mg/kg, Max | 50 |

| | | |
|---|---|---|
| 3. | Methanol, per cent. by mass, Max | 1 |
| 4. | Ethanol, per cent. by mass, Max | 1 |
| 5. | 2-propanol, per cent. by mass, Max | 1 |
| 6. | Methanol, ethanol and 2-propanol, per cent. by mass, Max | 1 |
| 7. | Acid insoluble ash, per cent. by mass, Max | 1 |
| 8. | Total insolubles, per cent. by mass, Max | 3 |
| 9. | Nitrogen, per cent. by mass, Max | 2.5 |
| 10. | Galacturonic acid, per cent. by mass on ash-free and dried basis, Min | 65 |
| 11. | Degree of amidation, per cent. by mass of total carboxyl groups of pectin, Max | 25 |
| 12. | Lead, mg/kg, *Max* | 2.0 |
| 13. | Copper, mg/kg, *Max* | 300 |
| 14. | Arsenic, mg/kg, *Max* | 5.0 |

**16. Carrageenan :**

(1) Carrageenan shall be yellowish or tan to white, coarse to fine powder that is practically odourless and as described below, namely:-

| | |
|---|---|
| Common Name | Carrageenan |
| INS No. | 407 |
| C.A.S No. | 9000-07-1 |

(2) Carrageenan shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|

| (1) | (2) | (3) |
|---|---|---|
| 1. | Loss on drying, per cent. by mass, on drying at 1O5 $^0$C till constant weight, Max | 12 |
| 2. | pH(1 in 100 suspension) | 8-11 |
| 3. | Viscosity, at 75$^0$ C (1.5% solution), Min | 5 cp |
| 4. | Sulfate, (as $SO_4$) on the dried basis, per cent. | 15 to 40 |
| 5. | Total ash, on the dried basis, per cent. | 15 to 40 |
| 6. | Acid-insoluble ash, per cent., Max | 1 |
| 7. | Acid-insoluble matter, per cent., Max | 2 |
| 8. | Residual solvents, per cent. of ethanol, isopropanol, or methanol, singly or in combination, Max | 0.1 |
| 9. | Total (aerobic) plate count, cfu/g, Max | 5000 |
| 10. | *Salmonella spp.* | Negative (per test) |
| 11. | *Escherichia coli* | Negative (in 1 g) |
| 12. | Cadmium, mg/kg, *Max* | 1.5 |
| 13. | Mercury, mg/kg, *Max* | 1.0 |
| 14. | Arsenic, mg/kg, *Max* | 3.0 |
| 15. | Lead, mg/kg, *Max* | 5.0 |

**3.2.12 Antioxidants:**

**1. Butylated hydroxyanisole**

(1) Butylated hydroxy anisole shall be in the form of white or slightly yellow waxy crystalline solid with an aromatic odour and as described below, namely:-

| | |
|---|---|
| Common Name | BHA |
| INS No. | 320 |
| C.A.S No. | 25013-16-5 |

| | |
|---|---|
| Chemical Name | A mixture of 3- and 2-tertiary butyl-4-hydroxyanisole; a mixture of 3- and 2-tertiary butyl-4-methoxyphenol. |
| Empirical Formula | $C_{11}H_{16}O_2$ |
| Molecular Weight | 180.24 |

(2) Butylated hydroxyanisole shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | a) Purity as $C_{11}H_{16}O_2$, per cent. by mass, Min<br>b) 3 tertiary butyl4-hydroxyanisole, per cent. by mass, Min | 98.5<br>85 |
| 2. | Melting point, $^0C$ | 48 to 63 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.05 |
| 4. | Phenolic impurities, per cent. by mass, Max | 0.5 |
| 5. | Specific absorption E 1 per cent.<br>(1 cm cell) in ethanol at<br>a) 290 nm<br>b) 228 nm | <br><br><br>190 Min 210 Max<br>326 Min 345 Max |
| 6. | Lead, mg/kg, *Max* | 2.0 |
| 7. | Arsenic, mg/kg, *Max* | 3.0 |
| 8. | Iron, mg/kg, *Max* | 5.0 |

**2. Dodecyl gallate:**

(1) Dodecyl gallate shall be a creamy white waxy solid, which may have a slightly bitter taste and as described below, namely:-

| | |
|---|---|
| Common Name | Lauryl gallate |

| | |
|---|---|
| INS No. | 312 |
| C.A.S No. | 1166-52-5 |
| Chemical Name | Dodecyl gallate, n-dodecyl (or lauryl) ester of 3,4,5-trihydroxybenzoic acid |
| Empirical Formula | $C_{19}H_{30}O_5$ |
| Molecular Weight | 338.45 |

(2) Dodecyl gallate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_{19}H_{30}O_5$, per cent. by mass, Min | 98.5 |
| 2. | Moisture, per cent. by mass, Max | 0.5 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.05 |
| 4. | Chlorinated organic compounds (as Cholrine) mass, mg/kg, Max | 100 |
| 5. | Free acid (as gallic acid), per cent. by mass, Max | 0.5 |
| 6. | Specific absorption at 275 nm,<br>Min<br>Max | <br>300<br>325 |
| 7. | Lead, mg/kg, *Max* | 2.0 |
| | Arsenic, mg/kg, *Max* | 3.0 |

**3. Propyl gallate:**

(1) Propyl gallate shall be a white to creamy-white crystalline, odourless solid with a slightly bitter taste and as described below, namely:-

| | |
|---|---|
| Common Name | Propyl gallate |
| INS No. | 310 |
| C.A.S No. | 121-79-9 |

| | |
|---|---|
| Chemical Name | Propyl gallate, and n-propyl ester of 3,4,5-trihydroxybenzoic acid |
| Empirical Formula | $C_{10}H_{12}O_5$ |
| Molecular Weight | 212.21 |

(2) Propyl gallate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_{10}H_{12}O_5$, per cent. by mass, Min | 99 |
| 2. | Moisture, per cent. by mass, Max | 0.5 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.05 |
| 4. | Melting range, $^0C$ | 146-150 |
| 5. | Chlorinated organic compounds (as cholrine), mg/kg, Max | 100 |
| 6. | Free acid (as gallic acid), per cent. by mass, Max | 0.5 |
| 7. | Lead, mg/kg, *Max* | 2.0 |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |

**4. Octyl gallate:**

(1) Octyl gallate shall be a white to creamy-white odourless solid which may have a slightly bitter taste and as described below, namely:-

| | |
|---|---|
| Common Name | Octylgallate |
| INS No. | 311 |
| C.A.S No. | 1034-01-01 |
| Chemical Name | Octyl gallate and n-octyl ester of |

| | |
|---|---|
| | 3, 4, 5-trihydroxybenzoic acid |
| Empirical Formula | $C_{15}H_{22}O_5$ |
| Molecular Weight | 282.34 |

(2) Octyl gallate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_{15}H_{22}O_5$, per cent. by mass, Min | 98.5 |
| 2. | Moisture, per cent. by mass, Max | 0.5 |
| 3. | Sulphated ash, per cent. by mass, Max | 0.05 |
| 4. | Melting range, $^0$C | 99-102 |
| 5. | Chlorinated organic compounds (as cholrine), mg/kg, Max | 100 |
| 6. | Free acid (as gallic acid), per cent. by mass, Max | 0.5 |
| 7. | Lead, mg/kg, *Max* | 2.0 |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |

**5. Ascorbyl palmitate**

(1) Ascorbyl palmitate shall be a white or yellowish white solid, with a citrus like odour and as described below, namely:-

| | |
|---|---|
| Common Name | Vitamin C palmitate |
| INS No. | 304 |
| Chemical Name | L-ascorbylpalmitate, 8-palmitoyl-3-keto-L-gulofuranolactone, 2, 3-dehydro-L threo-hexono- |

| | |
|---|---|
| | 1, 4-lactone-6-palmitate. |
| Empirical Formula | $C_{22}H_{38}O_7$ |
| Molecular Weight | 414.55 |

(2) Ascorbyl palmitate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirement |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_{22}H_{38}O_7$, per cent. by mass (on dry basis), Min | 95 |
| 2. | Sulphated ash, per cent. by mass (on dry basis), Max | 0.1 |
| 3. | Loss on drying, per cent. by mass, after drying in a vacuum oven at 56-60 $^0$C for one hour, Max | 2 |
| 4. | Lead, mg/kg, *Max* | 2.0 |
| 5. | Arsenic, mg/kg, *Max* | 3.0 |

**6. Sodium ascorbate:**

(1) Sodium Ascorbate shall be a white to yellowish crystalline solid and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium ascorbate |
| INS No. | 301 |
| C.A.S No. | 134-03-2 |
| Chemical Name | Vitamin C sodium and sodium L-ascorbate. |
| Empirical Formula | $C_6H_7Na0_6$ |

| | |
|---|---|
| Molecular Weight | 198.11 |

(2) Sodium ascorbate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Assay as $C_6H_7Na0_6$ ( on dry basis), per cent. by mass | 99 to 101 |
| 2. | Loss on drying, per cent. by mass, Max, after drying in vacuum over phosphorus pentoxide at $60^0$C for 4 hours | 0.25 |
| 3. | Lead, mg/kg, *Max* | 2.0 |
| 4. | Arsenic, mg/kg, *Max* | 3.0 |

**3.2.13 Flavour enhancers:**

**1. Monosodium L-glutamate:**

(1) Monosodium L-glutamate shall be in the form of white, practically odourless crystals or crystalline powder which may have either a slightly sweet or a slightly salty taste and as described below, namely:-

| | |
|---|---|
| Common Name | Sodium glutamate, MSG |
| INS No. | 621 |
| C.A.S No. | 142-47-2 |
| Chemical Name | monosodium L-glutamate monohydrate, sodium glutamate, MSG |
| Empirical Formula | $C_5H_80_4NNaH_20$ |
| Molecular Weight | 187.13 |

(2) Monosodium L-glutamate shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as ($C_5H_80_4NNaH_20$), per cent. by mass, Min | 99 |
| 2. | Loss on drying, per cent. by mass, at 98 $^0$C for 5h, Max | 0.5 |
| 3. | Chloride, per cent. by mass, Max | 0.2 |
| 4. | Lead, mg/kg, *Max* | 1.0 |
| 5. | Arsenic, mg/kg, *Max* | 2.0 |

**3.2.14 Glazing Agent:**

**1. Mineral Oil (low viscosity):**

(1) Mineral oil, food grade is a mixture of liquid hydrocarbons, essentially parafinic and napthenic in nature, obtained from petroleum, refined by the use of oleum, excluding the mineral oils produced by the hydrogenation process unless they have been subsequently refined by the use of oleum and also excluding other types of white mineral oils to which antioxidants may have been added for technological purposes which shall be colourless, transparent oily liquid, free from fluorescence, odourless, tasteless, and as described below, namely:-

| | |
|---|---|
| Common Name | Liquid paraffin, liquid petrolatum, food grade mineral oil, white mineral oil |
| INS No. | 905e |
| C.A.S No. | 8012-95-1 |

(2) Mineral Oil (low viscosity) shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Acidity or alkalinity | shall pass the test as per BIS standard |
| 2. | Readily carbonizable substances | shall pass the test as per BIS standard |
| 3. | Polynuclear aromatic hydrocarbons, absorbance<br>at wave lengths between 260-350 nm, Max | 0.10 |
| 4. | Solid paraffins | shall pass the test as per BIS standard |
| 5. | Sulphurs ( as $SO_4$) | shall pass the test as per BIS standard |
| 6. | Lead, mg/kg, *Max* | 1.0 |
| 7. | Arsenic, mg/kg, *Max* | 1.0 |

**2. Mineral Oil (High viscosity):**

(1) A mixture of highly refined paraffinic and naphthenic liquid hydrocarbons with boiling point above $350^0$, obtained from mineral crude oils through various refining steps including distillation, extraction and crystallization and subsequent purification by acid or catalytic hydro treatment which may contain antioxidants approved for food use shall be colourless, transparent oily liquid, free from fluorescence, odourless, tasteless and as described below, namely:-

| | |
|---|---|
| Common Name | Liquid paraffin, liquid petrolatum, food grade mineral oil, white mineral oil |
| INS No. | 905d |

| | |
|---|---|
| C.A.S No. | 8012-95-1 |

(2) Oil (High viscosity) shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Acidity or alkalinity | shall pass the test as per BIS standard |
| 2. | Readily carbonizable substances | shall pass the test as per BIS standard |
| 3. | Polynuclear aromatic hydrocarbons, absorbance at wave lengths between 260-350 nm, Max | 0.10* (test shall be as per BIS standard) |
| 4. | Solid paraffins | shall pass the test as per BIS standard |
| 5. | Sulphurs ( as $SO_4$) | shall pass the test as per BIS standard |
| 6. | Lead, mg/kg, *Max* | 1.0 |
| 7. | Arsenic, mg/kg, *Max* | 1.0 |

### 3.2.15 Humectant or Wetting Agent or Dispersing Agent:

### 1.Propylene glycol:

(1) Propylene Glycol shall be a clear, colourless, practically odourless, viscous liquid having a slight characteristic taste and as described below, namely:-

| | |
|---|---|
| Common Name | Propylene glycol |
| INS No. | 1520 |
| C.A.S No. | 57-55-6 |
| Chemical Name | 1, 2-propanediol, 1, 2 dihydroxypropane and methyl glycol |
| Empirical Formula | $C_6H_80_2$ |

| | |
|---|---|
| Molecular Weight | 76.1 |

(2) Propylene glycol shall conform to the requirements specified in the table below, namely:-

**Table**

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity as $C_6H_80_2$, per cent. by mass, Min | 99.5 |
| 2. | Moisture, per cent. by mass, Max | 0.2 |
| 3. | Acidity | shall pass test as per BIS standard |
| 4. | Sulphated ash (on dry basis), per cent. by mass, Max | 0.007 |
| 5. | Presence of other polyhydroxy compounds | Absent |
| 6. | Ethylene glycol | Absent |
| 7. | Lead, mg/kg, *Max* | 2.0 |
| 8. | Arsenic, mg/kg, *Max* | 3.0 |

### 3.2.16 Sweetner or Humectant or Sequestrant:

### 1. Sorbitol:

(1) Sorbitol shall be white hygroscopic powder having a sweet taste and as described below, namely:-

| | |
|---|---|
| Common Name | Sorbitol |
| INS No. | 420 |
| C.A.S No. | 50-70-4 |
| Chemical Name | d-sorbitol, d-glucitol, d-sorbite, d-sorbol, and 1,2,3,4,5,6-hevanehexal |
| Empirical Formula | $C_6H_{14}O_6$ |
| Molecular Weight | 182.17 |

(2) Sorbitol shall conform to the requirements specified in the table below, namely:-

| SI. No. | Characteristic | Requirements |
|---|---|---|
| (1) | (2) | (3) |
| 1. | Purity, as d sorbitol $C_6H_{14}O_6$, per cent. by mass. Mi*n* | 91 or 99 (Depending on the method of test used for analysis.) |
| 2. | Moisture per cent. by mass, *Max* | 1 |
| 3. | Melting range<br>a) Metastable<br>b) Stable | <br>92.5 $^0$C to 93.5 $^0$C<br>96 $^0$C to 97.5 $^0$C |
| 4. | Reducing sugars, per cent. by mass, *Max* | 0.2 |
| 5. | Sulphated ash, per cent. by mass, Max | 0.1 |
| 6. | Sulphates (as $SO_4$) per cent. by mass, Max | 0.01 |
| 7. | Chlorides (as Cl) per cent. by mass *Max* | 0.005 |
| 8. | Arsenic , mg/kg, *Max* | 3.0 |
| 9. | Lead , mg/kg, *Max* | 1.0 |
| 10. | Nickel, mg/kg, *Max* | 2.0] |

**[18][3.3 Other substances for use in food products**

**3.3.1 Flavouring agents and related substances**

1) Flavouring agents include flavour substances, flavour extracts or flavour preparations, which are capable ofimparting flavouring properties, namely taste or odour or both to food. The following type of Flavouring agents may be added to food as per Good Manufacturing Practices: -

(i) Natural flavours and natural favouring substances means flavour preparations and single substancerespectively, acceptable for human

consumption, obtained exclusively by physical processes from vegetables, for human consumption

(ii) Nature-identical flavouring substances means substances chemically isolated from aromatic rawmaterials or obtained synthetically; they are chemically identical to substances present in natural productsintended for human consumption, either processed or not.

(iii) Artificial flavouring substances means those substances which have not been identified in naturalproducts intended for human consumption either processed or not;

2) Use of antioxidants, emulsifying and stabilising agents and food preservatives in flavour -The flavouring agents may contain permitted antioxidants, emulsifying and stabilising agents and foodpreservatives.

3) Use of anticaking agent in flavours - Synthetic amorphous silicon dioxide (INS 551) may be used in powder flavouringsubstances to a maximum level of 2 percent.

4) Restriction on use of flavouring agents:-The use of the following flavouring agents is prohibited in any article of food, namely,-

(i) Coumarin and dihydrocoumarin;

(ii) Tonkabean (Dipteryl adorat);

(iii) β-asarone and cinamyl anthracilate

(iv) Estragole

(v) Ethyl methyl ketone

(vi) Ethyl-3-phenylglycidate

(vii) Eugenyl methyl ether

(viii) Methyl β napthyl ketone

(ix) p-Propylanisole

(x) Saffrole and isosaffrole

(xi) Thujone and isothujone (α & β thujone)

[69][(xii) 4,5 epoxydec-2(trans)-enal]

5) Solvent in flavour

Diethyleneglycol and monoethyl ether shall not be used as solvent in flavours.

**3.3.2 Lactulose syrup**

1) Lactulose syrup may be used in special milk based infant food formulations, which is to be taken under medical advice up to a maximum level of 0.5 per cent of final food subject to label declaration.

2) Lactulose syrup may be used in bakery products up to 0.5 per cent maximum by weight.

**3.3.3 Oligofructose**

Oligofructose may be added at not more than 10 per cent of the product, in the following products, subject to label declaration under sub-regulation 43 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, -

Dairy products like yoghurt, mousse, spreads, dairy based drinks (milkshakes, yoghurt drink), cheese, pudding, cream and ice-cream, frozen desserts like nondairy ice, sorbet and fruit ice, frozen yoghurt, flakes and ready-to-eat dry breakfast cereals, chocolate and sweets and carbohydrate based and milk product based sweets like halwa, mysore pak, boondi laddu, jalebi, khoyaburfi, peda, gulabjamun, rasgulla and similar milk product based sweets sold by any name; cooked sausages, ham and meat spreads.

[73]**[3.3.4 Trehalose. - (**1) Trehalose shall be in the form of white or almost white crystals; soluble in water, slightly soluble in ethanol.
(2) Trehalose shall be added at the level of good manufacturing practices (GMP) in all food categories except infant food provided that the standard specifications of such food products as prescribed under Food Safety and standards Regulations, 2011 are not altered with.
(3) It shall conform to the following requirements, namely: -

**TABLE**

| S. No. | Parameters | Limits |
|---|---|---|
| 1 | Loss on drying (%) | Not more than 1.5 |
| 2 | Total ash (%) | Not more than 0.05 |

(4) Trehalose may be added as an ingredient subject to label declaration under the provisions 1.8 of schedule-II of the Food Safety and Standards (Labelling and Display) Regulations, 2020, without health claims.
(5) Methods of analysis for trehalose shall be as specified in Joint FAO/WHO Expert Committee on Food Additives (JECFA) (2000).]

### 3.3.5 Phyto or Plant Stanol

[66][Phyto or Plant stanol esters may be added to the following products so as to allow users to easily restrict their consumption to maximum 3 g stanol per day through the use of either one portion containing maximum 3 g or three portions each containing 1 g and it shall be added subject to the table declaration under sub-regulation 48 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, namely:-]

(i) Fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drink, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars.

(ii) Products containing Phyto or Plant Stanols be sold in single portions containing either maximum 3 g or ‘maximum 1 g of Phyto or Plant Stanols, calculated as free Phyto or Plant Stanols, and if they do not contain so, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of Phyto or Plant Stanols, calculated as free Phyto or Plant Stanols, contained in such a portion;

### 3.3.6 Phyto or Plant Sterol

**(a)** The Phyto or Plant sterols from Non-Genetically Modified source may be used in the following categories of food products with their use at the level not exceeding 3 g/day;-

Fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drinks, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars, edible oils, and bakery products

Products containing Phyto or Plant Sterols be sold in single portions containing either maximum 3 g or maximum 1g of Phyto/ Plant Sterols, calculated as free

Phyto or Plant Sterols. And if they do not contain so, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of Phyto or Plant Sterol, calculated as free Phyto or Plant Sterol, contained in such a portion. In all events, the composition and labelling of the products should be such as to allow users to easily restrict their consumption to maximum 3g/day of Phytosterols through the use of either one portion of 3g or three portions containing minimum 1g.

**(b)** The products referred to in sub-clause (a) shall not exceed the Acceptable Daily Intake (ADI) for Phytosterols and shall contain the label declarations as provided in the clause 55 of sub-regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011**.]**

**[71][3.4 PROCESSING AIDS**

**3.4.1: DEFINITIONS AND CONDITIONS OF USE**

**(1) Processing aids included in these regulations**

The processing aids listed herein are recognised as suitable for use in foods in conformance with the provisions of these regulations and have been assigned an Acceptable Daily Intake (ADI) or determined (wherever applicable), on the basis of other criteria, to be safe and the use of processing aids in conformance with these regulations has to be technologically justified.

(**2) Product category**

The foods or food processing procedures, in which the processing aid is utilised, are defined by these regulations.

**(3) Food in which processing aids may be used**

The conditions, under which processing aids may be used in foods, are defined by these regulations.

**(4) Foods in which processing aids shall not be used**

Unless expressly permitted in these regulations, processing aids shall not be used in food processing.

**(5) "Processing aid"** means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

**(6) "Acceptable Daily Intake (ADI)"** means the amount of a processing aid in food expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk and a processing aid, meeting this criterion shall be used within the bounds of Good Manufacturing Practice (GMP) as specified in clause (11) of this sub-regulation.

**(7) Maximum permitted Level** of a processing aid, is the highest concentration of the processing aid, determined to be functionally effective in a food or food category and agreed to be safe and it is generally expressed as mg/kg of food.

**(8) "Residual level"** means the level of processing aid remaining in food after processing. The levels should be designated with respect to those directly measured by analysis or estimated by other means. Values are in mg/kg and values at the detection limit of available analytical procedures are reported as "Not more than".

**(9) "EC number"** (Enzyme Commission number) means the number which the Enzyme Commission uses to classify the principal enzyme activity.

**(10) Justification for the use of processing aids**

The use of a substance as a processing aid is justified when such use performs one or more technological functions during treatment or processing of raw materials, foods, or ingredients. Any residues of processing aids remaining in the food after processing should not perform a technological function in the final product.

**(11) Good Manufacturing Practice (GMP)**

All the processing aids subject to the provisions of these regulations shall be used under conditions of good manufacturing practices (GMP) which includes the following, namely: -

(a) the quantity of the substance used shall be limited to the lowest achievable level necessary to accomplish its desired technological function;

(b) residues or derivatives of the substance remaining in food should be reduced to the extent reasonably achievable and should not pose any health risk; and

(c) The substance is prepared and handled in the same way as a food ingredient.

**(12) Specifications for the identity and purity of processing aids**

(a) Substances used as processing aids should be of food grade quality. This can be demonstrated by conforming to the applicable specifications of identity and purity recommended under these regulations, and in case such standards are not specified, the purity criteria accepted by international bodies such as Codex Alimentarius may be adhered to.

(b) The safety of a substance used as a processing aid shall be demonstrated by the supplier or the user of the substance. The demonstration of safety shall include appropriate assessment of any unintended or unavoidable

residues resulting from its use as a processing aid under conditions of GMP.

**(13) Conditions for labelling**

The product covered by this Standard shall be labelled in accordance with the Food Safety and Standards (Packaging & Labelling) Regulation, 2011. Declaration of vegetarian or non-vegetarian irrespective of the residue level, has to be mentioned on the label.]