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 and an 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 postmanufacture 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 Yellow

(M/V) solution in distilled

water.

Colour Index Number (1975) No 19140 Class Monoazo.

Chemical Name Trisodium salt of 5-hydroxy-1-p-

sulphophenyl-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

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	87
	105±1°C for 2 hours, per cent by mass, Min.	
2.	Loss on drying at 135°C and Chlorides and Sulphates e	expressed 13
	as sodium salt, percent 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

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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 Synonyms	Sunset Yellow 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	87
	2 hours, per cent by mass, Min.	
2	Loss on drying at 135°C, percent by mass and Chlorides and Sulphates expressed as sodium salt, percent by mass,	13

	Max	
3.	Water insoluble matter, percent by mass, Max.	0.2
4.	Combined ether extracts, percent by mass.	0.2
	Max.	
5.	Subsidiary dyes, (lower sulphonated dyes including traces of	3.0
	orange II) percent by mass, Max.	
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
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FD and C red No.3, C.1. Food Red 14, LB-

Synonyms Rot-I Colour of the 0.1 Percent (M/V) Red

solution in distilled water

Colour Index Number (1975) No 45430 Class Xanthene

Chemical Name Disodium or dipotassium salt of 2',4', 5',

7', tetraiodo- fluerescein

Empirical formula $C_{20} H_6 O_5 I_4 Na_2$

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	87
	105°±1°C for 2 hours, per cent by mass, Min.	
2.	Loss on drying at 135°C percent by mass and Chlorides	13

	and Sulphates expressed as sodium salt percent by mass, Max.	
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	0.2
	(a) Tri-iodoresorcinol, percent by mass, Max.	0.2
	(b) 2.(2,4-dihydroxy-3,5-di-iodobenzoyl) benzoic acid, percent by mass, Max.	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
	maigo carinnic

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) Blue

solution in distilled water

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

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.	Characteristic	Requirement
No.		
1.	Total dye content, corrected for Sample dried at 105±1oC	85
	for 2 hours, per cent by mass, Min.	
2.	Loss on drying at 135oC, percent by mass and Chlorides	15
	and Sulphates expressed as sodium salt, 15 percent 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.	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 Empirical formula	all trans $\beta\text{-Carotene}$ C_{40} H_{56}	
Molecular Weight	536.89	
Melting Point	$183^{\circ}\text{C} \pm 1^{\circ}\text{C}$	

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 m μ to 484 m μ region. There shall be no cis-peak in the 330 m μ to 355 m μ 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 m μ .

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.

Synonym	ıs		C.I. Natural Green 3; Lebensmittel Green
			No.1
Colour	Index	Number	No.75810
(1956)			
Colour	Index	Number	No. 12499
(1924)			
Color			Green
Class			Phorbin (dihydrophorphin)
Chemica	l Name		Chlorophyll a - magnesium complex of
			1,3,5,8-tetramethyl 4-ethyl-2-vinyl-9-keto-10

carbomethoxy

phorbinphytyl-7-propionate.

Chlorophyll b magnesium complex 1,5,8 trimethyl-3-formyl-4-ethyl-2-vinyl-9-keto-10 carbomethoxyphorbinphytyl-7-propionate

Empirical formula Chlorophyll a - C₅₅H₇₂O₅N₄Mg

Chlorophyll b- C₅₅H₇₀O₆N₄Mg

Molecular Weight Chlorophyll a- 893.54

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

		Requiremen
Sl. No.	Characteristic	t
	Total combined phaeophytines and their magnesium	
1	complexes, percent by weight, max.	10
	Residual solvents, mg/kg, Max. Acetone, methanol, ethanol,	
2	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. Characteristic N	Type I	Type II	Type III AmmoniaPro	Type IV
0.	Plain	hite	cess	Sulphite Ammonia
1. Solid content, per cent by mass	62-77 0.01-	65-72	53-83	40-75
2. Colour intensity, Ammonical nitrogen per cent	0.12	0.06-0.10	0.08-0.36	0.10-0.60
3. by mass, max.	0.01	0.01	0.4	0.5
4. 4-Methylimidazole	-	-	Max.300 mg/kg & Max.200 mg/kg on equivalent	Max.1000 mg/kg & Max.250 mg/kg on equivalent colour
			colour basis	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

TABLE 2 - TYPE TEST REQUIREMENTS FOR CARAMEL

Sl. Characteristic	Type I	Type II	Type III	Type IV
N	Plain	Caustic	Ammonia	Sulphite
0.		Sulphite	Process	Ammonia
1. Total sulphur Percent by	Max 0.3	1.3-2.5	Max.0.3	1.4-10.0
mass. 2. Sulphur dioxide (as SO2)		Max. 0.2%		Max.0.5%
3. Total nitrogen, Percent by mass	Max.0.	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
	11 1 1		. 111 1 1.1	

All requirements shall be on solid basis except metallic impurities.

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',
	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

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 ₂ O)	2.02 g
Sulphuric acid, Sp-gr 1.84	2ml
Distilled water one litre	to make solution to

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.	Characteristic	Requirement
No.		
1.	Carotenoid	
	(a) Annatto extract in oil, expressed as bixin, percent by mass, Min.	y 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°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 C1 Food Red 7, L-Rot No.4, Coccine Nouvelle,

Cochineal Red A; EEC Serial No.E 124

Colour of the 0.1 Percent Red

(m/v) solution in distilled

water

Colour Index Number No. 16255

(1975)

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

Soluble in water. Sparingly soluble in Ethanol

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

TABLE

Requirements for Ponceau 4R

S1.	Characteristic	Requirement
No.		
1.	Total dye content, corrected for Sample dried at 105±1°C	85
	for 2 hours, per cent by mass, Min.	
2	Loss on drying at 135°C, percent by mass, Max. and	18
	Chlorides and Sulphates	
	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	Red
(m/v) solution in distilled	
water	
Colour Index Number	No.14720
(1956)	
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 19 | Version 1 (01.09.2023)

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
2.	for 2 hours, per cent by mass, Min. Loss on drying at 135°C, 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),	1.0
Max.	
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 \pm 15 percent of the declared value. Colour preparation and colour mixture shall also comply with the following requirements namely: -

Sl. I	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.1. 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)-

phenyl] alpha [4-(N-ethyl-3

Sulfonatobenzylimino]

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
	Total dye content, corrected for Sample dried at 105±1oC for	85
(i)	2 hours, percent by Mass, Minimum	
	Loss on drying at 135°C, and Chlorides and Sulphates	15
(ii)	expressed as sodium salt, per cent by Mass, Maximum	
(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.1. 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 C₃₇ H₃₄ O₁₀ N₂ S₂ Na₂

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	Requireme
		nt
(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 not less than 17 percent weight by weight
- (3) Substratum of Aluminium oxide not more than 83

percent. (4) Aluminium content in the lake weight not more than 44 percent by weight (5) Sodium chlorides and sulphates (as 2.0 than not more sodium salts) percent Inorganic matter (HCl insoluble) 0.5 not more than 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.
		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	not less than 50 percent
	(Al ₂ O ₃)	

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.	Characteristic	Requirements
No.		
(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°C	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, <i>Min</i>	96
2.	Sulphated ash, per cent. by mass, Max	0.1
3.	Melting range, ⁰ C	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 °C for 3 hours, per cent. by mass, Max	0.5
3.	Loss on ignition (at 800 °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 –

⁸²[(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)
рН	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
	Yeasts and moulds: Not more than 200 CFU/g
	E. coli: Negative per g
	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	+ Gluco	se (SvGn)					
Steviolmonoside	SvG1	н	Glcβ1-	13-[(β-D- glucopyranosyl)oxy]kaur-16-en- 18-oic acid	60129- 60-4	C26H40O8	481
Steviolmonoside A	SvG1	Glcβ1-	н	13-[(hydroxy]kaur-16-en-18-oic acid, β-D-glucopyranosy] ester	64977- 89-5	C26H40O8	481
Rubusoside	SvG2	Glcβ1-	Glcβ1-	13-[(β-D- glucopyranosyl)oxy]kaur-16-en- 18-oic acid, β-D-glucopyranosyl ester	64849- 39-4	C32H50O13	643
Steviolbioside	SvG2	Н	Glcβ(1- 2)Glcβ1-	13-[(2-O-β-D-glucopyranosyl-β-D- glucopyranosyl)oxy]kaur-16-en- 18-oic acid	41093- 60-1	C32H50O13	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	C38H80O18	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	C38He0O18	805
Stevioside B	SvG3	Glcβ(1- 3)Glcβ1-	Glcβ1-	13-[(2-O-β-D-glucopyranosyl)oxy]kaur-16-en- 18-oic acid, Ο-β-D-glucopyranosyl-deoxy-(1,3)-O-[β-D-glucopyranosyl ester). -	C38He0O18	805
Rebaudioside B	SvG3	Н	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	C38H60O18	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	C38He0O18	805
Rebaudioside E	SvG4	Glcβ(1- 2)Glcβ1-	<u>Glc</u> β(1- 2)Glcβ1-	13-[(O-β- D-gluc opyranosyl-(1,2)- O-[β-D-gluc opyranosyl)-oxy]- kaur-16-en-18-oic acid (4')-O-β-D- gluc opyranosyl-deoxy-(1,2)-O-[β- D-gluc opyranosyl ester	63279- 14-1	C44H70O23	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	C44H70O23	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	C44H70O23	967
Rebaudioside <i>D</i>	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	C50H80O28	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	C50H80O28	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	¥	C50H80O28	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	le.	C50H80O28	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-gster	-	C50H80O28	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	-	C50H80O28	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	*	C50H80O28	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	ā	C50H80O28	1129

Rebaudioside <i>M</i>	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	C56H60O33	1291
Related SvGn#1		-	(7)	-	(-	C21H30O11	458
Related SvGn#2		-	-	-	14	C40H70O24	982
Related SvGn#3		7.2	(2)	-	T-E	C32H52O15	676
Related SvGn#4		8	-	-	151	C50H80O28	1129
Related SvGn#5		-	(-)	.=	:#:	C40H70O24	982
Group 2: Stevi	ol + Rhami	nose + Gluc	ose (SvR1G	n)			
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	C38H60O17	789
Dulcoside C	SvR1G2	Н	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		C38He0O17	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	C44H70O22	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	-	C44H70O22	951
Rebaudioside N	SvR1G5	<u>Rha</u> α(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-β- D-glucopyranosyl ester	1220616- 46-5	CseHeoO32	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) ester]	1220616- 48-7	Ce2H100O37	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	*	Ce2H100O37	1436

Rebaudioside K	SvR1G4	<u>Glc</u> β(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	C50H80O27	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	C44H70O22	951
Rebaudioside K2	SvR1G4	<u>Glc</u> β(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	-	C50H80O27	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	C50H80O27	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)oxy]-kaur-16-en-18-oic acid, 2-O-6- deoxy-L-rhmnopyranosyl-β-D-glucopyranosyl ester	1313049- 59-0	C50H80O27	1112
Group 3: Stevio	ol + 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		C37H59O17	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	C43H68O22	937
Rebaudioside F2	SvX1G3	Glcβ1-	Glcβ (1- 2)[<u>Xylβ</u> (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	##X	C43H68O22	937
Rebaudioside F3	SvX1G3	Χ <u>у</u> ιβ(1-6) <u>Glc</u> β1-	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		C43H68O22	937
Rebaudioside R	SvX1G3	Glcβ1-	Glcβ(1- 2)[Glcβ1- 3] <u>Xyl</u> β1	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	C43H68O22	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	1811	C50H82O26	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		CsoHs2O26	1099
Rebaudioside V2	SvX1G5	Χ <u>у</u> Ιβ (1- 2)[<u>Glc</u> β(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-zylopyranosyl-3- O-β-D-glucopyranosyl-β-D- glucopyranosyl ester	(#)	C56H62O31	1261

Common Name	Trivial Name	R ₁	R ₂	Chemical Name	CAS Number	Chemical Formula	Formula Weight
Group 5: Stev	iol + Galac	tose + Gli	ucose (SvGa	i1Gn)		51 6	
Rebaudioside T1	SvGa1G4		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: Stevi	ol + Fructo	se + Gluc	ose (SvFruG	in)	57 U		20
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	5 4	C44H70O22	951
Group 7: Stevi	ol + -de-oxy	glucose	+ Glucose (SvdG1Gn)	<u> </u>		
Stevioside D	SvDg1G2	Glcβ1-	6-deoxy Glcβ(1- 2)Glcβ1-	13-[(2-O-β-D-6- deoxygluc opyranosyl-β-D- gluc opyranosy)oxy]kaur-16-en- 18-oic acid, β-D-gluc opyranosyl ester	*	C38He0O17	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-glucopyranosylester	-	C44H70O22	951
Stevioside E2	SvDg1G3	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	(2 2)	C44H70O22	951

Steviol (R1 = R2 = H) is the aglycone of the steviol glycosides.

Glc, Rha, Fru, deoxyGlc, Gal, Ara and Xyl represent, respectively, glucose_thamnose, 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

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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°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°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:

^{*}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°C	$+20.5^{\circ}$ to $+21.5^{\circ}$
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 $25 \pm 2^{\circ}$ 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
рН	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	$C_7H_5O_2Na$
Molecular Weight	144.11

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

SI.	Characteristic	Requirements
No.		

(1)	(2)	(3)
1.	Purity, expressed as C ₇ H ₅ O ₂ Na, 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,
	and phenyl carboxylic acid
Empirical Formula	$C_7H_6O_2$
Molecular Weight	122.12

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

SI.No.	Characteristic	Requirements
(1)	(2)	(3)
1.	Purity, as C ₇ H ₆ O 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, <i>Max</i>	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:-

SI.No.	Characteristic	Requirements
(1)	(2)	(3)
1.	Purity, as KNO ₃ , per cent. by mass, Min	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 ₂ SO ₄), per cent. by mass,	0.10
	Max	
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:-

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

1	Purity, as C ₆ H ₈ O ₂ , per cent. by mass(on dry	99
	basis), Min	
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.	97
	by mass, Min	
2.	Loss on drying when dried over silica gel	1
	for four	
	hours, per cent. by mass, Max	
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 ₃ H5O ₂ Na
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 ₃ H ₅ O ₂ Na, per cent. by mass, on	99
	dry basis, Min	
2.	Moisture, per cent. by mass, <i>Max</i>	1
3.	Matter insoluble in water, per cent. by	0.1
	mass, Max	
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.	Characteristic	Requirements
No.		
(1)	(2)	(3)
1.	Purity (as SO2), per cent. by mass, on dry	95
	basis, Min	
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 ₅ NO 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, <i>Min</i>	98.0
2.	Chlorides (as Cl), per cent. by mass, Max	0.2
3.	Sulphates (as SO ₄), per cent. by mass, <i>Max</i>	0.1
4.	Non-volatile matter, per cent. by mass, <i>Max</i>	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, (asC ₆ H ₅ Na ₃ O ₇), on dry basis, per cent.	99
	by mass, Min	
2.	Moisture, per cent. by mass, Max	
	a) Anhydrous	1
	b) Dehydrate	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 ₄ H ₄ O 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 ₄ H ₄ O 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 ₄ H ₆ O 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 $P_{3}O_{4}$,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	CaHPO ₄ (Anhydrous)		
Formula	CaHPO ₄ . 2H ₂ O (Dihydrate)		
Molecular	136.06 (Anhydrous)		
Weight	172.09 (Dihydrate)		

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

SI.	Characteristic	Requirements	
No.			
(1)	(2)	(3)	
1.	Purity as (CaHP04), after drying at 200	98 to 102	
	0C for 3 h, per cent. by mass		
2.	Loss on drying, per cent. by mass, after		
	drying at 200 °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 ₃ PO ₄
Molecular Weight	98.0

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

SI.	Characteristic	Requirements
No.		
(1)	(2)	(3)
1.	Purity as H ₃ PO 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)	
	5949-29-1 (monohydrate)	
Chemical Name	2-hydroxyl-1,2,3- propanetricarboxylic acid; B- hydroxytricarboxylic acid.	
Empirical Formula	C ₆ H ₈ O ₇ (anhydrous) C ₆ H ₈ O ₇ .H ₂ O(monohydrate)	
Molecular Weight	192.13 (anhydrous) 210.15 (monohydrate)	

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

SI.	Characteristic	Requirement
No.		
(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 ₄ H ₆ O 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 ₂ CO 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 ₆ H ₇ O ₆ Na), per cent. by mass	91 to 106
2	Moisture, per cent. by mass, Max	15
3	Matter insoluble in water, per cent. by mass, <i>Max</i>	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	$[C_6H_7O_2(OH) x$ $(OCH_2COONa)y]n$ $x = 2.00 \text{ to } 2.80$
	y = 0.20 to $1.00 = degree$ of substitution or $3.00 - x$
	x + y = 3.00 Structural units with degree of substitution of 0.20 178.14
	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.	Characteristic	Requirements
No.		
(1)	(2)	(3)
1	Purity, as sodium carboxy methyl cellulose	99.5
1	per cent. by mass, Min	(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 (Obtained by the simple addition of value obtained at SI No. (4 a 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	$[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$ $x = 1.50 \text{ to } 2.80$ $y = 0.20 \text{ to } 1.50 = \text{degree of substitution or } 3.00 - x$ $x + y = 3.00$ Structural units with degree of substitution of 0.20	

	178.14
	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 cent., Max	0.5
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:-

SI.	Characteristic	Requirements
No.		
(1)	(2)	(3)
1	Loss on drying, per cent. by mass, Max	
	a) Granular material	15
	b) Spray dried material	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:-

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	$[(C_6H_7O_6)_2Ca]$
Equivalent Weight (average)	219.00

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

SI. No.	Characteristic	Requirement
(1)	(2)	(3)
1	Purity as [(C ₆ H ₇ O ₆) ₂ Ca], 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:-

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	15

	at 105°C for 4 h, Max	
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.	0.5
	by mass, Max	
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 °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:-

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),	8
	Max	
4	Acid insoluble ash, per cent. by mass (on	1
	dry basis), Max	
5	Acid insoluble matter, per cent. by mass (on	3
	dry basis), Max	
6	Chlorides	Nil
7	Sulphates	Nil
8	Volatile acid (as acetic acid), per cent. by	10
	mass, Min	
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:-

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:-

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.	Characteristic	Requirements
No.		
(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.	1
	by mass, Max	
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	65

	ash-free and dried basis, Min	
11.	Degree of amidation, per cent. by mass of total	25
	carboxyl groups of pectin, Max	
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:-

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° 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,	0.1
	isopropanol, or methanol, singly or in	
	combination, Max	
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	ВНА
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:-

SI.	Characteristic	Requirements
No.		

(1)	(2)	(3)
1.	a) Purity as C ₁₁ H ₁₆ O ₂ , per cent. by mass, Min	98.5
	b) 3 tertiary butyl4-hydroxyanisole, per cent. by mass, Min	85
2.	Melting point, ⁰ C	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.	
	(1 cm cell) in ethanol at	
	a) 290 nm	190 Min 210 Max
	b) 228 nm	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.	Characteristic	Requirement
No.		
(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	100
	Cholrine) mass, mg/kg, Max	
5.	Free acid (as gallic acid), per cent. by mass,	0.5
	Max	
6.	Specific absorption at 275 nm,	
	Min	300
	Max	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:-

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, ⁰ C	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 °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 ₆ H ₇ NaO ₆
Molecular Weight	198.11

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

SI. Characteristic Requirements

No.		
(1)	(2)	(3)
1.	Assay as C ₆ H ₇ NaO ₆ (on dry basis), per cent. by mass	99 to 101
2.	Loss on drying, per cent. by mass, Max, after	0.25
	drying in vacuum over phosphorus pentoxide at 60°C for 4 hours	
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	$C_5H_8O_4NNaH_2O$
Molecular Weight	187.13

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

SI.	Characteristic	Requirements
No.		

(1)	(2)	(3)
1.	Purity as (C ₅ H ₈ O ₄ NNaH ₂ O), per cent. by mass, Min	99
2.	Loss on drying, per cent. by mass, at 98 °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 petrolatur food grade mineral oil, whi 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:-

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
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°, 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	$C_6H_8O_2$
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 ₆ H ₈ O 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 ₆ H ₁₄ O ₆ , per cent. by	91 or 99
	mass. Min	(Depending on the
		method of test used for
		analysis.)
2.	Moisture per cent. by mass, <i>Max</i>	1
3.	Melting range	
3.	a) Metastable	92.5 °C to 93.5 °C
	b) Stable	96 °C to 97.5 °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 <i>Max</i>	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 of imparting 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 products intended for human consumption, either processed or not.
- (iii) Artificial flavouring substances means those substances which have not been identified in natural products 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 ($\alpha \& \beta$ 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

- (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.]