

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 13th November, 2015

F.No P. 15025/208/2013-PA/FSSAI- Whereas the draft Food Safety and Standards (Food Products Standards and Food Additives) (Amendment) Regulations, 2015, were published as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F. No. P. 15025/208/2013-PA/FSSAI dated 6th February, 2015 in the Gazette of India, Extraordinary, Part III, Section 4 inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 23rd March, 2015;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by clause (e) of sub section (2) of section 92 read with section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

Regulations

1. (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) (Amendment) Regulations, 2015.

(2) They shall come into force on the date of their publication in the official Gazette.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011,-

(a) In regulation 3.1.3 relating to “Artificial Sweetener”, after sub regulation (5), and the entries relating thereto shall be added:

“ (6) **Use of Non Nutritive Sweetener.**—The non nutritive sweetener mentioned in column (2) of the Table below may be used only in the food articles mentioned in column (3) and in quantities not exceeding the limits mentioned in column (4) and as per the provisions contained in these regulations:

Sl.No.	Name of non-nutritive sweetener	Articles of food	Maximum level (mg/kg) (steviol equivalent)
(1)	(2)	(3)	(4)
1	Steviol Glycoside	Dairy based drinks flavored	200
		Dairy based desserts (ice-cream, frozen desserts, cream toppings)	330
		Yoghurt	200
		Fruit Nectars	200
		Non carbonated water based beverages (non alcoholic)	200
		Ice Lollies or edible Ice	270
		Jams, Jellies, Marmalades.	360
		Ready to eat cereals	350
		Carbonated water	200
		Soft drink concentrate	200 (in the final product after reconstitution)
		Chewing gum	3500

Provided further that the Steviol Glycoside may be marketed as table top sweetener in tablet form powder and liquid which may contain seven mg as Steviol equivalent per 100 mg. with carrier or filler as mentioned in the second proviso of Explanation II of sub-regulation (1) of regulation 3.1.3”.

(b) In regulation 3.2 relating to “Standards of food additives”, after sub-regulation 3.2.1 and the enteries relating thereto shall be added:

“3.2.2 Sweetener:- The standards for various sweeteners with characteristics are –

(I) Steviol Glycoside.—White to light yellow powder, odorless or having a slight characteristic odor. About 200 - 300 times sweeter than sucrose. The product is obtained from the leaves of *stevia rebaudiana bertonii*. 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. Stevioside and rebaudioside A are the component glycosides of principal interest for their sweetening property. Associated glycosides include rebaudioside B, rebaudioside C, rebaudioside D, rebaudioside F, dulcoside A, rubusoside and steviolbioside which are generally present in preparations of steviol glycosides at levels lower than stevioside or rebaudioside A.

Synonyms	INS no. 960.
Chemical name	Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy] kaur-16-en-18-oic acid, β-D-glucopyranosyl ester. Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester.
Empirical formula	Stevioside: C ₃₈ H ₆₀ O ₁₈ Rebaudioside A: C ₄₄ H ₇₀ O ₂₃
Formula weight	Stevioside: 804.88 Rebaudioside A: 967.03.
Solubility	Freely soluble in water Stevioside and rebaudioside A
pH	The main peak in the chromatogram obtained by following the procedure in Method of Assay corresponds to either stevioside or rebaudioside A. Between 4.5 and 7.0 (1 in 100 solution).
PURITY	
Total ash	Not more than percent.
Loss on drying	Not more than 6 percent (105°, 2h).
Residual solvents	Not more than 200 mg/kg methanol and not more than 5000 mg/kg ethanol (Method I in Vol. 4, General Methods, Organic Components, Residual Solvents).
Arsenic	Not more than 1 mg/kg Determine by the atomic absorption hydride technique [Use Method II to prepare the test (sample) solution].
Lead	Not more than 1 mg/kg Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Vol. 4 (under “General Methods, Metallic Impurities”).”

ASHISH BAHUGUNA, Chief Executive Officer
[ADVT.-III/4/Exty./187-O/15 (258)]

Note: - The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4, vide notification number F.No: 2-15015/30/2010, dated 1st August, 2011 and subsequently amended vide notification numbers:

- (i) F.No. 4/15015/30/2011, dated 7th June, 2013.
- (ii) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
- (iii) F.No. 5/15015/30/2012, dated 12th July, 2013.
- (iv) F.No. P.15025/262/2013-PA/FSSAI, dated 5th December, 2014.
- (v) F.No. 1-83/Sci Pan-Noti/FSSAI-2012, dated 17th February, 2015.
- (vi) F.No. 4/15015/30/2011, dated 4th August, 2015.
- (vii) F.No P. 15025/263/13-PA/FSSAI, dated 4th November, 2015.
- (viii) F.No. P.15025/264/13-PA/FSSAI, dated 4th November, 2015.