

NOTIFICATION

New Delhi, the 25th August, 2014

F. No. P. 15025/265/2013-PA/FSSAI.—The following draft of certain regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with section 16 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required by the said sub-section (2), for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of the period of thirty days from the date on which the copies of the Official Gazette in which this notification is published are made available to the public;

Objections or suggestion, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-110002;

The objections and suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period so specified, will be considered by the Food Authority.

Draft regulations

1. Short title and commencement.—(1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) (Amendment) Regulations, 2014.

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

(a) in regulation 3.1.3 relating to 'Artificial Sweeteners', in clause (1), relating to 'Use and sale of artificial Sweeteners', in the Table given thereunder,-

a) after item number VI, the following item number and entries thereto shall be inserted, namely:—

(1)	(2)	(3)	(4)
“VII	Aspartame and Acesulfame salt (INS 962)	Dairy-based drinks, flavoured and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, and whey based drinks).	350
		Dairy based desserts e.g. pudding, fruit or flavoured yoghurt,	350
		Jam, Jellies, marmalades.	1000
		Chocolate and chocolate products.	500
		Sugar free confectionery.	2000
		Sugar free chewing gum.	500
		Carbonated water.	350”

(b) in regulation 3.2 relating to 'Standards of Additives', after sub-regulation 3.2.1, and the entries relating thereto, the following sub-regulation, shall be inserted namely:—

“3.2.2 Sweetener: The standards for various sweeteners with characteristics are specified below:—

1 Aspartame-Acesulfame salt:

Synonyms

Aspartame-Acesulfame, INS No. 962

Definition

The salt is prepared by heating an approximately 2:1 ratio (w:w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallization to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.

Chemical names

6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L- α -aspartic acid.

[2-carboxy- β -(N-(b-methoxycarbonyl)-2-

	phenyl) ethylcarbamoyl)] . ethanaminium-6-methyl-4-oxo 1,2,3-oxathiazin-3-ide-2,2-dioxide.
C.A.S. number	106372-55-8
Chemical formula	C ₁₈ H ₂₃ O ₉ N ₃ S
Formula weight	457.46
Assay	63.0% to 66.0% aspartame (dried basis) and 34.0% to 37.0% acesulfame (acid form on a dried basis).
Description	A white, odourless, crystalline powder
Functional uses	Sweetening agent.
Characteristics identification	
Solubility	Sparingly soluble in water, and slightly soluble in ethanol.
Purity	
Loss on drying:	No more than 0.5% (105°, 4 h)
Transmittance:	The transmittance of a 1% solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0.95, equivalent to an absorbance of not more than approximately 0.022.
Specific Rotation:	[α] D ²⁰ +14.5 to +16.5. After preparing a solution of 6.2 g of sample in 100 ml formic acid (15N), make the measurement within 30 min of preparation of the solution. Divide the calculated specific rotation by 0.646 to correct for the aspartame content of the aspartame-acesulfame salt.
5-Benzyl-3,6-dioxo-2-piperazineacetic acid :	Not more than 0.5%
Lead:	Not more than 1 mg/kg ⁹ .

D. K. SAMANTARAY, Chief Executive Officer

[ADVT-III/4/Exty./191 F/14]

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 the 1st August, 2010 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.