

Regulations made under sections 6, 8 and 58.

SWEETENERS IN FOOD REGULATIONS, 1987

(LN. 1987/045)

1.8.1987

Amending enactments	Relevant current provisions	Commencement date
1990/064	reg. 2 and Schedule 1	1.7.1990

EU Legislation/International Agreements involved:

Directive 74/329/EEC

Directive 78/663/EEC

ARRANGEMENT OF REGULATIONS.

Regulation

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SCHEDULE 1.

1964-07

Food and Drugs

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**Subsidiary
1987/045**

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Title and commencement.

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1.(1) These regulations may be cited as the Sweeteners in Food Regulations 1987.

(2) These regulations shall come into operation on the 1st day of August, 1987.

Interpretation.

2. (1) In these regulations, unless the context otherwise requires-

“the British Pharmacopoeia 1980” means the edition of the British Pharmacopoeia published in 1980 in London by the Department of Health and Social Security;

“the British Pharmacopoeia 1980 Addendum 1982” means the Addendum to the British Pharmacopoeia 1980 published in 1982 in London by the Department of Health and Social Security;

“carbohydrate” means a substance which contains carbon, hydrogen and oxygen only, and in which the hydrogen and oxygen occur in the same proportion as in water;

“natural food substance” means any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment;

“the Act” means the Food and Drugs Act;

“permitted antioxidant” means any antioxidant in so far as its use is permitted by the Antioxidants in Food Regulations 1987;

“permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour Regulations 1987;

“permitted colouring matter” means any colouring matter in so far as its use is permitted by the Colouring Matter in Food Regulations 1980, as amended;

“permitted emulsifier” means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1990;

“permitted improving agent” means any improving agent in so far as its use is permitted by the Bread and Flour Regulations 1987;

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“permitted miscellaneous additive” means any miscellaneous additive in so far as its use is permitted by the Miscellaneous Additives in Food Regulations 1987;

“permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food Regulations 1987;

“permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food Regulations 1987;

“permitted stabiliser” means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1990;

“permitted sweetener” means any Sweetener specified in Part I of Schedule 1 which satisfies the specific purity criteria for that sweetener specified or referred to in Part II of that Schedule and, so far as is not otherwise provided for by any such specific purity criteria, satisfies the general purity criteria specified in Part III of that Schedule;

“sell” includes offer or expose for sale and includes have in possession for sale, and 'sale' shall be construed accordingly;

“sweetener” means any substance, other than a carbohydrate, whose primary organoleptic characteristic is sweetness, but does not include—

- (a) any natural food substance,
- (b) any permitted antioxidant,
- (c) any permitted bleaching agent,
- (d) any permitted colouring matter,
- (e) any permitted emulsifier,
- (f) any permitted improving agent,
- (g) any permitted miscellaneous additive,
- (h) any permitted preservative,
- (i) any permitted solvent,
- (j) any permitted stabiliser,
- (k) any starch, whether modified or not;

(2) For the purposes of these regulations, the supply of food, otherwise than by sale, at, in or from any place where food is supplied in the course of a business shall be deemed to be a sale of that food.

(3) Unless a contrary intention is expressed, all proportions mentioned in these regulations are proportions calculated by weight of the product as sold.

(4) Any reference in these regulations to a numbered regulation or schedule shall, unless the reference is to a regulation of, or schedule to, specified regulations, be construed as a reference to the regulation or schedule so numbered in these regulations.

Exemptions.

3. These regulations do not apply to any food (including any sweetener) which is-

- (a) not intended for sale for human consumption; or
- (b) intended at the time of sale or importation, as the case may be, for exportation to any place outside Gibraltar.

Sale and importation of food containing added sweeteners.

4. No person shall sell or import any food which has in it or on it any added sweetener other than a permitted sweetener.

Sale, importation and advertisement of sweeteners.

5.(1) No person shall sell or import any sweetener (including any sweetener with which any other substance has been mixed) which is intended for use in a catering establishment or for use by the ultimate consumer other than a permitted sweetener.

(2) No person shall sell or advertise for sale any sweetener (including any sweetener with which any other substance has been mixed) for use as an ingredient in the preparation of food unless the sweetener is a permitted sweetener.

Food for babies and young children.

6.(1) No person shall sell any food that is specially prepared for babies or young children if it has in it or on it any added sweetener.

(2) Paragraph (1) of this regulation shall not apply to food specially prepared for babies or young children with special dietary requirements.

Labelling provisions.

7.(1) No person shall sell a permitted sweetener (including a permitted sweetener with which any other substance has been mixed) which is not ready for delivery to the ultimate consumer or a catering establishment unless it is marked or labelled with-

- (a) the name of the permitted sweetener;
- (b) the serial number, if any, specified for the permitted sweetener in column 2 of Part I of Schedule 1;
- (c) the words 'for foodstuffs (restricted use)';
- (d) the name or business name and an address or registered office of the manufacturer or packer, or of a seller established within the European Economic Community; and
- (e) in the case of the permitted sweetener sorbitol syrup (E420) which contains after hydrolysis a level of total sugars exceeding 1%, the words 'contains after hydrolysis a level of total sugars of more than 1%' or substantially similar words.

(2) Without prejudice to paragraph (1) of this regulation, no person shall sell a permitted sweetener with which any other substance (including another permitted sweetener) has been mixed and which is not ready for delivery to the ultimate consumer or a catering establishment unless it is marked or labelled with the name of every other substance in the mixture.

(3) A permitted sweetener (including a permitted sweetener with which any other substance has been mixed) shall not be regarded as being marked or labelled in accordance with the foregoing paragraphs of this regulation unless the particulars with which it is required to be marked or labelled by those paragraphs appear-

- (a) on the packaging, or
- (b) on a label attached to the packaging, or
- (c) on a label that is clearly visible through the packaging,

in such a way that they are easy to understand, clearly legible and indelible and are not hidden, obscured or interrupted by any other written or pictorial matter.

Condemnation of food.

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8. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell or import, that food may be treated for the purposes of section 10 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

Penalties.

9. If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000.

Application of various sections of the Act.

10. Sections 46(2) and (3) (which relate to prosecutions), 47(1) and (2) (which relate to evidence of analysis), 49 (which relates to the power of a court to require analysis by the Government Chemist in the United Kingdom), 50 (which relates to a contravention due to some person other than the person charged), 51(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 52 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under these regulations and as if the reference in the said Section 49 to subsection (3) of Section 46 included a reference to that subsection as applied by these regulations.

Revocation.

11. The Artificial Sweeteners in Food Regulations are hereby Revocation. revoked.

SCHEDULE 1

PART I

PERMITTED SWEETNERS

Column 1 Name of Sweetener	Column 2 Serial Number
Acesulfame potassium	
Aspartame	
Hydrogenated glucose syrup	
Isomalt	
Lactitol	—
Mannitol	E421
Saccharin	
Sodium saccharin	
Calcium saccharin	
Sorbitol	E420
Sorbitol syrup	E420
Thaumatococin	
Xylitol	

PART II

SPECIFIC PURITY CRITERIA FOR PERMITTED SWEETENERS

Acesulfame potassium	
Synonym	
Chemical name	Potassium 3,4-dihydro-6-methyl-2,2,4-trioxo-1,2,6-oxathiazin-3-ide.
Empirical formula	C ₄ H ₄ KNO ₄ S.
Molecular weight	201.2
Description	White, odourless, crystalline powder or granules with an intensely sweet taste.
Content	Not less than 99.0% of C ₄ H ₄ KNO ₄ S on a volatile matter-free basis.
Volatile matter	Not more than 1.0% (determined by drying at 150°C to constant weight).
pH of a 1% aqueous solution	Not less than 6.5 and not more than 7.5.
Potassium acetate	Not more than 0.5%.
Fluoride	Not more than 30 mg/kg.

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Aspartame.	
Chemical name	(3s)-3-Amino-N[(x)-x methoxycarbonyl-phenethyl] succinamic acid
Synonym	L-Aspartyl-L-phenylalanine methyl ester
Empirical formula	C ₁₄ H ₁₈ N ₂ O ₅ .
Molecular weight	294.3.
Description	White, odourless, crystalline powder with an intensely sweet taste.
Content	Not less than 98.0% of C ₁₄ H ₁₈ N ₂ O ₅ on a volatile matter-free basis.
Volatile matter	Not more than 4.5% (determined by drying at 105 ⁰ C to constant weight).
Specific rotation, [x] 20 ⁰ C D	Not less than +12.5 ⁰ and not more than +17.5 ⁰ (determined using a 4% weight/volume solution on a volatile matter-free basis in 15M formic acid).
pH of a 0.8% aqueous solution	Not less than 4.0 and not more than 6.5.
Sulphated ash	Not more than 0.2% after ignition at 800 ± 25°C
5-Benzyl-3,6-dioxo-2 - piperazineacetic acid	Not more than 1.5%.
Hydrogenated glucose syrup	
Synonym	Hydrogenated high maltose glucose syrup.
Description	Clear, colourless, sweet-tasting, aqueous solution of sorbitol, hydrogenated oligosaccharides and hydrogenated polysaccharides prepared by the catalytic hydrogenation of glucose syrup. When dried or crystallised the product is white and crystalline
Content	D-glucitol: not more than 8%. 4-O-x-D-glucopyransoyl-D-glucitol: not less than 50% and not more than 90%. 0-x-D-glucopyranosyl-(1-4)-0-x-D- glucopyranosyl-(1-4)-D-glucitol: not less than 5% and not more than 20% -Hydrogenated tetrasaccharides and hydrogenated higher polysaccharides: not less than 2% and not more than 30%. Hydrogenated polysaccharides containing 21 or more D-glucopyranosyl or D-glucitol units: not more than 3%.
	The percentages referred to are calculated on a dry weight basis in each case.
Water	Not more than 26% (Karl Fischer).

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Reducing sugars	Not more than 0.3% on a dry weight basis, expressed as dextrose.
pH of a 40% aqueous solution	Not less than 4.0 and not more than 7.0
Sulphur dioxide	Not more than 10 mg/kg on a dry weight basis.
Sulphated ash	Not more than 0.1% after ignition at $800 \pm 25^{\circ}\text{C}$ calculated on a dry weight basis.
Sulphate	Not more than 0.01% on a dry weight basis, expressed as SO_4 .
Chloride	Not more than 50 mg/kg on a dry weight basis, expressed as Cl.
Nickel	Not more than 2 mg/kg on a dry weight basis, expressed as Ni.
Lead	Not more than 1 mg/kg on a dry weight basis, expressed as Pb.
Isomalt	
Chemical description	An approximately equimolar mixture of 6-0-x-D-glucopyranosyl-D-glucitol and 1-0-x-D-glucopyranosyl-D-mannitol.
Empirical formula	$\text{C}_{12}\text{H}_{24}\text{O}_{11}$
Molecular weight	6-0-x-D- glucopyranosyl-D-glucitol ($\text{C}_{12}\text{H}_{24}\text{O}_{11}$): 344.3 1-0-cx-D- glucopyranosyl-D-mannitol. ($\text{C}_{12}\text{H}_{24}\text{O}_{11}2\text{H}_2\text{O}$):380.3.
Description	White, odourless, crystalline. slightly hygroscopic solid with a sweet taste.
Content	Not less than 98.0% of 6-0-x-D- glucopyranosyl-D-glucitol and 1-0-cx-D- glucopyranosyl-D-mannitol; each shall be present in a proportion of not less than 43% (on a dry weight basis in each case).
Water	Not more than 7.0% (Karl Fisher).
Specific rotation, $[\alpha]_{20^{\circ}\text{C}}$	Not less than $+91.5^{\circ}$ (using a 4% weight/volume aqueous solution).
D	
Reducing sugars	Not less than 1.5% on a dry weight basis, expressed as dextrose.
D-Mannitol	Not less than 0.5% on a dry weight basis.
D-Sorbitol	Not less than 0.5% on a dry weight basis.
Ash	Not more than 50 mg/kg after ignition at $800 \pm 25^{\circ}\text{C}$, calculated on a dry weight basis.
Nickel	Not more than 2 mg/kg on a dry weight basis, expressed as Ni.
Lead	Not more than 1 mg/kg on a dry weight basis, expressed as Pb.

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Lactitol	
Synonyms	Lactit, Lactositol, Lactobiosit.
Chemical name	4-0-(β-D-galactopyranosyl)-D-glucitol
Empirical formula	C ₁₂ H ₂₄ O ₁₁
Molecular weight	344.32.
Specific rotation, [α] 20°C	
D + 13 to +,15° (using a 10% weight to D volume aqueous solution).	
Water	Lactitol monohydrate not more than 5.5% (Karl Fischer). Lactitol dihydrate not more than 10.5% (Karl Fischer).
Description	Colourless, aqueous syrup with a sweet taste. When dried, the resulting products, lactitol monohydrate and lactitol di- hydrate, are white, odourless and crystalline.
Content	Not less than 97.5% 4-0-(β -D-galactopyra- nosyl)-D-glucitol on a dry weight basis.
Other polyols	Not more than 2.5% on a dry weight basis.
Reducing sugars	Not more than 0.2% on a dry weight basis, expressed as lactose.
Chlorides	Not more than 100 mg/kg on a dry weight basis, expressed as Cl.
Sulphate	Not more than 100 mg/kg on a dry weight basis, expressed as SO ₄
Arsenic	Not more than 1 mg/kg on a dry weight basis, expressed as As.
Nickel	Not more than 1 mg/kg on a dry weight basis, expressed as Ni.
Lead	Not more than 1 mg/kg on a dry weight basis, expressed as Pb.
Ash	Not more than 0.1% after ignition at 800 ± 25°C calculated on a dry weight basis.

E421 Mannitol

The criteria for mannitol contained in Council Directive 78/663/EEC and in article 6(1)(a) of Council Directive 74/329/EEC, as amended.

Saccharin

The criteria in the monograph for saccharin contained in the British Pharmacopoeia 1980 at page 393.

Sodium saccharin

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The criteria in the monograph for saccharin sodium contained in the British Pharmacopoeia 1980 at page 394, as amended by the British Pharmacopoeia 1980 Addendum 1982 at page 99.

Calcium saccharin

Chemical name

1,2-

Benzisothiazol-3(2H)-one 1,1-dioxide, calcium salt.

Empirical formula

C₁₄H₈CaN₂O₆S₂

Molecular weight

404.4.

Description

White crystals or a white, crystalline powder; odourless or with a faint aromatic odour; with an intensely sweet taste.

Content

Not less than 99.0% of C₁₄H₈CaN₂O₆S₂ on a volatile matter-free basis.

Volatile matter

Not less than 11.0% and not more than 15.0% (determined by drying at 105⁰C to constant weight)

Free acid or alkali

Complies with the test in the monograph for saccharin sodium in the British Pharmacopoeia 1980.

Melting point of isolated saccharin

Complies with the test in the monograph for saccharin sodium in the British Pharmacopoeia 1980.

Related substances

Complies with the test in the monograph for saccharin sodium in the British Pharmacopoeia 1980.

Arsenic

Complies with the test in the monograph for saccharin sodium in the British Pharmacopoeia 1980

Heavy metals

Complies with the test in the monograph for saccharin sodium in the British Pharmacopoeia 1980.

E420 Sorbitol

The criteria for sorbitol contained in Council Directive 78/663/EEC and in article 6(1)(a) of Council Directive 74/329/EEC, as amended

E420 Sorbitol syrup

The criteria for sorbitol syrup contained in Council Directive 78/663/EEC and in article 6(1)(a) of Council Directive 74/329/EEC, as amended

Thaumatococin

Description

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Odourless, cream coloured, proteinaceous powder with an intensely sweet taste obtained from aqueous extracts of the arils of the fruit of *Thaumatococcus daniellii* (Benth).

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Specific absorption, $E_{1\%}$	Not less than 12.0 and not more than 12.5(determined at the wavelength of maximum absorbance, about 279 nm, using a 0.1% weight/volume aqueous solution at pH 2.7).
Nitrogen	Not less than 16.0% on a volatile matter-free basis
Carbohydrate	Not more than 3.0% on a volatile matter-free basis.
Volatile matter	Not more than 9.0% (determined by drying at 105°C to constant weight)
Sulphated ash	Not more than 2.0% after ignition at 800 ± 25°C calculated on a volatile matter-free basis.
Aluminium	Not more than 0.01% on a volatile matter-free basis.
Xylitol	
Chemical name	meso-Xylitol
Empirical formula	$C_5H_{12}O_5$
Description	White, odourless, crystalline powder or crystals with a sweet taste
Content	Not less than 98.0% of meso-xylitol, $C_5H_{12}O_5$.on a volatile matter-free basis
Volatile matter.	Not more than 0.5% (determined by drying at 60°C over phosphorus pentoxide in a vacuum for 4 hours).
Reducing sugar	Not more than 0.2% on a volatile matter-free basis, expressed as dextrose.
pH of a 10% aqueous solution	Not more than 0.5% singly and not more than 1.0% in total on a volatile matter-free basis
Other polyols	1.0% in total on a volatile matter-free basis
Ash	Not more than 0.1% after ignition at 800 ± 25°C
Nickel	Not more than 2 mg/kg on a volatile matter-free basis, expressed as Ni.
Lead	Not more than 1 mg/kg on a volatile matter-free basis, expressed as Pb

PART III.

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GENERAL PURITY CRITERIA APPLICABLE TO PERMITTED SWEETENERS EXCEPT WHERE OTHERWISE PROVIDED BY SPECIFIC PURITY CRITERIA.

No permitted sweetener shall contain more than-

- (a) 3 milligrams per kilogram of arsenic;
- (b) 10 milligrams per kilogram of lead.