

COMMISSION DIRECTIVE 2001/52/EC
of 3 July 2001
amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽¹⁾, as amended by Directive 94/34/EC ⁽²⁾ of the European Parliament and of the Council, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽³⁾, as amended by Directive 96/83/EC ⁽⁴⁾, lists those substances which may be used as sweeteners in foodstuffs.
- (2) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽⁵⁾, as last amended by Directive 2000/51/EC ⁽⁶⁾, sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC.
- (3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/31/EC for mannitol (E 421) and acesulfame K (E 950).
- (4) It is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the *Codex alimentarius* by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) It is consequently necessary to adapt Directive 95/31/EC.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In the Annex to Directive 95/31/EC, the text concerning E 421 mannitol and E 950 acesulfame K shall be replaced by the text in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2002 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 3 July 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27.

⁽²⁾ OJ L 237, 10.9.1994, p. 1.

⁽³⁾ OJ L 237, 10.9.1994, p. 3.

⁽⁴⁾ OJ L 48, 19.2.1997, p. 16.

⁽⁵⁾ OJ L 178, 28.7.1995, p. 1.

⁽⁶⁾ OJ L 198, 4.8.2000, p. 41.

ANNEX

E 950 ACESULFAME K**Synonyms**

Acesulfame potassium, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one, 2,2-dioxide

Definition

Chemical name	6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
Einecs	259-715-3
Chemical formula	C ₄ H ₄ KNO ₄ S
Molecular weight	201,24
Assay	Content not less than 99 % of C ₄ H ₄ KNO ₄ S on the anhydrous basis

Description

Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose

Identification

A. Solubility	Very soluble in water, very slightly soluble in ethanol
B. Ultra violet absorption	Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
C. Positive test for potassium	Passes test (test the residue obtained by igniting 2 g of the sample)
D. Precipitation test	Add a few drops of a 10 % solution of sodium cobaltnitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced

Purity

Loss on drying	Not more than 1 % (105 °C, two hours)
Organic impurities	Passes test for 20 mg/kg of UV active components
Fluoride	Not more than 3 mg /kg
Lead	Not more than 1 mg/kg

E 421 MANNITOL**1. Mannitol****Synonyms**

D-mannitol

Definition

Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose

Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	C ₆ H ₁₄ O ₆
Molecular weight	182,2
Assay	Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis

Description

White, odourless, crystalline powder

Identification

A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C
C. Thin layer chromatography	Passes test
D. Specific rotation	[α] _D ²⁰ ; + 23° to + 25° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

Purity

Loss on drying	Not more than 0,3 % (105 °C, four hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

2. Mannitol manufactured by fermentation**Synonyms**

D-mannitol

DefinitionManufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii*

Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	C ₆ H ₁₄ O ₆
Molecular weight	182,2
Assay	Not less than 99 % on the dried basis

Description

White, odourless crystalline powder

Identification

A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C
C. Thin layer chromatography	passes test
D. Specific rotation	[α] _D ²⁰ : + 23° to + 25° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

Purity

Arabitol	Not more than 0,3 %
Loss on drying	Not more than 0,3 % (105 °C, four hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Lead	Not more than 1 mg/kg
Aerobic mesophilic bacteria	Not more than 10 ³ /g
Coliforms	Absent in 10 g
<i>Salmonella</i>	Absent in 10 g
<i>E. coli</i>	Absent in 10 g
<i>Staphylococcus aureus</i>	Absent in 10 g
<i>Pseudomonas aeruginosa</i>	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g'