

**COMMISSION DIRECTIVE 2000/51/EC**  
**of 26 July 2000**  
**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 <sup>(1)</sup>, as amended by European Parliament and Council Directive 94/34/EC <sup>(2)</sup>, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs <sup>(3)</sup>, as amended by Directive 96/83/EC <sup>(4)</sup>, 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 <sup>(5)</sup>, as amended by Directive 98/66/EC <sup>(6)</sup>, 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 maltitol syrup (E 965(ii)). It is consequently necessary to adapt that Directive.
- (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) 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 965 (ii)) maltitol syrup 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 2001 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 twentieth day following its publication in *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

*For the Commission*

David BYRNE

*Member of the Commission*

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 27.

<sup>(2)</sup> OJ L 237, 10.9.1994, p. 1.

<sup>(3)</sup> OJ L 237, 10.9.1994, p. 3.

<sup>(4)</sup> OJ L 48, 19.2.1997, p. 16.

<sup>(5)</sup> OJ L 178, 28.7.1995, p. 1.

<sup>(6)</sup> OJ L 257, 19.9.1998, p. 35.

## ANNEX

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

D-mannitol

**Definition**

Mannitol is manufactured by catalytic hydrogenation of a mixture of glucose and fructose made from invert sugar

*Chemical name*

D-mannitol

*Einecs*

200-711-8

*Chemical formula* $C_6H_{14}O_6$ *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

 $[\alpha]^{20}_D$ : + 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, 4 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

**Definition**Mannitol can also be manufactured by discontinuous fermentation under aerobic conditions a conventional strain of the yeast *Zygosaccharomyces rouxii**Chemical name*

D-mannitol

*Einecs*

200-711-8

*Chemical formula* $C_6H_{14}O_6$ *Molecular weight*

182,2

*Assay*

Not less than 99 % on the dried basis

**Description**

White, odourless crystalline powder

**Identification**

- A. Solubility
- B. Melting range
- C. Thin layer chromatography
- D. Specific rotation
- E. pH

Soluble in water, very slightly soluble in ethanol, practically insoluble in ether  
Between 164 and 169 °C.

Passes test

$[\alpha]^{20}_D$ : + 23° to + 25° (borate solution)

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
- Loss on drying
- Reducing sugars
- Total sugars
- Sulphated ash
- Chlorides
- Sulphate
- Lead
- Aerobic mesophilic bacteria
- Coliforms
- Salmonella*
- E. coli*
- Staphylococcus aureus*
- Pseudomonas aeruginosa*
- Moulds
- Yeasts

Not more than 0,3 %

Not more than 0,3 % (105 °C, 4 hours)

Not more than 0,3 % (as glucose)

Not more than 1 % (as glucose)

Not more than 0,1 %

Not more than 70 mg/kg

Not more than 100 mg/kg

Not more than 1 mg/kg

Not more than 10<sup>3</sup>/g

Absent in 10 g

Absent in 10 g

Absent in 10 g

Absent in 10 g

Absent in 10 g

Not more than 100/g

Not more than 100/g'

**'E 965(ii) SYRUP MALTITOL****Synonyms**

Hydrogenated high-maltose-glucose syrup, hydrogenated glucose syrup

**Definition**

A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup. The article of commerce is supplied both as a syrup and as a solid product.

*Assay*

Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis

**Description**

Colourless and odourless, clear viscous liquids or white crystalline masses

**Identification**

- A. Solubility
- B. Thin layer chromatography

Very soluble in water, slightly soluble in ethanol

Passes test

**Purity**

- Water
- Reducing sugars
- Sulphated ash
- Chlorides
- Sulphate
- Nickel
- Lead

Not more than 31 % (Karl Fischer)

Not more than 0,3 % (as glucose)

Not more than 0,1 %

Not more than 50 mg/kg

Not more than 100 mg/kg

Not more than 2 mg/kg

Not more than 1 mg/kg'