MALTITOL

Prepared at the 46th JECFA (1996), published in FNP 52 Add 4 (1996) superseding specifications prepared at the 33rd JECFA (1988), published in FNP 38 (1988) and in FNP 52 (1992). Metals and arsenic specifications were revised by JECFA in 2001. An ADI 'not specified' was established at the 41st JECFA (1993)*

SYNONYMS D-Maltitol, hydrogenated maltose, INS No. 965

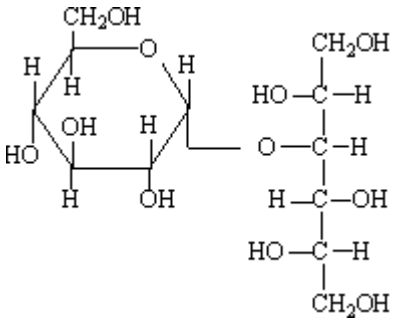
DEFINITION

Chemical names alpha-D-Glucopyranosyl-1,4-D-glucitol

C.A.S. number 585-88-6

Chemical formula $C_{12}H_{24}O_{11}$

Structural formula



Formula weight 344.31

Assay Not less than 98.0%

DESCRIPTION White crystalline powder

FUNCTIONAL USES Sweetener, humectant, stabilizer, bulking agent

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Very soluble in water, slightly soluble in ethanol

Melting range (Vol. 4) 148 - 151°

Thin layer chromatography (Vol. 4) Passes test
Proceed as directed under *Thin Layer Chromatography of Polyols*
Use the following:

Standard solution
Dissolve 50 mg of reference standard maltitol (available from US Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD 20852, USA) in 20 ml water

Test solution
Dissolve 50 mg of the sample in 20 ml of water

PURITY

Water (Vol. 4) — Not more than 1.0% (Karl Fischer Method)

Specific rotation (Vol. 4) — [alpha] 20, D: Between +105.5 and +108.5°(5% w/v solution)

Sulfated ash (Vol. 4) — Not more than 0.1%
Test 2 g of sample (Method I)

Chlorides (Vol. 4) — Not more than 50 mg/kg
Test 10 g of sample by the Limit Test using 1.5 ml of 0.01N hydrochloric acid in the control

Sulfates (Vol. 4) — Not more than 100 mg/kg
Test 10 g of sample by the Limit Test using 2.0 ml of 0.01N sulfuric acid in the control

Nickel (Vol. 4) — Not more than 2 mg/kg
Proceed as directed under *Nickel in Polyols*

Reducing sugars (Vol. 4) — Not more than 0.1%
Proceed as directed under *Reducing Substances (as glucose*), Method II. The weight of cuprous oxide shall not exceed 20 mg

Lead (Vol. 4) — Not more than 1 mg/kg
Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, “Instrumental Methods.”

METHOD OF ASSAY

Determine the maltitol content of the sample using *liquid chromatography* (see Volume 4)

Apparatus
Liquid chromatograph (HPLC)
Detection: Differential refractometer maintained at constant temperature
Integrator recorder
Column: AMINEX HPX 87 C (or equivalent resin in calcium form), length 30 cm, internal diameter 9 mm
Eluent: Double distilled degassed water (filtered through Millipore membrane filter 0.45 µm)
Chromatographic conditions
Column temperature: 85 ± 0.5° ; Eluent flow rate: 0.5 ml/min

Standard preparation
Dissolve an accurately weighed quantity of standard reference maltitol in water to obtain a solution having known concentration of about 10.0 mg of maltitol per ml.

Sample preparation

Transfer about 1 g of the sample accurately weighed to a 50 ml volumetric flask, dilute with water to volume and mix.

Procedure

Separately inject equal volumes (about 20 µl) of the sample preparation and the standard preparation into the chromatograph. Record the chromatograms and measure the responses of the maltitol peak. Calculate the quantity, in mg, of maltitol in the portion of sample taken by the following formula:

$$50 \times C \times \frac{R_U}{R_S}$$

where

C = the concentration, in mg per ml, of maltitol in the standard preparation

R_U = the peak response of the sample preparation

R_S = the peak response of the standard preparation

*The specification for Maltitol was not revised in 2001. This revision will be adopted by the 67th JECFA (2006).