SORBITOL

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). Metals and arsenic specifications revised at the 57th JECFA (2001). An ADI 'Not specified' was established at the 26th JECFA (1982).

SYNONYMS D-Glucitol, D-sorbitol, sorbit, sorbol, INS No. 420(i)

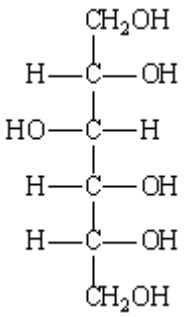
DEFINITION

Chemical names D-Sorbitol

C.A.S. number 50-70-4

Chemical formula $C_6H_{14}O_6$

Structural formula



Formula weight 182.17

Assay Not less than 97.0% of $C_6H_{14}O_6$ of total glycitols and not less than 91.0% of D-sorbitol on the anhydrous basis. The term glycitols refers to compounds with the structural formula CH_2OH-$(CHOH)_n$-CH_2OH, where n is an integer less than or equal to 4.

DESCRIPTION White hygroscopic powder, crystalline powder, flakes or granules

FUNCTIONAL USES Sweetener, humectant, sequestrant, texturizer, stabilizer, bulking agent

CHARACTERISTICS

IDENTIFICATION

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

Melting range (Vol. 4) 88 - 102°

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 sorbitol (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% (Karl Fischer Method)
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	Not more than 0.3% Proceed as directed under *Reducing Substances (as Glucose*), Method II. The weight of cuprous oxide shall not exceed 50 mg
Total sugars	Not more than 1% (as glucose) Weigh 2.1 g of the sample into a 250 ml flask fitted with a ground glass joint, add 40 ml of 0.1N hydrochloric acid, attach a reflux condenser, and reflux for 4 h. Transfer the solution to a 400 ml beaker, rinsing the flask with about 10 ml of water, neutralize with 6N sodium hydroxide and proceed as directed under *Reducing Substances(as Glucose*) Method II. The weight of the cuprous oxide shall not exceed 50 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 polyol 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^{o}
Eluent flow rate: 0.5 ml/min

Standard preparation
Dissolve an accurately weighed quantity of sorbitol in water to obtain a solution having known concentration of about 10.0 mg of sorbitol 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 each peak. Calculate separately the quantities, in mg, of sorbitol and other glycitols in the portion of sample taken by the following formula:

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

in which C is the concentration, in mg per ml, of sorbitol in the standard preparation; R_U is the peak response of the sample preparation and R_S is the peak response of the standard preparation.