

# Maltitol Solution

## 1 Nonproprietary Names

BP: Liquid maltitol  
PhEur: Maltitolum liquidum  
USPNF: Maltitol solution

## 2 Synonyms

E965; hydrogenated glucose syrup; *Finmalt L*; *Lycasin HBC*; *Lycasin 80/55*; *Maltisorb 75/75*; *Maltisweet 3145*; maltitol syrup.

## 3 Chemical Name and CAS Registry Number

Maltitol solution [9053-46-7]

## 4 Empirical Formula Molecular Weight

The PhEur 2002 describes liquid maltitol as an aqueous solution of a hydrogenated, partly hydrolyzed starch, with not less than 68% w/w of solid matter and not more than 85% w/w. This is composed of a mixture of mainly D-maltitol ( $\geq 50\%$  w/w), D-sorbitol ( $\leq 8\%$  w/w), and hydrogenated oligo- and polysaccharides, all quoted on an anhydrous basis.

The USPNF 20 describes maltitol solution as an aqueous solution of a hydrogenated, partially hydrolyzed starch. It contains, on the anhydrous basis, not less than 50% w/w of D-maltitol ( $C_{12}H_{24}O_{11}$ ) and not more than 16.0% w/w of D-sorbitol ( $C_6H_{14}O_6$ ). See also Section 18.

## 5 Structural Formula

See Section 4.

## 6 Functional Category

Suspending agent; sweetening agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Maltitol solution is used in oral pharmaceutical formulations as a bulk sweetening agent, either alone or in combination with other excipients, such as sorbitol. Maltitol solution is also used as a suspending agent in oral suspensions as an alternative to sucrose syrup since it is viscous, noncariogenic, and has a low calorific value. It is also noncrystallizing and therefore prevents 'cap-locking' in syrups and elixirs.

Maltitol solution is additionally used in the preparation of pharmaceutical lozenges<sup>(1)</sup> and is also used in confectionery and food products.

## 8 Description

Maltitol solution is a colorless and odorless, clear viscous liquid. It is sweet-tasting (approximately 75% the sweetness of sucrose).

## 9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for maltitol solution.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Conductivity	+	—
Reducing sugars	+	+
Chloride	—	$\leq 0.005\%$
Sulfate	—	$\leq 0.01\%$
Lead	$\leq 0.5$ ppm	—
Nickel	$\leq 1$ ppm	—
Heavy metals	—	$\leq 0.001\%$
Water	15.0–32.0%	$\leq 30.0\%$
Residue on ignition	—	$\leq 0.1\%$
Maltitol (dried basis)	$\geq 50.0\%$	$\geq 50.0\%$
Sorbitol (dried basis)	$\leq 8.0\%$	$\leq 16.0\%$

## 10 Typical Properties

Boiling point: 105 °C

Flash point: >150 °C

Density: 1.36 g/cm<sup>3</sup> at 20 °C

Heat of combustion: 10.0 kJ/g (2.4 kcal/g)

Osmolarity: the osmolarity of an aqueous maltitol solution is similar to that of a sucrose solution of the same concentration. A 10% v/v aqueous solution of *Lycasin 80/55* (Roquette) is iso-osmotic with serum.

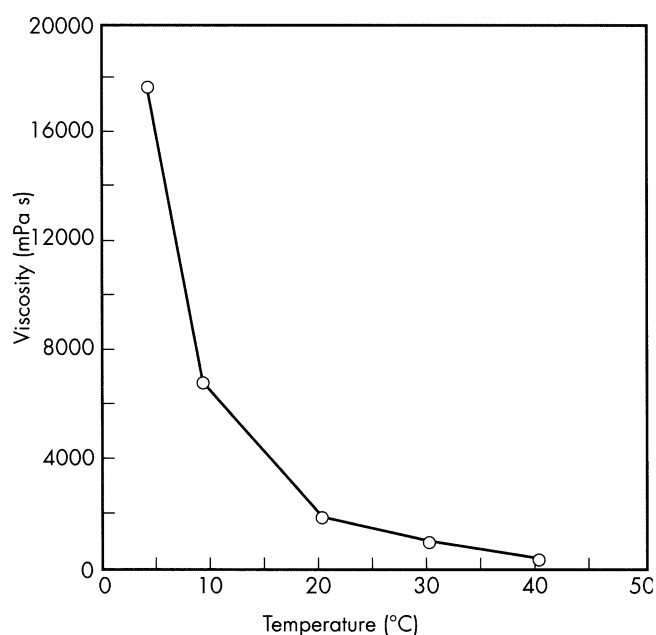
Refractive index:  $n_D^{20} = 1.478$

Solubility: miscible with ethanol (provided the ethanol concentration is less than 55%), glycerin, propylene glycol, and water. Insoluble in mineral and vegetable oils.

Viscosity (dynamic): maltitol solution is a viscous, syrupy, liquid. At 20 °C, a solution of *Lycasin 80/55* (Roquette) containing 75% of dry substances has a viscosity of approximately 2000 mPa s (2000 cP). With increasing temperature, the viscosity of a maltitol solution is reduced; see Figure 1. The viscosity of maltitol solutions also decreases with decreasing concentration of dry solids, at a constant temperature. Maltitol solution may also be mixed with sorbitol solution to obtain blends of a desired viscosity.

## 11 Stability and Storage Conditions

Maltitol solution is stable for at least 2 years at room temperature and pH 3–9. Following storage for 3 months at 50 °C, maltitol solution at pH 2 underwent slight hydrolysis (1.2%) and became yellow colored. At pH 3, and the same storage conditions, no color change was apparent although very slight hydrolysis occurred (0.2%). At pH 4–9, no hydrolysis occurred although a very slight yellow color was formed under alkaline conditions.<sup>(2)</sup>



**Figure 1:** Viscosity of maltitol solution (*Lycasin 80/55*), containing 75% of dry substances, at different temperatures.

Formulations containing maltitol solution should be preserved with an antimicrobial preservative such as sodium benzoate or a mixture of parabens. Maltitol solution is non-crystallizing.

Maltitol solution should be stored in a well-closed container, in a cool, dry place.

## 12 Incompatibilities

## 13 Method of Manufacture

Maltitol solution is prepared by the hydrogenation of a high-maltose syrup that is obtained from starch by enzymatic hydrolysis. The maltitol solution produced from this process consists of the hydrogenated homologs of the oligosaccharides contained in the original syrup.

## 14 Safety

Maltitol solution is used in oral pharmaceutical formulations, confectionery, and food products and is considered to be less cariogenic than sucrose.<sup>(3-6)</sup> It is generally regarded as a nontoxic, nonallergenic, and nonirritant material. However, excessive oral consumption (more than 50 g daily) may cause flatulence and diarrhea.

The WHO, in considering the safety of maltitol solution, did not set a value for the acceptable daily intake since the levels used in food to achieve a desired effect were not considered a hazard to health.<sup>(7,8)</sup>

LD<sub>50</sub> (rat, IP): 20 g/kg<sup>(9)</sup>

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

## 16 Regulatory Status

Accepted for use in confectionery, foods, and nonparenteral pharmaceutical formulations in Europe and the USA.

## 17 Related Substances

Maltitol; sorbitol.

## 18 Comments

Hydrogenated glucose syrup is a generic term used to describe aqueous mixtures containing mainly D-maltitol, along with D-sorbitol and hydrogenated oligosaccharides and polysaccharides. Such mixtures can vary widely in their composition and hence physical and chemical properties. Products containing up to 90% of maltitol are usually known as maltitol syrup or maltitol solution. Preparations containing a minimum of 98% of maltitol are designated maltitol.

## 19 Specific References

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## 20 General References

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## 21 Author

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## 22 Date of Revision

5 March 2002.