

Maltitol

1 Nonproprietary Names

BP: Maltitol
PhEur: Maltitolum

2 Synonyms

Amalty; E965; hydrogenated maltose; *Lycasin*; *Malbit*; *Maltisorb*; *Maltit*; D-maltitol.

3 Chemical Name and CAS Registry Number

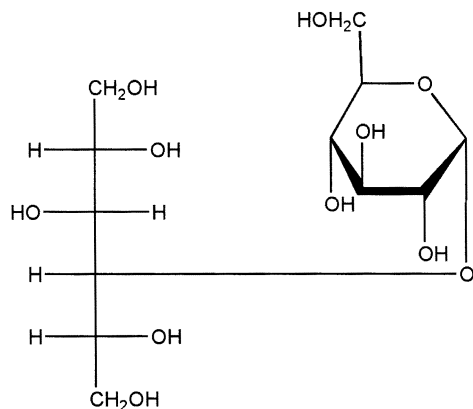
4-O- α -D-Glucopyranosyl-D-glucitol [585-88-6]

4 Empirical Formula Molecular Weight

C₁₂H₂₄O₁₁

344.32

5 Structural Formula



6 Functional Category

Coating agent; diluent; granulating agent; suspending agent; sweetening agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Maltitol is widely used in the pharmaceutical industry in the formulation of oral dosage forms. It is a noncariogenic bulk sweetener, approximately as sweet as sucrose, well adapted as a diluent for different oral dosage forms, wet granulation, and hard coating.

8 Description

Maltitol occurs as a white, odorless, sweet, crystalline powder. It is a disaccharide consisting of one glucose unit linked with one sorbitol unit via an α -(1 \rightarrow 4) bond.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for maltitol.

Test	PhEur 2002
Identification	+
Characters	+
Appearance of solution	+
Conductivity	+
Reducing sugars	+
Related substances	+
Lead	≤ 0.5 ppm
Nickel	≤ 1 ppm
Water	$\leq 1.0\%$
Microbial contamination	+
Bacterial endotoxins	+
Assay (dried basis)	98.0–102.0%

10 Typical Properties

Compressibility: 9.5%

Density (bulk): 0.79 g/cm³ ⁽¹⁾

Density (tapped): 0.95 g/cm³ ⁽¹⁾

Flowability: 5 seconds ⁽¹⁾

Melting point: 148–151°C

Particle size distribution:

95% ≤ 500 μ m, 40% ≥ 100 μ m in size for *Maltisorb P200* (Roquette); 95% ≤ 200 μ m, 50% ≥ 100 μ m in size for *Maltisorb P90* (Roquette).

Solubility: freely soluble in water. See also Table II.

Viscosity (dynamic): see Table III.

Table II: Solubility of maltitol (*Maltisorb*). ⁽¹⁾

Solvent	Solubility at 20°C unless otherwise stated
Water	1 in 0.67
	1 in 0.48 at 40°C
	1 in 0.33 at 60°C
	1 in 0.22 at 80°C
	1 in 0.18 at 90°C

Table III: Viscosity (dynamic) of maltitol (*Maltisorb*) aqueous solutions at 20°C. ⁽¹⁾

Concentration of aqueous maltitol solution (% w/v)	Viscosity (mPa s)
10	8
20	10
30	11
40	15
50	24
60	70

11 Stability and Storage Conditions

Maltitol has good thermal and chemical stability. When it is heated at temperatures above 200°C, decomposition begins (depending on time, temperature, and other prevailing conditions). Maltitol does not undergo browning reactions with amino acids, and absorbs atmospheric moisture only at relative humidities of 89% and above, at 20°C.

12 Incompatibilities

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13 Method of Manufacture

Maltitol is obtained from hydrogenated maltose syrup. Starch is hydrolyzed to yield a high-concentration maltose syrup, which is hydrogenated with a catalyst. After purification and concentration, the syrup is crystallized.

14 Safety

Maltitol is used in oral pharmaceutical formulations, confectionery, and food products and is considered to be noncarcinogenic. It is generally regarded as a nontoxic, nonallergenic, and nonirritant material.

Digestion of maltitol follows two different metabolic pathways: absorption in the small intestine and fermentation in the large intestine (colon). These two metabolic pathways must thus be considered when evaluating the energy value.

The hydrolysis of maltitol in the small intestine releases sorbitol and glucose. Glucose is actively transported and rapidly absorbed, whereas sorbitol absorption is passive. The nonabsorbed sorbitol and nonhydrolyzed maltitol are fermented by the microflora in the colon. The relative importance of the two absorption pathways depends on numerous individual factors and is related to the quantity of maltitol ingested. Excessive oral consumption (>50 g daily) may cause flatulence and diarrhea.

Maltitol exhibits a low glycemic index and can therefore, under medical supervision, have a place in the diet of diabetic patients. The intake of maltitol must be taken into account for the calculation of the daily glucidic allowance.

The WHO in considering the safety of maltitol 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.^(2,3)

15 Handling Precautions

Observe normal precautions appropriate to circumstances and quantity of material handled. Eye protection and gloves are recommended.

16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in oral pharmaceutical formulations.

17 Related Substances

Maltitol solution.

18 Comments

Maltitol is not fermented by oral bacteria and is neither acidogenic nor cariogenic. The EINECS number for maltitol is 209-567-0.

19 Specific References

- 1 Roquette Frères. Technical literature: *Maltisorb* crystalline maltitol, 1999.
- 2 FAO/WHO. Evaluation of certain food additives and contaminants. Thirty-third report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1989; No. 776.
- 3 FAO/WHO. Evaluation of certain food additives and contaminants. Forty-sixth report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1997; No. 868.

20 General References

- Moskowitz AH. Maltitol and hydrogenated starch hydrolysate. In: Nabors LO, Gelardi RC, eds. *Alternative Sweeteners*, 2nd edn. New York: Marcel Dekker, 1991: 259-282.
- Portman MO, Kilcast D. Psycho-physical characterization of new sweeteners of commercial importance for the EC food industry. *Food Chem.* 1996; 56(3): 291-302.

21 Author

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22 Date of Revision

1 October 2002.