

# Maltose

## 1 Nonproprietary Names

JP: Maltose

## 2 Synonyms

*Advantose 100*; 4-O- $\alpha$ -D-glucopyranosyl- $\beta$ -D-glucose; 4-( $\alpha$ -D-glucosido)-D-glucose; malt sugar; maltobiose.

## 3 Chemical Name and CAS Registry Number

4-O- $\alpha$ -D-Glucopyranosyl- $\beta$ -D-glucopyranose      anhydrous  
[69-79-4]

4-O- $\alpha$ -D-Glucopyranosyl- $\beta$ -D-glucopyranose monohydrate  
[6363-53-7]

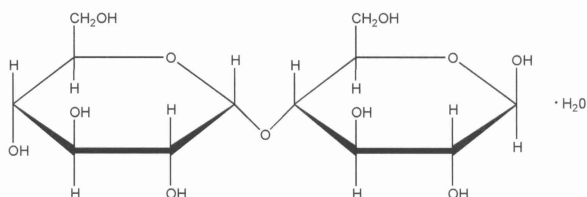
## 4 Empirical Formula

$C_{12}H_{22}O_{11}$   
 $C_{12}H_{22}O_{11} \cdot H_2O$

## Molecular Weight

342.31 (anhydrous)  
360.31 (monohydrate)

## 5 Structural Formula



## 6 Functional Category

Sweetening agent; tablet diluent.

## 7 Applications in Pharmaceutical Formulation or Technology

Maltose is a disaccharide carbohydrate widely used in foods and pharmaceuticals. In parenteral products, maltose may be used as a source of sugar, particularly for diabetic patients.

Crystalline maltose is used as a direct-compression tablet excipient in chewable and nonchewable tablets.<sup>(1-3)</sup>

## 8 Description

Maltose occurs as white crystals or as a crystalline powder. It is odorless and has a sweet taste approximately 30% that of sucrose.

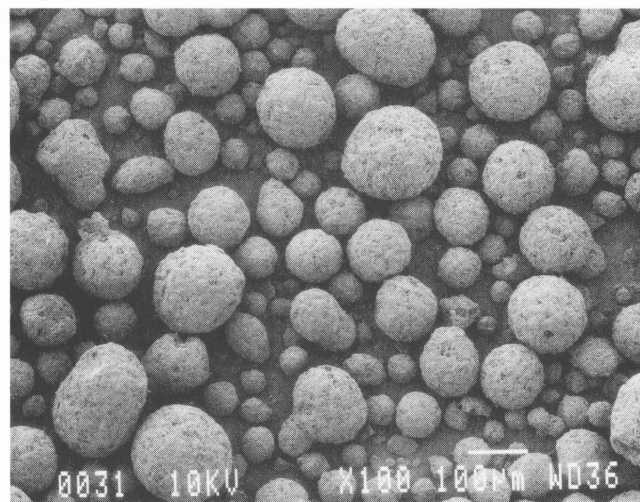
## SEM: 1

*Excipient*: Crystalline maltose

*Manufacturer*: SPI Pharma Group

*Lot No.*: 8K110947

*Magnification*: 100 $\times$



## 9 Pharmacopeial Specifications

See Table I.

**Table I:** Pharmacopeial specifications for maltose.

Test	JP 2001
Identification	+
Specific rotation	+126° to +131°
pH (10% w/v aqueous solution)	4.5–6.5
Clarity and color of solution	+
Chloride	≤0.018%
Sulfate	≤0.024%
Heavy metals	≤4 ppm
Arsenic	≤1.3 ppm
Dextrin, soluble starch and sulfite	+
Nitrogen	≤0.01%
Related substances	+
Loss on drying	≤0.5%
Residue on ignition	≤0.10%
Assay (dried basis)	≥98.0%

## 10 Typical Properties

**Acidity/alkalinity:** pH = 4.5–6.5 for a 10% w/v aqueous solution.

**Angle of repose:** 37.1° for *Advantose 100*.<sup>(3)</sup>

**Density (bulk):** 0.67–0.72 g/cm<sup>3</sup> for *Advantose 100*.<sup>(1)</sup>

**Density (tapped):** 0.73–0.81 g/cm<sup>3</sup> for *Advantose 100*.<sup>(1)</sup>

**Dissociation constant:** pK<sub>a</sub> = 12.05 at 21°C

**Flash point:** >149°C for *Advantose 100*.<sup>(1)</sup>

**Flowability:** 18% (Carr compressibility index) for *Advantose 100*.<sup>(3)</sup>

**Melting point:** 102–103°C with decomposition.

**Particle size distribution:** 15–20% greater than 300 µm, and 70–75% greater than 150 µm in size for *Advantose 100*.<sup>(1)</sup>

**Specific surface area:** 0.08 m<sup>2</sup>/g for *Advantose 100*.<sup>(1)</sup>

**Solubility:** very soluble in water; very slightly soluble in cold ethanol (95%); practically insoluble in ether.

## 11 Stability and Storage Conditions

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

## 12 Incompatibilities

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## 13 Method of Manufacture

Maltose monohydrate is prepared by the enzymatic degradation of starch.

## 14 Safety

Maltose is used in oral and parenteral pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material. However, there has been a single report of a liver transplantation patient with renal failure who developed hyponatremia following intravenous infusion of normal immunoglobulin in 10% maltose. The effect, which recurred on each of four successive infusions, resembled that of hyperglycemia and was thought to be due to accumulation of maltose and other osmotically active metabolites in the extracellular fluid.<sup>(4)</sup>

LD<sub>50</sub> (mouse, IV): 26.8 g/kg<sup>(5)</sup>

LD<sub>50</sub> (mouse, SC): 38.6 g/kg

LD<sub>50</sub> (rabbit, IV): 25.2 g/kg

LD<sub>50</sub> (rat, IP): 30.6 g/kg

LD<sub>50</sub> (rat, IV): 15.3 g/kg

LD<sub>50</sub> (rat, oral): 34.8 g/kg

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and rubber or plastic gloves are recommended. When heated to decomposition, maltose emits acrid smoke and irritating fumes.

## 16 Regulatory Status

In the USA, maltose is considered as a food by the FDA and is therefore not subject to food additive and GRAS regulations. Included in the FDA Inactive Ingredients Guide (oral solutions). Included in parenteral products available in a number of countries worldwide.

## 17 Related Substances

Glucose, liquid.

## 18 Comments

Crystalline maltose, e.g., *Advantose 100* (SPI Pharma Group), is spray-dried to produce spherical particles with good flow properties. The material is also nonhygroscopic and is highly compressible.

The EINECS number for maltose is 200-716-5.

## 19 Specific References

- 1 SPI Pharma Group. Technical literature: *Advantose 100 crystalline maltose*, 1997.
- 2 Bowe KE, Billig JL, Schwartz JB, *et al.* Crystalline maltose: a direct compression pharmaceutical excipient. *Pharm Technol Eur* 1998; 10(5): 34, 36, 37, 40.
- 3 Mulderrig KB. Placebo evaluation of selected sugar-based excipients in pharmaceutical and nutraceutical tableting. *Pharm Technol* 2000; 24(5): 34, 36, 38, 40, 42, 44.
- 4 Palevsky PM, Rendulic D, Diven WF. Maltose-induced hyponatremia. *Ann Intern Med* 1993; 118(7): 526–528.
- 5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 2274.

## 20 General References

Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory* 1996. Tokyo: Yakuji Nippo, 1996: 299.

## 21 Author

PJ Weller.

## 22 Date of Revision

1 October 2002.