

# Maltodextrin

## 1 Nonproprietary Names

BP: Maltodextrin  
PhEur: Maltodextrinum  
USPNF: Maltodextrin

## 2 Synonyms

*C\*Dry MD; Glucidex; Glucodry; Lycatab DSH; Maldex; Maltagran; Maltrin; Maltrin QD; Paselli MD10 PH; Star-Dri.*

## 3 Chemical Name and CAS Registry Number

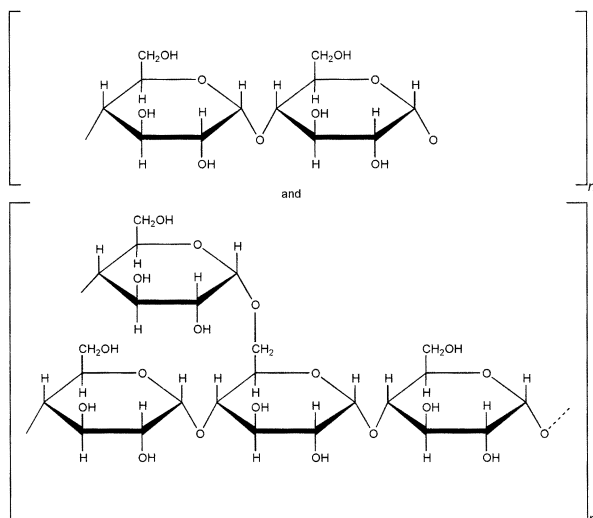
Maltodextrin [9050-36-6]

## 4 Empirical Formula Molecular Weight

$(C_6H_{10}O_5)_n \cdot H_2O$  900–9000

The USPNF 20 describes maltodextrin as a nonsweet, nutritive saccharide mixture of polymers that consist of D-glucose units, with a dextrose equivalent (DE) less than 20; see also Section 18. The D-glucose units are linked primarily by  $\alpha$ -(1→4) bonds but there are branched segments linked by  $\alpha$ -(1→6) bonds. It is prepared by the partial hydrolysis of a food-grade starch with suitable acids and/or enzymes.

## 5 Structural Formula



## 6 Functional Category

Coating agent; tablet and capsule diluent; tablet binder; viscosity-increasing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Maltodextrin is used in tablet formulations as a binder and diluent in both direct-compression and wet-granulation or

agglomeration processes.<sup>(1-7)</sup> Maltodextrin appears to have no adverse effect on the rate of dissolution of tablet and capsule formulations; magnesium stearate 0.5–1.0% may be used as a lubricant. Maltodextrin may also be used as a tablet film former in aqueous film-coating processes. Maltodextrin grades with a high DE value are particularly useful in chewable tablet formulations.

Maltodextrin may also be used in pharmaceutical formulations to increase the viscosity of solutions and to prevent the crystallization of syrups. Therapeutically, maltodextrin is often used as a carbohydrate source in oral nutritional supplements because solutions with a lower osmolarity than isocaloric dextrose solutions can be prepared. At body osmolarity, maltodextrin solutions provide a higher caloric density than sugars.

Maltodextrin is also widely used in confectionery and food products, as well as personal care applications. See Table I.

Table I: Uses of maltodextrin.

Use	Concentration (%)
Aqueous film-coating	2–10
Carrier	10–99
Crystallization inhibitor for lozenges and syrups	5–20
Osmolarity regulator for solutions	10–50
Spray-drying aid	20–80
Tablet binder (direct compression)	2–40
Tablet binder (wet granulation)	3–10

## 8 Description

Maltodextrin occurs as a nonsweet, odorless, white powder or granules. The solubility, hygroscopicity, sweetness, and compressibility of maltodextrin increase as the DE increases. It may be physically modified to improve its physical and functional characteristics.

## 9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for maltodextrin.

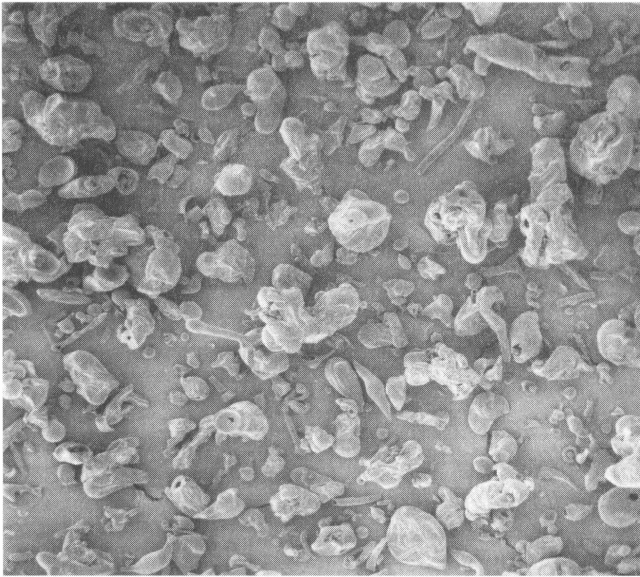
Test	PhEur 2002	USPNF 20
Identification	+	—
Characters	+	—
Microbial limits	+	+
pH (20% w/v solution)	4.0–7.0	4.0–7.0
Loss on drying	≤6.0%	≤6.0%
Residue on ignition	≤0.5%	≤0.5%
Heavy metals	≤10 ppm	≤5 ppm
Protein	—	≤0.1%
Sulfur dioxide	≤20 ppm	+
Dextrose equivalent	≤20	≤20

**SEM: 1**

*Excipient:* Maltodextrin (Maltrin M100)

*Manufacturer:* Grain Processing Corp.

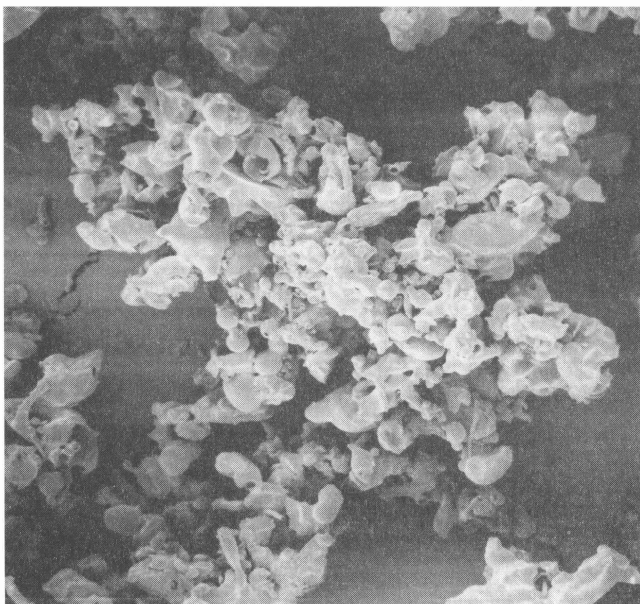
*Magnification:* 100 ×

**SEM: 2**

*Excipient:* Maltodextrin (Maltrin M500)

*Manufacturer:* Grain Processing Corp.

*Magnification:* 100 ×

**10 Typical Properties**

**Angle of repose:**

35.2° for *Maltrin M500*<sup>(5)</sup>

28.4° for *Maltrin M510*<sup>(5)</sup>

**Density (bulk):**

0.43 g/cm<sup>3</sup> for *Lycatab DSH*

0.26 g/cm<sup>3</sup> for *Maltrin QD M500*

0.51 g/cm<sup>3</sup> for *Maltrin M040*

0.54 g/cm<sup>3</sup> for *Maltrin M050*

0.54 g/cm<sup>3</sup> for *Maltrin M100*

0.57 g/cm<sup>3</sup> for *Maltrin M150*

0.61 g/cm<sup>3</sup> for *Maltrin M180*

0.30 g/cm<sup>3</sup> for *Maltrin M440*

0.34 g/cm<sup>3</sup> for *Maltrin M500*

0.56 g/cm<sup>3</sup> for *Maltrin M510*

0.35 g/cm<sup>3</sup> for *Maltrin M550*

0.37 g/cm<sup>3</sup> for *Maltrin QD M550*

0.40 g/cm<sup>3</sup> for *Maltrin M580*

0.13 g/cm<sup>3</sup> for *Maltrin M700*

**Density (tapped):**

0.63 g/cm<sup>3</sup> for *Lycatab DSH*

0.32 g/cm<sup>3</sup> for *Maltrin QD M500*

0.54 g/cm<sup>3</sup> for *Maltrin M510*<sup>(5)</sup>

**Density (true):**

1.419 g/cm<sup>3</sup>

1.334 g/cm<sup>3</sup> for Maltodextrin FCC

1.410 g/cm<sup>3</sup> for *Maltrin M500*

1.425 g/cm<sup>3</sup> for *Maltrin M510*

**Moisture content:** hygroscopicity increases as DE increases.

Maltodextrin is slightly hygroscopic at relative humidities less than 50%. At relative humidities greater than 50%, the hygroscopicity of maltodextrin increases nonlinearly.

**Particle size distribution:** *Maltrin* is available in various grades with different particle size distributions.

For *Lycatab DSH*: maximum of 15% greater than 200 μm, and minimum of 80% greater than 50 μm in size.

**Solubility:** freely soluble in water; slightly soluble in ethanol. Solubility increases as DE increases.

**Specific surface area:**

0.54 m<sup>2</sup>/g for *Maltrin QD M500*

0.31 m<sup>2</sup>/g for *Maltrin M510*<sup>(5)</sup>

**Viscosity (dynamic):** less than 20 mPa s (20 cP) for a 20% w/v aqueous solution of *Lycatab DSH*. The viscosity of maltodextrin solutions decreases as the DE increases.

Viscosity is 3.45 mPa s for a 20% w/v aqueous dispersion of *Star-Dri* (AE Staley Co.).

**11 Stability and Storage Conditions**

Maltodextrin is stable for at least 1 year when stored at a cool temperature (<30°C) and less than 50% relative humidity. Maltodextrin solutions may require the addition of an antimicrobial preservative.

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

**12 Incompatibilities**

Under certain pH and temperature conditions maltodextrin may undergo Maillard reactions with amino acids to produce yellowing or browning. Incompatible with strong oxidizing agents.

**13 Method of Manufacture**

Maltodextrin is prepared by heating and treating starch with acid and/or enzymes in the presence of water. This process partially hydrolyzes the starch, to produce a solution of glucose polymers of varying chain length. This solution is then filtered, concentrated, and dried to obtain maltodextrin.

**14 Safety**

Maltodextrin is a readily digestible carbohydrate with a nutritional value of approximately 17 kJ/g (4 kcal/g). In the USA, it is generally recognized as safe (GRAS) as a direct human food ingredient at levels consistent with current good manufacturing practices. As an excipient, maltodextrin is generally regarded as a nonirritant and nontoxic material.

**15 Handling Precautions**

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection is recommended. Maltodextrin should be handled in a well-ventilated environment and excessive dust generation should be avoided.

**16 Regulatory Status**

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral tablets and granules). Included in nonparenteral medicines licensed in the UK.

**17 Related Substances**

Corn syrup solids; dextrans; dextrin; starch.

**Corn syrup solids**

**Comments:** corn syrup solids are glucose polymers with a DE  $\geq 20$  and are prepared, in a similar manner to maltodextrin, by the partial hydrolysis of starch.

**18 Comments**

Various different grades of maltodextrin are commercially available for food and pharmaceutical applications from a number of suppliers: e.g., *Lycatab DSH* (Roquette Frères), *Maltrin* (Grain Processing Corp.) and *Star-Dri* (AE Staley Co.). The grades have different physical properties such as solubility and viscosity, depending upon their DE value. The dextrose equivalent (DE) value is a measure of the extent of starch-polymer hydrolysis and is defined as the reducing power of a substance expressed in grams of D-glucose per 100 g of the dry substance.

The EINECS number for maltodextrin is 232-940-4.

**19 Specific References**

- 1 Li LC, Peck GE. The effect of moisture content on the compression properties of maltodextrins. *J Pharm Pharmacol* 1990; **42**(4): 272–275.
- 2 Li LC, Peck GE. The effect of agglomeration methods on the micrometric properties of a maltodextrin product *Maltrin 150*. *Drug Dev Ind Pharm* 1990; **16**: 1491–1503.
- 3 Papadimitriou E, Efentakis M, Choulis NH. Evaluation of maltodextrins as excipients for direct compression tablets and their influence on the rate of dissolution. *Int J Pharm* 1992; **86**: 131–136.
- 4 Visavarungroj N, Remon JP. Evaluation of maltodextrin as binding agent. *Drug Dev Ind Pharm* 1992; **18**: 1691–1700.
- 5 Mollan MJ, Çelik M. Characterization of directly compressible maltodextrins manufactured by three different processes. *Drug Dev Ind Pharm* 1993; **19**: 2335–2358.
- 6 Muñoz-Ruiz A, Monedero Perales MC, Velasco Antequera MV, Jiménez-Castellanos MR. Physical and rheological properties of raw materials. *STP Pharma (Sci)* 1993; **3**: 307–312.
- 7 Symecko CW, Romero AJ, Rhodes CT. Comparative evaluation of two pharmaceutical binders in the wet granulation of hydrochlorothiazide: Lycatab DSH vs. Kollidon 30. *Drug Dev Ind Pharm* 1993; **19**: 1131–1141.

**20 General References**

- Grain Processing Corporation. Technical literature: *Maltrin maltodextrins and corn syrup solids for pharmaceuticals*, 1998.
- Roquette Frères. Technical literature: *Lycatab DSH excipient for wet granulation*, 1992.
- Shah A, Buckton G, Booth S. Characterisation of maltodextrins using isothermal microcalorimetry. *J Pharm Pharmacol* 2000; **52**(Suppl.): 183.

**21 Authors**

SO Freers, S Neves.

**22 Date of Revision**

18 October 2002.