# SOLBIOTE<sup>TM</sup> TREHALOSE SG

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### Bringing Sustainable Solutions to Biopharmaceuticals

Our high-purity and low-endotoxin saccharide products provide you solutions for biologics, vaccines, and cell-based therapeutics development.

Discover our philosophy: Pharmaceutical Ingredients x Sustainability

> PLATINUM Top 1% ecovadis Sustainability Rating MAR 2024



### Achieving equitable well-being for all; no one shall be left behind

We are dedicated to the sustainable production of life-changing excipients, SOLBIOTE<sup>™</sup>, to create a prosperous future for both people and the planet. We aspire to go beyond simply providing pharmaceutical solutions to deliver universal health; we ensure equitable access to quality healthcare for all.

Product inquiries to:

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Nagase & Co., Ltd.

Life & Healthcare Products Department dnfct@ex.nagase.co.jp





# Injectable Grade of Maltose

### General

Maltose is a reducing disaccharide consisting of two glucose molecules linked by an  $\alpha$ -1,4 bond. Maltose is manufactured from starch using enzyme technology.

Historically maltose has been a common disaccharide consumed by humans when assimilated into the body from consuming carbohydrate based foods. More recently, maltose has been used as an excipient for tablets and granulation, and as a carbon source in cell culture medium.

MALTOSE PH is highly purified crystalline maltose monohydrate, and has low endotoxin.

MALTOSE PH is intended for injection and intravenous fluid as energy source etc.

Chemical formula:  $C_{12}H_{22}O_{11} \cdot H_2O$ Molecular weight: 360.31 CAS RN®: 6363-53-7

#### Properties

- High purity maltose
- Low endotoxin level guaranteed
- Good water solubility (61.9 g/100 g-H<sub>2</sub>0  $\cdot$  20°C)
- Relatively compatible with oils
- The surface tension of a 1% solution is almost the same value as pure water.
- Because it is highly purified, maltose can be used for injection, as an excipient for solid, inhalation and topical formulations, and as a reagent.



### Scientific reports

Maltose has been studied and reported also in various non-pharmaceutical applications.

Purpose	Title	Reference	
Growth inducer of culture embryo	Breeding of new citrus cultivars by Embryo culture (No.1) Effect of saccharides on embryo growth <i>in vitro</i> .	Bulletin of the Agricultural Research Institute of Kanagawa Prefecture,133, 75-81 (1991)	
Growth inducer of culture plant microspore	Formation of Calli from Isolated Microspore Cultures of Asiatic Hybrid Lily 'Connecticut King'	Journal of the Japanese Society for Horticultural Science, 69(1), 52-56 (2000)	
Growth inducer of culture leaf disc	Effects of Sugar on callus and organ formation from leaf segments of Chrysanthemum	Plant Tissue Culture Letters, 3(2), 71-77 (1986)	
Growth inducer of culture wheat anther	An efficient anther culture method for obtaining a higher frequency of pollen embryos in <i>Triticum aestivum</i> L.	Bullentin of the RIAR, Ishikawa Agricultural College, 3, 19-25 (1993)	
Growth inducer of culture rice anther	Improvement of medium and the use in rice anther culture	Bull. Tokushima. Pref. Agri. Res. Ins., 3, 31-38 (2006)	
Improver of productivity of actives from culture cells	Intermittent maltose feeding enhances pacilitaxel production in suspension culture of Taxus chinensis cells.	Biotechnol Lett., 22, 22, 1793-1796 (2000)	

### Packaging

25 kg (PE bag in carton box)

MANUFACTURER : Nagase Viita Co., Ltd. CONTACT : Nagase & Co., Ltd.

Life & Healthcare Products Department E-mail: dnfct@ex.nagase.co.jp

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## \land Nagase Viita

# For Culture Media

### What is MALTOSE PH ?

- Maltose is a reducing disaccharide consisting of two glucose molecules linked by an α-1,4 bond
- Maltose is manufactured from starch by enzyme technology
- MALTOSE PH is highly purified crystalline maltose monohydrate with low endotoxin



#### Effect of MALTOSE PH supplementation on antibody production by CHO cell

#### Methods

- CHO-K1 cells were inoculated at 0.3 × 10<sup>6</sup> cells/mL in duplicates in a DMEM/F12-based protein free chemically defined medium (PFCDM) supplemented with 2 g/L D-(+)-glucose, or glucose with an additional 10 g/L MALTOSE PH in single-use Erlenmeyer flasks.
- The cultures were incubated in a humidified incubator at 37°C, 8% CO<sub>2</sub> and a rotation speed of 110 rpm. Cell culture supernatants were collected daily on days 0-5 and 7, and monoclonal IgG antibody (anti-Her2) titers were determined by nephelometry using IMMAGE 800 (Beckman Coulter).



#### Results

- Two g/L of glucose was chosen as the base glucose concentration because this will allow for a premature but controlled cell growth constraint due to glucose depletion on Day 4.
- IgG titer reached a maximum of 340 mg/L on Day 5 in the culture containing 2 g/L glucose as a carbon source.
- IgG production continued in the MALTOSE PH supplemented cultures Days 5 through 7 to reach 600 mg/L.

### Effect of MALTOSE PH supplementation on cell viability and viable density

#### Methods

- The CHO-K1 cells were inoculated and cultured as described in the previous experiment.
- Viable cell density (VCD) and culture viability were analyzed by Vi-Cell XR Cell Viability Analyzer (Beckman Coulter, Brea, CA) according to manufacturer's instructions.



#### Results

- Growth of CHO-K1 cells reached a maximum viable cell density (VCD) of 8.9 × 10<sup>6</sup> cells/mL on Day 5 when cultured using 2 g/L glucose.
- MALTOSE PH supplemented cultures attained a higher maximum VCD of 10.2 × 10<sup>6</sup> cells/mL and longer culture viability compared to the culture containing only 2 g/L glucose.

All the data were provided by Dr. Say Kong Ng of Bioprocessing Technology Institute (BTI)

#### Summary

- MALTOSE PH can be used by the CHO-K1 cells as a carbon source to maintain culture viability and IgG production upon glucose depletion.
- MALTOSE PH supplementation to the CHO-K1 cell culture in addition to glucose increased the IgG titer compared to the culture with only glucose as a carbon source.
- MALTOSE PH supplementation along with glucose improved the growth of CHO-K1 cell compared to the culture without MALTOSE PH supplementation.
- It demonstrates that MALTOSE PH can effectively improve the productivity of antibody when used to supplement glucose as a carbon source.

#### Reference

Application of maltose as energy source in protein-free CHO-K1 culture to improve the production of recombinant monoclonal antibody. Leong DSZ *et al.* Sci Rep. 2018 Mar 6;8(1):4037.

#### **Product Information**

#### HIGH PURITY MALTOSE

Product Name	Purity/Other	Packaging	Regulatory Approval	Others
MALTOSE PH	Not less than 98.0% /Low Endotoxin	25kg PE bag in a carton box	• JP • CP	<ul> <li>US Type II DMF</li> <li>China DMF</li> <li>Kosher, Halal</li> </ul>

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