

# SOLBIOTE™

Bringing Sustainable Solutions  
to Biopharmaceuticals



Nagase Viita, the first company in the world to mass produce Trehalose, has launched a new product brand SOLBIOTE™. This brand features high-purity, low-endotoxin Trehalose (TREHALOSE SG) and Maltose (MALTOSE PH) saccharide-based pharmaceutical excipients. Nagase Viita confidently offers a stable supply of SOLBIOTE™ as an integrated manufacturer of the Trehalose and Maltose, guaranteeing exceptional quality.



## Achieving Equitable Well-Being for All

### SOLBIOTE™ Commitment:

- Stability solutions
- Excellent quality
- Sustainable manufacturing and stable supply

### Stability Solutions:

- ✓ SOLBIOTE™ is an excellent protein stabilizer
- ✓ Protects cells, nucleotides, and exosomes against damage from drying, freezing, and thawing
- ✓ Preserves the quality of antibody therapeutics and vaccines during storage and distribution



### Exceptional quality:

- ✓ High-purity and low-endotoxin
- ✓ Comply with the global regulatory requirements of the pharmaceutical industry
- ✓ Achieve superior quality with our extensive knowledge and expertise in saccharide production

### TREHALOSE SG

- Highly purified trehalose dihydrate crystalline with a low endotoxin specification
- Does not participate in the Maillard reaction
- Remarkable heat and acid resistant
- High in glass transition temperature ( $T_g$ ,  $T'_g$ )

#### Applications

- Stabilization of antibodies, peptides, and vaccines for injection
- Stabilization of exosomes
- Additive for culture medium (e.g., stem cells)
- Preservation of platelets

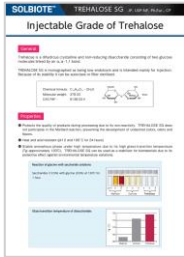
### MALTOSE PH

- Highly purified maltose monohydrate crystalline with a low endotoxin specification
- Good water solubility
- Compatible with oils

#### Applications

- Active ingredient for infusion fluid
- Solubility enhancer and stabilizer of freeze-dried anti-cancer agents for injection
- Stabilizer of Immunoglobulins
- Carbon source of culture medium

Related brochures are available to download



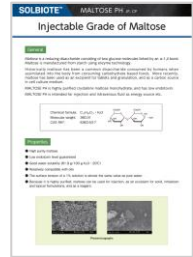
*Injectible Grade of  
TREHALOSE SG*



*TREHALOSE SG  
For Antibody  
Purification Use*



*TREHALOSE SG  
For Exosome  
Production and Storage*



*Injectible Grade of  
MALTOSE PH*

Grade		Injection Grade	
Product Name		<b>TREHALOSE SG</b>	<b>MALTOSE PH</b>
Purity		<b>≥99.0% (Trehalose)</b>	<b>≥98.0% (Maltose)</b>
Endotoxin		<b>&lt;0.3 EU/g</b>	<b>&lt;0.6 EU/g</b>
Regulatory Approval	JP	✓	✓
	USP-NF	✓	
	Ph. Eur.	✓	
	CP	✓	✓
	US DMF	<b>Type IV</b>	<b>Type II</b>
	China DMF	<b>F20170000105 (A)</b>	<b>F20200000041 (I)</b>
Other	Kosher	✓	✓
	Halal	✓	✓

### Sustainable manufacturing and stable supply:

- ✓ Utilize starch and enzymes derived from soil microorganisms
- ✓ Trehalose dihydrate crystalline and maltose monohydrate crystalline are highly purified with a low endotoxin specification
- ✓ No solvents listed in ICH Q3C Class 1, 2 or 3 are used through manufacturing processes
- ✓ Our integrated manufacturing process ensures exceptional quality control and a stable supply by overseeing the procurement of raw materials, to saccharide production and purification in our factory in Japan.

#### Procurement of raw materials and resources



Our commitment to responsible procurement ensures raw materials (e.g. starch) are obtained without deforestation or human rights violations.

#### Environmentally friendly saccharide production



Utilizing starch and enzymes, Trehalose and Maltose are produced efficiently through strategic inventory management and manufacturing planning; minimize waste and CO<sub>2</sub> emissions, and preserve water resources.

#### Purification and recrystallization



Process of purification and recrystallization to produce highly purified Trehalose and Maltose with a low endotoxin specification.



For our dedication to sustainable manufacturing, human rights, and procurement, we have been awarded a Platinum rating by EcoVadis, a sustainability survey organization in France covering over 180 countries. Platinum is the highest rank, given to the top 1% of over 130,000 companies assessed.

We sincerely continue to commit sustainability and social responsibilities towards a better future of the people and the Earth.