



# Product Specification

Product group: Biopharma  
 Brand name: BioHale® Trehalose Dihydrate  
 Article code: SAP 1182228, 1181599  
 Product descriptions: Trehalose Dihydrate  
 low endotoxin grade  
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**Product name:** BioHale® Trehalose Dihydrate high purity, low endotoxin grade.  
 Conforms to Ph. Eur., USP-NF, JP, ChP monographs on the date of manufacture  
**Product description:** Appearance: White or almost white crystals or crystalline powder. Sweet taste.  
**Residual solvents:** (CPMP/ICH/283/9): The products are produced without the use of Class 1 and Class 2 organic solvents per ICH Q3C. Class 3 solvent (Acetone) is quantitated to level well below ICH requirements.  
**Solubility:** Freely soluble in water, slightly soluble in Methanol, practically insoluble in Ethanol.

<u>Test</u>	<u>Specification</u>
Identification (IR)	Conforms to standard
Identification (Naphtol)	Complies
Identification (Glycin)	Complies
Identification (HPLC)	Complies
Reducing sugars	≤ 0.1 %
Appearance of solution	Clear, colorless
Color of solution	A <sub>720</sub> ≤ 0.033, A <sub>420</sub> -A <sub>720</sub> ≤ 0.067 (in 10 cm cuvette)
pH	4.5 to 6.5
Specific optical rotation	+197° to +201°
Assay (HPLC)	98.0 - 101.0 % (anhydrous basis)
Impurity A (+ D Glucopyranose (Glucose))	≤ 0.5 %
Impurity B (Oligosaccharides)	≤ 0.5 %
Each unspecified Impurity	≤ 0.2 %
Total Impurities	≤ 0.5% (for RRT<1.0) and ≤ 0.5% (for RRT>1.0)
Total Impurities	≤ 1.0% for total
Chlorides	≤ 125 ppm
Sulfates	≤ 200 ppm
Soluble Starch	Complies
Water content (KF)	9.0 - 11.0 %
Residual solvent Acetone	≤ 900 ppm
Sulfated Ash/Residue on Ignition	≤ 0.1 %
Total Nitrogen	≤ 0.005 %
Total Aerobic Microbial Count	≤ 50 CFU/g



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Total Yeasts and Mold Count	≤ 10 CFU/g
E.coli	Absent in 10 g
Salmonella	Absent in 10 g
Staphylococcus aureus	Absent in 10 g
Pseudomonas aeruginosa	Absent in 10 g
Bacterial Endotoxins (EU/g)	≤ 0.3 EU/g
Elemental Impurities	Complies when tested
Arsenic (inorganic)	Complies when tested
Heavy Metals	≤ 5 ppm
Iron	≤ 5 ppm

**Packaging:** HDPE drum with a PE inner liner, 20Kg and 1 Kg net

**Storage:** Keep in original, unopened packing and away from strongly odorous materials  
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

This document substitutes all previous versions issued for the brand names mentioned above.  
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

**Name** : Sander van Gessel  
**Job Title** : Director ITS  
**Signature** :

A blue ink facsimile signature of Sander van Gessel, consisting of several overlapping, stylized strokes.

This document is controlled by a validated, electronic system and is valid without signature.  
The above facsimile signature is only for display.