

Product group: Biopharma  
 Brand name: BioHale® Sucrose  
 Article code: SAP 1178771, 1182224  
 Product descriptions: Sucrose low endotoxin grade  
 Document No.: PD-0814      Page 1 of 2

**Product name:** BioHale® Sucrose high purity, low endotoxin grade  
 Conforms to Ph. Eur., USP-NF, JP, ChP Specifications on the date of manufacture  
**Product description:** White or almost white, crystalline powder, or lustrous, colorless or white or almost white crystals. Odorless, sweet taste.  
**Residual solvents:** (CPMP/ICH/283/9): The products are produced without the use of Class 1 organic solvents per ICH Q3C. Class 2 solvent (Methanol) and Class 3 solvent (Acetone) are quantitated to level well below ICH requirements.  
**Solubility:** Very soluble in water, slightly soluble in Ethanol, practically insoluble in anhydrous Ethanol.

<u>Test</u>	<u>Specification</u>
Identification (IR)	Conforms to standard
Identification (Cupric tartrate)	Complies
Clarity of solution	Clear
Color value	≤ 10
Color value	≤ Y4
Conductivity	≤ 5 µs/cm
Specific optical rotation	66.3 to 67.0
Dextrins	Complies
Reducing sugars	≤ 0.07%
Reducing sugars	Complies
Sulfites	≤ 10 ppm
Sulfate	≤ 60 ppm
Residue on Ignition	≤ 0.05 %
Calcium	≤ 0.03 %
Heavy metals	≤ 5 ppm
Loss on drying	≤ 0.1 %
Residual solvent Methanol	≤ 300 ppm
Residual solvent Acetone	≤ 900 ppm
Total Aerobic Microbial Count	≤ 10 CFU/g
Total Yeasts and Mold Count	≤ 10 CFU/g
Staphylococcus aureus	Absent in 10 g
Salmonella	Absent in 10 g
E. coli	Absent in 10 g
Pseudomonas Aeruginosa	Absent in 10 g
Bacterial Endotoxins (EU/g)	≤ 0.25 EU/g
Assay	98.0-102.0%

Identification (IR)  
 Identification (Cupric tartrate)  
 Clarity of solution  
 Color value  
 Color value  
 Conductivity  
 Specific optical rotation  
 Dextrins  
 Reducing sugars  
 Reducing sugars  
 Sulfites  
 Sulfate  
 Residue on Ignition  
 Calcium  
 Heavy metals  
 Loss on drying  
 Residual solvent Methanol  
 Residual solvent Acetone  
 Total Aerobic Microbial Count  
 Total Yeasts and Mold Count  
 Staphylococcus aureus  
 Salmonella  
 E. coli  
 Pseudomonas Aeruginosa  
 Bacterial Endotoxins (EU/g)  
 Assay



## Product Specification

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Individual known Impurity (Raffinose/ Theanderose, Glucose, Fructose)	≤ 0.2%
Unknown Impurities	≤ 0.1%
Total Impurities	≤ 2.0%
Elemental Impurities	Complies

**Packaging:** HDPE drum with a PE inner liner, 20kg net/1kg 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:** Bastiaan Dickhoff  
**Job title:** ITS Director

This document is controlled by a validated, electronic system and is valid without signature.