Product Specification

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

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.

Test	Specification
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	≤ 10ppm
Sulfate	≤ 60ppm
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%

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Release date: 03-12-2024

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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

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