

## **Product Specification**

Product group: Biopharma

Brand name: BioHale® Sucrose

Article code: SAP 1178771, 1182224

Product descriptions: Sucrose low endotoxin grade

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**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 ≤ 0.07% Reducing sugars Reducing sugars Complies Sulfites ≤ 10ppm Sulfate ≤ 6oppm 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/q Total Yeasts and Mold Count ≤ 10 CFU/q Staphylococcus aureus Absent in 10 g Salmonella Absent in 10 q E. coli Absent in 10 q Pseudomonas Aeruginosa Absent in 10 g Bacterial Endotoxins (EU/g) ≤ 0.25 EU/g 98.0-102.0% Assay

DFE Pharma GmbH & Co. KG



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Individual known Impurity (Raffinose/ Theanderose,

Glucose, Fructose)  $\leq 0.2\%$ Unknown Impurities  $\leq 0.1\%$   $\leq 2.0\%$ 

**Total Impurities** 

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.

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Job title: ITS Director

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