

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 | ≤ Y ₄ |
| 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% |

DFE Pharma GmbH & Co. KG

Kleiver Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 06-06-2026; 15:15 UTC

Release date: 03-12-2024

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

| | |
|--|----------|
| Individual known Impurity (Raffinose/ Theanderose, Glucose, Fructose) | ≤ 0.2% |
| Unknown Impurities | ≤ 0.1% |
| | ≤ 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.

Name: Bastiaan Dickhoff
Job title: ITS Director

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