

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<br>≤ 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<br>Complies when tested |
| Elemental Impurities        |                                    |
| 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:** Frank Fox  
**Job title:** Global Category Director

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