BSE/TSE – Statement

Product group:	Biopharma
Brand name:	BioHale® Sucrose, Trehalose
Document No.:	PD-0815 Page 1 of 1

Dear Customer,

We herewith certify that BioHale® Sucrose and Trehalose do not fall into the scope of the requirements laid down in Note for Guidance EMA/410/01 rev 3.
Sucrose and Trehalose are manufactured exclusively from non-animal derived substances and there is no risk of contamination with any animal derived substance. Also these materials are not put in contact with a product of animal origin at any point of production and packaging.

This statement 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.

With kindest regards,

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG
Klever 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: 16-11-2026; 10:52 UTC

Release date: 15-01-2021