

BSE/TSE - Statement

Product group:

Biopharma

Brand name:

BioHale® Sucrose,

Trehalose

Document No.:

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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.