Residual Solvents-Statement

Product group: Biopharma
Brand name: BioHale® Sucrose
Document No.: PD-0818

Dear Customer,

Herewith we certify the following:

For manufacturing of our products BioHale® Sucrose no other solvents than purified water, methanol and acetone are used.

This is certified with reference to the solvents listed in ICH guidance Q3C <Residual Solvents>, USP general chapter <467> as well as any other non-ICH solvents in the raw materials, manufacturing process and product.

Acetone is classified as a Class 3 solvent with low toxic potential (5000 ppm limit), whereas methanol is classified as a Class 2 solvent (Option 1 limit 3000 ppm).

Methanol and Acetone are fully removed from the product through evaporation during the process, and the absence of those solvents in the finished product is tested against the specified max. residue (max. 300 ppm for methanol and max. 900 ppm for acetone) in each individual batch. These results are reported on each Certificate of Analysis for every batch produced.

No other Class 1, Class 2 (other than methanol) and Class 3 (other than acetone) solvents are likely to be present in BioHale® Sucrose.

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 : MAJ Nijman
Job title : Global Quality Director
Signature :

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