

Raw Material of Animal Origin
Statement on BSE/TSE
Liquid Handling Products

Sartorius Liquid Handling declares that Sartorius Pipette tips, are considered free of BSE/TSE transmission. We declare that our products do not come in contact or are exposed to any animal derived materials during manufacturing or processing at Sartorius Biohit Liquid Handling Oy.

As tallow derived additives may be used in the manufacture of the raw material of Sartorius tips, the elimination of the risk of Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow" is certified based on the manufacturing process of the raw material.

The tallow derivatives used for the production of the plastic materials undergo a series of severe process steps during manufacture:

- Normally, pre-treatment of tallow and/or animal fat with strong acids
- Hydrolytic cleavage at temperatures above 200°C, under pressure, for more than 20 minutes
- Transesterification of the fatty acids with methanol at temperatures above 200°C, under pressure, for more than 20 minutes
- Reduction of fatty acid methyl esters with hydrogen at temperatures above 200°C, under high pressure, for more than 20 minutes

According to the revised opinion of the EU Scientific Steering Committee on the Safety of Tallow (June 2001) and the recommendation for inactivation of TSE included (among others) in the Commission Directive 2000/6/EC, in the report of APAG of April 2001 and also in the Regulation (EC) N.1774/2002, the above-mentioned treatments do ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material.

The additional exposure of the plastic materials to temperatures ranging from 150°C to 300°C during 30 seconds up to several minutes, represents an additional safety factor ensuring the complete protection in respect of TSE/BSE for plastic materials.

Thus, tallow derived materials used in the raw material of the products fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3". Sartorius suppliers declare that the tallow derivatives are Category 3 materials and are manufactured under conditions given in the aforementioned Note for Guidance.

Signed:  Date: 17th January 2019

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