



Biotage GB Limited
Dyffryn Business Park
Ystrad Mynach
Hengoed
Mid Glamorgan CF82 7TS
UK
Tel: +44 1443 811811
Fax: +44 1443 815660
Website: www.biotage.com

Transmissible Spongiform Encephalopathy (TSE)

Biotage GB Limited can confirm that all polystyrene backbone resin materials and silica based products are produced from either petroleum – based chemicals or inorganic salts. Raw materials are traceable and do not contain materials of animal or biological origin. Ancillary chemicals used in production processes do not contain materials of animal or biological origin.

We therefore have every reason to expect that resin materials do not contain Transmissible Spongiform Encephalopathy, however, this has not been confirmed by analysis or testing.

Tallow derived additives may be used in the manufacture of columns, cartridges, wells, and well plates however materials do not contain latex, gluten or lactose. Biotage processes do not latex, gluten or lactose.

STATEMENT ON THE USE OF TALLOW DERIVATIVES FOR FOOD CONTACT PLASTICS (AS AGREED UPON BY APME (NOW PIEUR) MEMBER COMPANIES)

The concerns relative to BSE/TSE in the context of plastics materials used in contact with food are linked to the use of additives of animal origin: tallow derivatives. These products (fatty acids, fatty alcohols, metallic soaps, fatty amides, fatty acid esters, glycerine) are incorporated into plastics as lubricants, slip agents, anti – static agents as well as emulsifiers, anti – oxidants or corrosion inhibitors. They are primarily extracted from tissues of ovine or bovine origin. The tallow derivatives used for the production of our plastics materials undergo a series of severe process steps during manufacture:

Normally, pre – treatment of tallow and/or animal fats with strong acids.

Hydrolytic cleavage at temperatures above 200°C, under pressure, for more than 20 minutes, yielding glycerine and fatty acids

Transesterification of the fatty acids with methanol at temperatures above 200°C, under pressure, for more than 20 minutes, yielding fatty acid methyl ester

Reduction of fatty acid methyl esters with hydrogen at temperatures above 200°C, under pressure, for more than 20 minutes, yielding fatty alcohols

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 200/6/EC, in the updated report of APAG of April 2001 and also in Regulation (EC) N.1774/2002, the above – mentioned treatments do ensure complete inactivation of any TSE / BSE agent regardless of the source and type of the material. The additional exposure of the plastic materials to temperatures ranging from 150°C to 300°C during 30 seconds up to several minutes, both at the compounding step and in the final conversion process, represents an additional safety factor ensuring the complete protection of people's health in respect of TSE / BSE for plastic materials used in contact with food.

Our suppliers declare that the tallow derivatives are Category 3 materials and are manufactured under the conditions given in the Note for Guidance, LMEA/410/10, rev. 3, part 6.4 (Tallow Derivatives).

Revision 4
September 2019

Registered in England & Wales No. 1033865