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## **TSE/BSE STATEMENT For Buffers, Reagents, and Water**

### **Background:**

Transmissible spongiform encephalopathies (TSEs) and bovine spongiform encephalopathies, also known as prion diseases, are a group of progressive, incurable, and invariably fatal conditions that are associated with the degeneration of the nervous system in many animals, including humans, cattle, and sheep. TSE diseases are characterized by long incubation periods ranging from several months for TSE, to several years for BSE. During the incubation period there is no visible indication of the disease.

### **GeminiBio Statement:**

All components used during production have been evaluated to have been produced in a manner that Gemini Bioproducts, LLC would indicate that there is negligible risk for TSE/BSE contamination. The products made by GeminiBio do not contain, nor are they derived from, specified risk material as defined in Commission Decision EMA 410/01/rev. 3. Materials were sourced from vendors where the risk of TSE/BSE would be classified as negligible due to their composition or production methods.

There is a possibility that some materials used in the manufacturing process may come into contact with tallow. As tallow derived additives may be used in the manufacture of the raw material 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 high pressure, for more than 20 minutes
- Reduction of fatty acid methyl esters with hydrogen at temperatures above 200°C, under pressure for more than 20 minutes.

According to 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

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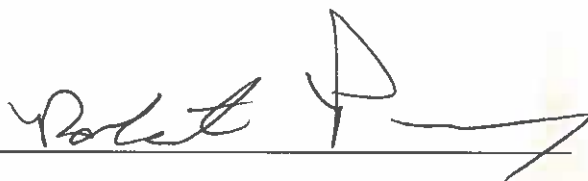


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exposure of the plastic materials to temperatures ranging from 150°C to 300°C during 30 seconds up to several minutes, represents an additional safety factor ensuring the complete protection in respect of TSE/BSE for plastic materials.

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 EMA/410/01, rev. 3". GeminiBio suppliers declare that the tallow derivatives are category 3 materials and are manufactured under conditions given in the aforementioned Note for Guidance.



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Chief Scientific Officer

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