

Cotia, January 06, 2016.

To: Genix Industria Farmacêutica Ltda.
Anápolis – GO.

AFFIRMATION OF GELATINE SAFETY: BSE / TSE

Dear Ladies and Gentlemen,

We would like to provide you with comprehensive information in respect of the BSE-safety of gelatine. In fact: Gelatine is safe and healthy.

The safety of gelatine is predominantly guaranteed by using carefully selected raw materials. Additionally, studies have proven that the manufacturing process is capable to inactivate TSE infectivity even in a very high dosage. But under normal circumstances, it is very unlikely that infectivity would enter the process at all.

1. Since the first outbreak of BSE in some European countries, the gelatine industry in general and GELITA AG in particular have conducted comprehensive tests and investigations on gelatine and gelatine hydrolysates with respect to their safety status. These activities have taken place in close cooperation with scientists of national and international health authorities and the relevant government departments.
Amongst others, the following authorities and institutes categorize gelatine as safe:
The Spongiform Encephalopathy Advisory Committee (SEAC) in the United Kingdom, the TSE Advisory Committee of the US Food and Drug Administration (TSEAC), the Federal Institute for Pharmaceuticals and Medicinal Products (BfArM) in Germany, the OIE (Office International des Epizooties), the World Health Organisation (WHO) and the Scientific Steering Committee (SSC) of the European Union.
2. By nature, the raw materials used for gelatine production (hides, hide splits and bones) are safe:
Only raw materials from healthy slaughtered animals, released for human consumption are used. International scientists and the WHO have classified cattle bone, hides, cartilage and connective tissue as category IV material, what means that no infectivity could be identified in these tissues. Thus, there is only the possibility of a surface contamination by BSE infectivity from infective central nervous tissue, just in the very rare case that an animal is infected, but not detected.
- 3. Also very stringent legal requirements have been put into effect to secure that only products with no likelihood regarding a risk of BSE-transmission are put on the market. In Brazil, a feeding ban for the importation, commercialization and the use of animal protein “in natura”, as well as the use of ruminant-based meat and bone meal was first implemented in 1996 (Ministerial Ordinance no. 365 of the Ministry of Agriculture) - later superseded by the Ordinance no. 290 of 16 July 1997, also superseded by the Normative Instruction no. 6 of 1 February 2001– which upheld the restrictions set out in Ordinances 365 and 290. The removal of specified risk material (SRM) is mandatory.

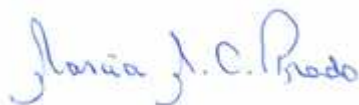
As a result of these and our own activities, we can again confirm the following points:

- a) Only raw materials obtained from healthy animals, deemed fit for human consumption on the basis of official veterinary ante- and post mortem inspection are utilized for GELITA[®] gelatine manufacturing in Brazil.
- b) The Brazilian facilities where bovine hides and skins are sourced are audited on a regular basis by both the Veterinary Authority from the Federal Inspection Service-SIF and Gelita do Brasil Ltda. personnel.
- c) The World Organization for Animal Health (OIE) classifies Brazil as a negligible risk country for BSE. In this respect, it is also important to point out that Brazil continues to be a BSE-free country. This disease has never been notified in the Brazilian territory and is of mandatory notification.
- d) A traceability system is in place that guarantees the traceability between customers and suppliers of raw material.

To take all these points together, this means that our strictly controlled raw material selection process and the high degree of reliability and safety of the production processes involved correspond to the stringent provisions and regulations currently in force and leads even beyond. Thus, according to thorough scientific knowledge, there is no health risk attached to our gelatine or gelatine hydrolysates. The risk of transmission of BSE to humans by our products can be ruled out, an opinion equally accepted by scientists and regulatory authorities.

Yours sincerely,

GELITA do Brasil Ltda.



Marcia Maria Costola do Prado
Regulatory Affairs Manager
Tel.: 5511 2163 8046
e-mail: marcia.prado@gelita.com



Silvia Marola
Quality Manager