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Anápolis, March 17, 2025

GENIX INDÚSTRIA FARMACÊUTICA LTDA – QUALICAPS BRASIL, manufacturer of empty hard gelatin capsules, in compliance with RDC 34/2015 (Good Manufacturing Practices for Excipients), informs that its capsules are produced with bovine gelatin supplied by GELITA DO BRASIL, PB BRASIL INDÚSTRIA E COMÉRCIO DE GELATINAS LTDA, and GELNEX INDÚSTRIA E COMÉRCIO LTDA.

All of these companies have manufacturing plants in Brazil and exclusively use animal-derived materials sourced from cattle born and raised in Brazil, in regions considered free from Bovine Spongiform Encephalopathy (BSE).

Best regards,

Patrícia J. M. Tannús
Gerente da Qualidade – RT
Genix Ind. Farmacêutica Ltda.

Cotia, January 18, 2024.

AFFIRMATION OF GELITA® GELATINE AND GELATINE HYDROLYSATES SAFETY: BSE / TSE

Dear Ladies and Gentlemen,

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

The safety of gelatine and gelatine hydrolysates 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 and gelatine hydrolysates 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 and gelatine hydrolysates 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 and gelatine hydrolysates 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.

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. The removal of specified risk material (SRM) is also mandatory in Brazil.

GELITA DO BRASIL LTDA.

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

a) Only raw materials obtained from healthy animals born, raised and slaughtered in BSE free countries, being Brazil the major supplier, are utilized for GELITA® gelatine and gelatine hydrolysates manufacturing in Brazil. The bovine animals were classified fit for human consumption on the basis of official veterinary ante-and post-mortem inspection.

b) The facilities where bovine hides and skins are sourced are audited on a regular basis by both the Official Veterinary Authority and GELITA do Brasil personnel.

c) The World Organization for Animal Health (OIE) classifies Brazil as a negligible BSE risk country.

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.

Sebastião L. da Rocha Neto
Quality and Regulatory Affairs Manager

GELITA DO BRASIL LTDA.

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TO WHOM IT MAY CONCERN

Statement: 001 | Edition: 17 | Date: August 22, 2023 | Expiry date: December 31, 2028

Statement - BSE-TSE – Safety of bovine hide gelatin and hydrolysates

We, the undersigned, hereby certify that the gelatins and the gelatin/collagen hydrolysates produced by:

- Tessenderlo Group NV, division PB Leiner in Vilvoorde Belgium,
- PB Gelatins GmbH in Nienburg, Germany,
- PB Gelatins UK Ltd. in Treforest, United Kingdom,
- PB Leiner S.A. in Santa Fe, Argentina,
- PB Leiner USA in Davenport, United States of America,
- PB Brasil Industriae E Comercio de Gelatinas Ltda in Acorizal, Brazil and/or
- PB Gelatins (Heilongjiang) Co., Ltd. in Nehe city (P.R. China),

are produced on the basis of raw materials sourced from healthy animals slaughtered in registered slaughterhouses and declared fit for human consumption after ante- and post-mortem inspection.

- All the raw materials, gelatins and gelatin/collagen hydrolysates comply with all current legal requirements worldwide.
- All the scientific and regulatory bodies worldwide have never questioned the safety of hide gelatin and gelatin/collagen hydrolysates.
- The World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code states that gelatin of skins and hides are safe and no BSE related restrictions should be posed upon the trade of gelatin produced thereof.
- In March 2016, the FDA published its final rule (21 CFR Parts 189 & 700 - Federal Register :: Use of Materials Derived From Cattle in Human Food and Cosmetics) and the following was stated: "*This final rule also clarifies that gelatin made from cattle-derived material is not, and never was, considered a prohibited cattle material so long as it is manufactured using customary industry processes. If there remained in the marketplace any confusion as to status of gelatin derived from cattle materials, the new definition provided by this final rule should remove that confusion*".

- All the hides used for the production of gelatin are sourced in countries or regions declared of negligible or controlled BSE risk following the classification system of the WOAH.

- A TSE inactivation study commissioned by the Gelatine Manufacturers of Europe association (GME) in 2003 has scientifically proven that, in the unlikely event that BSE contaminated raw materials are used for the production of gelatin, this contamination could not be found back in the gelatin itself. The study was peer reviewed and published in Biotechnology (2004). The results have been accepted by the European Food Safety Authority (EFSA) and by the US FDA TSE Advisory Committee.

Dr. Mohammed Boularas
Regulatory Affairs Officer

Itá/SC, January 13, 2025

CUSTOMER
Qualicaps

PRODUCT
Beefskin Gelatin 270 Bloom 08 Mesh

BSE/TSE STATEMENT

Gelnex Indústria e Comércio Ltda. acknowledges that the raw material used in the manufacturing of Gelnex **Beefskin Gelatin** is derived from animals born, raised, and slaughtered in Brazil under the supervision of a veterinarian, and considered fit for human consumption ante- and post-mortem. According to OIE (World Organization for Health), Brazil is considered at negligible risk for bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE).

Brazil also bans the use of ruminant-based meat and bone meal through which BSE is passed to cattle. Based on these factors, it is highly improbable for infected material to be found in the supply chain. However, the raw material also undergoes an alkaline treatment and hydrolysis during the process of collagen extraction, which any infection would not survive.

Marcos Pinto Ribeiro
Quality System Coordinator

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