

Barcelona, 15/11/2012

MANUFACTURER'S DECLARATION
TO WHOM IT MAY CONCERN
CERTIFIES

That the components (raw materials and products)¹ of bovine origin contained in Scharlau products come from healthy and Transmissible Spongiform Encephalopathy (TSE)-free animals originating from TSE-free countries (New Zealand, Australia), duly documented and certified by the health authorities in the country of origin and in the country of manufacture. In any case, Scharlau's manufacturing process includes a thermal treatment of $\geq 100^{\circ}\text{C}$ for a minimum of 15 minutes and a spray-drying step with instantaneous heating at $180\text{-}200^{\circ}\text{C}$.

That all those suppliers that provide us with raw material that may be affected by TSE have the Certificate of Suitability (CEP) alluded to in the General Text (5.2.8) and in the General Monograph of the European Pharmacopoeia concerning TSE risk assessment. According to the EDQM, Scharlab S.L. does not require a Certificate of Suitability for (Scharlau Microbiology) products containing bovine/ruminant components since all current Scharlab SL suppliers of raw materials of this nature comply with the TSE legislation as they possess valid and appropriate certification and therefore the TSE risk has been eliminated prior to the material reaching Scharlau's Microbiology plant.

Therefore, to the best of our knowledge and belief, Scharlau Microbiology products do not pose any risk to users with regard to the TSE agent at this time.

That, if the product is enzymatically processed, the enzyme preparation comes from a vegetal source or from healthy animals other than bovine species, free from foot-and-mouth disease, and other controlled infectious diseases.

Scharlau Microbiology has all the relevant documentation for each of its production batches as is stated by Scharlab SL ISO 9001:2008 (Reg. No. 05 100 10294 TMS)

1) This certification covers the following raw materials or components, and all Scharlau Microbiology products that contain them:

Bile Art. No. 07-039; Bile Salts No 3 Art. No. 07-525; Beef Extract Art. No. 07-515; Brain Extract Art. No. 07-076; Skimmed Milk Art. No. 06-019; Casein Pancreatic Peptone Art. No. 07-154; Casein Acid Hydrolysate Art. No. 07-151; Casein Trypsic Peptone (Tryptone) Art. No. 07-119; Gelatine Pancreatic Peptone Art. No. 07-153; Heart Extract Art. No. 07-077; Lactalbumin Art. No. 07-455; Meat Extract Art. No. 07-075; Meat Peptone Art. No. 07-152; Peptone from Casein Art. No. 07-489; Proteose-peptone # 3 Art. No. 07-625 and Tryptose Art. No. 07-197.

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