



**Scharlab S.L.**

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**TO WHOM IT MAY CONCERN**

Scharlab S.L. states hereby that the raw materials or components listed in the annex to this statement are according to the guideline 'Note for guidance on minimising the risk of Bovine and transmitting animal spongiform encephalopathy agents via medicinal products', reviewed on July 2011 (EMA/410/01 rev. 3), and thus

- 1) The raw materials or components of bovine origin come from healthy and transmissible spongiform encephalopathy (TSE from now on) free animals originated from TSE-free countries (New Zealand and/or Australia), duly documented and certified by the health authorities in the country of origin and in the country of manufacture. Anyway, our manufacturing process includes a thermal treatment over 100°C for a minimum of 15 minutes and a spray-drying step with instantaneous heating at 180-200°C,
- 2) All those suppliers that provided us with raw material that may be affected by TSE have the certificate of suitability (CEP) required in the above-mentioned guideline and therefore, according to EDQM, our media do not require such certificate as the risk has been prior eliminated,
- 3) If the product is enzymatically processed, comes from vegetal sources or comes from healthy animals other than bovine species, free from foot-and-mouth disease and other controlled infectious diseases, the firm has all relevant documentation for each batch guaranteeing the traceability according the requirements of ISO 9001 and ISO 13485.

Consequently, to the best of our knowledge and belief, products listed or containing components listed in the annex of Scharlab brand do not pose any risk to users in regards to TSE agents.

Should you require more information do not hesitate to contact us.

Anna Torres  
Quality, environment and Health&Safety department



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ARTICLES INCLUDED IN THIS STATEMENT			
Article	Description	Article	Description
06-019	Skimmed milk	07-039	Bile
07-075	Meat Extract	07-076	Brain Extract
07-077	Heart Extract	07-119	Casein trypsic peptone (Tryptone)
07-151	Casein acid hydrolysate	07-152	Meat peptone
07-153	Gelatine pancreatic peptone	07-154	Casein pancreatic peptone
07-197	Tryptose	07-455	Lactalbumin
07-489	Peptone from casein	07-515	Beef extract
07-525	Bile salts #3	07-625	Proteose-peptone

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