

BSE/TSE & GMO Certificate

VWR Catalogue Number	822070ZA
Description	Cryoinstant tubes 1 ml, mixed, Maintenance freeze medium for bacterial cultures storage
Country of Origin	Made in Portugal
Date of Issue (dd/mm/yyyy)	07/01/2020

We certify and declare:

That the components (raw materials and products)¹⁾ of bovine origin contained in these products come from healthy and Transmissible Spongiform Encephalopathy (TSE)-free animals originating 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. That all raw materials used are provided in the category IC and IB (Tissues with no detectable infectivity, or Lower-infectivity tissues). In any case, the 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 $170\text{--}200^{\circ}\text{C}$.

That all those suppliers that provide the manufacturer 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, the manufacturer, does not require a Certificate of Suitability for (microbiology) products containing bovine/ruminant components since all its current 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 the manufacturer's plant.

Therefore, to the best of our knowledge and belief, these 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.

That all suppliers of vegetable (or microorganisms) raw materials origin (Soy Peptone, Malt Ext, Vegetable Peptone, Yeast Extract, etc.) certify, doesn't contain any raw material or manufacturing auxiliaries animal origin and that they are manufactured according to European regulations (EC) 1829/2003 and (EC) 1830/2003 regarding to GMO (Free-GMO). The manufacturer has all the relevant documentation for each of its production batches as is stated by UNI EN ISO 9001:2015 (N° de Registro del certificado 39 00 0931111) and UNI CEI EN ISO 13485:2016 (N° de Registro del certificado 39 05 0931111) for product IVD CE.

¹⁾ This certification covers the following raw materials or components, and all products that contain them: Bile ; Bile Salts No 3; Beef Extract; Brain Extract; Skimmed Milk; Casein Pancreatic Peptone; Casein Acid Hydrolysate; Casein Trypsin Peptone (Tryptone); Gelatine Pancreatic Peptone; Heart Extract; Lactalbumin; Meat Extract; Meat Peptone; Peptone from Casein; Proteose-peptone # 3 and Tryptose. And vegetable raw material: Soy Peptone, Malt Extract, Vegetable Peptone, Yeast Extract, etc.

*Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
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