



## BSE/TSE MANUFACTURER'S DECLARATION Count tact™ agar - Ref 43501

### To Whom it may concern

We hereby testify that the above mentioned product, contains casein peptones (bovine milk – Australia/New Zealand) and therefore, conforms where appropriate to:

- Monograph of European Pharmacopoeia chapter 5.2.8 "*Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products*"
- "*Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products*" (EMA/401/01 Rev.3 – March 2011).
- FDA's Code of Federal Regulations Title 9 section 94.18

Cow milk and derivates from cow milk are excluded from the scope of the above guideline provided that the milk is suitable for human consumption and that the materials (i.e. enzymes) used during the manufacturing process of the product are not from ruminant origin.

Casein peptones used to prepare the above mentioned product fulfil these requirements.

We also testify that the above mentioned product is manufactured within premises where all the potentially infectious bovine or ruminant ingredients originate from BSE free countries, according to the USDA list.

Also note the fact that bioMérieux holds all the certificates of origin and the sanitary certificates of raw materials of animal origin which are part of its culture media formulation and ensures the traceability from the raw material to the final product.

bioMérieux would like to point out that the above mentioned product is intended for *in vitro* diagnostic use and/or for laboratory microbiological controls, and should not be used as manufacturing material (e.g. seed stock culture preparation, industrial scale fermentations, etc...), and that it is your responsibility to validate and implement a cleaning procedure for your equipment after the use of this product.

Please, also note the fact that certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of pathogenic agents. It is therefore recommended that this product be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale)

Should any additional information be necessary, feel free to contact us.  
With our Kind Regards,

Marcy l'Etoile, May 25th, 2012

  
B. van den BRAND  
Executive Director Quality  
EU/ASPAC/METERA

BioMérieux S.A