

Collagenase NB
Neutral Protease NB
Clostripain NB

Statement regarding Transmissible Spongiform Encephalopathy (TSE) safety

Collagenase NB, Neutral Protease NB and Clostripain NB are manufactured by the pharmaceutical company Nordmark Arzneimittel GmbH & Co. KG in Germany which produces collagenase for pharmaceutical purposes (wound healing) in compliance with international GMP regulations. The pharmaceutical standard also applies to manufacture of Collagenase NB, Neutral Protease NB and Clostripain NB ensuring superior quality products with high safety standard. Collagenase NB, Neutral Protease NB and Clostripain NB do not contain and are not derived from specified risk material as defined in Commission Decision 97/534/EC. Collagenases, neutral protease and clostripain are expressed by the bacterium *Clostridium histolyticum* and are released in high concentrations into the culture medium. This culture medium contains components of animal origin which are well-established culture media ingredients. Collagenase NB, Neutral Protease NB and Clostripain NB are produced from the fermentation product and by further purification processes in which only materials of inorganic or synthetic chemical origin are used. On request a SERVA Certificate of Origin (CoO) is available for all Collagenase NB and Neutral Protease NB products and Clostripain NB. The CoO provides information about product and source materials' origin. Nordmark holds a Certificate of Suitability (TSE-CEP) which was granted by the European Directorate for the Quality of Medicine (EDQM). For Collagenase NB 1 GMP Grade, Neutral Protease NB GMP Grade and Collagenase NB 6 GMP Grade a letter of access which allows the use of the TSE-CEP for filing to the authorities and a TSE-risk Statement are issued by Nordmark. SERVA Electrophoresis GmbH assumes no liability concerning application of SERVA Collagenases NB and Neutral Proteases NB: Collagenase NB 1 Premium Grade, Collagenase NB 4 Standard Grade, Collagenase NB 5 Sterile Grade, Collagenase NB 4G Proved Grade, Collagenase 8 Broad Range, Neutral Protease NB and Clostripain NB are designed for research purposes, only. Collagenase NB 1 GMP Grade, Neutral Protease NB GMP Grade and Collagenase NB 6 GMP Grade are designed for dissociation of tissue for isolation of cells for transplantation into humans. The enzymes are not intended for use in humans. Responsibility for clinical use and the methods to isolate, purify and transplant islets lies solely with the providing physician/researcher.