

TSE/BSE Certificate

Formula Hill: $C_{12}H_{22}CaO_{14} \cdot H_2O$
Molar Mass: 448,4 g/mol
CAS N°: 66905-23-5

Date of print: 25 March 2024

102712 Calcium D-gluconate monohydrate, USP

The note for the guidance EMA/410/01 Rev. 3 of the EC considers the requirements of raw materials used for human and veterinary medical products. The document introduces risk assessment into the regulatory compliance process for products derived from TSE/BSE-relevant animal species.

We certify that this product is manufactured without the use of raw materials of animal or human origin.

During processing the product does not come in contact with animal material.

Therefore, the product does not fall under the scope of the above-mentioned guideline and is not concerned by the TSE/BSE issue.
