

**Specification**

Culture Media Ingredient.

**Description**

This Peptone is obtained after a partial enzymatic (peptic) digestion process of animal tissues. This process is carried out in such a way that it produces a high proportion of peptides of low molecular weight, free amino acids and other growth factors. Although all of these constituents make its definition very difficult, it has a high nutritive capacity that makes it suitable for supporting toxin production by microbes and as a basic nutrient for very fastidious microorganisms.

Among the raw materials used in its preparation, the bovine constituents belong to the category IB, according to "Note for Guidance EMEA/410/01 Rev. 3". The bovine tissue is sourced from New-Zealand, and comes from herds declared free from Bovine Spongiform Encephalopathy and Foot-and-Mouth disease after examination by the Veterinary Authorities.

The product does not contain and is not derived from specified risk material as defined in the European Commission Decision 97/534/EC.

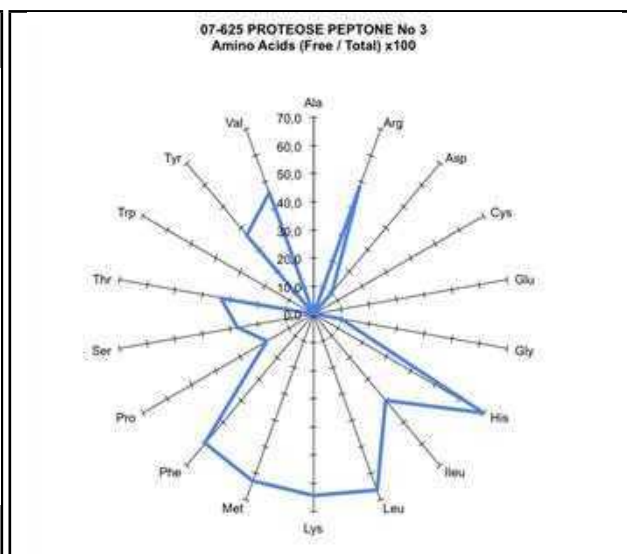
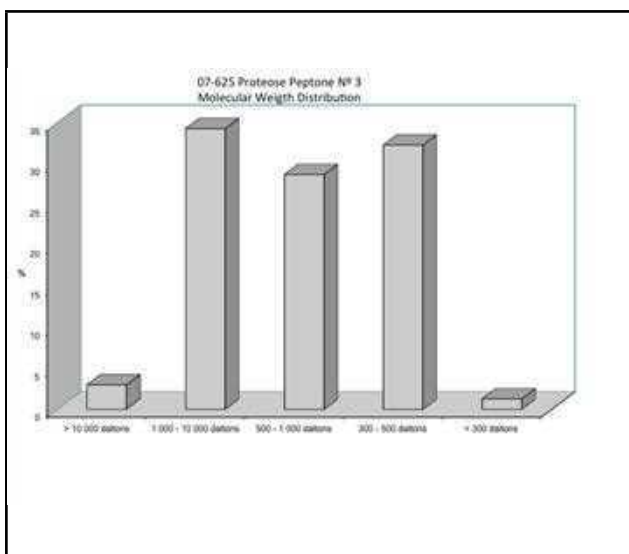
It also complies with the General Monograph 1483 on "Products with Risk of Transmitting Agents of Animal Spongiform Encephalopathies" in the current European Pharmacopoeia. The other constituents are of porcine origin. The manufacturing process includes autoclaved at 123°C for a 30 minutes and instantaneous heating at 180°C minimum on spray drying. (Note: These parameters can be changed and specified in the Certificate of Analysis for each batch).

**Physico-chemical characteristics**

Appearance powder.....	Cream to beige
Solubility in water 2%.....	Total
Stability after autoclave.....	No precipitate
Loss on drying (% Moisture).....	≤ 6,00
pH (solution 5%).....	6.5 - 7.5
Total nitrogen TN (% w/w).....	11 - 12.5
Amino nitrogen AN (% w/w).....	3.5 - 5.0
Residue on ignition (%).....	≤ 16.0
Proteoses.....	Present

**Microbiological limits**

Total aerobic count.....	< 10000 CFU/g
Coliforms.....	< 10 CFU/g
Moulds and yeasts.....	< 20 CFU/g
<i>Staphylococcus aureus</i> .....	absent in 10 g
<i>Escherichia coli</i> .....	absent in 10 g
<i>Salmonella spp</i> .....	absent in 25

**Storage**

For laboratory use only. Keep tightly closed, away from bright light, in a cool dry place (+4 °C to 30 °C).