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Collagenase Product Raw Material Certification

Worthington Biochemical Corporation, an ISO9001 Certified primary producer of Collagenases for life science research and related applications, certifies that Brain Heart Infusion (BHI) fermentation media has not been used in the production of any collagenase product(s). Since 1987, all Collagenase manufacturing and purification has taken place at Worthington's facilities located in Lakewood, New Jersey, USA. Prior to 1987, all production occurred at Worthington's Freehold, New Jersey, USA, facility.

Please note that Worthington currently utilizes several other animal-based media component raw materials in the fermentation processes from which this enzyme is purified. These components include proteose peptones and casein hydrolysates for which supplier information and certifications are available upon request. Please note that, although Certificates of Suitability are not currently available from most suppliers, Certificate of Origin(s) are provided that certify that all animal sourced components used in the manufacture of these media components are from territories including Australian, New Zealand and/or North American origin, from animals suitable for human consumption. No other animal tissues, products or derived additives are used.

For casein hydrolysates, suppliers certify that the milk was sourced from healthy animals in the same conditions as milk collected for human consumption. No other materials of ruminant origin are used in the process(es). Additional supplier certifications also specify that bovine materials used at any stage of production include none of the following:

1. Specified risk materials ("SRMs"): the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia of cattle 30 months and older, and the tonsils and distal ileum of all cattle;
2. Small intestine of all cattle, except for small intestines from which the distal ileum is removed using an FDA- approved procedure;
3. Material from non-ambulatory disabled cattle;
4. Material from cattle not inspected or passed;
5. "Mechanically separated beef": a food product that is finely comminuted by a mechanical process that separates skeletal muscle and other parts from bone.

In addition, these materials, along with the other fermentation media components, are also sterilized at 121°C, 22PSI for a minimum of 30 minutes according to Worthington Standard Operating Procedures, prior to use and inoculation for the production of fermentation-sourced products.

Signed: _____ *James S. Zacka* _____ Date: 5-May-2017

Print: James S. Zacka
Title: Vice-President