

Summary of the application: peptide Angiotensin 1-7 for food supplement

Applicant: Farmaricci Since 1905 S.r.l., Via Terre Risaie, 4, 84131, Salerno, Italy

Angiotensin 1-7 is an endogenous substance produced in the human and animal organism. It is a heptapeptide whose sequence is L-Asp-L-Arg-L-Val-L-Tyr-L-Ile-L-His-L-Pro and is made up of 7 amino acids: aspartic acid, arginine, tyrosine, histidine, proline, valine and isoleucine.

The peptides are defined as peptide sequences within a protein that exert a beneficial effect on body functions and/or have a positive impact on human health, beyond its known nutritional value. As reported in this study, countless peptides have food uses because are widely distributed in a wide range of both plant and animal food proteins. This peptide actually contributes to the physiological processes of the human organism and its supplementation as a food supplement can support the organism. It is made up of amino acids and therefore cannot be considered a disadvantageous substance from a nutritional point of view. The intended use of peptide supplementation is to support the body and provide nutrients that are a source of nitrogen and amino acids which the body requires for tissue growth and maintenance.

The target population to which the food supplement is aimed is the general adult population.

The angiotensin 1-7 peptide is produced according to chemical synthesis in a plant certified by ISO 9001:2015 and produced with a processes performed in a plant GMP approved and by qualified employees. a guaranteed minimum degree of purity of 98%. The synthesis process allows you to keep the result under control and avoid the presence of physical, chemical and biological contaminants. Analytical data demonstrate that residues of the processing aids are either undetectable or within levels that do not present a safety concern.

The substance is studied all over the world and in scientific literature there are countless in vivo and in vitro tests and clinical studies that describe its physiological activity and guarantee a high safety and tolerability profile.

The pre-clinical toxicology studies carried out showed that the substance is safe for intake at a dose of 0.10 mg/kg per day and that at these doses it did not produce significant toxicological effects. The various clinical studies on humans have shown a high tolerability of the substance and the maximum dose at which dose-limiting toxicities were detected in humans corresponds to a dosage of 0.70 mg/kg per day.

In this dossier, however, the recommended doses are much lower than those that present adverse reactions. In fact the minimal daily dose suggested is 1,000 mg and the maximum daily dose proposed is 1,750 mg of Angiotensin 1-7 (which corresponds to 0,025 mg/kg body weight (bw) per day for adults for a 70 kg person) for example like one gastro-resistant capsule or included in cyclodextrin for day, each one will contain 1.00 mg or 1.75 mg of Angiotensin 1-7.

The suggested use of the heptapeptide Angiotensin 1-7 is only as an ingredient of food supplement applications for oral intake of gastro-resistant formulation and/or cyclodextrins to protect the molecule from deactivation in the stomach (as indicated in the ADME section of the dossier), like tablets, capsules, powder, etc. and not as an ingredient in any other food products.

It can be concluded that this peptide, based on the manufacturing process, on the clinical studies conducted in humans and on the proposed use as an ingredient in food supplements as described in this dossier, it does not raise concerns for human health and does not present any safety or toxicological problems.