
2.2 PUBLIC SUMMARY OF THE DOSSIER

SCOPE OF THE APPLICATION

The present dossier documents the compliance of Leucyl aminopeptidase produced by *Rhizopus oryzae* AE-PER with the criteria laid out in Regulation (EC) 1332/2008 on food enzymes, i.e.:

- the food enzyme is safe for consumers in its intended uses
- it fulfils a reasonable technological need in food processing
- its use does not mislead consumers.

EXISTING AUTHORISATIONS OF THE FOOD ENZYME

Aminopeptidase from *Rhizopus oryzae* has been evaluated for its safety and technological need and authorised in Japan.

The food enzyme object of this dossier has been used in food processing for over 20 years.

PRODUCTION METHOD

The food enzyme object of this dossier is produced by fermentation of the microorganism *R.oryzae* in pure culture. No foreign microorganisms are allowed to develop during the enzyme manufacturing process.

During the fermentation, run in closed tanks, the microorganism is provided with nutrients, water and aeration. It develops and produces the food enzyme.

After the fermentation is over, the microorganism is eliminated from the liquid broth containing the food enzyme. This broth is partially purified and concentrated, to maximize the enzyme contents.

The concentrate is then mixed with other ingredients, in order to stabilize it for its storage, transportation and use in the food industry.

The food enzyme preparation complies with international specifications (JECFA), ensuring absence of contamination by toxic substances or noxious microorganisms.

The whole production process is run according to the requirements of the European Food Law and Food Hygiene Regulation. Production premises are regularly inspected by authorities.

TOXICOLOGICAL STUDIES

The food enzyme object of the present dossier was subjected to several toxicological studies to confirm its safety for consumers. The mutagenicity studies showed that the food enzyme does not have the potential to damage the genetic material of living organisms, including mammals. The oral toxicity study showed

that the food enzyme does not exhibit signs of toxicity, up to doses that are several hundred times higher than those which are consumed via food.

CONCLUSIONS ON THE SAFETY OF THE FOOD ENZYME

Based on the safety of the production microorganism, on the toxicological studies, and on previous evaluations by official experts, it is concluded that the food enzyme object of this dossier is safe in its intended uses.

USES OF THE FOOD ENZYME IN FOOD PRODUCTION

The food enzyme catalyses the conversion of substrate, proteins and peptides into products, amino acids. Proteins and peptides are present in many food raw materials and ingredients, and therefore the food enzyme is typically used in the following food processes:

- Milk processing
- Protein processing
- Yeast processing

The food enzyme is either removed or denatured at (or before) the end of the food manufacturing process. Therefore it cannot have any technological function anymore in final foods.

CONCLUSIONS ON THE TECHNOLOGICAL NEED OF THE FOOD ENZYME

Leucyl aminopeptidase has been used for several decades in above food production processes, which by itself demonstrate the technological need, together with the above listed benefits.

The Leucyl aminopeptidase from *Rhizopus oryzae* object of the present dossier has itself been used for over 20 years in food processing.

THE USE OF THE ENZYME WILL NOT MISLEAD THE CONSUMERS

This food enzyme does not perform any technological function in the final foods containing ingredients prepared with the help of this enzyme. Moreover, the food products prepared with the help of this food enzyme do not have other characteristics than what is expected by the consumer.

This food enzyme has been used for the above described technological function in food processes for many years.