Safety evaluation of a food enzyme containing leucyl aminopeptidase, oryzin and aspergillopepsin I from the non-genetically modified Aspergillus sp. strain AE-PR

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00220
Adopted 10-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing leucyl aminopeptidase, oryzin and aspergillopepsin I produced from the non-genetically modified A. oryzae strain AE-PR. Additional information was requested from the applicant during the assessment process on 22 January 2024 and received on 29 May 2025. Additional information was also spontaneously submitted by the applicant on 28 December 2023.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a solid-state fermentation system with conventional process controls in place.
Formulation Unknown
Downstream processing After completion of the fermentation, the enzyme is extracted with [...] and then the solid biomass is removed from the suspension by filtration. The filtrate containing the enzyme is further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded.
Average TOS (w/w) 92.2 %
Average activity/TOS 0.0 U/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production strain in the food enzyme was demonstrated

Allergenicity When used for the production of distilled alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining intended uses, the risk of allergic reactions upon dietary exposure to this food enzyme, particularly for natto and melon allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after natto and melon consumption

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1, G2), ochratoxin A, sterigmatocystin, T-2 toxin, HT-2 toxin, deoxynivalenol and zearalenone was examined in all food enzyme batches and all were below the limit of quantification (LoQ) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.005 µg/kg; Cd, Hg = 0.001 µg/kg each; As = 0.002 µg/kg. LoQs: aflatoxins (B1, B2, G1, G2) = 0.2 µg/kg each; ochratoxin A = 0.5 µg/kg; sterigmatocystin, T-2 toxin, HT-2 toxin, zearalenone = 10 µg/kg each; deoxynivalenol = 20 µg/kg.