Safety evaluation of the food enzyme leucyl aminopeptidase from the non-genetically modified Lichtheimia ramosa strain AE-PER

1 Report

Status Finished
EFSA question number EFSA-Q-2014-00354
Adopted 12-11-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme leucyl aminopeptidase from R. oryzae (strain AE-PER). The dossier was updated on 18 February 2014. Additional information was requested from the applicant during the assessment phase on 25 March 2024 and received on 26 May 2025

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a fermentation system with conventional process controls in place.
Formulation Unknown
Downstream processing After completion of the fermentation, the enzyme is extracted with water and the biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is concentrated and purified, 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) 89.9 %
Average activity/TOS 1.0 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 The Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that the likelihood is low.

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, zearalenone, HT-2, deoxynivalenol was examined in all food enzyme batches and was below the limits of quantification (LoQ) of the applied analytical methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.005 mg/kg; As = 0.002 mg/kg; Cd, Hg = 0.001 mg/kg each. LoQs: aflatoxins (B1, B2, G1 and G2) = 0.5 µg/kg each; ochratoxin A = 0.5 µg/kg; sterigmatocystin = 20 µg/kg; T-2 toxin = 100 µg/kg; zearalenone = 50 µg/kg; HT-2 = 250 µg/kg; deoxynivalenol = 100 µg/kg.