Safety evaluation of a food enzyme containing leucyl aminopeptidase and Xaa-Pro dipeptidyl-peptidase activities from the non-genetically modified Aspergillus sp. strain DAP 19-109

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00247
Adopted 08-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing leucyl aminopeptidase and Xaa-Pro dipeptidyl-peptidase activities from Aspergillus sojae strain DAP 19-109. Additional information was requested from the applicant during the assessment process on 04 March 2024 and 03 July 2026 and received on 04 June 2024 and 23 July 2026.

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 [...] and then, the solid biomass is removed from the suspension by centrifugation. The supernatant containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 21.7 %
Average activity/TOS 2.7 LAP/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 In conclusion, when used for the production of distilled alcohol, 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 cannot be excluded, but 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 and G2), ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone, kojic acid, cyclopiazonic acid and 3-nitropropionic acid was examined in all food enzyme batches and was below the limit of detection (LoD) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoDs: aflatoxins (B1, B2, G1, G2) = 0.5 µg/kg each; sterigmatocystin = 100 µg/kg; zearalenone = 100 µg/kg; ochratoxin A = 0.5 µg/kg; T2 toxin = 100 µg/kg; kojic acid = 1 mg/ kg; cyclopiazonic acid = 1 mg/kg; 3-nitropropionic acid = 1 mg/kg.