Safety evaluation of a food enzyme containing carboxypeptidase C, oryzin and leucyl aminopeptidase activities from the non-genetically modified Aspergillus sp. strain FP 12-385

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00264
Adopted 09-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing carboxypeptidase, oryzin and leucyl aminopeptidase activities from a non-genetically modified Aspergillus sojae strain FP 12-385. Additional information, requested from the applicant during the assessment process on 20 December 2023 and 1 June 2026, was received on 18 June 2024 and 17 June 2026, respectively

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 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) 19.1 %
Average activity/TOS 0.6 ACP/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 the food enzyme, particularly for wheat, natto and melon allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after wheat, 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, zearalenone, kojic acid, cyclopiazonic acid and 3-nitropropionic acid was examined in batches 1, 2 and 3 and was below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2), ochratoxin A = 0.5 µg/kg each; sterigmatocystin, zearalenone = 100 µg/kg each; T-2 toxin = 0.1 mg/kg; kojic acid, cyclopiazonic acid, 3-nitropropionic = 1 mg/kg each.