Safety evaluation of a food enzyme containing oryzin activity from the non-genetically modified Aspergillus sp. strain FL 72-230

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00248
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of two food enzyme containing oryzin and leucyl aminopeptidase activities or only the leucyl aminopeptidase activity from a non-genetically modified Aspergillus sojae strain FL 72-230. Additional information, requested from the applicant during the assessment process on 22 November 2023 and 27 April 2026, was received on 20 May 2024 and 12 May 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 followed by filtration. The filtrate 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 filtration membrane and is discarded
Average TOS (w/w) 20.5 %
Average activity/TOS 339.3 U/mg TOS

3 EFSA tested impurities

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

Allergenicity In conclusion, 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 the food enzymes, 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, zearalenone, kojic acid, cyclopiazonic acid and 3-nitropropionic acid was examined in batches 1–4 and all were below the limit of quantification (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.