Safety evaluation of the food enzyme oryzin from the non-genetically modified Aspergillus sp. strain LP 4–1281

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00267
Adopted 08-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Oryzin from a non-genetically modified A. oryzae strain LP 4-1281. Additional information, requested from the applicant during the assessment process on 8 February 2024 and 1 June 2026, was received on 8 August 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) 16.6 %
Average activity/TOS 209.1 CFA/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 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 three batches and all were 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. 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.