Safety evaluation of the food enzyme pectinesterase from the non-genetically modified Aspergillus luchuensis strain CBS 148463

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00222
Adopted 10-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme pectinesterase from a non-genetically modified A. luchuensis strain CBS 148463. Additional information was requested from the applicant during the assessment process on 24 January 2024 and 11 July 2015 and received on 27 February 2024 and 7 October 2025, 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 the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded
Average TOS (w/w) 16.8 %
Average activity/TOS 54.7 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 When used for the production of distilled alcoholic beverages, 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, particularly for pollen-allergic individuals, cannot be excluded.

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), fumonisins (B1 and B2), ochratoxin A, T-2 toxin, HT-2 toxin and zearalenone was examined in all food enzyme batches and was below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg; As = 0.01 mg/kg; Cd = 0.01 mg/kg; Hg = 0.005 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2) = 0.1 µg/kg each; fumonisins (B1, B2) = 250 µg/kg each; ochratoxin A = 2.5 µg/kg; T-2 toxin = 10 µg/kg; HT-2 toxin = µg/kg; zearalenone = 6 µg/kg.