Safety evaluation of the food enzyme endo-polygalacturonase from the non-genetically modified Rhizopus oryzae strain MC3-3-9

1 Report

Status Finished
EFSA question number EFSA-Q-2016-00656
Adopted 08-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme pectinase from Rhizopus oryzae MC3-3-9. Additional information was requested from the applicant during the assessment process on 21 May 2024, 29 May 2026 and 16 June 2026 and received on 27 November 2024, 05 June 2026 and 22 July 2026.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium under [. . .] fermentation 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 microfiltration. 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) 8.0 %
Average activity/TOS 11.1 PGU/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 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 in papaya-and pollen-allergic individuals, cannot be excluded. The likelihood of papaya-related reactions will not exceed the risk of reactions after papaya 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 and zearalenone was examined in six food enzyme batches, and all were below the limit of quantification (LoQ) of the applied method.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 0.5 µg/kg each; ochratoxin A = 0.5 µg/kg; sterigmatocystin = 20/100 µg/kg; T-2 toxin = 0.1 mg/kg and zearalenone = 50/100 µg/kg.