

Safety evaluation of the food enzyme endo-polygalacturonase from the non-genetically modified *Aspergillus tubingensis* strain SPG 10-1199

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00271](#)

Adopted 25-06-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme endo-polygalacturonase from a non-genetically modified *Aspergillus tubingensis* strain SPG 10-1199. Additional information, requested from the applicant during the assessment process on 23 April 2024 and 19 February 2026, was received on 19 July 2024 and 28 April 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 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) 23.2 %

Average activity/TOS 1014.0 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 In conclusion, the Panel considered that, under the intended conditions of use, a 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, zearalenone and fumonisins (B1, B2) was examined in all batches and was below the limit of quantification (LoQ) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2), ochratoxin A, fumonisins (B1, B2) = 0.5 µg/kg each; sterigmatocystin, zearalenone = 100 µg/kg each; T-2 toxin = 0.1 mg/kg.