Safety evaluation of the food enzyme containing endo-polygalacturonase and pectinesterase activities from the non-genetically modified Aspergillus luchuensis strain GSP-4-404

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00265
Adopted 14-04-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing endo-polygalacturonase and pectinesterase activities from the non-genetically modified Aspergillus luchuensis GSP-4-404. Additional information was requested from the applicant during the assessment process on 18 December 2023 and 26 January 2026 and received on 18 June 2024 and 25 February 2026.

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 membrane and is discarded
Average TOS (w/w) 11.4 %
Average activity/TOS 524.4 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 the Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly in 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, G2), ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone and fumonisins (B1, B2) was examined in three food enzyme batches (batches 1, 2, 3 in Table 1) and was below the LoQs of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQ for batches 1–3: Pb =0.05 mg/kg; As = 0.1 mg/kg; LoQ for batch 4: Pb =5 mg/kg; As = 3 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2), ochratoxin A = 0.5 µg/kg each; fumonisins (B1, B2) = 0.5 mg/kg; sterigmatocystin, zearalenone = 100 µg/kg each; T-2 toxin = 0.1 mg/kg.