

Safety evaluation of the food enzyme pectin lyase from the genetically modified *Aspergillus niger* strain CCTCC M 2023341

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00525](#)

Adopted 18-06-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme pectin lyase from *A. niger* CCTCC M 2023341. Additional information was requested during the risk assessment phase. Following the reception of additional data, EFSA requested a clarification teleconference on 15 June 2026, after which the applicant provided additional data on 16 June 2026.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, fed-batch fermentation system with conventional process controls in place.

Formulation Unknown

Downstream processing After completion of the fermentation, the solid biomass is removed from the fermentation broth 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 filtration membrane and is discarded.

Average TOS (w/w) 22.3 %

Average activity/TOS 165.0 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. The absence of recombinant DNA in the food enzyme was demonstrated.



Allergenicity In conclusion, the Panel considered that under the conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that the likelihood is low

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

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05/0.01 mg/kg; As = 0.005 mg/kg; Cd = 0.005 mg/kg; Hg = 0.003 mg/kg. LoQs: aflatoxins B1 and G1 = 0.1 µg/kg each and aflatoxins G2 and B2 = 0.03 µg/kg each; ochratoxin A = 0.2 µg/kg; fumonisin B1 = 20 µg/kg; fumonisin B2 = 20 µg/kg; deoxynivalenol = 20 µg/kg; HT-2 toxin = 10 µg/kg; T-2 toxin = 10 µg/kg; zearalenone = 10 µg/kg; sterigmatocystin = 10 µg/kg. LoQs (batch used for toxicological studies): aflatoxins B1 and G1 = 0.1 µg/kg each and aflatoxins G2 and B2 = 0.2 µg/kg each; ochratoxin A = 1 µg/kg; deoxynivalenol = 20 µg/kg; HT-2 toxin = 0.01 mg/kg; T-2 toxin = 0.1 mg/kg; zearalenone = 17 µg/kg; LoD (sterigmatocystin) = 6 µg/kg.