

Safety evaluation of the food enzyme cellulase from the non-genetically modified *Aspergillus niger* strain AC 4-984

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00240](#)

Adopted 12-09-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme cellulase from a non-genetically modified *Aspergillus niger* (strain AC 4-984). Additional information was requested from the applicant during the assessment phase on 22 January 2024 and was received on 19 July 2024

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 water and the biomass is removed from the fermentation broth by centrifugation, followed by microfiltration. The filtrate containing the enzyme is 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) 17.2 %

Average activity/TOS 44.0 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 when used for the production of distilled alcohols, 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 cannot be excluded, but 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, G2), fumonisins (B1, B2), ochratoxin A, sterigmatocystin, T-2 toxin and zearalenone was examined in three food enzyme batches, and all were below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQ for batches 1–3: Pb = 0.05 mg/kg; LoQ for batch 4: Pb = 5 mg/kg. LoQ for batches 1–3: As = 0.1 mg/kg; LoQ for batch 4: 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.