



Safety evaluation of the food enzyme abstract aspergillopepsin I from the non-genetically modified Aspergillus niger strain CCTCC M 2023234

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00425](#)

Adopted 09-12-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme aspergillopepsin I from a non-genetically modified *A. niger* strain CCTCC M 2023234. Additional information, requested from the applicant during the assessment phase on 2 May and 20 November 2025 was received on 28 August and 25 November 2025, respectively.

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 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 the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded

Average TOS (w/w) 22.1 %

Average activity/TOS 1298.7 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 /

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 0.01 mg/kg; Cd = 0.005 mg/kg; Hg = 0.005 mg/kg. LoQs: aflatoxin B1 = 0.1 µg/kg; aflatoxin B2 = 0.03 or 0.2 µg/kg (depending on the batch); aflatoxin G1 = 0.1 µg/kg; aflatoxin G2 = 0.03 or 0.2 µg/kg (depending on the batch); fumonisins (B1, B2) = 20 µg/kg each; ochratoxin A = 0.2 or 1 µg/kg (depending on the batch); deoxynivalenol = 20 µg/kg; toxin T-2 = 10 or 0.01 µg/kg (depending on the batch); HT-2 = 10 or 0.01 µg/kg (depending on the batch); zearalenone = 10 or 17 µg/kg (depending on the batch); sterigmatocystin = 10 µg/kg.