



Safety evaluation of the food enzyme prolyl oligopeptidase from the genetically modified *Aspergillus niger* strain NZYM-MR

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00630](#)

Adopted 12-11-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Prolyl oligopeptidase from *Aspergillus niger* NZYM-MR. Additional information, requested from the applicant during the assessment process on 02 April 2025, was received on 10 June 2025.

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) 16.1 %

Average activity/TOS 4.1 AU(P)/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 The panel considered that, under the intended 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 fumonisin B2 and ochratoxin A was examined in all food enzyme batches and all were below the limit of detection (LoD) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Comments LOQ: Pb =0.5 mg/kg. LoDs: fumonisin B2 = 0.3 µg/kg; ochratoxin A = 0.3 µg/kg.