Safety evaluation of the food enzyme cellulase from the non-genetically modified Aspergillus niger strain HBI-AC01

1 Report

Status Finished
EFSA question number EFSA-Q-2022-00518
Adopted 09-10-2025
Previous authorisations The applicant submitted a dossier in support of the application for authorisation of the food enzyme cellulase from a non-genetically modified Aspergilus niger (strain HBI-AC01). Additional information, requested from the applicant during the assessment phase on 18 September 2023 and 23 September 2025, and were received on 24 January 2024 and 26 September 2025

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 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) 30.9 %
Average activity/TOS 13.4 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 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 fumonisins and ochratoxin A was examined in three food enzyme batches and was below the limit of quantification (LoQ) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.05 µg/g. LoQs: fumonisins = 0.05 mg/kg; ochratoxin A = 5 µg/kg.