Safety evaluation of the food enzyme glucan 1,4-α-glucosidase from the genetically modified Aspergillus niger strain NZYM-DM

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00221
Adopted 09-10-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucan 1,4-α-glucosidase from Aspergillus niger NZYM-DM. Additional information, requested from the applicant during the assessment process on 23 January 2025 and were received on 27 May 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 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) 12.3 %
Average activity/TOS 6.0 AGU/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 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 fumonisin B2 and ochratoxin A was examined in all food enzyme batches and all were below the limit of detection of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments Pb: LoQ = 0.5 mg/kg. LoDs: fumonisin B2 = < 0.0003 mg/kg; ochratoxin A = < 0.0003 mg/kg.